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The Integration of Traditional Chinese Medicine in the United Kingdom: From A Regulatory Perspective

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Abstract

Introduction

The use of Traditional Chinese Medicine (TCM) is expanding world-wide, including in the UK and yet there is limited scientific evidence on its safety, quality and efficacy. This research aims to understand how TCM has developed in the UK, and to assesses the extent to which the regulatory system ensures that TCM therapies are safe, of good quality and effective, and that practitioners and premises meet adequate standards.

Methods

Primary data was gathered through 105 hours of participant observation in a TCM clinic, 38 interviews with TCM industry stakeholders, and 106 questionnaires collected from the TCM users. Secondary data was collected through literature review. Data was analysed using thematic analysis, actor-network theory (ANT), and responsive regulation. A framework was developed to assess the performance of TCM regulations.

Results

From the 1990s TCM has grown rapidly in the UK and the research found a network of six key stakeholders instrumental in this growth. 10 regulations are now in use focusing on safety, quality and efficacy of TCM products, practice, premises and practitioners. The impacts of regulations mostly relate to the use of herbal medicine; other areas such as standardising education or unifying registration criteria were less impacted.

Conclusion

TCM has undergone a process of modernisation and scientisation and through globalisation it has been reshaped by local contexts. In the UK, TCM became a part of complementary and alternative medicine (CAM) as a result of the interplay between regulators and a network of key TCM stakeholders. Responsive regulation has been applied to TCM but it falls short of achieving its aim. The UK-TCM regulation is weak in controlling standardised practice and delivering effective inspection of products.

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Glossaries

Part 1: List of Acronyms

ATCM	The Association of Traditional Chinese Medicine and Acupuncture UK
ANT	Actor-network Theory
BAcC	The British Acupuncture Council
CAM	Complementary and alternative medicine
CM	Chinese medicine
EMA	European Medicines Agency
FTCMP	The Federation of Traditional Chinese Medicine
LTA	Legal Theory of Autopoiesis
NHS	UK National Health Services
NICE	National Institute for Health and Care Excellence
RCHM	Register of Chinese Herbal Medicine
RR	Responsive regulation
TCM	Traditional Chinese medicine
WHO	World Health Organisation
WTO	World Trade Organisation

Part 2: List of TCM terms

Acupuncture	针灸, the therapy originated from China, to insert small needles into various points of body to stimulate nerve impulse. The TCM acupuncture is based on 'qi'
Cupping	拔罐 indicates TCM therapy evacuating air inside glass cups to make a negative press pulling cups sticky on skin to treat pain
Deqi	得气, the feeling of needles injecting into body
Ear candling	Ear waxing by placing a candle in canal
Guasha	刮痧 indicates therapy using tools to scrape or rub skin to relive blood stagnation
Herbal medicine	中草药, a traditional medicine using plants in China for long time with its own diagnosis system

Qi	气, vital energy
Shiatsu	Type of Japanese massage
Tuina	推拿 indicates a form of alternative massage originated from China
Yin and Yang	Two opposite forces in Chinese philosophy

PART I: Introduction, Background Information and Thesis Structure

Chapter 1

1.1 General situation and starting point of this research

As a part of the Chinese national health system, Traditional Chinese medicine (TCM) is widely used in China (Meng, et al., 2015). Following Chinese immigration patterns, TCM has also now spread to other countries (Wu and Wang, 2007). In the UK, TCM clinics and shops are commonly found in city centres, malls and streets in many places. The promotion of TCM therapies and their effects, such as herbal medicine and acupuncture, can be easily found on the internet. This research started from the questions of why and how TCM, as an exotic medical system, has stepped into the UK society and found a foothold here.

Both everyday observation and previous studies, such as Hsu (2008), Ye (2016) and Chen, Wang and Liu (2019), indicate the rapid development of TCM in the UK. However, this has raised concerns regarding public safety, quality and efficacy of practice (House of Lords, 2000). Of particular concern are reports that show how the inappropriate use of TCM causes harm (Ernst, 2010; Ye, 2016). The complexity of TCM (especially herbal medicine system) causes difficulties in quality control and set quality standards, especially in places outside China (Leong et al., 2020). In addition, direct comparison of TCM medicines with placebo indicates that the efficacy of such products may be insignificant (Lewith, Flower & Lai, 2012). A deeper understanding of these concerns about TCM is needed, as is knowledge of the measures that have been taken to protect the public when using healthcare services.

1.2 Background information to define the scale and concept of this research

1.2.1 TCM in China

As early as the 16th century, a development occurred whereby China began incorporating elements of Western science (Elman, 2005). Elman (2005) identified different phases of this development. In the late Ming Dynasty, the first phase proposed by Elman (2005), the Jesuits brought natural studies to China. China attempted to absorb these Western elements without upsetting its own system of knowledge. One example Elman (2005) used is the introduction of astronomy and the Western calendar. The interest in using astronomy to predict eclipses and

explain celestial anomalies drew the Chinese authority closer to the Jesuits. However, the Chinese did not fully adopy Western knowledge but used it to investigate and confirm ancient Chinese learnings.

The shift from Ming to Qing Dynasty in Chian corresponds to Elman's second phase (2005), from this time the Vatican began opposing the Qing court. In response in 1827, the Qing court ceased all missionary activities. Later, in Elman's (2005) third phase of science development in China, the Qing scholars enthusiastically incorporated knwoledge from the Jesuits into their efforts to restore ancient Chinese medicine (CM, *zhongyi*, 中医), among other things. Such integration of Western knowledge into ancient Chinese kneolwdge system, such as traditional medicine, was defined by Elman (2005) as quasi-scientific, because what the Chinese really highly praised is still their national Han concept and Confucian philosophy. The Qing Chinese authority and its scholars believed that Western learning was 'derivative' and Chinese learning was 'the source of all reliable knowledge' (Elman, 2005, p. 236).

From the beginning of the 20th century, the various impacts of the Qing court, including social, political and economic impacts on CM were further identified in Lei's work (2004). This caused CM to transform institutionally, clinically, and epistemologically (Lei, 2014). The Qing court realised the strength of Western countries tthrough warfare. The clear success of Wester social development led to moves towards social transformation in China.[1] CM was involved in this transformation process as well (Tian & Wang, 2007). The process of integrating CM with Western medicine[2] began as early as the end of the 19th century, despite doubts about its lack of scientific explanation and foundations. Lei (2014) used the example of the 1894 Hong Kong plague when CM practitioners claimed to have cured some plague patients drawing on the ancient CM theory of *qi* to identify symptoms. However, the theory of *qi* could not be used to distinguish between infections and contagious diseases, and it was severely challenged by the airborne nature of the plague. Later, in the 1911 Manchurian plague, the Chinese authority began to design a state public healthcare system by paying more attention to collective health

1 The success of the Meiji Revolution in Japan was considered as an example during the Wuxu Revolution in China that using a Western mode of development could help to rebuild feudalistic societies (Mehl, 2000).

2 The term 'Western medicine' used in this research indicates medicines from Western countries used by Western people which were considered exotic in China as early as the 16th century (Yuan et al., 2016). The term is used to distinguish these medicines from the indigenous medicines used by Chinese people. The term 'Western medicine' used in this research does not indicate the 'modern medicines' developed since the 19th century (Silvano, 2020). From sociological and anthropologic perspectives, 'Western medicine' is a product of colonialism and shows the ability of dominant Western societies to mark other cultures and medicines as minorities (Gale, 2014). Furthermore, the term 'Western medicine' used in this research follows the Chinese translation habit of being written as 西医, which was found by consulting the 2004 Chinese Terms in Traditional Chinese Medicine and Pharmacy. Further Chinese characters will be used where official English translations are missing and readers of this thesis may need the original words in Chinese for further searching.

conditions and the preventive function of medicines (Lei, 2014).

In the early 20th century, in response to continuous Western influence, the former Chinese government, the Beiyang Government (officially the Republic of China) and the Nanking National Government, shifted the lead role in the CM industry to foreigners and medical academics with overseas experiences, and even suggested abolishing CM (Liu, 2007). The dominant medical staff who had experienced biomedical training had led to a great challenge to the surevival of CM (Lei, 2014). The superior ability of Western medicine to diagnose, prevent and control infectious diseases forced CM to innovate. "Pattern differentiation and treatment determination" (Bianzheng lunzhi) (Lei, 2014: 167-92) was invented in 1931 and developed to be an essential part of CM in the middle of the 20th century. Another integrative strategy applied on CM was to let the CM physicians accumulate empirical experiences directly from their patients' bodies. The empirical tradition, coupled with lab research on Chinese material medica through not rigourously scientifice, moved CM closer in direction of modernity. Seeing the continuous attempt to integrate CM and Western medicine, Lei (2014) illustrated that neither Western medicine nor CM was a monolithic category. "Mongerl medicine" was the term used by Lei (2014) to describe the transformation of CM at this stage involving the integration of Western medicine into CM to save the tradition but thereby also endangering its authenticity.

CM in China was not officially promoted until 1949 with the establishment of the People's Republic of China (PRC). CM, through its use of natural herbs and simple equipment, satisfied the country's health needs and helped with the poor level of national health and wellbeing (Hsu, 2008). Also, the Chinese Communist Party (CCP) selected CM as a part of its spiritual building strategy to show that the party could unite and remould old traditions so that the party could transform feudal China into the new socialistic China (Taylor, 2005). A new round of transformation of CM then started. The word 'traditional (Chuantong, 传统)' was added and the medical system began to be known from this time as Traditional Chinese Medicine (TCM) (Chuantong Zhongyi, 传统中医). For Hsu (2008) this name bring together the long history of this medicine in old China with its new identity that it has been officially approved and used in government-run medical institutions by the *Xueyuanpai* (学院派), Chinese medical academics. Compared with Western medicine, there is little robust scientific evidence proving the validity of TCM (Talyor, 2005), and political factors are also relevant to the development of the field of TCM, such as with the addition of Mao Zedong's thoughts to TCM textbooks (Wei, 2013; Scheid & Karchmer, 2016).

From 1968 to 1983, based on Mao's thoughts to redress rural healthcare ineuqualities in China, the policy of barefoot doctors was carried out. These barefoot doctors provided low cost medical services to the rural masses by simple acupuncture and herbal medicine. An essential part of the strategy was that the barefoot doctors worked as agents to integrate Western medicine and TCM (Xu & Hu, 2017). The barefoot doctors accelerated the spread of Western medicine in China as it was easier to use than TCM (Fang, 2012), popularised TCM across the world, and inspired the WHO Alma Ata Declaration to focus on primary healthcare (Scheid, 2013).

Under different state authorities in China, TCM has been continuously reworked and reinvented and used as a tool of state building and promoting national identity (Scheid, 1999; Hsu, 2008). Although firmly supported and promoted by the national government, the importance of TCM was not formally confirmed until the issue of Article 21 of the Constitution of the PRC in 1982, which encouraged the development of TCM.[3] With this, TCM began to hold a more equal position with Western medicine at the turn of the 21st century (Scheid, 1999). The health system in China then integrated TCM with Western medicine as both were used in hospitals and taught in educational institutions (Scheid, 2002). The *56th World Health Assembly* (the governing body of the World Health Organisation) fully adopts in 2003 the position that national governments should formulate policies and accelerate legislation for traditional medicines (WHO, 2003a). Later, the *WHO Traditional Medicine Strategy: 2002–2005* has further guided the development of traditional medicines in World Health Organisation (WHO) member countries (WHO, 2002). The Chinese government finally published a special law to regulate TCM 13 years after the 56th Assembly. The *Law of the PRC on Traditional Chinese Medicine* gave a legal and official definition of TCM as the medical system containing all the therapies, including herbal medicine,[4] acupuncture,[5] cupping,[6] and Tuina[7] massage as used by the Han people and minor nationalities based on ancient medical theories (Zhang, 2019).

[3] Original words: 《中华人民共和国宪法》.第一章 总纲. 第二十一条国家发展医疗卫生事业，发展现代医药和我国传统医药，鼓励和支持农村集体经济组织，国家企业事业组织和街道组织举办各种医疗卫生设施，开展群众性的卫生活动，保护人民健康. Translation: Constitution of the PRC, Part I General Principle, Section 21, the country develops medicine and health industry, develops modern medicine and traditional medicine; the country encourages and supports rural economic organisations, national public institutions, enterprises and district organisations to hold types of medical and healthcare facilities, to conduct public healthcare activities, and to protect public health.

[4] Indicates Chinese Herbal Medicine, a traditional medicine (using plants) used in China for long time with its own diagnosis system (House of Lords, 2000).

[5] Indicates the therapy originated from China, to insert small needles into various body points to stimulate the nerve impulse. TCM acupuncture is based on '*qi*' (vital energy) (House of Lords, 2000).

[6] 拔罐 indicates TCM therapy evacuating air inside glass cups to make a negative press pulling cups sticky on skin to treat pain (Department of Health, Shantou, 2021).

[7] 推拿 indicates a form of alternative massage originating in China (Ernst, 2019).

Up until now, TCM in China is still regulated in different ways comparing with China's regulation towards Western medicine (*Pharmaceutical Regulation Law of the PRC*). For safety, the overall pharmacovigilance measures in China were considered insufficiently comprehensive and effective (Zhang et al., 2012),[8] and there are very few restrictions in Chin regarding TCM's use of animal, mineral or special herbal ingredients (*The Regulation on Protection of Traditional Chinese Medicine*; *Pharmaceutical Regulation Law of the PRC*). For quality, there are the manufacturing requirements for TCM are not as rigourous as those for Western medicines (*Law of the PRC on Traditional Chinese Medicine*); different requirements for educational quality also apply to TCM practitioners. People who learned TCM through apprenticeships are also eligible to register as doctors in China, but Western medical doctors must not register until they graduate from formal educational institutions (*Law of the PRC on Medical Practitioners*; *Measures for Doctor Qualification Examination of Apprentices and Masters of Traditional Medicine*). For efficacy, there are no regulations in China for TCM when applying for market authorisation.[9] Unburdened by laws and regulations in China, TCM has played a unique and growing role in the health system in China.

Based on the above information, the scope of China-TCM studied in this research is a statutorily regulated medical system in China, which is part of the national health system and practised by those who have passed a doctor registration examination, regardless of their educational background/ China-TCM includes the therapies of herbal medicine, acupuncture, cupping, and Tuina massage.

1.2.2 TCM in the UK

Scheid (1999) studied the early form of TCM appearing at international stage at the end of the 20th century. There is no reliable literature (for the literature searching strategy, see Section 1.3) stating the exact time when TCM first appeared in the UK, but some data were found to link the rise of TCM in the UK with the rapid growth of China against globalisation trend. Barnes (2005) defined five chronological periods regarding how the West dealt with China and its medicine. Europe formed its first impression of TCM dating back to the 13th century. Chinese

[8] Just before the submission of the thesis, the PRC Pharmacovigilance Management Practice was issued in December, 2021. Considering the lack of assessment of the operation and performance of this Pharmacovigilance Practice, this sentence has not been modified as a result of the issuance.

[9] According to the PRC Guidance of Syndrome TCM Clinical Research Technologies, there are indicators to evaluate the efficacy of TCM at the research stage, but these indicators are not required when TCM product manufacturers apply for drug registration and market authorisation (National Medical Products Administration, 2020).

medical theories, such as *qi*, *yin* and *yang*, and the five phases (or five elements in later contexts) more or less fit into Galen's theory in the West. This relationship between TCM and Western medicine carried through to the 19th century. In Barnes' (2005) second period, there was trade between China and Europe during the early Qing dynasty (1660–1736). During this period, more substantial TCM values, such as the utilisation of herbs, were recognised by the West due to the Jesuit missionaries' translations. However, the TCM practices of moxa and acupuncture were seldom mentioned during this time.

In Barnes' (2005) third period, TCM further appeared in Europe in the form of a growing number of publications, contributed by the increased trade between China and Europe and the popularity of chinoiserie. The Europeans subsequently became aware of moxa and acupuncture. Moxa was specifically mentioned by Barnes (2005), since it was incorporated into Western medical literature and integrated into Europe. Consequently, its Chinese origins gradually faded away. Regarding acupuncture, Bivins (2000) noted that the first knowledge of acupuncture in the West was at the end of the 17th century. However, Western doctors did not attempt to understand the Chinese cultural thoughts behind acupuncture therapy, and they considered treating patients according to ancient books inappropriate. Thus, the Western doctors failed to fully utilise acupuncture.

In Barnes' (2005) fourth period (1737–1804), China's resistance to Western paradigms and rejection of diplomats and trade caused Western scientific and technological development to surpass that of China, including medical practices. The West, mainly in Britain according to Bivins (2000), began explaining therapies, such as acupuncture, using neurophysiological knowledge, which has led to the modernisation of Western acupuncture. The fifth period, which Barnes (2005) designated to be the first half of the 19th century, presented an enormous amount of literature about TCM spreading throughout the Western world. Barnes (2005) divided the reportage on TCM in the fifth period into fifth genres: 1) foreign observers including traders, naturalists, and missionaries; 2) scholarly studies and translations based on Chinese texts in libraries; 3) transcendentalists publishing magazine articles about Chinese culture; 4) physicians and surgeons discussing Chinese healing practices (such as the English acupuncture monograph); and 5) scientific accounts, including experiments and clinical experiences, published in medical journals. With the publication of these experiments and clinical experiences, some TCM practices, such as herbs, moxa and acupuncture, were considered legitimate in the West. However, other TCM elements, such as the concepts of yin and yang, were considered superstitious.

In the late 20th century, a major stimulus to the popularity of acupuncture in the West was US President Nixon's visit to China in early 1972[10], and from then the Western world gradually accepted this foreign medicine. Of all the TCM therapies, the theories and system of acupuncture were the easiest and most acceptable for Westerners, and thus learning acupuncture soon became popular. An example of one of its easiest aspects is the clear needling points mapped on the body's meridian lines, as seen in Figure 1.1.

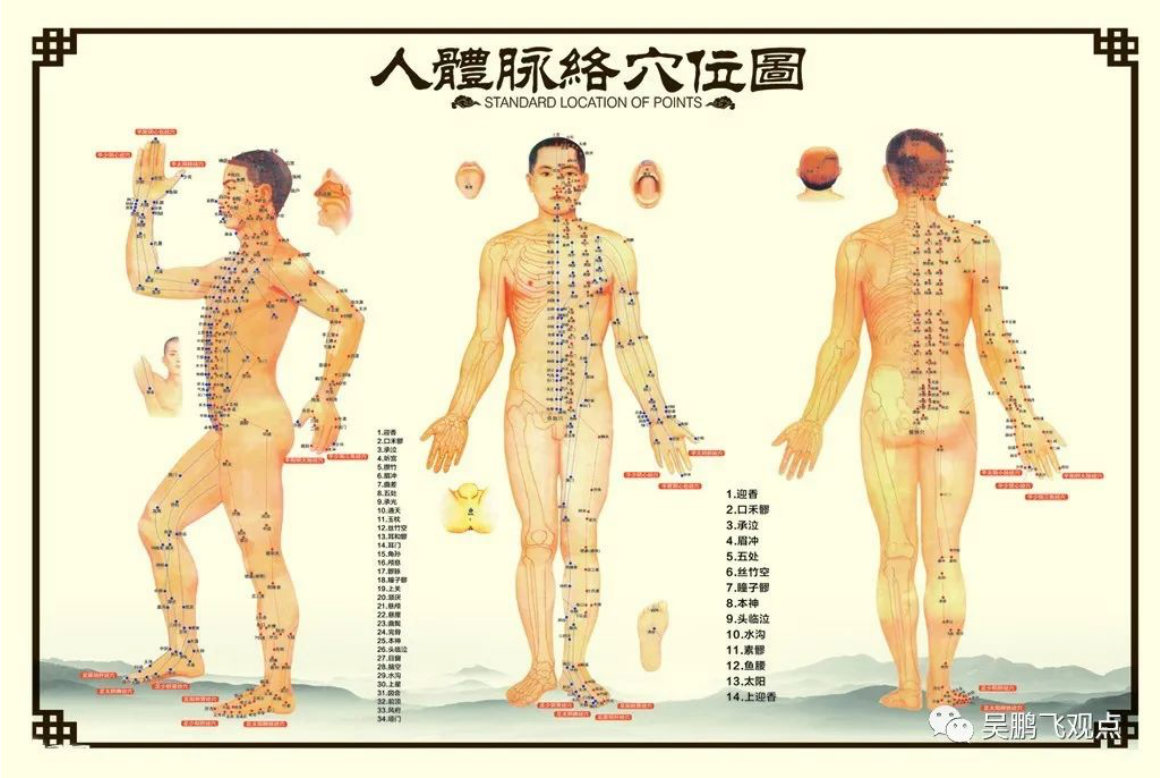


Image 1.1 Acupuncture needling points (Source: Chinanews.org, 2020)

Ryan (2008) suggested that the early colonial relationship between Britain and Hong Kong established a channel for cultural and material exchange. Starting from the *Reform and Opening-up Policy* (Gaige Kaifang, 改革开放), the exchange channel was expanded. Later in the 1990s, the rise of the Asian economy was rapid. China has a large amount of labour for mass production, and it thus developed its economy at this time by exporting goods to other places where productivity was relatively low (Lal, 2000). With this, China was eager to become a part of the international economic system, and China would have more weight and credibility in international society. As such, more markets would open up and China would become more involved in global affairs and events (such as the high-tech revolution since the 1990s) (Prime,

[10] This has also been mentioned in study like Ramey & Buell (2004).

2002). After joining the World Trade Organisation (WTO) in 2001, China became formally involved in international society (Prime, 2002). Since then, there has been an upsurge in emigration among Chinese, some of whom are attracted by the prospect of financial gain in foreign countries (such as the UK, where 393,141 ethnic Chinese people were counted in the 2011 census in England and Wales, making up 0.7% of total population) (Zhuang, 2006). These immigrants carried with them cultural and material inputs from China. One representative Chinese cultural value is an emphasis on family and an expansion of its network, based on which Chinese immigrants built small businesses hiring just a few people. Later, these were gathered into business bodies and became communities (Lal, 2000). Some of these immigrants run Chinese medicine shops (Latham & Wu, 2013) and these may be the rudiments of the later TCM clinics based in and around Chinatowns.

As is mentioned above TCM in the UK is practised in clinics, rather than in hospitals, as in China. This is because TCM has altered its position from being a part of the national health system to a branch of complementary and alternative medicine (CAM) (House of Lords, 2000). The House of Lords (2000) briefly defined CAM as therapies and disciplines that are excluded from mainstream medical care.[11] The US National Cancer Institute (NCI) gives a lexical definition of *mainstream medicine* to be a system where doctors and other health professionals (i.e., nurses and pharmacists) use drugs, radiation, or surgery to treat diseases; it provides emic synonyms of mainstream medicine which include allopathic medicine, biomedicine, conventional medicine, orthodox medicine and Western medicine. To distinguish from mainstream medicine, Dixon (2008) highlighted the words 'unconventional', 'holistic', 'parallel', 'folk' and 'Eastern' as the first impression of CAM. Moreover, to split the term CAM, therapies named 'complementary' are normally used with mainstream medicines, whilst therapies named 'alternative' can replace mainstream therapies (US National Centre for Complementary and Integrative Health, n.d.—this definition was referred to by the UK National Health Service).

However, the boundary between complementary and alternative therapies is not clear, some therapies belonging to these two categories overlap.[12] Also, scientific evidence has paid attention to differentiating mainstream medicine and CAM. Mainstream medicines use

[11] This research uses 'mainstream medicine' to indicate modern biomedicines used in the UK, but, as footnote 2 states, sometimes 'Western medicine' is used when translating or quoting statements of the research participants. This is due to their habit of saying '西医(Xiyi)' in China.

[12] The NHS uses the example of aromatherapy, which is sometimes used as a complementary treatment and sometimes as an alternative treatment. It is not necessary to provide a rigorous clarification of complementary and alternative medicines as they have the same intention of treating or curing a health condition.

carefully designed trials and research to test therapeutic approaches so that they are safe and effective, while CAM therapies normally lack sufficient research to provide scientific evidence for making medical decisions (Tabish, 2008). As for patients' decision making, previous studies have illustrated that patients obtain information on using CAM therapies from various sources, including recommendations from friends, the internet, and magazines. There are fewer scientific concepts to determine the use of CAM (Evans et al. 2007), and information may be selected according to patients' beliefs and values (Nichol, Thompson & Shaw, 2011). As for medical professionals, Leach (2010) designed a framework for clinical decision making in CAM to include more sources of evidence, such as traditional evidence, expert opinion and clinical cases and assessment, which can act as different types of evidence in clinical practice. Despite this, Leach (2010) still noted that systematic high-quality reviews and clinical trials are excellent evidence but insufficiently seen in TCM research.

Besides the above CAM features, TCM has the characteristic of being 'traditional'. Using compounds isolated from natural products to make new drugs is considered to mark the beginning of the 'modern' era since the nineteenth century (Madigan, Martinko & Parker, 2006). Traditional medicines are typically made with natural products and have been documented as existing before the nineteenth century (Yuan et al., 2016). Even in the mid-twentieth century, traditional medicines were still 'primitive' and used mostly in non-Western places (Dixon, 2008). Traditional medicines were thus marginalised by modern societies.

However, traditional medicines did not wither away, and survived after times of 'competition, co-existence, co-operation, integration and modification'. Traditional medicines have nowadays succeeded in flourishing based on their culturally resonant theories, and are believed to prevent, diagnose and treat diseases despite the introduction of biomedical knowledge and technologies (Dixon, 2008). Traditional medicines do not refer particularly to something old or obsolete, as they have actually transformed over time. The core of traditional medicines is their cultural features. The House of Lords Report (2000) has stressed the importance of the Chinese cultural underpinning of TCM theory when defining this medical system. TCM is defined by the House of Lords as driven by the theories of qi energy and of yin and yang,[13] which are the basis of therapies such as acupuncture, herbal medicine, massage and Qigong. Among the therapies of TCM, the 6th report has especially clarified: 1) that the type of acupuncture based on qi is traditional Chinese acupuncture, while the type based on nerve impulses is Western

[13] 阴阳 indicates two opposite forces in Chinese philosophy. Yin is a female, cold, dark, passive power; yang is masculinity, light and warmth (Oxford Dictionary of Philosophy [2nd edition]).

acupuncture; 2) the well-organised type of herbal medicine using substances derived from plant is actually phytotherapy, while Chinese herbal medicine as a therapy of TCM has more emphasis on its unique diagnosis system; 3) Shiatsu is a type of massage from Japan but adopts qi as its operating principle in a similar way as massage under a TCM classification.

Table 1.1 presents some statistics on CAM used in the UK. These studies indicated a noticeable proportion of people in the UK had used CAM therapies. Also, the number of CAM practitioners has grown annually throughout the 20th century (Brook, 1998).

Year	Literature	Source	Base no. of participants	No./proportion of CAM utilisation	Reasons for CAM utilisation
1999	Ernst & White, 2000	BBC random telephone survey	1,204	20% sample used CAM in previous years (including herbalism, aromatherapy, homoeopathy, acupuncture, massage, and reflexology)	Perceived effectiveness, positive inclination towards it and its relaxing effects
2005	Hunt et al., 2010	Health Survey for England	7,630	40% reported lifetime CAM use, 26.3% used CAM in previous 12 months (including massage, aromatherapy, and acupuncture)	Predictable effectiveness towards mental health, suffering from depression,
2008	MHRA, 2014a	2008 MHRA survey placed on Ipsos MORI	2,305	35% of participating adults had used herbal medicines (26% in the past 2 years)	TCM practitioners are trustful to users, and TCM is suitable for more serious medical conditions
2000–11	Posadzki et al., 2013	A review of 89 surveys	97,222	51.8% reported lifetime CAM use, 41.1% reported CAM used in previous year (herbal medicine, homeopathy, aromatherapy, massage, and reflexology)	NA
2015	University of Bristol, Centre for Academic Primary Care,	Ipsos MORI, led by the National Institute for	4862	16% reported to see a CAM practitioner in the last 12 months	For musculoskeletal problems, pain, mental health, sleep problem, tiredness, and fatigue

	(Sharp, et al., 2018)	Health Research			

Table 1.1 Some statistics of CAM used in the UK

The development of TCM as a branch of CAM has also been noted. Studies have characterised the utilisation and development of TCM in the EU as "widely used and attracts interests" (Uzuner et al., 2010: 1), "embracing unprecedented opportunities" (Liu et al., 2016: 360), and "[non-Asian countries] recognised the huge therapeutic potential" (Fung & Linn, 2015: 1). In the UK, there were approximately 3,000 TCM clinics in the UK, 600 of them based in London, at the beginning of the 21st century (Wang & Kong, 2006). The same study also calculated that 2.5 million people use TCM therapies each year with expenditure of more than £90m (Wang & Kong, 2006). However, this study did not specify the original sources of such statistics, and no other studies have provided related data.

The popularity of TCM and concerns about the safety, quality and efficacy of TCM, as mentioned earlier, attracted the regulatory attention of the UK government. Briefly, a series of regulations can be identified which manage non-mainstream medicine in the UK, including TCM. These regulations (see Section 1.3) include the *Medicines Act 1968*, *EU Directive 2001/83/EC*, *EU Directive 2004/24/EC*, the *Human Medicine Regulations 2012* and others. At the same time, some regulatory approaches initially applied to UK mainstream medicines have gradually involved CAM, for instance the *Good Manufacturing Practice* (GMP) and the *Yellow Card Scheme* (YCS). Some official documents, such as the 6th Report of the House of Lords (2000), are published periodically to advise and improve TCM-related regulatory work.

In summary, the UK-TCM studied in this research is a medical system which is presently a popular branch of CAM, and one which lacks the robust scientific evidence for statutory control; as such, it is excluded by the UK mainstream health system. The UK-TCM is open to practitioners and patients from all nations, and its practice is impacted by multiple rules and legislations. The therapies of the UK-TCM include, but are not limited to, the therapies of Chinese herbal medicine (simplified as herbal medicine in this research, as phytotherapy is within its scope), Chinese-type acupuncture (simplified as acupuncture), and massage (as Shiatsu shares a theoretical basis with TCM).

1.3 Literature review setting the context of the regulatory landscape of the UK-TCM

Literature was reviewed to lay foundation and provide an overview of the regulatory landscape

of the UK-TCM. A narrative literature review method was used to enable a broad search of the overall situation of TCM regulations in the UK, while remaining focused on the aim. The literature search was undertaken through Newcastle University Library using ProQuest and PubMed, and the search terms can be seen in Table 1.2. The search produced peer-reviewed articles, articles, reviews, books, conference reports and book chapters published in English and Chinese between 1970–2020, in the fields of human, public health, medicine and herbal medicine. Experimental reports, clinical studies, animal studies, and biological and chemical ingredients analysis were excluded. The first round of the search identified 89 related articles (excluding 34 duplicates). The same strategies were later used in Google Scholar for a supplementary search. A further search was conducted using the references in the articles from the first search; with this process, more official reports and legislative documents were identified.

Traditional Chinese medicine **OR** *Chinese medicine* **OR** *Chinese traditional Medicine* **OR** *Herbal medicine* **OR** *Acupuncture* **OR** *Complementary medicine* **OR** *Alternative medicine* **OR** *Complementary and alternative medicine*	AND	**OR** *Develop* **OR** *Regulatory system* **OR** *Regulatory regime* **OR** *Legislation* **OR** *Law*	AND	*the UK* **OR** *British* **OR** *Europe* **OR** *European Union*

Table 1.2 Literature searching terms

This liliterature review has two sections: 1) a review of official regulations in the UK related to TCM in chronological order; and, 2) a chronological review of important documents that influenced the regulations of the UK-TCM.

1.3.1 The development of TCM regulations in the UK

Various documents were identified as affecting TCM practice today, including documents regulating certain therapies, such as herbal medicines and acupuncture. These documents include both regulations and laws that affect the TCM industry (see Appendix II), and official reports, consultations, and government response to reports that influence the policy making of the concrete regulations (see Appendix III). Figure 1.1 shows the timeline of all regulations (in solid suaqres) and influential documents (in dotted squares) in a chronological order.

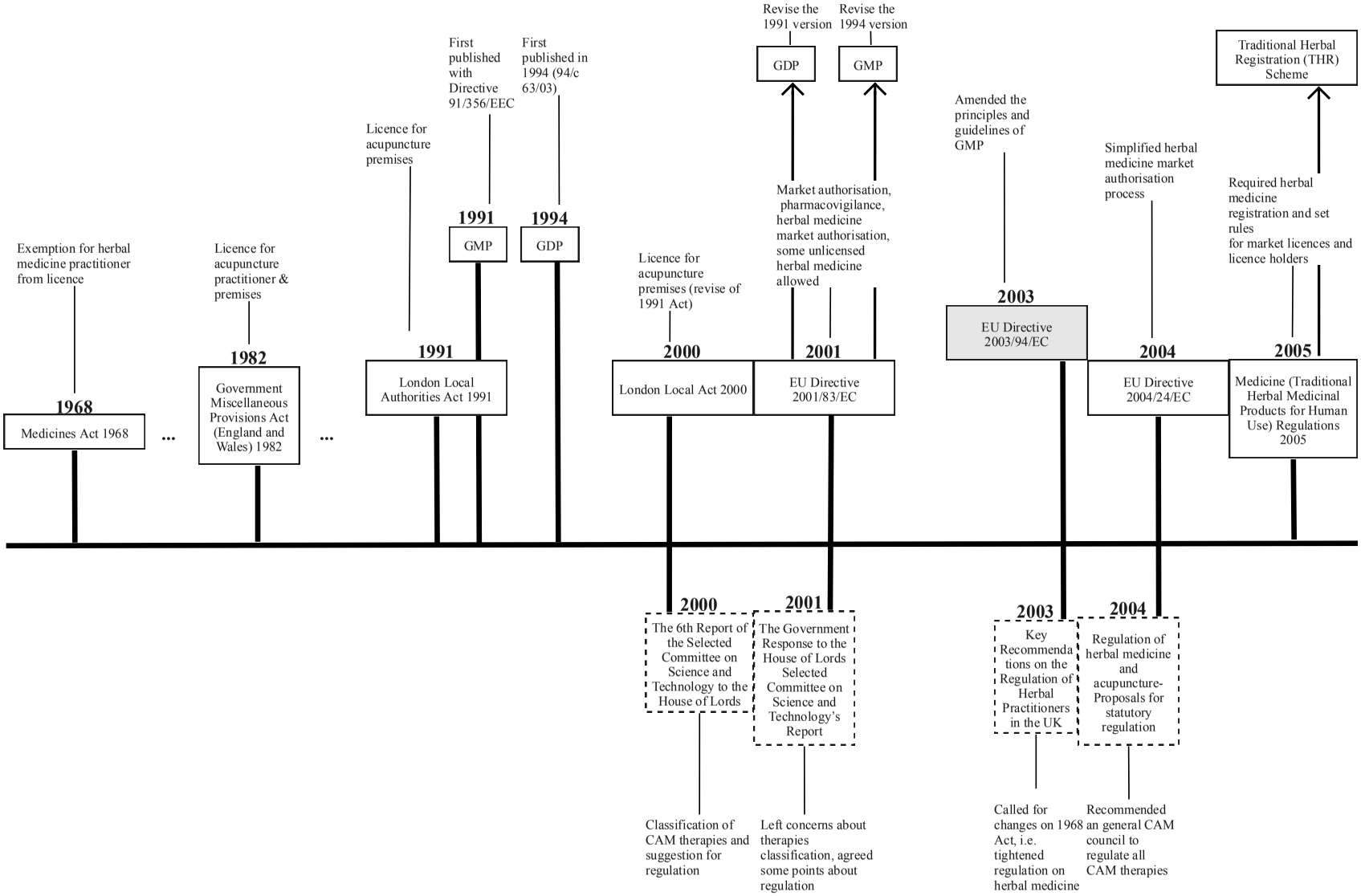

Exemption for herbal medicine practitioner from licence
1968
Medicines Act 1968
...
Licence for acupuncture practitioner & premises
1982
Government Miscellaneous Provisions Act (England and Wales) 1982
...
Licence for acupuncture premises
1991
London Local Authorities Act 1991
First published with Directive 91/356/EEC
1991
GMP
First published in 1994 (94/c 63/03)
1994
GDP
Licence for acupuncture premises (revise of 1991 Act)
2000
London Local Act 2000
Revise the 1991 version
GDP
Revise the 1994 version
GMP
Market authorisation, pharmacovigilance, herbal medicine market authorisation, some unlicensed herbal medicine allowed
2001
EU Directive 2001/83/EC
Amended the principles and guidelines of GMP
2003
EU Directive 2003/94/EC
Simplified herbal medicine market authorisation process
2004
EU Directive 2004/24/EC
Traditional Herbal Registration (THR) Scheme
Required herbal medicine registration and set rules for market licences and licence holders
2005
Medicine (Traditional Herbal Medicinal Products for Human Use) Regulations 2005
2000
The 6th Report of the Selected Committee on Science and Technology to the House of Lords
Classification of CAM therapies and suggestion for regulation
2001
The Government Response to the House of Lords Selected Committee on Science and Technology's Report
Left concerns about therapies classification, agreed some points about regulation
2003
Key Recommendations on the Regulation of Herbal Practitioners in the UK
Called for changes on 1968 Act, i.e. tightened regulation on herbal medicine
2004
Regulation of herbal medicine and acupuncture- Proposals for statutory regulation
Recommended an general CAM council to regulate all CAM therapies

Figure 1.1 Historical regulation of TCM in the UK

Before 1968 in the UK, common law enabled people to choose a healthcare provider, and thus practitioners could legally provide different types of medical treatment (Mills, 2001). Much freedom was left to the practitioners as to how they should conduct themselves.

Coffin established an early herbalist association in the UK (Denham, 2013). Coffin adopted similar treatment approaches to those used in Thomsonian herbal practice in America (i.e., using steam baths and cayenne), and he set up local groups of the Friendly Botanic Society of Great Britain in the 1850s.[14] In the latter nineteenth century, more herbalists societies appeared and spontaneously began to develop herbalism practices.[15] These societies worked to distinguish herbalism from metaphysics and supernatural powers, as herbalism is grounded in the rational and empirical rather than the mysterious. These societies suggested that herbalism should focus on providing healthcare, developing more characteristic material medica (i.e., a specific herbal pharmacopoeia), producing books and other academic materials, and establishing educational institutions. The contribution of these herbalist societies is considered an early prototype of today's practitioner association (Brown, 1985).

However, what the herbalist societies did was considered insufficient for herbalism to compete with orthodox medicines. Moreover, herbalists faced obstacles, such as the 1941 bill which made the sale of herbal medicine illegal (Pharmacy & Medicines Bill, 1941). Although the 1941 bill repeatedly stated that its regulations would not prevent herbalists from practising, the requirement for formal labels on substances recommended as medicine hindered the business of UK herbalists. Attempts were thus made by the herbalist societies to move herbal practice closer to science, such as by establishing educational institutions for professional training and joining more qualified societies/associations to guarantee the moral character of the herbalists and avoid issues created by underqualified individuals. Nevertheless, herbalism still failed to achieve official recognition and was placed in opposition to biomedicine by medical professionals in later time (Brown, 1985).

The right to practise for herbalists was not formally upheld until the *Medicines Act 1968* (1968 Act), which was the first legal document to regulate herbal medicine officially (Wilkinson,

[14] The actual date of the establishment of Coffin's Society was uncertain. Because membership of this society was automatically given when buying the Botanic Guide to Health, and this Botanic Guide (*A Botanic Guide to Health and the Natural Pathology of Disease*) was first published in the 1850s (the earliest version found was published in 1848), this research infers the early UK CAM association was set up at that time.

[15] Such as the National Association of Medical Herbalists of Great Britain (NAMH) founded in 1864, and the Society of United Medical Herbalists of Great Britain (the United Society), founded in 1877.

2007; Dixon, 2007). Article 12(1) of the 1968 Act provided herbal medicine practitioners with the legal right to prescribe herbal medicine, and to sell, supply, manufacture or assemble herbal medicines on the herbalists' premises without a manufacturer's or wholesale dealer's licence. Article 12(2) allowed over-the-counter (OTC) pre-packaged herbal remedies to be sold if the medicines are made by drying, crushing or commuting, and the medicines use labels to indicate only the constituent plant or plants, making no recommendations for their medical use. Article 12(1) thus sought to protect public safety from herbal medicines that are not industrially produced, because an individual consultation is needed before a medicine is prescribed (see 1, Appendix II).

As for acupuncture, Cloatre and Ramas (2019: 247) described the acupuncture practice in the UK as being 'within … common law on bodily and psychological harm'.[16] That said, the legal precondition for practising acupuncture is that it should not cause harm. The regulations of concern here were established in the 1990s. District regulations include the Government Miscellaneous Provisions Act (England and Wales) 1982 (1982 Act) for practitioner licensing and premises requirements, the Civic Government (Scotland) Act 1982 (Order 2006) for practitioner licensing and business inspection, and the Local Government (Miscellaneous Provision) (Northern Ireland) Order 1985 for business registration. As this research focuses on practices in England, the 1982 Act was given special attention. The 1982 Act empowers and requires the local authorities to license the personnel and premises for acupuncture practice as it is classified as special skin treatment (see 2, Appendix II). In London, there are also local level regulations managing acupuncture practice within the area. The London Local Authorities Act 1991 (1991 Act), as later amended by the London Local Act 2000 (2000 Act), regulates the eligible premises for acupuncture practice and related registration requirements for special treatment premises license. One noticeable point of the 1991 Act is that it allows a licence exemption under some certain conditions (see 3, Appendix II). The exemption relates closely to TCM as it permits members of approved specific bodies of health practitioners to practise without a premises licence. The list of 'approved specific bodies' can be checked with district authorities, such as councils.

The regulations concerning TCM-related therapies remained fragmented until the end of the twentieth century. At this time, the UK public became very interested in non-mainstream therapies, causing a rapid expansion in the CAM market, and the UK government was aware

[16] This may suggest that regulating acupuncture practice is not an easy task, and that judging acupuncture related offences by cases under common law rules is simpler than creating a statute for regulation.

that this deserved closer scrutiny. Concerns were raised about public health policy, including if: 1) a good regulatory structure would provide adequate protection to the public; 2) there is sufficient evidence to assess CAM therapies; 3) there are rich sources of information on CAM treatment; and, 4) CAM practitioners are properly trained and how to coordinate National Health Services (NHS) provisions with CAM treatment.

In 2000, the House of Lords Select Committee on Science and Technology developed a report reflecting the overall development of CAM in the UK and appealed for attention to be paid to CAM therapies, to include their safety, efficacy, and training, as well as research and manufacturing. The Sixth Report of the Selected Committee on Science and Technology to the House of Lords (2000 Report) provided a summary of the regulation of all such therapies in the UK till the end of the twentieth century, and emphasised the importance of their regulation, given their wide and increasing use in the UK and the concomitant potential risk (see 1, Appendix III). The 2000 Report used the term CAM to identify the complex non-Western or non-biomedical independent therapies or medical systems not in the UK's "mainstream medical care".

One notable contribution of the 2000 Report was its categorisation of CAM therapies in the UK into three groups (see Table 1.3). Group one indicates the 'principal disciplines' that have independent diagnostic methods and important positions in the CAM field. Group two indicates those CAM therapies sometimes used in conventional medicine but without their own diagnostic skills. Group three contains the remainder of CAM therapies that have less scientific evidence to support them. TCM is classified in the third group because of the lack of evidence on its safety, efficacy, and mechanism of action. In general, the 2000 Report stated that each therapy could establish their own standard of regulation instead of CAM being regulated as a whole entity. The 2000 Report suggested that each profession unite their fragmented regulatory bodies to develop their own regulatory structure through synergy. In general, there are two types of regulation, statutory and voluntary, and the 2000 Report considered that effective voluntary regulation would be enough to protect patients and organise practitioners. The difference is that statutory regulation has the force of law to ensure that regulations are as effective as intended. The benefit of statutory regulation is protection of title, so that only practitioners registered with statutorily regulated healthcare professional bodies[17] could legally use a particular title and

[17] There are currently 12 statutorily regulatory healthcare professional bodies: the General Chiropractic Council, the General Dental Council, the General Medical Council, the General Optical Council, the General Osteopathic Council, the General Pharmaceutical Council, the Health and Care Professional Council, the Nursing and Midwifery Council, the Pharmaceutial Society of Northen Ireland (General Medical Council, n.d.).

claim to practise certain therapies. This may make statutory regulation stronger than the voluntary route as a single register of practitioners would be established as a single reference point for the public to check practitioners' qualifications; practitioners ineligible for registration would be excluded and those guilty of misconduct would be struck off.

According to the features of the therapies in each group, the 2000 Report then suggested possible routes of regulation to improve public protection. In group one, osteopathy and chiropractic have already been statutorily regulated under acts of parliament. The other professions in group one were encouraged to approach statutory regulation. The group two therapies were advised to promote stronger self-regulation, ideally under a united regulatory body. The group three therapies were encouraged to self-regulate, but the establishment of an evidence base for each therapy was urged. The 2000 Report suggested that statutory regulation cannot be applied to a medical system without scientific measurement recognised by the mainstream medical system; this explains the current voluntary regulatory status of TCM as a whole, with some regulations applied to acupuncture and herbal medicine.

Group 1	Group 2	Group 3	
Professionally organised CAM therapies	Therapies used to complement conventional medicine and which do not purport to embrace diagnostic skills	3a	3b
		Long-established and traditional medical system	Alternative therapies lacking evidence
Acupuncture: a needle therapy originating from China	Alexander technique: a taught technique	Anthroposophical medicine: healing forces through soul and spirit	Crystal therapy: crystals can absorb and transmit energy
Chiropractic: therapy to treat musculo-skeletal complaints	Aromatherapy: using plant extract essential oils	Ayurvedic medicine: ancient Indian medical system	Dowsing: traditional method to identify underground water
Herbal medicine: remedies derived from plants	Bach and other flower remedies: flower containing power	Chinese herbal medicine	Iridology: studying eyes to diagnose problems
Homeopathy: emotional therapies	Body work therapies: massage is one such	Eastern medicine: Egyptian synthesis of elements	Kinesiology: using muscle testing to diagnose problems
Osteopathy: manipulation focusing on musculo-skeletal problems	Counselling stress therapy: to guide patients to work through thoughts	Naturopathy: natural laws appearing both inside and outside of the body	Radionics: using invisible energy to detect diseases before they happen
	Hypnotherapy: using hypnosis to treating diseases	TCM	
	Meditation: relaxing therapies		
	Reflexology: feet massage		
	Shiatsu: Japanese light stress massage		
	Healing: spiritual healing		
	Maharishi Ayurvedic medicine: a medical system promoting transcendental meditation		
	Nutritional medicine: use of nutritional methods		
	Yoga: a system of adopting postures		

Table 1.3 Classification of CAM therapies in three groups according to the 2000 Report

In addition to the classification (Table 1.3) and suggestion of a regulatory route, the 2000 Report made more a precise suggestion of regulatory bodies for therapies wishing to be formally regulated. Creating a specific law targeted on one CAM therapy (normally an act of parliament) and establishing a statutory regulatory body is a strong route for pursuing statutory regulation, but the cost is high. The 2000 Report then suggested a statutory route for CAM therapies, either by establishing a regulatory body by order of parliament, or joining a closed group in the Health Professional Council (HPC). Both routes were within the provision of the Health Act 1999, and thus created lower costs than making a new law. By such means, the General Osteopathic Council (GOsC) stated that the cost of regulation to individual osteopaths under statutory

regulation would be similar to that under voluntary regulation. However, this was because the large number of osteopaths split the overall cost into a low average amount for individuals, and the GOsC thus referred to the fact that smaller scale therapies would be unable to achieve the same cost-effective route of statutory regulation. This may explain the reason why there are only fragmented small-scale associations conducting voluntary regulation of TCM.

The *Government Response to the House of Lords Selected Committee on Science and Technology's Report on Complementary and Alternative Medicine* (2001 Response) was then produced by the Department of Health (2001) and it agrees with many points in the 2000 Report (see 2, Appendix III). The 2001 Response emphasised the importance of an evidence-based system of CAM therapies, especially one which would prove the efficacy of CAM beyond placebo. The evidence base of many CAM therapies at that time was not robust, and so the 2001 Response stated that voluntary regulation would be the best approach for most CAM therapies. However, the 2001 Response also pointed out that the current regulatory system did not work as effectively as expected, because the classification of CAM therapies was too broad and involved many cross-over disciplines. The then current fragmented regulatory system covered all CAM therapies, but the regulations might overlap. To resolve this issue, the 2001 Response suggested an alternative classification. Taking TCM as an example, it suggested that acupuncture and herbal medicines have statutory regulation, and indeed TCM uses acupuncture and herbal medicines as its main therapies. Thus, the 2001 Response suggested moving group three therapies that include herbal remedies and acupuncture, such as Chinese medicine and Ayurveda (which are complete systems with long histories and a range of therapies alongside herbs and acupuncture), become redefined as herbal medicine and acupuncture categories in group one, but retain their individual identities and traditions. This flexible route to regulation was for the benefit of both patients and practitioners, and such actions were to be implemented as soon as practicable. The suggestions from the 2000 Report and the corresponding response from the 2001 Response are summarised in Table 1.4.

Sixth Report of 2000	Practice	Group	Group 1: acupuncture and herbal medicines	
			Group 2: massage and reflexology	
			Group 3: TCM	
		Regulation	Group 1: strive for statutory regulation	
			Group 2: in need of single regulatory body	
			Group 3: may apply self-regulation	
	Products	Evidence (also	Safety	Research needed for evidence

		for practice)		base
			Quality	Research needed for evidence base
			Efficacy	Research needed for more than pleasing effects
		Information	Attention needed for how the public get information	
		Delivery	Mainstream medical professionals as gatekeepers	
	Practitioner	Education and training	Standards needed	
Government Response of 2001	Practice	Group	For therapies crossing the boundaries of groupings, statutory regulation or professional regulation could be applied for the parts of the therapies within their group	
		Regulation	1. Single regulatory body is needed for each therapy 2. Statutory regulation is expected based on sufficient evidence	
	Products	Evidence (also for practice)	Safety	1. Article 12 of the Medicines Act 1968 is weak 2. EU legislative framework is expected 3. Improved exclusion of toxic ingredients 4. Still respects the habits of practitioners
			Quality	Respects the habits of practitioners
			Efficacy	1. Pleasing effect is also an effect 2. Research on diagnosis is needed
		Information	1. NHS professionals should be familiar with CAM 2. The public should have access to information	
		Delivery	GPs are important for integration of CAM	

			and mainstream medicines
	Practitioner	Education and training	1. Registration association ensures qualifications and advanced training 2. Accreditation board is a route for standardised education 3. National occupation standards are needed

Table 1.4 Information extracted from the 2000 Report and the 2001 Response

The concerns of the 2000 Report and 2001 Response were soon after partly addressed by the publication of the *EU Directive 2001/83/EC* (2001 Directive). For general medicinal products, the 2001 Directive stated in Article 40 that member States of the EU require a manufacturer's authorisation for medicinal products, and this authorisation also applies to products for export and import from a third country. The 2001 Directive then emphasised the importance of good manufacturing practice (GMP) for medicinal products for human use and the principles and guidelines on GMP were published by the EU Commission in the rules governing medicinal products in the EU Community, Volume 4.[18] Articles 84 and 85b(3) of the 2001 Directive urged the EU Commission to publish guidelines on good distribution practice (GDP).[19] Article 108 of the 2001 Directive requires implementing measures for a quality system which would perform pharmacovigilance activities. It also urged the holders of market authorisation to be proactively responsible for the pharmacovigilance requirements of the medicinal products placed on the market.

For herbal medicine regulation, the 2001 Directive marked a major change in the legal market position of herbal medicines and thus impacted the UK (see 5, Appendix II) by setting market access rules for herbal medicine with insufficient clinical data on safety and effectiveness, but which had been used for over 30 years (15 years within the EU) (Chapter 2a, 2001 Directive). Acceptance of long-term use as a measurement of the safety of the product was a consequence of the insufficient evidence on the safety of herbal medicine. Moreover, considering that there might be medical products ineligible for applying such market authorisation, the 2001 Directive also allowed unlicensed medical products to be supplied to individual patients on request but only by an authorised healthcare professional [Section 5(1), 2001 Directive]. As such, the 2001

[18] The EU GMP was first published in Commission Directive 91/356/EEC, but the 91 Directive did not mention herbal medicinal products. The 91 Directive covers all medicinal products at that time using the reference in Article 16(1) of Directive 75/319/EEC, which states that EU member States shall take all appropriate measures to ensure that the manufacture of the proprietary medicinal products is subject to authorisation. The Volume 4 Rules was the first EU GMP documentation specifying the implementation of GMP on herbal medicinal products.

[19] The EU GDP was first published in 1994 (94/c 63/03), and the 2001 Directive provided the basis for its revised version published in 2013.

Directive regulated commonly used herbal medicinal products for the first time.

Although the 2001 Directive established an ideal model for regulating herbal medicines, problems remain. One urgent problem is the discretion that was left to EU member States to decide the identification of an 'authorised healthcare professional' who is allowed to practise using unregistered simple or manufactured herbal remedies with individual patients.[20] The former UK regulation on unlicensed herbal medicine, the 1968 Act, however, did not restrict the qualifications of a practitioner of herbal medicine, and therefore consideration was required concerning who could be deemed qualified. Because of the urgent need to bridge the gap between the 1968 Act and the 2001 Directive, together with the emphasis on regulating CAM therapies made by the 2000 Report and the 2001 Response, a report was produced by the Herbal Medicine Regulatory Working Group (HMRWG) (commissioned by the Department of Health, the Prince of Wales Foundation for Integrated Health and the European Herbal Practitioners Association) in 2003 (2003 Report) to make recommendations on the regulation of herbal practitioners in the UK (see 3, Appendix III).

The 2003 Report suggested changes to the former regulations, especially Section 12 (1) of the 1968 Act. This included tightened regulation on checking the qualifications of herbal practitioners who prescribe unlicensed medicine and on products produced by a third part, either by industrialised approaches or non-compliance with GMP regulations and the 2001 Directive. To achieve stronger regulation of herbal practitioners, the 2003 Report urged the development of the *National Professional Standards of Herbal Medicine,*[21] and more importantly made some concrete recommendations for the selection of proper regulatory bodies. The 2003 Report rejected the suggestion made by the 2000 Report that herbalists join the HPC as herbal medicine was not well established in UK mainstream healthcare, and such a large body might be unable to represent each of the smaller disciplines within general herbal medicine, i.e., distinguishing and presenting differences between Western herbal medicine and herbs in TCM. The 2003 Report then suggested regulating herbal medicine either under an independent Herbal Council or a CAM Council that included all CAM therapies. A CAM Council would have more members, cover more therapies and be lower cost, and would have a greater impact on the public due to its size and structure.

Compared with a general CAM Council which would have to consider the needs of various

[20] Article 5(1) of the 2001 Directive enables products that are ineligible for registration to be supplied by an authorised healthcare professional upon personal request by individual patients.
[21] See EHPA (n.d.) about National Professional Standards.

therapeutical groups, an independent Herbal Council would understand the needs of the herbalists better and therefore better represent them to the public and official departments. Good examples of this are the osteopathy practitioners regulated by the GOsC and chiropractic practitioners regulated by the General Chiropractic Council (GCC). The performance of the GOsC and GCC within the past five years (from 2015) was reviewed according to the Standards of Good Regulation of the Professional Standards Authority (n.d.) for general standards,[22] guidance and standards,[23] education and training,[24] registration,[25] and fitness to practise.[26] The GOsC assessed all five aspects from 2015–2020, and noted that the GCC performed well in most aspects but less well in general standards (failure to collect sufficient equality information, 2019–2021), registration (failure to prevent non-registrants using protected titles, 2018–2019), and fitness-to-practice (failure to solve cases reported quickly, 2015–2017). This means the regulators of the GOsC and GCC can generally protect patients and reduce harm, in order to promote professional standards and maintain public confidence. A Herbal Council is expected to perform similarly and provide targeted services to herbalists, although it would cause higher costs as fewer registered members could share the expenditure of the Council.

Also in 2003, the *EU Directive 2003/94/EC* (2003 Directive) required inspections of medicine manufacturers, which amended the principles and guidelines of GMP of medicinal products for human use and investigational medicine products for human use. In 2004, the 2001 Directive was amended and became the *EU Directive 2004/24/EC* (2004 Directive) to include a clear definition of herbal medicines and preparations, and certain sections were also modified to simplify applications for market authorisation (see 6, Appendix II). Article 16(g) of the 2004 Directive also applies various rules from the 2001 Directive to products granted traditional use registration. These rules include requiring market authorisation, establishing competent authorities in member States, and conducting pharmacovigilance activities (see 6 (2), Appendix 1). The 2004 Directive came into force in 2011, and it gave a seven year period for medicines already in stock to be sold.

The 2004 Directive stressed the need for TCM regulation. As reported by BO1, the continuous

[22] General standards: the regulator should provide clear general information, clear budget with appropriate functions to achieve purses, understand the diversity of registrants and patients, report performance and address concerns, and cooperate with other stakeholders.
[23] Guidance and standards: the regulator should maintain up-to-date healthcare service standards and provide guidance.
[24] Education and training: the regulator should maintain up-to-date education standards and standards to examine the eligibility of educational providers.
[25] Registration: the regulator should maintain and publish registration instruction with an explanation of the process of registration, and guarantee the registrants are fit to practice.
[26] Fitness to practice: the regulator should ensure there is a mechanism to discover and resolve unfitness to practice (and all decisions are consistent with this mechanism), prioritise the safety of patients, and complaints are allowed.

expansion of TCM in the UK attracted the attention of the UK government, which sought to place TCM under statutory regulation at the beginning of the twenty-first century. The Department of Health produced the *Regulation of Herbal Medicine and Acupuncture-Proposals for Statutory Regulation* (2004 Proposal) to make suggestion for the regulation of herbal medicine and acupuncture (see 4, Appendix III). The 2004 Proposal consulted the 2000 Report and the 2001 Response, summarised the work and recommendations from the working groups set by the Department of Health regarding herbal medicine and acupuncture, and developed advice and plans for further regulation to focus on public safety and ensure the regulatory standards were effective. A major suggestion of the 2004 Proposal was to establish a shared statutorily regulated body. The 2004 Proposal, similar to the view presented in the 2003 Report, considered it unfeasible for TCM, acupuncture or herbal medicine practitioners to join the HPC due to the inapplicable professional group classifications in the HPC. These classifications may have been caused by the inadequate establishment of herbal medicine and acupuncture professions in mainstream healthcare, and some entry requirements were hard to achieve, i.e., the difficulty of proving an equal educational level for practitioners educated abroad. A new type of regulatory body was thus recommended by the 2004 Proposal.

The 2004 Proposal recommended establishing a shared CAM Council for the practice and practitioners of herbal medicine, acupuncture, and other CAM therapies such as Ayurveda, TCM, and Western herbal medicine. This CAM Council could recruit more members than a single therapy body, and the average cost paid by individual members would thus be lower as more people would share the total expenditure of establishing statutory regulation. The functions of this CAM Council would include registering eligible members and providing them with officially recognised titles, determining the standards of education and training, giving advice on standards of conduct, and setting rules on misconduct. If these functions of the CAM Council were achieved, the Council would be able to protect both practitioners and the public, while also organising a network for the related stakeholders, i.e., employers and educators. Also, under standardised regulation by the CAM Council, herbal medicine and acupuncture could be promoted and developed. The 2004 Proposal had a detailed design for such a CAM Council, including its registration procedure (also for already-registered health professionals and practitioners qualified outside the EEA), a set of committees, standards of proficiency, conduct of practitioners, CPDs, investigation of misconduct and fitness to practice (FTP) and an appeal channel for registered members. However, no such CAM Council exists at the time of this study, and the suggestions of the 2004 Proposal were laid aside for reasons unknown.

In 2005, the UK government enacted the Medicine (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (2005 Regulations) to implement the requirements of all three EU directives (see 7, Appendix II). The 2005 Regulations required herbal medicine registration and set rules for market licences and licence holders (normally indicating manufacturers). Details of how to apply for such a licence were announced in the Traditional Herbal Registration (THR, see 8, Appendix II) scheme launched in 2005 by the MHRA (2014b). The THR scheme assigns authorisation numbers to herbal medicines that meet the requirements of safety and quality, and which have a long tradition of use (MHRA, 2019). As for medicinal efficacy, the MHRA only requires a medicine to be "plausible" (Barber, 2014: 4).

In 2006, a new point-based immigration system replaced the old work permit scheme (Home Office, 2006). This impacted the UK-TCM industry because the new immigration system required higer registration fee as a visa sponsor, set new steps to hire a foreign employee and requested English ability of prospective employee.

In 2007, a white paper titled *Trust, Assurance and Safety—The Regulation of Health Professionals in the 21st Century* (2007 White paper), was published by the Department of Health and Social Care (2007) to appeal for more standardised regulation on health professionals (see 5, Appendix III). While this white paper did not provide specific guidance on the regulation of TCM practitioners, it did set up a working group to look into the statutory regulation of herbalists, acupuncturists and TCM practitioners.

Reviewing the 2003 and 2004 reports and the 2007 white paper, as well as other documents on the practitioner regulation issue, such as the officially consulted reports of *Good Doctors, Safer Patients by* Chief Medical Officer (2006) and the *Regulation of the Non-Medical Healthcare Professions* by Department of Health (2006), a steering group was established by the Department of Health to suggest further concerns about practitioner regulation made by the 2000 Report and the 2001 Response. The steering group emphasised the importance of reforming Section 12 (1) of the 1968 Act and thus to place the unlicensed individually prescribed medicines under the scope of Article 5(1) of the 2001 Directive. The steering group suggested in its *Report to Ministers from The Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK* (2008 Report) (Great Britain. Department of Health, 2008) that a straightforward route for aligning with the 2001 Directive would be to statutorily regulate practitioners to make them qualified to use unlicensed

medicine. The 2008 Report agreed with the problem of cost raised in the 2003 Report, in that a larger regulatory body would mean a lower average cost. The 2008 Report thus suggested that TCM practitioners (as well as herbalists and acupuncturists) be regulated by the HPC, as it has experience of regulating health professionals (see 6, Appendix III).

However, the Department of Health (2009) soon rejected the possibility of statutory regulation in A *joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK* (2009 Consultation) regarding the suggestions of the 2008 Report and the white paper. The 2009 Consultation emphasised three types of risk in TCM (as well as other CAM therapies) in need of urgent regulation. These were: qualifications granted to ineligible practitioners; inappropriate practices leading to unexpected medical outcomes; and, hygiene concerns on premises where healthcare services are provided. Statutory regulation was not considered the most appropriate approach to addressing these risks. Statutory regulation is high cost, takes a long time, and requires investment in human resources. The TCM industry stakeholders considered that the UK government would be more willing to spend such time and money on 'other more urgent legislation'. The 2009 Consultation thus suggested alternative routes for regulation instead of new legislation (see 7, Appendix III). After listing the advantages, disadvantages and explanations concerning multiple regulatory routes, the 2009 Consultation established various questions which required responses from the public, practitioners, and other stakeholders, to decide the preferred way to regulate TCM (and other CAM therapies). The 2009 Consultation appeared on the website of the Department of Health for 15 weeks, and 6,669 responses were received. The Department of Health made a further analysis report in 2011 (2011 Report) to report on public opinion of the regulation of TCM (and other CAM therapies) (see 8, Appendix III).

After the issue of the 2004 Directive, GMP started to impact TCM by working on traditional herbal products to regulate and inspect manufacturer licences as well as other aspects (i.e., premises and personnel) needed to quality control [*Explanatory memorandum to the Medicines (Traditional herbal medicinal products for human use) Regulations 2005*; Select Science, 2009]. In 2009, Appendix 7 on the manufacture of herbal medicinal products in Volume 4 of GMP came into operation (see 10, Appendix II). Appendix 7 applies to 'starting material' in the manufacture of herbal medicinal products, including medicinal plants, herbal substances, or herbal preparations. It also provided information on how to ensure the quality of herbal

medicinal products, including agricultural and collection practices,[27] storage, production equipment, documentation, processing, and sampling for quality control. GDP (see 11, Appendix II) also operates in accordance with the 2001 Directive and is guided by the *EU Commission Guidelines 2013/C 343/01* and *2015/C 95/01*, to regulate the distribution of medicinal products.[28]

In the UK, the implementation of GMP and GDP is under the inspection of the MHRA.[29] GMP and GDP inspections start once a person applies for a manufacturer or wholesaler licence. Three types of inspection exist in the UK, including: a risk-based inspection collecting data through compliance reports; product-related inspections operating by assessing a market authorisation application; and, a triggered inspection that may be activated by a whistle blower. If the manufacturer/distributor passes the inspection with the outcome confirmed as compliance with the principles of GMP/GDP, a GMP/GDP certificate will be issued to the manufacturer/distributor. The information on the GMP/GDP certificate can be found in the MHRA-GMDP database. In addition, the MHRA requires the registration of manufacturers, importers, and distributors of active substances, since inspections related to active substances are based on risk and thus may escape from GMP regulation. Information on such registrations can be found in the MHRA-GMDP database.

The 2011 Report summarised that the majority (85%) of the respondents were in favour of statutory regulation to ensure the qualifications of practitioners and the safety of practices. The British Acupuncture Association (BAcC), as the representative of the TCM association, wrote to the Secretary of State for Health regarding the issues in the 2009 Consultation, and called for improvement in the statutory regulation of acupuncturists (BAcC, 2011). However, some respondents were against statutory regulation as TCM (and other CAM therapies) lack robust scientific evidence, and statutory regulation may mislead the public that these therapies are as reliable as mainstream medicine. Alternatively, professional voluntary regulation was acceptable. Other routes of regulation were not favoured by the respondents.

The 2011 Report stated that TCM, herbalism and acupuncture should all be regulated in the same way by the HPC, or a newly established CAM Council as a suboptimal choice, or by local

[27] Detailed information on agricultural and collection practices is in the Guidelines on Good Agricultural and Collection Practice (GACP) for Starting Material of Herbal Origin (HMPC, 2006).
[28] GDP was revised in 2007 to involve blood products, in 2013 for medicinal products, and in 2015 for active pharmaceutical ingredients (APIs) and excipients.
[29] Information on GMP and GDP inspections, including authorisation, certificate after inspection and statement of non-compliance can be found at Gov.uk. (2020). Some manufacturers based in China are found to be under these inspections and have the related certificate.

authorities as an easy and cost-effective regulator. If the systematic regulation of TCM were achieved, it would, on one hand, protect the title and functions of the practitioners, and, on the other hand, guarantee the consumers' options for healthcare would not be decreased after the 2004 Directive came into force. The 2011 Report did point out further directions for TCM (and separate herbalism and acupuncture) regulation, but it also pointed out the confusion of the respondents, which may render some contents of the 2009 Consultation invalid. The confusion appeared in: uncertainty over which regulatory route would be the most cost-effective; uncertainty whether practitioners should be required to have a high competency in English; and, uncertainty whether all the respondents understood the references and evidence used by the 2009 Consultation.

As a conclusion to the 2011 Report, the Secretary of the Department of Health expressed that the government wished to accelerate the regulation for CAM practitioners, especially herbalists, before the 2004 EU Directive came into force in April 2011. To carry on the regulation of herbalists, the Secretary appealed to the HPC to establish a statutory registration regime for herbal medicine practitioners, and it was aimed to have related legislation ready in 2012 for UK health departments. Until any changes were made by the prospective laws, the MHRA remained in charge of most herbal medicine affairs. For example, the unlicensed herbal medicines already in stock before 30 April, 2011 could still be supplied to the public. The Secretary considered that the former voluntary regulation on acupuncture worked effectively by complying with local authority hygiene requirements (Lansley, 2011).

Also in 2011, the UK working visa system reduced the number of tier two visa holders to 20,700 per year (Home Office UK Border Agency, 2011). Such applicants need to find jobs with a higher income[30] and sponsors who still have a quota to hire non-nationals. Also, the employers had to apply for a restricted sponsor certificate to obtain limited visa sponsorship places if they wished to hire foreigners for job positions which were not in urgent need due to a lack of labour. As a result, the BOs reported that it became more complicated to bring TCM practitioners from China to the UK.

In 2012, a year after EU Directive 2004/24/EC came into effect, the Human Medicines Regulations 2012 (2012 Regulations, see 9, Appendix II) was issued to amend Sections 12(1–2) of the 1968 Act. Some unlicensed herbal medicines remained exempt from regulation on

[30] In the 2006 point system, a tier two visa applicant with a PhD would need to earn a minimum salary of £15,000 per year; in the 2011 system, the minimum salary was £20,000.

condition that they are prepared for a specific person in their presence and by request, on the practitioner's private premises. The need for the treatment is judged by the practitioners in the 2012 Regulations, rather than by the user, as was the case in the 1968 Act. Also, it should be noted that since the requirement for GMP and GDP was clarified by EU directives and implemented in the UK, the 2012 Regulations did exempt manufacturer and wholesaler licences for TCM products on general sale, as the 1968 Act did. Regulation 17 of the 2012 Regulations implements the EU requirements on manufacture authorisation (see contents of manufacturer authorisation in 2001 Directive and 2003 Directive). A manufacturer licence is required if a person manufactures, assembles or imports medicinal products from a state other than the EEA; when importing, the licence holder must comply with GMP, and active substances used as starting materials should also comply with GMP. Data on the manufacture and importation of herbal medicinal products can be found in the MHRA-GMDP database. A wholesaler licence is required for wholesale distribution of medicinal products, and when distributing the products, the licence holder must comply with GDP. Moreover, the 2012 Regulation added new requirements for labelling, advertising and excluding ingredients to implement the pharmacovigilance requirements of the 2001 and 2004 Directive.

The Yellow Card Scheme (YCS, see 12, Appendix II) is used in the UK in accordance with the pharmacovigilance requirements of the 2001 and 2004 Directive emphasised in the 2012 Regulations. The YCS was established in early 1964 (BMJ, 2000), and gradually developed and expanded by the MHRA to monitor more types of adverse reaction (ADRs), medical device incidents, defective medicines, and fake medicines, as well as other safety concerns. The operation of the YSC depends on spontaneous reporting by health professionals and the public. Herbal and homeopathic medicines used in the UK are under the inspection of the YCS (Avery et al., 2011; Yellowcard.mhra.gov.uk., n.d.a). Also in 2012, a completed version of guidance classifying herbal medicines was published by the UK government (Gov.uk.2012). The guidance defines herbal medicines as products containing substances only derived from plants. In other words, CMs that contain animal or mineral ingredients disallowed in the UK.[31]

In 2014, guidance on banned and restricted herbal ingredients was extracted from the 2012 Regulation list of herbal medicinal products specified for the purposes of regulation and carried out by the MHRA (MHRA list) (MHRA, 2014c). The ingredients included in this list were

[31] See the webpage of ATCM- Chinese Herbal Medicine, the Department for Environment, Food & Rural Affairs, 2014, and the Department for Business, Innovation & Skills, 2012 [withdrawn already] for further information on using mineral ingredients as a food supplement with labelling requirements (see Gov.uk, 2021); also reported by CP 4, 6, 7, 11 and SUP 1.

restricted under various legal provisions in the UK.[32] Some substances used in TCM were identified. During the fieldwork for this research, another list named *The Checklist of TCM Banned or Restricted from Non-Doctors in the UK* was produced by the UK-TCM Federation (Federation checklist); this list spread among CPs as their prescribing reference. The banned or restricted ingredients in the two lists are summarised in Table 1.5. There are two noticeable points. Firstly, not all the ingredients listed have been shown to be harmful for human use. The risks and adverse effects of these ingredients were identified through case report or control studies (see superscript C below), or through experimental data extracted from modelling or animal tests, such as Evodia rutaecarpa in Baburin et al. (2018); Sophora tonkinensis in Chen et al. (2017c); and Prunus armeniaca in Chaouali et al. (2013); some of these, e.g., Asarum, lack information indicating detailed harm for medicinal use. Secondly, the requirements below only indicate those for oral or internal use. The MHRA List specified the requirements for external use as: 1) Aconitum carmichaelii[33] under limited dose; 2) Strychnos nux-vomica[34] can only be prescribed by a registered doctor; 3) Ephedra,[35] Datura metel,[36] Areca,[37] and Lobelia[38] can only be supplied in a registered pharmacy and by a registered pharmacist; 4) ingredients containing Arisolochia acid[39] cannot be used in unlicensed medicines.

[32] These legal provisions include: The Medicines (Aristolochia and Mutong etc.) (Prohibition Order 2001 SI 1841) to prohibit unlicensed Aristolochia and ingredients with Aritolochia species; The Human Use Regulation 2012 Regulation 214, to restrict making medicine to registered doctors; The Human Use Regulations 2012 No. 1916 Schedule 20 Part 1 containing herbs forbidden to be sold without the supervision of a pharmacist; The Human Use Regulations 2012 No. 1916 Schedule 20 Part 2 containing herbs with restricted dose to be sold without supervision of a pharmacist; The Medicines for Human Use (Kava-kava) (Prohibition) Order 2002 SI 1370 to prohibit oral use of Kava-kava; The Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 to prohibit medicine containing Senecio or its extract.

[33] Fuzi, 附子, stuck on the skin in powder form or boiled spices to treat pain (Huatuo, 2010).

[34] Maqianzi, 马钱子, concocted into powder form and spread on the skin for detumescence (PRC Pharmacopeia, 2020).

[35] Mahuang, 麻黄, mixed into a powder with soapstone and oyster and placed on the skin to treat foot sweat (Tao, 2013).

[36] Yangjinhua, 洋金花, the plant is burned and its smoke inhaled for a calming effect (PRC Pharmacopeia, 2020).

[37] Binglang, 槟榔, mixed with huanglian and egg white and rubbed into the skin for detumescence (Department of Health, Gansu, 1970).

[38] Banbianlian, 半边莲, cut and mixed with cheqiancao, zuanyanjianye and spit, and applied to the skin to treat cellulitis (Deng, 2002).

[39] Plants with Arisolochia acid used in TCM normally indicate fangji 防几, mutong 木通, xixin 细辛 (made into powder and inhaled through the nose to treat a stuffy nose, Pujifang, 1980).

Requirement	Botanic name*	Common name	Chinese pinyin/ name	Common functions*
Under specific dose or need special attention	Aconitum carmichaelii Debx.[abc]	Aconite	Fuzi/ 附子	To treat prostration
	Ephedra sinica[abc]	Ephedra	Mahuang/ 麻黄	To treat water retention
	Datura metel L.[abc]	Stramonium	Yangjinhua/ 洋金花	To treat pain, cough, also to calm down
	Psoralea corylifolia L.[bc]		Buguzhi/ 补骨脂	To improve kidney function
	Asarum[b]	(Chinese) wild ginger	Xixin/ 细辛	To treat cold, especially blocked nose
	Pinellia ternata (Thunb.) Breit.[bc]		Banxia/ 半夏	To reduce phlegm
	Evodia rutaecarpa (Juss.) Benth.[bc]		Wuzhuyu/ 吴茱萸	To reduce cold in body, stop diarrhoea and vomit
	Xanthium sibiricum Patr.[bc]		Cangerzi/ 苍耳子	To treat a cold, especially blocked nose
	Cnidium monnieri (L.) Cuss[b]		Shechuangzi/ 蛇床子	To treat genital itching
	Melia toosendan Sieb.et Zucc.[bc]		Chuanlianzi/ 川楝子	To treat parasites in abdomen
	Prunus armeniaca L. var. ansu Maxim.[b]	Bitter apricot	Ku Xingren/ 苦杏仁	To treat cough
	Curculigo orchioides Gaertn.[b]	Cali musil	Xianmao/ 仙茅	To treat erectile dysfunction
	Lobelia inflata[a]	Lobelia	Bnbianlian/ 半边莲	To treat toxic insect bites on skin
	Sophora tonkinensis Garnep.[b]		Shandougen/ 山豆根	To treat throat pain
	Polygonum multiflorum Thunb.[bc]	Fo-Ti	Shouwu/ 首乌	To treat constipation

Supplied only in registered pharmacy and by registered pharmacist/ or someone with licence	Areca catechy[ac]	Areca	Binglang/ 槟榔	To treat parasites in abdomen
	Punica granatum L.[a]	Pomegranate	Shiliu Pi/ 石榴皮	To treat parasites in abdomen
	Dendrobium nobile Lindl.[b]		Shihu/ 石斛	To treat dry mouth and low appetite
	Gastrodia elata B1.[b]		Tianma/ 天麻	To treat hyperspasmia and convulsions
	Cibotium barometz (L.) J.Sm.[b]		Gouji/ 狗脊	To improve kidney function
	Cistanche deserticola[b]		Roucongrong/ 肉苁蓉	To improve kidney function
	Panax quinquefolium L.[b]	American Ginseng	Xiyangshen/ 西洋参	To improve weak body
	Picrorhiza scrophulariiflora Pennell[b]		Huhuanglian/ 胡黄连	To reduce body's internal heat
Not permitted in unlicensed medicines	Akebia quinante (Thunb.) Decne[a]	Motong	Mutong/ 木通	To treat water retention
	Aristolochia[ac]	Isotrema manshuriense	Guan Mutong/ 关木通	To treat water retention
	Senecio scandens Buch.-Ham.[ab]	Ragwort; Groundsel	Qianliguang/ 千里光/刘寄奴	To treat infections on skin and eyes
	Stephania tetrandra S. Moore[ac]	Fangji	Fangji/ 防己	To treat water retention
	Arisolochia debelis[a] (leaf)		Tianxianteng/ 天仙藤	To treat pain
	Arisolochia debelis[a] (Root)		Qing Muxiang/ 青木香	To improve digestion
Containing chemical or	Niu Huang Jie Du Pian[bc]	Niu-Huang Chien-tu-pein	Niuhuang Jiedu Pian 牛黄解毒片	To treat infections

biomedical ingredients	An Gong Niu Huang Wan[b]		Angong Niuhuang Wan 安宫牛黄丸	To treat convulsions
	Celestial Emperor Heart-Supplementing Elixir[b]	Cheon-wang Bo-sim Dan	Tianwan Buxin Da 天王补心丹	To improve heart function
Only prescribed by doctor or dentist	Strychnos nux-vomica L.[abc]	Poison Nut	Maqianzi/ 马钱子	To treat injury

Table 1.5 Banned or restricted TCM ingredients

*Source: *Pharmacopoeia of the PRC*

[a] Ingredients included in the *Banned and Restricted Herbal Ingredients List of the MHRA*

[b] Ingredients included in the Federation checklist

[c] Harmful cases identified through the literature search

An independent Herbal Medicines and Practitioners Working Group was established during the 2013 parliament to find options to regulate herbal practitioners and advise the government. The group was led by Prof. David Walker[40], and was comprised of herbal practitioners and experts from the Herbal Medicines Advisory Committee (HMAC). The work of the group was supported by the Department of Health and the MHRA. The group produced its report in 2015 (2015 Report) to assess the development of the herbal medicine industry in the UK during the 15 years since the 2000 Report and 2001 Response (Walker, 2015). There were two parts to the regulations on managing herbal medicines used in the UK. Herbal products achieving the standards of the THR were granted market licences, but the number of herbal products with a licence were small (around 300) in 2015. The other unlicensed herbal medicines were under the scope of the 1968 Act, as amended by the 2012 Regulations, to be used and prepared by practitioners in their own premises after one-to-one consultation.

The 2015 Report then pointed out three risks under the previous regulations, including permission of off-site manufacturing of products, problematic categorisation of herbal ingredients as food supplements, and an unreviewed list of banned and restricted herbal ingredients. To resolve these risks, further regulations on herbal medicine were urged. However, the 2015 Report considered statutory regulation to be inappropriate due to the missing evidence base of herbal practice, insufficient data collected concerning the harms of unlicensed herbal medicines, and defective education and practice standards for practitioners. The 2015 Report suggested that improving standards of the utilisation of herbal medicines should come first, and started to collect more robust data on the safety and efficacy of herbal medicines as an initial step to protect the public rather than establishing immediate statutory regulation.

The Department of Health responded to the 2015 Report in 2017 (2017 Response) (Blackwood, 2017) by: supporting further research, standards development, and a review of the banned ingredients lists; rejecting the regulation of herbal medicines in the same way as food; rejecting a change in how the 2012 regulation managed unlicensed herbal medicine practised by practitioners in their own premises; and, discussing a future route for regulation and cooperation with the European Commission after Brexit.

1.3.2 Classification of existing regulations

Among the regulations mentioned in the above Section 1.3.1, there are 10 existing regulations

[40] Porf David Walker was the deputy Chief Meidcal Officer for England at the time of leading the working group.

currently in use. This thesis then classified these existing regulations according to their types of regulatory instruments, regulatory objectives, regulatory targets and enforcements. The classification could provide a clearer concept of the roles and functions of these regulations. Especially the (3) part of this section has set the regulatory targets in clauses of practice, prodcuts, people and premesis (4Ps), which provides indicator for later data analysis about the performance of regulations.

(1) Regulatory instruments

Regulatory instruments are political interventions made to direct social and economic behaviour. The regulatory system for TCM in the UK is hierarchical, from the EU to the district level according to the regulatory instrument (see Table 1.6). The EU Commission (n.d.) classified the types of regulatory instruments in its Better Regulation Toolbox #18 as 'hard', 'soft, 'education and information' and 'economic instruments'; similar classifications and definitions are also mentioned in Oxford LibGuides (2022) on EU secondary legislation, which emphasise that the 'hard' instruments are binding rules while the other types are non-binding:

a. Hard regulatory instruments direct behavioural change through legal enforcement. These instruments are binding acts, and are present at the EU level as Regulations, Directives and Decisions (Consolidated version of the Treaty on the Functioning of the European Union, 2012). The TCM-related regulatory instrument is the 2001 and 2004 EU Directive. These Directives are not as general as the Regulations, which are directly binding on all member States, and not as narrow as Decisions which are only aimed at a specific group. This gives EU member States the autonomy to design specific forms and methods to achieve the requirements of the Directives (Hatzopoulos, 2013). Thus, the UK government was able to implement the requirements of the 2001 and 2004 Directives according to the domestic situation. Although the freedom to implement is given to member States, hard regulatory instruments are criticised for being an immutable framework covering different national situations and government capacities in member States, and the compliance of member States is predicted to be unsatisfactory (Versluis, 2005). For now, with Brexit, the EU legislation applied before December 2020 is now transformed into UK domestic legislation (legislation.gov.uk, n.d.). No changes have been seen in TCM-related regulations at present (March, 2021).

b. Soft regulations support and supplement the deficits and gaps in hard regulations. Basic soft regulations are: self-regulation, technical standards, recommendations, and open methods of

co-ordination (OMC).[41] Soft-regulations are frequently applied to TCM. Firstly, TCM as a medical system in the UK is mainly under self-regulation, allowing the industry to find its own suitable and flexible way to align with the political objectives. Then, GMP and GDP serve as international standards to guide and consolidate the national standards for medical products. Some of the requirements of the 2004 Directive work similarly to the OMC. The 2004 Directive requires member States to recognise the registration of herbal medicinal products granted in other member countries.

Other regulatory instruments at the EU level include: 1) education and information with various guidelines to ensure targeted groups are better informed; and 2) economic instruments which are normally part of legislation to deliver more market-based regulatory approaches, such as taxes and fines. These two types of instruments are often part of the requirements in hard or soft regulations. At the UK level, regulations are often in the form of acts of parliament, private acts, and statutory instruments (SI). These acts indicate new laws, changes to existing laws and approval of bills. They are understood to be statute law in the UK that applies to the whole nation (UK Parliament, n.d.). Private acts apply to individuals or groups, while SIs develop more detailed and perhaps more complex orders, rules and regulations according to the broad framework of EU Directives and acts of parliament. SIs work as a subsequent, delegated or subordinate form of EU directive (before Brexit) and act of parliament (House of Commons Information Office, 2008). The existing acts of parliament related to TCM include: the Local Government (Miscellaneous Provision) Act 1982. The existing private act related to TCM is the London Local Authorities Act 1991 (and its amendments in the 2000 Act). The existing SIs related to TCM include: Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, and the Human Medicines Regulations 2012. Under these two SIs, the THR Scheme and Yellow Card Scheme are used as regulatory tools and systems for registration work and pharmacovigilance inspection and report.

Regulation level	Regulatory instruments	Regulation
EU level	Hard regulation —Directive	EU Directive 2001/83/EC & 2004/24/EC
	Soft regulation —self regulation	Industry self-regulation
	Soft regulation —technical	GMP

[41] OMC: A form of intergovernmental policymaking cooperation (EUR-Lex, n.d.).

	standards	GDP
	Soft regulation —OMC	Centralised and decentralised market authorisation
	Education and information	Part of hard or soft regulations
	Economic instruments	Part of hard or soft regulations
UK level	Acts of parliament	The Local Government (Miscellaneous Provision) Act 1982
	Private acts	The London Local Authorities Act 1991 & 2000
	Statutory instruments (Secondary law)	The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulation 2005
		The Human Medicines Regulations 2012
	Schemes	THR Scheme
		Yellow Card Scheme

Table 1.6 The regulatory/ policy instruments of the existing regulations

(2) Objectives: safety, quality and efficacy

The WHO (2003b) defines the goal of well-performed pharmaceutical regulation as the protection and promotion of public health by ensuring the safety, quality and efficacy of medicines. However, ensuring and improving the safety, quality and efficacy of TCM is not easy. The WHO pointed out in its 2002 TM strategy that TM is deeply connected with the cultures and histories of its countries of origin, and thus the mechanism of TCM works differently to biomedicine. Such differences cause obstacles when researching TM using the same standards and level as biomedicines (such as by conducting RCTs),[42] and thus both the national and international guidelines related to TM safety, efficacy and quality are missing. The WHO revised its appeal again in its 2014 TM strategy in order to call for national scale regulation of TCM to ensure 'the quality assurance, safety and effectiveness of T&CM practice and products'. As for the UK, improving medicine safety, quality and efficacy has always been the major responsibility of the UK's national departments, no matter whether in the period of the MCA or MHRA (House of Commons, 2003).

[42] This point is also in line with other studies, such as Adam (2002), who considered that biomedicine is dominant globally and caused inequality to many alternative medicines that do not define their efficacy based on biomedical approaches; to address this inequality, more empirical studies are emphasised (Thelwall, 2021).

The regulatory objectives of each document are summarised in Table 1.7. As for the current UK-TCM regulatory system, only the 2004 Directive included all three regulatory objectives of safety, quality and efficacy. The other regulations focused on safety and quality issues.

Regulations	**Safety**	**Quality**	**Efficacy**
Local Government (Miscellaneous Provision) Act 1982	✓		
London Local Authorities Act 1991	✓		
London Local Authorities Act 2000	✓		
EU Directive 2004/24/EC	✓	✓	✓
The Medicines Regulations 2005	✓	✓	
Traditional Herbal Registration (THR) Scheme	✓	✓	
Human Medicines Regulations 2012	✓	✓	
GMP		✓	
GDP		✓	
Yellow Card Scheme	✓		

Table 1.7 Regulatory objectives of the current TCM regulations

(3) Targets: practice, practitioner, products, premises

The regulatory targets of each document are summarised in Table 1.8. First, as for the regulation of practitioners, this research has found, in line with Walker (2015), that few regulations relate to practitioners. The 1982 Local Act requires a licence for people practising acupuncture. The Human Medicines Regulation Act 2012 exempts eligible practitioners from obtaining a manufacturer licence. The GMP sets standards for manufacturing personnel as part of its regulation of products.

Then, as for the regulation of acupuncture, the current situation is discussed regarding the scope of the NHS. The NHS has produced a regulatory framework that allows referral of 'biomedically recognised' acupuncture utilisation prescribed by doctors or other NHS professionals. Such utilisation of acupuncture is suggested by NICE (2020) and provided by external personnel within NHS community clinics (see nhs.uk, n.d.). For acupuncture practice outside the regulation scope of the NHS, acupuncturists can either voluntarily register themselves to a professional body, or practise freely under the rules of other legislation concerning skin treatment or commercial behaviours (Cloatre & Ramas, 2019).

Most existing regulations on TCM concentrate on products. There are seven regulations managing the registration of herbal medicinal products, the exemption of individually prescribed herbal medicines, the manufacturing and distribution of herbal medicines, and the data collection of adverse effect of herbs (Table 4.6). However, the 1982 Government Act, the Local Act 1991 and the London Act 2000 regulate premises for acupuncture to guarantee practice safety; the Human Medicines Regulation 2012 exempts premises from licence if occupied by practitioners or manufacturers, and the GMP sets standards for manufacturing and storage places as part of its regulation of products.

Regulation	Practice	Products	People	Premises
Local Government Act 1982			✓	✓
London Local Authorities Act 1991				✓
London Local Authorities Act 2000				✓
EU Directive 2004/24/EC		✓		
The Medicines Regulations 2005		✓		
Traditional Herbal Registration (THR) Scheme		✓		
Human Medicines Regulations 2012		✓	✓ exemption	✓ exemption
GMP		✓	✓sub-requirements	✓ sub-requirements
GDP		✓		
Yellow Card Scheme		✓		

Table 1.8 Regulatory targets of the current TCM regulations

(4) Enforcement

Strong law enforcement and other compliance mechanisms are considered an essential part of effective pharmaceutical regulation (Boxtel, Santoso & Edwards, 2008). The MHRA provides the enforcement framework derived from the Regulatory, Enforcement and Sanctions Act 2008 for medicines in the UK (MHRA, 2010), which includes stages of prevention of non-compliance, identification of non-compliance, investigatiin of non-compliance, use of sanctions for non-compliance, and the outcome of enforcement action. Although the MHRA does not

specify whether this framework has been applied to TCM, similar approaches used in UK-TCM regulations can be detected. The enforcement and compliance mechanism for UK-TCM regulation is summarised in Table 1.9 indicating their five stages of enforcement provided by Sanctions Act 2008. Regarding these regulations:

a. All TCM-related regulations have been published to stakeholders and the public as a warning approach to prevent non-compliance. The GMP and GDP have published specialised guidance to inform the industry about the latest rules for medicine manufacturing and distribution (MHRA, 2017a);

b. The Local Act 1982, the 2004 EU Directive, and the Traditional Herbal Registration (THR) Scheme requires evidence to identify and assess compliance, while the GMP and GDP take inspection as an identification approach;

c. The THR Scheme follows the principles of the 2005 Regulations to investigate non-compliance by checking related documents; the Yellow Card Scheme has a more systematic investigation procedure conducted by the MHRA, manufacturers or medical specialists;

d. All TCM regulations have sanctions prepared for non-compliance. Sanctions include being guilty of an offence and facing a fine and changes to licence status. The 2005 Regulations can enforce urgent safety restrictions and the withdrawal of products. The 2012 Regulations can impose infringement notices and sentence offenders with penalties applicable to medicines breaching provisions, pharmacovigilance regulations and information and labelling requirements; the 2012 Regulations and its related Yellow Card Scheme can apply penalties and prison sentences for breaching the requirements of the THR, labelling, and advertisements for traditional herbal medicinal products. The GMP and GDP have a compliance escalation procedure to ensure satisfactory improvements in manufacturing and distribution;

e. As outcomes, all the regulations expect that illegal activities will cease and, if possible, that no repeat offences occur. Only the two MHRA leading regulatory schemes, the THR and the Yellow Card Scheme, have a completed five-stage mechanism, but all the regulations clearly define their sanctions for non-compliance to guarantee implementation.

Regulation	**Regulatory targets**	**Stage 1: Prevention**	**Stage 2: Identification**	**Stage 3: Investigation**	**Legal process**	**Stage 4: Sanction**	**Stage 5: Anticipated Outcome**
Local Act 1982	Registration of practitioner and premises of acupuncture	Published regulation	Requires information for assessment		Lawsuit and prosecution	- Guilty of an offence - Fine - Suspension of cancellation of registration - Relinquish licence	- Cease illegal activities - Prevent offences in the future (re-registration is not allowed without consent of the court)
London Act 1991	Registration of premises of acupuncture	Published regulation			Lawsuit and prosecution	- Guilty of an offence - Fine - Relinquish licence	- Cease illegal activities
London Act 2000	Registration of premises of acupuncture	Published regulation			Lawsuit and prosecution	- Guilty of an offence - Fine - Relinquish licence	- Cease illegal activities
2004 EU Directive	Registration of traditional herbal medicinal products	- Published regulation - Published monograph	Requires evidence for registration		NA (leave to member States)	- Application could be refused - Requires compliance measures of member States	- Requires compliance

The Medicines Regulation 2005	Registration of traditional herbal medicinal products	Published regulation		- Licence holder keeps documents for suspect ADRs - Open these documents for inspection - Licence holder provides information of the time that the product has not been on the market and the volume of sale	Lawsuit and prosecution	- Licence may be cancelled if the product has not been on the market for three years - Licence may be relinquished, suspended or varied for its use, supply or marketing, and the licence holder should notify of such changes - Urgent safety restrictions - Recall or withdraw the product - Guilty of an offence	- Cease illegal activities
THR Scheme	Registration of traditional herbal medicinal products	Published online	Requires evidence for registration	Follow the principles of the 2005 Regulations	Lawsuit and prosecution	Follow the principles of the 2005 Regulations	Follow the principles of the 2005 Regulations
Human Med Regulation	Registration of traditional herbal medicinal	Published regulation			Lawsuit and prosecution	- Guilty of an offence - Fine - Imprisonment	- Cease illegal activities

2012	products; requirements of labelling/package/ advertisements of medicines; licence exemption for eligible premises, manufacturer and products						
GMP	Each node or medical products manufacturing	- Published regulation - Orange Guide 2017	Inspection (risk-based/ products-related/ triggered)		Grading on inspection findings to be: - critical deficiency (harmful for patients) - major deficiency (non-compliance with market	- Letter of decision - Requires confirmation of decision - Inspection report - Compliance escalation: a. Monitor the improvement b. Meet the manufacturers to inform of the consequence of non-compliance c. Return inspection if improvement is	- Cease illegal activities - Prevent the offence in the future

					authorisation, deviation from requirements, failure to carry out satisfactory batch, many other deficiency) - other (does not fulfil GMP but cannot be classified)	unsatisfactory - Refusal or suspension of licence	
GDP	Each node or medical products distribution	- Published regulation - Green Guide 2017	Inspection (risk-based/ triggered)		Same as GMP grading	- Letter with decision - Requires confirmation of decision - Inspection report - Compliance escalation - Refusal or suspension of licence	- Cease illegal activities - Prevent the offence in the future

Yellow Card Scheme	Data collection of adverse effect of medicines	- Published online (after investigation) - Publish leaflet, fact sheet or alert	Report	ADRs: - Investigate the report - Record and confirm the report - Assess the report Fake products: - Investigation into the business place and seize suspected items	- Report more detailed information - Commit to database - Assessment - Signal detection or impact analysis - Signal evaluation and prioritisation - Risk benefits evaluation and advice from Commission on Human medicines (CHM) (MHRA, 2012)	ADRs: - Warning - Restrict the indication of use - Change legal status of the product - Remove the product - Publish leaflet, fact sheet or alert Defective products: - Consult with doctors Fake products: - Work with manufacturers - Formal enforcement - Fine - Imprisonment - Civil injunction	- Cease illegal activities - Prevent the offence in the future

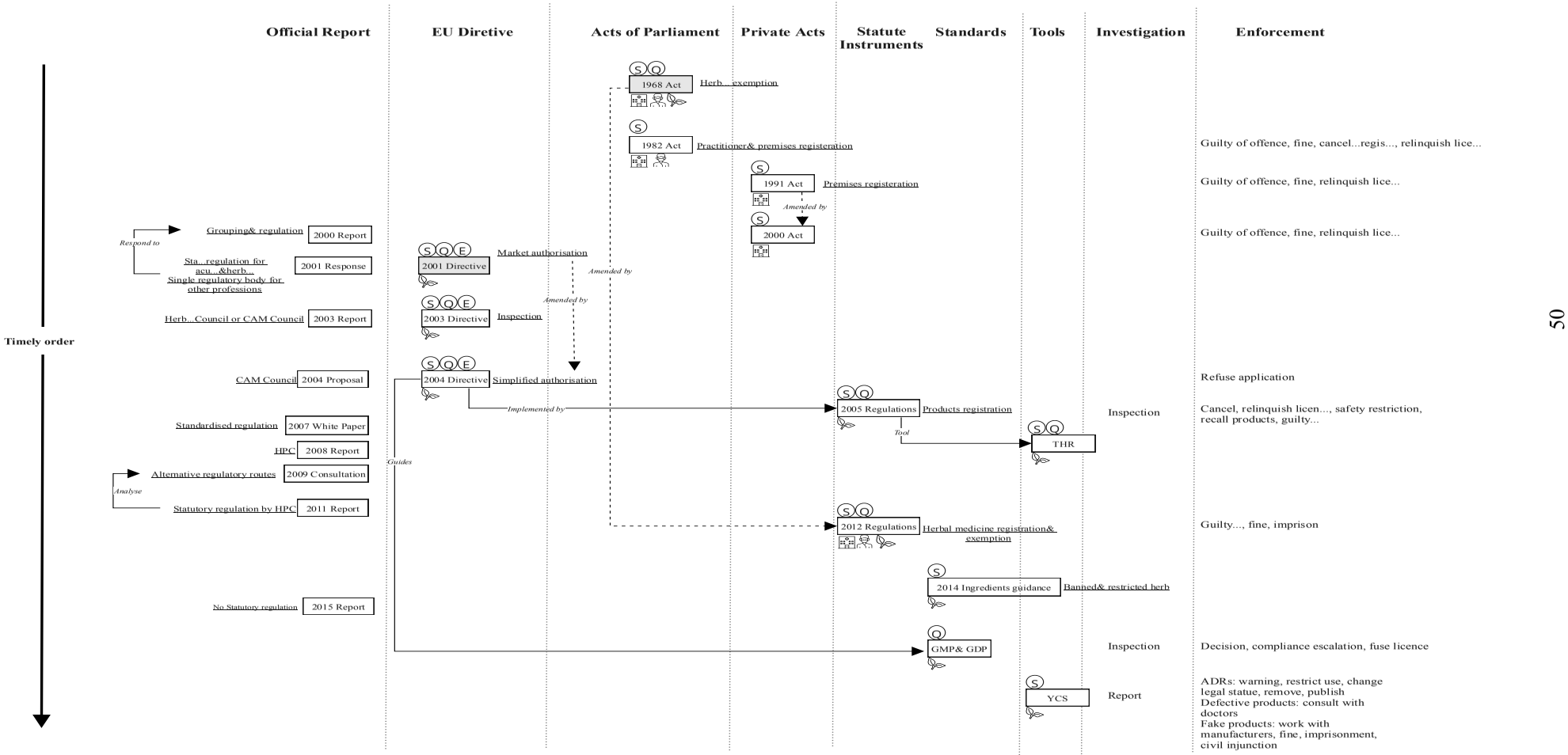
Table 1.9 Enforcement of regulations on TCM

1.3.3 Summary of the existing UK-TCM regulatory structure

This section depicted the historical development of TCM regulation (see Figure 1.2). Written regulations concerning TCM and its related therapies used in the UK were first seen in the 1968 Act, proceeding to the current 2012 Regulations. Over more than half a century, various governmental reports have been published to explore cost-effective regulation of TCM (and other CAM therapies), for the mutual benefit of practitioners and the public. These reports have repeatedly suggested and rejected statutory regulation in consideration of alternative routes. As a result, TCM in the UK remains under voluntary regulation by several regulatory bodies. Such voluntary regulation grants much freedom to the TCM industry.

To minimise the potential harm to the public caused by the free (and sometimes chaotic) regulation, legislation and rules are used to control the operation of the UK-TCM industry at multiple levels. The UK government regulates TCM by acts of parliament, private acts, and SIs, which are implementation measurements of EU directives. Most of these regulations concentrate on product management. Four regulations (the 1982 Act, 1991 Act, 2000 Act and 2012 Regulations) also focus on premises. Two regulations (the 1982 Act and 2012 Regulations) also control practitioners. Although the EU directives are aimed at regulating all three regulatory objectives of the safety, quality and efficacy of TCM, the actual implementation at the UK level only targets safety and quality. Regulation of the efficacy of TCM practice and products is left undetermined.

All the existing regulations have their compliance mechanisms, but only three (the 2005 Regulations and THR, GMP and GDP, and Yellow Card Scheme) have investigation approaches by inspection or the receipt of reports. The sanctions of other regulations are normally decided by law courts, and common sanctions include the cancellation or suspension of registrations or licences, or being found guilty of an offence, resulting in fines or imprisonment.


Official Report
EU Diretive
Acts of Parliament
Private Acts
Statute Instruments
Standards
Tools
Investigation
Enforcement
Timely order
1968 Act
Herb... exemption
1982 Act
Practitioner& premises registeration
1991 Act
Premises registeration
Amended by
2000 Act
Guilty of offence, fine, cancel...regis..., relinquish lice...
Guilty of offence, fine, relinquish lice...
Guilty of offence, fine, relinquish lice...
Respond to
Grouping& regulation
2000 Report
Sta...regulation for acu...&herb...
Single regulatory body for other professions
2001 Response
2001 Directive
Market authorisation
Amended by
Herb...Council or CAM Council
2003 Report
2003 Directive
Inspection
Amended by
CAM Council
2004 Proposal
2004 Directive
Simplified authorisation
Refuse application
Implemented by
2005 Regulations
Products registration
Inspection
Cancel, relinquish licen..., safety restriction, recall products, guilty...
Tool
THR
Standardised regulation
2007 White Paper
HPC
2008 Report
Guides
Alternative regulatory routes
2009 Consultation
Analyse
Statutory regulation by HPC
2011 Report
2012 Regulations
Herbal medicine registration& exemption
Guilty..., fine, imprison
2014 Ingredients guidance
Banned& restricted herb
No Statutory regulation
2015 Report
GMP& GDP
Inspection
Decision, compliance escalation, fuse licence
YCS
Report
ADRs: warning, restrict use, change legal statue, remove, publish
Defective products: consult with doctors
Fake products: work with manufacturers, fine, imprisonment, civil injunction

Ⓢ Safety related Ⓠ Quality related Ⓔ Efficacy related Practice related Practitioner related

Premises related Products related Existing regulation Expired regulation

Relationship ----- Changes

Figure 1.2 The UK-TCM regulatory system

1.4 Baseline of this research

A baseline for comparison is required to be able to follow the transformation of TCM after its journey from China to the UK and under the impact of the UK social and regulatory environment. As is seen in Section 1.2, TCM has been continuously changing due to social and political reasons. As such, there has never been a static homogeneous baseline, but rather one that is complex and dynamic. Scheid (2002) documented how CM has been constituted from a plurality of practices and throughout its long history it has changed by incorporating foreign elements at various points, including some biomedical concepts. No standardised, uniform, homogeneous form of CM existed at any point in China, and was exported and transformed in other places. CM (or TCM) has never been purely 'Chinese'. It has always existed in multiple forms in China and elsewhere and has changed historically by incorporating new political, social, technological and other elements from time to time.

I have therefore adopted the baseline in the context of this research as the form of TCM practice that practitioners in the UK used first. 'First' refers to the time at the end of the 20th century when Chinese immigrants flowed into many foreign countries, including the UK (Zhuang, 2006; Tran, 2009; Ye, 2016), and these immigrants brought TCM as a form of livelihood which then became a 'global phenomenon and big business' (Scheid, 2002). The baseline was founded on background information on TCM education and regulation in China and data were collected during fieldwork, especially interviews, by asking questions about "the modification of practice", "differences between practice in the UK", "the impact of regulation", and "your feelings about the regulation" (for the detailed interview protocol, see Appendix I). This involved the non-Chinese practitioners (NCPs) who may not have started their practice working in the 1990s. TCM as it was first used by both CPs and NCPs was considered to compare their current practices up to the time of conducting interviews in 2019 to 2020, as no changes have been made to the current TCM regulations since the 2004 EU Directive came into force in 2011; thus, a comprehensive and stable regulatory system could be mapped.

1.5 Gaps found in the literature and the necessity of conducting this research

After defining the research scale of China-TCM and UK-TCM, a brief literature review was conducted as preliminary preparation to understand the current progress of relevant research outcomes, and determine the gaps and deficits that might be addressed by this research.

Seeing the development of TCM in Europe in the late 20th century, Scheid (1999) predicted three possible routes for the future of TCM against the hegemony of biomedicine across the world: 1) some TCM therapies would be adopted as medical tools, but the core of TCM would be destroyed; 2) TCM might find a way to be institutionalised and standardised as it was in China; or 3) TCM could prove its efficacy based on personal experience and modern research, and then continue developing as a new tradition. Although the House of Lords report (2000) has provided a definition of the UK-TCM (Section 1.3.1), this definition was made 20 years ago; as such, there is not comprehensive according to a daily observation of TCM clinics operating in the UK today. Whether the current UK-TCM is consistent with Scheid's prediction (1999), and how TCM transformed itself into its current form, remain unclear. An up-to-date and comprehensive description of the current UK-TCM and an analysis of factors shaping it are required.

Besides, although the WHO encourages the implementation of regulation for traditional medicine practices and practitioners to enhance 'safety, quality and effectiveness' and make traditional medicines, including TCM, more acceptable in a modern health system (WHO, 2013), various concerns need to be resolved to enable CAM to meet the WHO's appeal. At this moment, evidence supporting the safety, quality and efficacy of TCM is insufficient even though it is trusted by many people (Chan, 2016). Cases of harm caused by inappropriate use of TCM occur often, such as the two fatal cases reported in Chinese literature of females who received acupuncture from an unqualified practitioner, who wrongly penetrated their heart and lung (Ernst, 2010). Further research is demanded to address the safety concerns with TCM, especially concerning the maximum dose of single ingredients, drug interactions between different herbal ingredients, and the use of TCM with biomedical drugs (Fung & Linn, 2015).

However, as Chan (2016) stated, the dilemma with driving TCM research forward lies in the difficulty of designing rigorous RCTs for herbal medicines which have numerous ingredients, and which are administered by those with inadequate education and training compared to health professionals (especially those based outside China); there is also a lack of funding. For the

quality concern, Li, Duke and Roufogalis (2003) stated that farming and harvesting impact the quality of plants, and so a pharmacopoeia or monograph is needed to help identify plants and standardise their quality before they become medicinal products. Such a monograph for herbs normally does not exist outside China. Li, Duke and Roufogalis (2003) also pointed out that the processing and implementation of government quality controls (i.e., good manufacturing practice) affects the quality of TCM products. One common approach to assessing the quality of TCM products is the use of only one or some chemical markers, but such an approach is inappropriate for TCM which contains many different components (Song et al., 2013).

As for the efficacy of TCM, the medical outcomes of TCM therapies cannot be confirmed based on the limited available research (Zhao et al., 2019). A systematic review of existing TCM clinical trials found methodological defects of TCM clinical trials registered with the online database of the US National Library of Medicine (Chen et al., 2017a). Some of the registered trials failed to design rigorous research procedures, or the trials collected only small samples, or remained unfinished after long period of time. Scheid et al. (2015) argued that the medical outcomes of TCM may vary for people living in different areas and thus the general efficacy of TCM therapies is hard to ascertain. On the regulations to address the safety, quality and efficacy concerns of TCM and protect the public, some key directions of effective regulation of CAM (including TCM) were found in the literature:

(1) The current CAM therapies lack scientific evidence and may cause harm to the public. If there is no scientific evidence to measure and prove the safety and efficacy of CAM, it will not be recognised and accepted by mainstream medicine, making regulatory decisions difficult. Thus, one main essential direction of CAM regulation is to develop TCM, both therapies and products, to be closer to science (Wahlberg, 2007; Cramer et al., 2010; Chan, Hu & Robinson, 2015).

(2) The popularity of CAM therapies is clear from the level of consumer demand (Wiese, Oster& Pincombe, 2010). The importance of consumer needs has been mentioned in the literature as a boost to the economy of the healthcare market, and in terms of reducing the burden on the public health system and better meeting people's individual health demands (Dixon, 2008; Røtnes & Dybvik Staalesen, 2010; The Economist & Intelligence Unit, 2016). The 2002 WHO Traditional Medicine Strategy specifically mentioned the importance of the availability of traditional medicine in its member states (WHO, 2002). The 2014 strategy again emphasised the significance of protecting and

conserving traditional medicine resources (WHO, 2013). The following points are essential to the creation of consumer-friendly regulations:

a. When regulating CAM, consumers should have reasonable access to CAM (Stuttaford et al., 2014); moreover, consumers' ethnic backgrounds, cultural beliefs and values need special attention as culture is an important factor affecting healthcare options, and knowledge of CAM's original countries and related cultural basis are thus required for regulators (Shaw, 2001; Clarke, Doel, & Segrott, 2004; Rochelle & Marks, 2011);

b. Another issue in regard to CAM consumers is to inspect and ensure the credibility and quality CAM promotions (Teng, Shaw & Barnes, 2015), which constitute advertising (or in other words how CAM providers deliver information), as well as the accuracy of the information delivered by mainstream medical healthcare providers (such as GPs who might refer CAM therapies) (Van der Schee & Groenewegen, 2010; Czaenaeska-Iliev & Robinson, 2016).

(3) Identifying professional values and improving the professionalism of CAM occupational groups is of importance to CAM regulation (Tyreman, 2011; Timmons, 2011; Clarke, Doel & Segrott, 2004).

There is a need to explore whether the regulation of CAM has made progress in meeting the above requirements. Some studies have presented shortcomings in the CAM regulatory regime:

(1) As of the first decade of the 21st century, the existing regulations had not contributed to the modernisation of CAM (Stone, 2005);

(2) Whether long-term use of CAM (EU Directive 2004/24/EC) can be considered adequate evidence of the protection of the public is doubtful. The long-term use of medicine does not have the same scientific credibility as rigorously designed modern medical research. The only function of the long-term use requirement is to reduce the risk caused by adulteration (McCartney, 2014; Cox, 2004);

(3) The regulation of CAM in the UK was assessed to be fragmented, with disagreements between different organisations and stakeholders (Roach, 2000).

The issues mentioned above on UK-CAM regulation have been noted for some years, and indeed some studies in CAM regulation have been done. These include: the influence on healthcare outcomes of CAM therapies given by practitioners with a background in mainstream medicine and limited experience of CAM training and education (Bishop et al., 2012); the impact of value chain on the quality of CAM products (Cramer et al., 2010); and, the considerations of mainstream medicine when prescribing traditional medicines (TMs) for patients (Teng, Shaw & Barnes, 2015). More importantly, few existing studies have directly explored the interactions between CAM regulation and TCM. TCM has a deep cultural background relating to the large number of ethnic Chinese in the UK and exists mainly in Chinese communities. To research the development, integration, and regulation of TCM in the UK would add the following value to CAM studies:

(1) To have a deeper understanding of CAM, and hopefully provide suggestions for other CAM therapies with a cultural basis, such as kampo and hambang;

(2) To understand differences in TCM education, practice, supply and regulations in the UK and China, and to provide advice on how to localise and regulate medicine involving issues from two countries, which is of importance against the background of globalisation;

(3) To provide more thoughtful consideration of the health coverage for immigrants.

1.6 Research aims, questions and objectives

Under these conditions, this research explores the process and status of the integration of TCM in UK society and the extent to which the regulations guarantee the integrated TCM to be safe, qualified, and effective. Also, the additional regulatory challenges that could impact the UK-TCM after Brexit will be considered. The results of this research will be valuable for the regulations of other CAM therapies. To fill in the gaps of the previous studies, this research aims to understand how TCM has adapted to the UK social and regulatory contexts and to explore the extent to which the regulatory system works to ensure safe and effective medicinal products, qualified practitioners, eligible premises, and adequate practice (the 4Ps). To achieve the research aim, the following research questions are asked:

(1) How is TCM practised in the UK?

(2) Which regulations are relevant to TCM in the UK?

(3) What is the impact of the regulatory system on TCM?

These questions will be addressed through the following research objectives:

(1) To map the current form of TCM practised in the UK and to understand how it has been transformed;

(2) To review the historical and existing regulations relevant to the UK-TCM and to identify how these regulations manage TCM products (medicine), practitioners (and other relevant personnel), premises and practice;

(3) To assess the performance of the regulatory system of TCM and determine if the regulatory system ensures that TCM is safe, effective and of adequate qualification.

1.7 Structure of this thesis

The thesis is divided into four rest parts: methodology, results, analysis, discussion and conclusion. The methodology part includes Chapter 2 describing the theoretical approaches and Chapter 3 describing the methods. Chapter 2 includes: the actor-network theory (ANT) used to guide the exploration of the adaptation of TCM to the UK context; and, responsive regulation to provide an ideal model of a regulatory system for the UK-TCM. The theoretical framework in Chapter 2 was developed to analyse how the answers to the research questions (in Chapters 4 and 5) meet the research aim. Chapter 3 contains a discussion of the methods employed to collect data, including ethnographic observation, semi-structured interviews and questionnaire. Data from the literature review has provided background context in Part I. The data from the ethnographic observation provides a narrative description of the current situation of UK-TCM. The data from the semi-structured interviews provides detailed information obtained from various stakeholders in the UK-TCM industry by documenting their personal experiences and thoughts. Data from the questionnaire supplements the other data by collecting concepts from TCM users. Finally all data was collected, coded and interpreted through thematic approaches, and presented in the results sections of Chapters 4 and 5.

Chapter 4 interprets the data collected by the ethnographic observation and the questionnaire, whereas Chapter 5 contains data collected through interviews. Chapter 4 provides a preliminary map of the current TCM in the UK by describing the daily operation of a TCM clinic and the data collected from their clients. Chapter 5 enriches this map by drawing portraits of the key stakeholders through their stories about the development of UK-TCM, which are missing in the literature.

Chapters 6-7 contain analysis. Chapter 6 first uses modernisation and globalisation theories to explain the possible reason and route for this transformation. The latter part of Chapter 6 then uses ANT to analyse the two transformation phrases of: 1) how the self-contained UK-TCM industry formed; 2) how regulatory elements helped establish the present UK-TCM. Chapter 7 uses the approach of responsive regulation to understand and assess the performance of the existing TCM regulatory system. It first analyses how responsive regulation can be applied in TCM regulation, and then evaluates whether the existing TCM regulatory system has achieved the ideal pattern of responsive regulation, before pointing out the inherent deficits of responsive regulation and discussing whether TCM regulations have avoided these deficits. This chapter uses appraisal materials (i.e., the OECD regulation assessment toolkit and the WHO traditional medicine strategy) to measure the performance of TCM regulation under the responsive regulatory mode.

The last part of the thesis contains two chapters. Chapter 8 provides some reflection on the grey areas of the current regulatory system and the role of TCM as a culturally featured medical system which is important for the health coverage of immigrants in the UK; Chapter 9 provides a concluding discussion.

PART II: Methodology

Chapter 2. Theoretical framework

This chapter provides a theoretical framework for the conceptual orientations which were used to guide data collection and analysis to understand how TCM operates in the UK and how the relevant regulations perform. This theoretical framework combines actor-network theory (ANT) and Braithwaite's notion of responsive regulation. ANT is used to explore the current TCM industry in the UK and its adaptation to the social and regulatory environment; Braithwaite's responsive regulation enables an understanding of the structure of the existing TCM regulatory system, and the performance and potential impacts of this regulatory system.

2.1 Analysis of the UK-TCM industry through actor-network theory

ANT is used to explore how a medical system kept growing and operating to become an influential phenomenon worthy of research. Regarding the data analysis for this thesis, ANT reveals how the connections within the industry were built, and how the connections changed and impacted the industry. The main concept of this part of the theoretical framework is derived from Latour, especially the 2005 book *Reassembling the Social* and Callon, Rip and Law (their work from 1986–2011).

2.1.1 Understanding the actor world concept

Callon, Rip and Law (1986) supposed the whole world to be an actor world, to which anything people wish to study belongs. They further stated that countless human and non-human/ individual and collective entities are involved in the actor world as entities which continuously act and react with one another. This aligns with Latour's concept of society (2005: 5) as 'a type of connection between social and non-social heterogenous elements'. When using this view to understand society, many elements, such as people, animals, and technology, are gathered to be mediated into a stable form. All these human and non-human elements, or in other words as actants[43] in Latour (2005)'s work, operate separately or spontaneously to impact the operation

[43] In ANT, both human and non-human act in network, both have agency. 'Actor' is automatically relats to human, whilst actant is the one Latour used for both human and non-human to overcome the problem of the word 'actor' being associated with just human agents. This thesis thus use 'actant'.

of a system (Law, 2011).

To study the multiple actants and the various associations among them that are scattered and not constant, a relativistic method is needed. ANT can render the social world traceable and make social relations visible by associating heterogeneous elements with one another. Latour (2005) suggested that ANT can be used to identify that which is not assembled. ANT mainly works by following social actants and describing rather than explaining the network they form, in the belief that description contains more information and goes further than an explanation (Latour, 2005). Even when controversies emerge, ANT does not solve these controversies by settling them to a specific domain but rather allows the social actants to deploy the controversies. To conclude, ANT studies how a network forms, what relationships exist, how the relationships change, how different relationships and actants are involved in the network, and how the network achieves stability (Cresswell, Worth and Sheikh, 2010).

In simpler words, ANT works to open the black box. Based on previous studies (such as Pinch, 1992 and Smith & Tatarewicz, 1994), Besel (2011) used the term black box to indicate a 'technical artifact', in that people know its functions and expected outcomes but ignore its internal working process. Latour (1999) stated that the development of a scientific or technological process is not linear. The understanding and knowledge of a scientific or technological process is not gradually established for lay people. More particularly, when a technology runs better, people tend to focus on its inputs and outputs rather than its 'opaque and obscure' operational process.

The black box idea was later expanded to other areas to refer to widely accepted knowledge used on a regular basis as a matter of fact (Besel, 2011). An actor world is known to people in the form of a network of simplified entities. A real actor network is not simple but an entity containing a series of discrete sub-level entities with well-defined characteristics. We could regard an actor world as a big black box formed by a series of sub-level smaller black boxes. To understand the formation and operation of this actor world, some subordinate boxes are simplified as points. The proper operation of each box and the proper operation of all the connected boxes as a whole are of the same significance to the changes in the composition and functioning of an actor world. Using descriptive functions to study a social network, and its formation and operation, ANT thus opens the black box and can be used to examine its internal ontology and construction (Stalph, 2019).

2.1.2 Translation as an approach to simplifying the world

To understand the actual and detailed operation of ANT, translation is central to ANT as it explains how different entities appear in order to render the complex world (Callon, Rip & Law, 1986). The literature has described translation as a broad process of coordinating and mediating the interests of different actants into concordance (Callon, 1984; Latour, 1988). The acting mechanism of translation is for one principal (main/primary) actant to reinterpret and displace the interests of other actants who were brought into the network by the principal to align with the collective interests (Callon, 1984). Concrete approaches to adjusting these interests include the 'displacement', 'drift', 'invention', and 'creation' of the connections between actants (Latour, 1988). As a result, the actants can accept, manage or reject being mobilised, juxtaposed and collated from their status as heterogeneous fragments into a united entity that clearly represents their interests (Law, 1992). Several researchers have paid attention to the effects of translation (mostly based on the work of Callon) and successfully applied the translation process to promote understanding and analysis of systems and expected changes to systems. Heeks and Stanforth (2015) focused on technology development, Rivera and Cox (2016) on the non-adoption of a collaborative technology, and Hu (2011) considered the planning of information systems in the community. The implementation of translation in this research was in a similar manner to the study of a medical system.

There are 'four moments' of translation (Callon, 1984) that show how translation is accomplished and a network is built (see Figure 2.1):

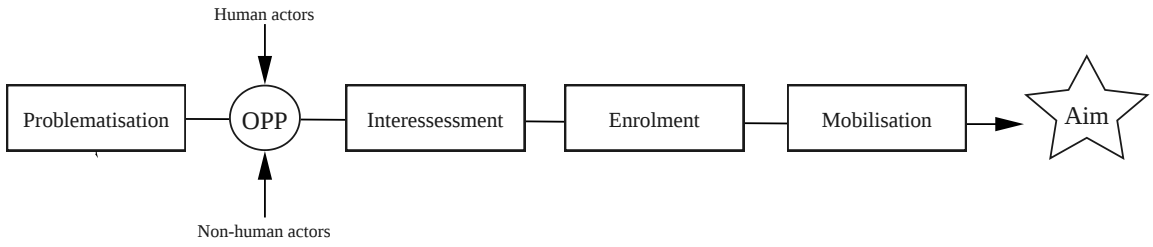


Figure 2.1 Elements of translation in ANT

a. Problematisation

In the initial stage of translation, problematisation answers the question of 'how to become indispensable' or how to build alliances (Callon, 1986: 6). Law (1986) stated that one could exercise control of others by creating an actor network to achieve a goal. The one controlling

others and forming the network is the principal actant, who wishes to make themselves indispensable to the other actants by defining a common problem. Principal actants can then bring in other relevant actants who contribute to the configuration of the problem-solving network. The principal actants not only perceive 'the other actants' as contributing to problem solving, but also need to ensure that all actants suggest a proposed solution route or at least a way forward to the problem. The principal actants then set an obligatory passage point (OPP), which works as a funnel so that the actants can only address their problems by passing through the OPP. Sometimes actants may need to adjust (or compromise, see Young, Borland & Coghill, 2010) their existing interests to pass through the OPP.

b. Interessement

The second stage, interessement, answers the question of how to lock the alliances in place. Callon (1984) suggested that the relationship of the identified actants with the principal actant has not yet been tested at the problematisation stage. The actants may resist or struggle against being involved in a specific network. As Rivera and Cox (2016) stated, any entity may simultaneously be the actant of other networks, and their positions, identities, and interests may be at odds with the problematised network. The formation of actants is gradually adjusted. Interessement indicates a series of actions used by the principal actants to adjust and lock the other actants into their network. Callon (1984) specifically mentioned that devices, including various strategies and interventions, are used to implement the actions of interessement. In reality, narratives, workshops, technology, physical devices, political forces or textual contents can all be used as devices (Hansen & Clausen, 2017; Papadopoulos & Wongkaew, 2008).

c. Enrolment

Whichever interessement devices are used, there is no guarantee of the successful establishment of a network, as Callon (1984) stated. Alliances are only achieved when enrolment is accomplished. Approaches to enrolment include negotiations, trials of strength and tricks that accompany interessement and enable it to be successful. Callon (1986) introduced negotiation as a common process in enrolment, during which the definition and distribution of roles played by actants are determined and tested. As possible outcomes of negotiation, actants may finally be enrolled through the ways of 'physical violence (against the predators), seduction, transaction and consent without discussion' (Callon, 1984: 12).

d. Mobilisation

Mobilisation is the last moment of translation which answers the questions of 'who speaks/

represents whom'. Callon (1984) defined the mechanism of mobilisation as the rendering of a network which was not so beforehand; in order to mobilise, someone needs to displace and reassemble the actants so that they perform as a unit of force. This 'someone' is a spokesperson. Callon (1984) stated that only a few individuals are involved in interessement and enrolment, and these individuals represent the uncountable other actants. Among these representatives, the principal actants borrow the forces of the passive agents (or intermediaries, according to Callon) to reduce the number of representatives and elect a spokesperson. In doing so, the final spokesperson should be supported by most of the actants within the network, and thus the spokesperson is able to represent the whole network, modify the behaviours of the other actants, stabilise the network, and remain loyal to the principle actants. Callon (1984) noted that the spokesperson has legitimacy in speaking for all the network, but also emphasised that there might be problems in clearly expressing the willingness of the network; this is because the network does not possess an articulate language as non-human actants are also involved. However, once the consensus of the network is achieved, a constraining network is built, and the spokesperson starts to push towards the united goal of the network.

Callon's case study (1984) of scallops and fishermen in Brittany's St. Brieuc Bay was the initial example of how translation explains the construction and development of a network and illuminates the application of ANT for many other possible research fields. The principal actants in Callon's study were three researchers who wished to test whether the new scallop breeding methods from Japanese farming would be applicable in St. Brieuc Bay, where the local scallops were being fished to a species-threatening situation. The three researchers first identified the other actants, including the associated scientific communities of the three researchers, and the scallops and the fishermen. They also identified what these actants wanted: the science communities wanted more knowledge about scallop breeding, the scallops wished to survive, and the fishermen wanted to continue scallop fishing. To build an alliance, the researchers set themselves as the OPP, since the other actants could not attain what they wanted independently (see Figure 2.2). The interessement devices in Callon's study were the knowledge of the scientists and related approaches to using collectors and tow ropes to anchor the larvae (which latter become scallops). After negotiation, trials and tricks, all these actants were enrolled into the network, and the three researchers became the representatives of the whole network.

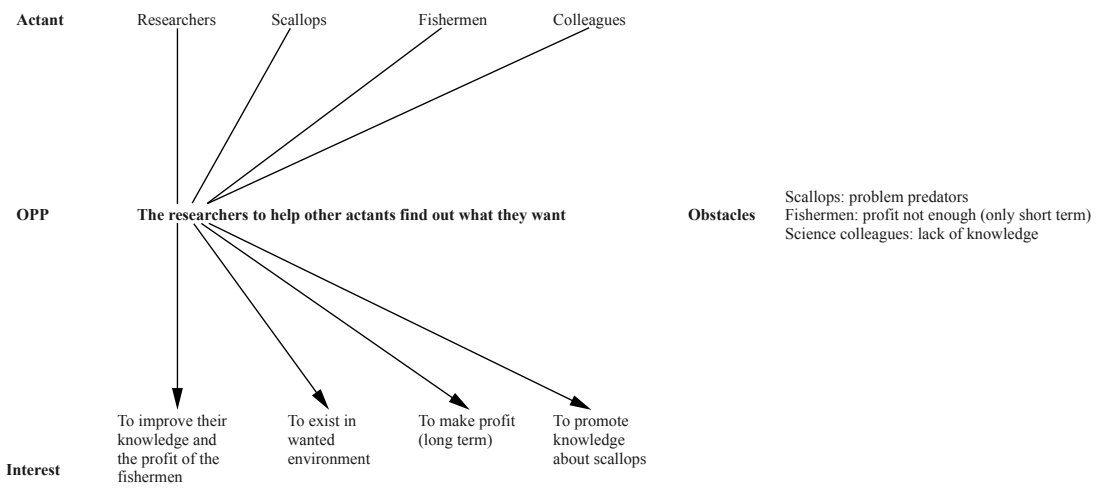


Figure 2.2 Problematisation process of Callon's study of scallops

There are existing studies applying ANT in healthcare issues in these years. Examples include Wickramasinghe, Bail and Tatnall (2007) using ANT to open the black box of a complex healthcare technology, the operation of networkcentric healthcare model; Bilodeau and Potvin (2018) used ANT to understand how different entities (human and non-human) impact healthcare intervention; Altabailbeth, Caldwell and Volante (2020) used ANT to find out the dynamic interplay between entities and their corporate work to lead to the outcome of healthcare organisation integration. In this research, the UK-TCM world is complex with many participants involved simultaneously; the data on these participants (both human and non-human), their activities and motivation for these activities should be collected to analyse how these participants form an actor network and how they operate with it.

2.2 Regulatory framework based on Braithwaite's concept

Although ANT can explain the position of the regulatory system in the UK-TCM actor network, the decision, delivery and operation of regulatory policies, a further theory is needed to guide the assessment of the performance of the regulations in relation to the research aim. Authorities use regulations as an approach to adjust behaviours according to certain standards, which can be either intentional or unintentional, direct or indirect. For instance, taxation to generate the target behaviours of a specific population (Koop & Lodge, 2017). Also, the form of regulation can either be statutory or self-regulatory (Kosti et al., 2019). Section 1.3 introduced some official rules and actions to regulate TCM in the UK, and it is also seen that some self-regulatory approaches in the UK-TCM industry exist, such as the voluntary practitioner registration stated

in Chapter 4. However, a more concrete and systematic model of a regulatory framework is needed to answer the research aim, namely, to analyse and assess objectively the current regulation of TCM and provide suggestions for its improvement. To address these aims, Braithwaite's concept of responsive regulation (Ayres & Braithwaite, 1992) is taken as the theoretical approach.

2.2.1 Three fundamental theories to build responsive regulation

In Scott's view (2004), there are three essential components for regulation: 1) rules, goals or values set to clarify what is to be controlled; 2) a monitoring mechanism; and, 3) actions to deliver control. In the 20th century, more regulations, rather than deregulation, were demanded as privatisation grew with the rise of neoliberalism (Braithwaite, 2011). Since the establishment of the Office of Telecommunications (Oftel) under the *Telecommunications Act 1984* as a non-ministerial government department to regulate British telecommunications, new regulatory agencies (for water, gas, electricity and train) gradually appeared in the UK, bringing more market competition and the need to protect consumers. These new regulatory agencies show that the function of government transformed from direct and tight control to steering and inspection. Managing a market or industry through a regulatory framework rather than a monopolistic approach is a common way for a regulatory state to delivers its power (Braithwaite, 2011).

However, implementing a comprehensive regulatory framework that covers various issues needs sufficient government capacity and resources (i.e., finance) (Scott, 2004). The limited fiscal capacity of some local English governments has been seen in terms of support for civil service facilities, against the background of privatisation and market deregulation during the 1980s and 1990s (Lobao et al., 2018). For example, the Prescot council had to sell the public library because of an insufficient budget (Goodman, 2018). That is, regulatory agencies lacking capability may find it difficult to provide effective regulation, which requires a high volume of input.

Scott (2004) explained that a successful hierarchical regulation needs input from multiple aspects, such as public understanding of regulations, rigorous monitoring mechanisms, and formal enforcement. Regarding the difficulties of precisely completing each step of hierarchical regulation, Scott suggested the possibility of conducting a 'de-centring' model of regulation. A de-centralised, or in Scott's terms 'post-regulatory' (2004), model can improve governing

mechanisms which do not rely heavily on 'recourse to the authority and sanctions of government'; moreover, a post-regulatory model may compensate for certain issues with hierarchical regulation. This includes the focus on law to enlarge the capacity of control over the process of ordering (such as the operation of a market), and to mitigate potential risks rather than control the risks afterwards by involving non-state actants. Scott (2004) identified three theoretical concepts that are relevant to achieve the aim of the post-regulatory model: Foucault's concept of governmentality, the legal theory of autopoiesis (LTA) by Teubner (1987), and responsive regulation.

Originating from Foucault's lecture titled '*Security, territory and population*' in 1978, the concept of governmentality spread rapidly in English-speaking places via the book *The Foucault Effect* (1991). It is normally defined as the 'art of government', in that governing is not limited in political scope but can involve a wide range of control techniques and be applied to a wide variety of objects. Governmentality challenges the old concept of state law as the centre of governing by paying attention to the mechanism of how law adjusts the regulated, and more importantly to how it adjusts the purposes of regulation. Governmentality refutes sovereign power as the only approach to the exercise of regulation. It undermines the differences between public power and other sources of power in order to have an impact on the world. That is, law is just one tactic for governing. Any other type of power with a monitoring and behaviour-modifying mechanism can be used for governance. That is, governmentality reformed the understanding of regulation by acknowledging the limitation of the role and effectiveness of law, and added more possibilities for adjusting behaviours through various sources of power.

LTA is a theory that sees legal autonomy in the self-reproduction of a communication network and understands its relation to society as interference with other autonomous communication networks. LTA is rooted in the limited capability of control of laws because the world is constituted of different autonomous independent sub-systems. The interdependency of these closed subsystems causes difficulties in communication, and the lack of valid communication thus impedes laws from exercising control. Occasionally, different sub-systems might align well with others in a particular set, and LTA terms such alignment 'structural coupling'. Such coupling suggests that the power of control can be strengthened when differences between sub-systems are minimised. That said, regulatory control could succeed by understanding the order within the targeted other sub-systems. LTA then raises a regulatory route to implement indirect intervention over the 'control of self-regulation' (see Teubner, 1987; Black, 1996). Scott

simplifies this as steering the targeted social systems to guarantee compliance with regulatory goals. However, in LTA, there is the suggestion that thinking can be performed differently in respect of a particular set of values, by encouraging self-regulation rather than the direct control of law under the steering of regulators.

Scott introduced responsive regulation as the third type of post-regulatory model, describing it as the evolution of governmentality and LTA. Before the formal introduction of responsive regulation, the theory of responsive law by Nonet and Selznick (2001) was adopted to explain the definition of the ideal rule of law. The core of their argument is that a legal system is tied to the environment in which its laws are formulated and applied; political power is not the major factor in the creation of regulations and thus they cannot be arbitrary. Also, Nonet and Selznick considered that, in order to achieve any regulatory purpose, it was essential to focus on and make timely adjustments to institutional arrangements that may frustrate such achievement. They then argued that ideal law 'may require a relaxation of central authority in the interest of more effective cooperative action' (Nonet & Selznick, 2001: 100). The Selznick school argued that arbitrariness would be reduced through increased autonomy and the weight of law, with better regulation and substantive justice being achieved when laws work beyond formal regularity and procedural fairness (Nonet & Selznick, 2001).

Scott (2004) wanted to use these post-regulatory approaches to replace the old-fashioned regulatory actions that rely heavily on hierarchical control by law, despite the fact that they work ineffectively in many situations. Scott (2001) himself admitted that abandoning hierarchy in regulation might mean 'no regulation at all'. The ideal type of regulation, which may be negotiable or dependent on the market, should incorporate notions of uniformity, certainty and predictability (McDonald, 2004).

Adopting the advantages of the LTA, governmentality, responsive law and the classic regulation empowered by command law, responsive regulation was considered an advanced model of regulation that promoted regulatory intervention at the lowest possible level to secure the desired outcomes, while retaining the capacity to intervene more (Scott, 2004). Braithwaite (in his book with Ayres, 1992) has challenged the set position of deterrence-based regulation by removing unnecessary rules to guarantee as much freedom and rationality as possible. This idea is especially suited to regulation in fields with multiple participants in a changing environment in need of an alternative regulatory route. The principle of responsive regulation is to conduct inspection depending on the profile and behaviours of the entities according to

their specific features, and to take corresponding actions, including legal enforcement and other approaches, through escalation (Organisation for Economic Co-operation and Development, 2014 & 2018a). Responsive regulation is considered in this research to be the best interpretation of a comprehensive regulatory model, which suggests adjusting/regulating behaviours by various means (as in Foucault's governmentality), considering the particular values of the subjects of the behaviours (as in LTA). The ideal route for implementing such adjustments is to reduce arbitrariness (as in the theory of responsive law), without denying the hierarchical regulation made by state power and solid laws and while retaining the option to impose penalties and use other enforcement methods (as in classic regulation).

2.2.2 Responsive regulation approaches and their implementation in current UK-TCM regulation

The principles of responsive regulation can be divided into two aspects: 1) the use of various sources of power to target different behaviours motivated by multiple values; and, 2) reducing arbitrariness in regulations but retaining the deterrence of law. The concrete strategies of responsive regulation are thus divided into two directions: horizontal and vertical, which Ayres and Braithwaite (1992) referred as delegation and escalation.

Generally speaking, delegation means the involvement of private actants who share regulatory tasks and functions at the same level within the market; escalation helps to supplement the market by inserting governmental interventions in an uplifted direction. Ayres and Braithwaite emphasised that there is no best choice of regulation as between delegation or escalation, as these two strategies actually support each other (see Figure 2.3). Regulatory tasks can be delegated to private actants only when there are traditional forms of regulation, such as reinforcement; by delegating regulation, the traditional regulators, such as governments, can achieve their regulatory goal while allowing the market to remain 'laissez-faire'; however, the regulators should keep in mind that delegation will not always meet regulatory needs, and other approaches such as escalation intervention to law may be demanded to secure compliance once delegation fails. If the escalation approaches are strong enough, the market is at the 'quasi-laissez-faire' status and the delegated actants can operate their regulatory duties smoothly; once the delegated regulation works effectively, government needs not escalate to enforcement. That said, delegation and escalation form a circular pattern of responsive regulation. When reading this chapter, one should bear in mind that responsive regulation has no one best regulatory approach. The best strategy will depend on the context, regulatory culture, and history of the

regulated.

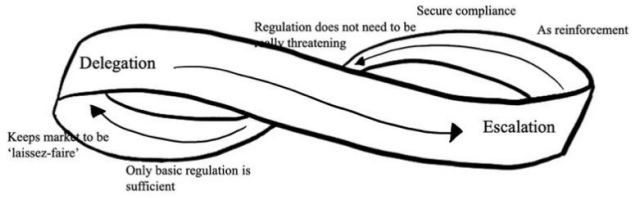


Figure 2.3 Relations between delegation and escalation

There are some common approaches for escalation and delegation that can be considered for their application in this research. Ayres and Braithwaite described the *tit-for-tat* (TFT) strategy as focus of escalation, and considered that the best way for regulators to secure compliance is by performing as 'benign big guns'. That is, the regulators use punitive approaches as a shield, but implement persuasion first. The big guns are always in support, so that regulators have the confidence to speak softly at first, and it is predictable that the bigger and more cruel the guns are, the more easily the regulators can achieve success by persuasion, and therefore the more effective the regulation. The advantages of TFT are obvious since the regulator can easily adjust its regulatory approaches. However, these can be neither solely deterrent nor solely cooperative because some of the persons being regulated are profit motivated. While this requires strong regulation, it must also respect those motivated by a sense of responsibility. In so doing, it can save money and time compared with the pure regulation by law, and can prevent resistance to regulation or the seeking of loopholes.

Pyramidal escalation is a detailed analytical approach in TFT used to resolve deficits in official capacity and decide on the nodes for punishment and persuasion. A regulation pyramid escalates from the most deliberative approach at its bottom, where the regulated is highly compliant to the gradually more demanding interventions at the top, where compliance reduces (Braithwaite, et al., 2005, see Figure 2.4). The regulatory pyramid has the advantage of being flexible as it is dynamic without having pre-set actions to apply in a specific situation; it is also cost-effective as there is evidence for each regulatory action and the cost does 'not go beyond necessary' (Braithwaite, 2005).

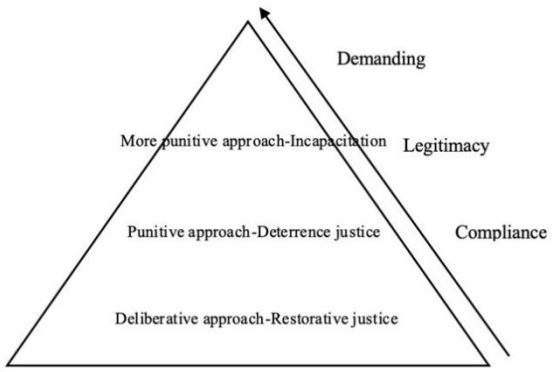


Figure 2.4 A basic responsive regulation pyramid

The pyramid mode is used by TFT to take specific actions against the potential harm produced by plural motivation. There are two basic types of pyramid. The first type happens between the regulators and a single entity, such as a firm. Braithwaite (1985) described the effects of a pyramid pattern as being a concrete solution of TFT in his early work titled *To Punish or Persuade*. Braithwaite (1985) emphasised the enhanced effects of escalation through a wider range of sanctions rather than binary punishment or persuasion. This range of enforcements includes economic approaches, reputational deterrence, moral education, and the law. The pyramid then starts from the most modest approach such as with cooperation at the bottom, and places law at its apex to assert coercive control. In order to have these options of enforcement, it is considered that the regulated are less likely to deviate from basic cooperation.

The second type of pyramid transcends the scale of the single entity to target industry-wide regulation. This pyramid has self-regulation at its base, escalating to enforced self-regulation, compulsory regulation with discretionary punishment, and compulsory regulation with nondiscretionary punishment. Regulation is described as a game of negotiation that has enforcement as the outcome of the negotiation process. The gradually escalating enforcement provides the regulated with the space and time to reduce compliance costs by making concessions to the regulators. The pyramid form of escalation is thus regarded as a win-win solution for both the regulator and regulated. Two objectives of the regulatory pyramid were emphasised by Nielsen and Parker (2009): that the regulation should first improve the voluntary compliance of the regulated rather than using deterrence to punish their resistance and non-compliance; second, the regulation should respect and remember people's moral commitment to comply with the regulatory goal.

In addition, the escalation pyramid is not a unidirectional uplifting process; Ayres and Braithwaite (deriving the idea from Scholz, 1984a & b) stated that TFT is both provocative and

forgiving. When the regulated are willing to cooperate, the regulator should forgive any history of wrongdoing by de-escalating down the pyramid to less stringent enforcement and regulatory strategies. De-escalation not only indicates the forgiveness of the regulator in giving the regulated a second chance, but also works to maximise the difference between the cooperation and punishment payoffs that allow the regulated to bear in mind the tougher enforcement they never faced. That is, forgiving (but not forgetting) helps to build a commitment to future compliance.

According to Ayres and Braithwaite, a pyramid applied to the regulation of the health-related industry would not be very complicated. They considered that a line of sanctions should be effective, from persuasion to warning, to civil penalty, to criminal penalty, to licence suspension and finally to licence revocation. This research uses a similar pattern of pyramid which applies well to the UK-TCM regulation.

Besides the approach of an escalation strategy, Ayres and Braithwaite also emphasised delegation as a means of resolving regulatory issues, as delegation is the base of an escalation pyramid. Delegation can redress the potential risks embodied in traditional regulation. When delegation works effectively, the upper level of escalating interventions is seldom activated. However, successful delegation must be able to provoke greater intervention once non-compliance and other problems go out of control. Three common delegation approaches are identified: 1) tripartism, indicating that regulatory tasks are shared among public interest groups (PIGs); 2) enforced self-regulation, where regulatory tasks are shared between the business entity itself; and, 3) partial industry intervention, where regulatory tasks are shared between the industry association and the competitor of the business entities. All three delegation approaches help to build a firmer base and prevent the possible activation of higher levels of regulatory intervention. Tripartism prevents the regulators from being captured by ill-natured business entities, leading to corruption which harms the public. Mixed self-regulation provides intermediate regulatory choices to guarantee both the discretion of the industry and the authority of the regulators. Partial-industry regulation uses cheaper approaches to regulate only a part of the industry, such that the regulated and unregulated parts compete and restrict each other to prevent private collusion and capture. All these approaches can be deployed simultaneously to compensate for the drawback of pyramid regulation in reacting sequentially.

In this research, data on TCM-relevant regulations and their impact and concrete operation were collected to analyse how this regulatory system works and could be improved. Previous studies

have shown the possibility to apply responsive regulation in controlling pharmaceutical industry (Brushwood, 2001; Ritter, 2010; Bandiera, 2014). These studies recommended responsive regulation as a method to avoid over-regulation and to chase outcomes that would beneficial the public; responsive regulation then provides alternative approaches as a proactive controlling strategy of government to get help from consumer groups and the market to impact the consumer preferences and encourage various selling behaviour; responsive regulation can also increase compliance of pharmaceutical industry when the official department are powerless to strongly control complex market environment where multi-national pharmaceutical companies are involved. As previously introduced in the background part, the current regulation of TCM in the UK is under a combination of state and self-regulation. Also, a regulation pyramid can be identified in the UK-TCM regulation, the UK-TCM regulation is under self-regulation at most time, but it is also inspected and charged by the reginal and national legislations in the UK, then some of the UK legislation is under the guidance and instructions of the EU order. Data collection should be able to test such hypothesis and analyse the concrete pyramidal framework of TCM regulation in the UK. In other words, Braithwaite's responsive regulation theory would help to address the research objectives of the identifying the UK-TCM regulation and its impact.

2.2.3 Assessing the performance of the UK-TCM regulatory system

First, although responsive regulation is applicable to UK-TCM regulation in terms of explaining structure and operation, it should be questioned if this responsive TCM regulation has attained the perfect mode assumed by Ayres and Braithwaite (1992). Both the escalation and delegation approaches used in TCM regulation will thus be assessed to see whether the pyramid of TCM regulation in the UK was successfully built. Second, I referred to Baldwin and Black's concepts (2008) on the critiques of Braithwaite's responsive regulation. General escalation is considered distant from real cooperation because it responds according to the different motivations of the regulated actants. The regulated do not in fact surrender to regulatory power because their motivations are precisely targeted, and instead of being persuaded. Baldwin and Black (2008) suggested a more efficient means of regulation through the analysis of types of regulated persons, leading to the tailoring and targeting of regulatory responses on a case-by-case basis rather than a generalised TFT strategy.

Also, Baldwin and Black indicated that Braithwaite's responsive regulation represents an ideal form of regulation that only happens between the broad concepts of the regulator and regulated.

The actual regulator and regulated are constituted of many people, organisations, and other non-human entities (the concept of actant in ANT). To roughly apply RR to regulatory areas containing multiple players may thus cause confusion.

Further, step-by-step uplifting escalation is considered by Baldwin and Black to be slow in reacting to catastrophic risks, and indeed Braithwaite himself agreed (2014) that police should resolve high risk attacks such as suicide bombings in a crowded place as soon as possible, rather than gradually seeking solutions via an escalating order. To decide the up and down of regulatory action by the extent of cooperation rather than the seriousness of real issues is inappropriate.

When applying Braithwaite's responsive regulation to practice, more realistic factors need to be considered. Baldwin and Black emphasised that the success of an escalation pyramid needs the support of a legislature, including regulatory agencies and rules with appropriate responses. The work of the legislature is of significance. In addition, though Baldwin and Black confirmed the effect of the de-escalation mechanism in regulation, they also advised paying attention to potential prejudice from regulators, as it is they who decide on the triggers for de-escalation that may make the moving-down process difficult.

As for delegation approaches, Ayres and Braithwaite suggested strategies such as tripartism to compensate for the shortcomings of escalation. However, at the time of their research in 1992, they admitted there was insufficient research on the practical implementation of tripartism and its cost-effectiveness compared to traditional regulation. Recent research by Heijden (2020) found that tripartism can lead to bias, as the third party prefers to report obvious problems with lower risks which are easier to identify. In this regard, tripartism was repudiated by Baldwin and Black, since the possibility of PIGs becoming 'shadow regulators' and the capacity to resolve and restrict this possibility was not addressed.

The above statement described above were used to test the implementation of responsive regulation on the UK-TCM and assess the performance of such a regulatory system from the perspective of Ayres and Braithwaite's responsive regulation theory. A third assessment route was designed combining three assessment tool kits and documents, including *Measuring regulatory performance evaluating the impact of regulation and regulatory policy* (Coglianese, 2012), *Effective drug regulation: A multicountry study* (Ratanawijitrasin et al., 2002) and *WHO traditional medicine strategy: 2014-2023* (WHO, 2013), to evaluate further the effectiveness

of the UK-TCM regulatory system from broader perspectives. Three major documents were consulted.

The first is the framework on measuring the regulation work developed by the Secretary-General of the Organisation for Economic Co-operation and Development (OECD). This framework was produced by Coglianese (2012) and provided the fundamental basis for the evaluation of the regulations and recommendations for improving policymaking in the context of globalisation; as such, it is suited to this research. The UK is a member of the OECD, and the regulation of TCM is firmly connected to the globalisation of healthcare delivery. Coglianese introduced three forms of evaluation, which I concluded are not firmly connected and are instead more a progressive relationship (Figure 2.5).

The three forms are: 1) *regulatory administration* indicates the extent to which a policy is well delivered; 2) a well delivered and designed policy increases *behavioural compliance*; and, 3) high compliance behaviours are likely to result in satisfactory *outcome performance*. Coglianese (2012) defined the outcomes of regulations as the most essential aspect in evaluating the effects of regulation, because the aim of all regulation is to adjust behaviour and improve outcomes. Evaluation is thus the process of exploring if the outcomes reduce the targeted problems. Coglianese (2012) then used two features to assess outcome performance: 1) indicators of actual measurements to reflect the changes before and after regulation; and, 2) attribution, which refers to the causal pathway from the regulation to the change of indicator. These two features have two further sub-types: 1) indicators that measure the reduction of targeted problems and other values such as cost or side effects; and, 2) relationships between the policy and the changes in indicators, which can be either attributional to explain the casual factor or non-attributional to illustrate the improvement level.

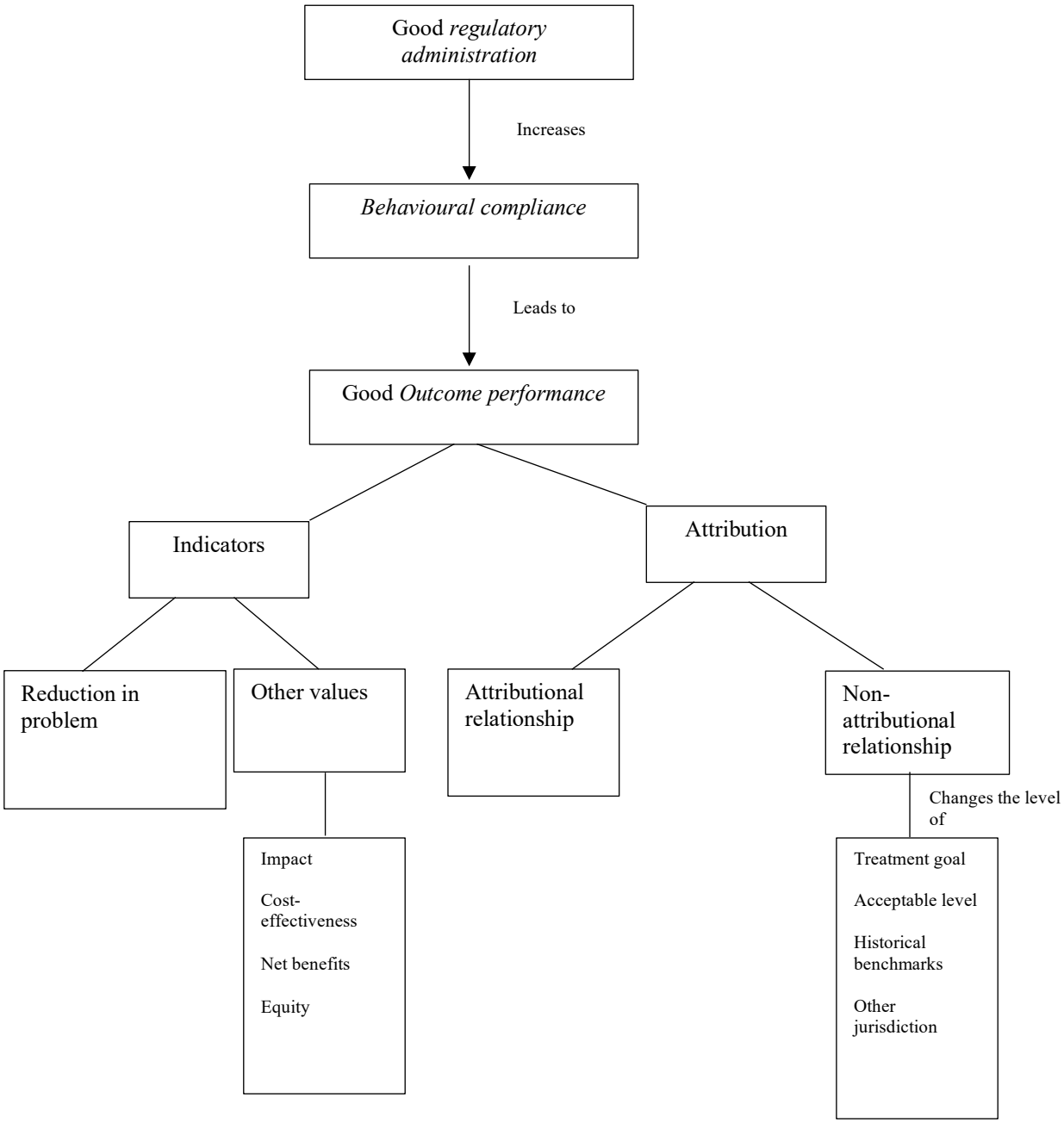


Figure 2.5 OECD evaluation framework

The second consulting document used is a report produced by Ratanawijitrasin et al. (2002) for the WHO health system evaluation. This 2002 WHO report takes the outcomes of regulation as the most important aspect of the evaluation. It considered "ensuring the safety, efficacy and quality of drugs available to the population" and rational use of medicine as the common and major aim of an effective pharmaceutical regulation. Effective regulation should thus establish specific functions (and sub-level of regulatory actions) to achieve the regulatory aims of safety, efficacy, quality and availability, simultaneously or respectively. The common regulatory actions used in the WHO member countries in their pharmaceutical regulation are summarised in Table 2.1. Each function should be measured to see if their sub-level actions reduced non-

compliance or problems with the regulatory aims of safety or efficacy or quality; or if these regulatory actions brought additional value to the regulation in question.

Functions of regulation	Regulatory action	Aim
Product registration	Product types	Safety/ Quality
	Source of products	Safety/ Quality
Licensing	Manufacturer	Safety
	Importer	
	Retailer	
	Wholesaler	
	Premises	
	Practice	
	Person	
Inspection and surveillance	GMP	Quality
	Distribution channels	
	Adverse reaction	Safety, Quality
Control	Insurance	Safety
	Price	
	Promotion and advertising	Safety/ Efficacy
	Prescribing	Safety
	Generic substituting	Safety/ Quality/ Efficacy
	General sales	

Table 2.1 Domains of official control in pharmaceutical regulations

An effective regulatory system does not necessarily include all these regulatory functions. For instance, the 2002 report stated that many countries exclude herbal medicine from the highest regulation level, because the lack of scientific evidence and lab data on herbal medicine meant that the requirement of efficacy was hard to apply. Thus, considering the controversy of regulating herbal medicine and other CAM therapies, and in line with the research aim, I consulted the WHO (2002) traditional medicine strategy of 2002–2005 and its revised version of 2014–2023, to understand the essential factors in the regulation of TM. The 2002 strategy called for the continuous development of TM regulation. Previous regulations in the EU concentrated more on herbal medicines based on *The Guidelines for the Assessment of Herbal Medicines*, which guided the evaluation of safety, quality, efficacy, intended use and information for the public (WHO, 1991). Comprehensive instructions were later provided in the 2014 strategy to cover more aspects of TM regulation. The 2014 strategy suggested that the regulation of TM be applied in each WHO member country by building a base of knowledge

on CAM and its regulation, regulating its products, practices and practitioners, and integrating it into the healthcare system (Table 2.2).

Regulation direction	Contents
Knowledge base of TM management	To understand and recognise the role of TM
	To strengthen the knowledge and evidence base
	To strengthen sustainable resources
Regulation on products, practice and practitioners	To understand and recognise the importance of product regulation
	To regulate practices and practitioners in the aspects of education and training, skills development, services and therapies
Integration of TM into healthcare services	To capitalise on the contribution of TM
	To ensure consumers can make informed choices

Table 2.2 Directions in the regulation of traditional medicines

Some additional documents were also consulted. The Lancet Commission on Essential Medicines (Wirtz et al., 2017) suggested more up-to-date essential areas for the evaluation of pharmaceutical regulation, similar to the 2002 WHO report, such as the establishment of a website to publish medicine registration information, inspections of pharmacovigilance, and control of international medicine importing. Studies such as that of Dixon (2008) on the regulation of CAM practitioners provide advice on strengthening the safety and practice of medicine and, if possible, its efficacy and quality, by applying rules to practice, education and training, and registration and licencing.

In summary, this research built a framework to evaluate the performance of the UK-TCM regulatory system in four steps: 1) whether the UK-TCM regulation had built a comprehensive and mature responsive regulation system; 2) identify any deficiencies found in responsive UK-TCM regulation, including the divergence of current TCM regulation from an ideal responsive regulation system and whether the TCM regulation has avoided some implicit problems of responsive regulation; 3) whether the TCM regulation has led to regulatory actions to achieve regulatory functions (Table 2.1) to reduce non-compliance or problems with safety, efficacy or quality; 4) to what extent non-compliance or problems with safety, efficacy or quality have reduced, and why/why not this was so.

For evaluation steps 1) and 2), a descriptive analysis is provided in later chapters. For evaluation steps 3) and 4), Table 2.3 presents a checklist. A conclusive assessment based on the four-step evaluation process is provided later.

Regulatory Functions	**Regulatory approach**	**Legal resource**	**Position in responsive regulation**	**Regulatory objective**	**Regulatory target**	**Improved or not**	**Improvement level**	**Reason for (non-) improvement**
What is the regulation function that the regulatory action aims to achieve? (e.g. products registration)	What regulatory actions are issued to reduce non-compliance? (e.g. TCM products regulation)	Which regulation or law requires the left regulatory action? (e.g. 2005 and 2012 Regulations requires THR)	Which level of the responsive regulation pyramid does the left regulatory action belong to? (e.g. discretionary command regulation)	Which of the 4P regulatory objectives is the target of the regulatory action? (e.g. products)	Which of the three regulatory targets is the aim of this regulatory action? (e.g. safety)	√ or ×	Low to high	Why was the improvement level in non-compliance high or low? (e.g., there are grey areas that are limited controlled)
Etc. …								
Etc. …								

Table 2.3 Example checklist of evaluation steps three and four of the evaluation frameworks

Chapter 3. Methodology and Methods

This chapter begins by outlining the methodology and methods applied in this study and their rationale in relation to the research objectives and questions, the data collection process, and the obstacles met when implementing these methods. The chapter also presents an explanation of how a thematic approach was employed to guide the data analysis.

3.1 Methdology and data sources

To explore the nature of the UK-TCM industry and the performance of its related regulations which lacks robust statistical data, qualitative methodology is suitable for this research. Qualitative research works inductively in nature to enable the researcher to gain insights and discover meanings behind a given situation (Mohajan, 2018). The researcher hereby can collect data and interpret meaning from it to understand the social phenomenon and the activities of targeted populations or places. To study a medical practice originating from China (see Section 1.2.1), this research locates its position more from a Chinese perspective to make comprisations between TCM in China and in the UK in order to understand the transformation and current shape of TCM in the UK under the regulatory impacts.

Research objective one was to map the current TCM practice and understand its transformation; primary data was essential for this. The existing definition of the UK-TCM was given by the Sixth Report of the House of Lords (2000) 23 years ago, but as noted this classification is unclear and confused with some other CAM therapies (Section 1.3.1). More precise and up-to-date information is required from those who have witnessed and experienced the development of TCM in the UK. To achieve research objective one, information was required about: 1) the current UK-TCM practice; and 2) the structure of the current UK-TCM industry. To achieve this objective, the stakeholders of the UK-TCM industry had to first be identified, including their experiences and stories, current working manner, business type and interaction with other stakeholders. Some secondary data from the literature provided supplementary background information concerning these stakeholders.

Research objective two was to identify and review the historical and existing regulations relevant to current UK-TCM practices; here, both primary and secondary data was required. Fieldwork data (such as the stories of stakeholders) was used, to find the regulations really influencing the TCM industry and to reveal any new points that may not have been considered

as influential in previous studies [e.g. the impact of district regulations and the role of district councils, described in Section 5.2.1 (2), which are seldom mentioned in the literature]. The sources of secondary data include published policies, regulations and related reports, online information from official websites and databases, enquiries to relevant departments and the current literature. The regulations and related official documents were reviewed to understand the progress and changes of UK-TCM related regulation. Online information, enquiries to official departments and the literature revealed the detailed operation of these regulations.

Research objective three was to assess the performance of the regulatory system of TCM to ensure the practices, practitioners, products and premises are safe, effective and of adequate quality. This research objective was to assess: 1) if all regulatory objectives are comprehensively covered; 2) if all regulatory targets are adequately achieved; and 3) if there are other requirements for the regulatory system. The sources of data were the statements of TCM industry stakeholders, public opinions and comments on the current regulations from official reports, consultations and other papers. Some information in the footnotes of later chapters was obtained through the internet (i.e. via Google) to complement the narrative of the fieldwork participants.

This research involves patients recruited by virtue of being NHS patients or services users, a dependent or carer of a patients, or a user of NHS & Health/Social Care Facilities. This research is reported to involve human patients (users) within the UK and Northern Ireland; this research is reported to use of questionnaires, observation and focus groups; this research is reported to discuss sensitive topics, such as drug use; this research is reported to collect or analyse information, such as commercial contract or licence. This research has been granted with ethics approval from Newcastle University Ethics Committee in June, 2018. No conflict of interest was involved in this research.

3.2 Methods and data collection

When studying the regulations, it was important to consider in-depth the voices of all stakeholders, so that the researcher could understand how the regulations work and are implemented, as well as how they affect people (Squires & Dorsen, 2018). This research then planned to go deep into the field and to record the fieldwork data faithfully. When a deep study is needed, such as with this investigation of TCM in the UK, ethnography can be employed. Jones and Smith (2017) describes how ethnography can “get inside the way each group of

people sees the world", and this is used as a method to experience people's life and document their culture in a particular setting (Goodson & Vassar, 2011). Ethnography normally starts to work through an inductive approach, in order to study the social phenomenon in general and then to answer specific research questions (Reeves et al., 2013).

As an open-ended research approach, ethnography can aid the understanding of large numbers of variables in one setting. Thus, it can be used in healthcare studies where the dynamics of decision making, such as the relationship between patients and healthcare providers and the cultural background of the patients, need to be understood (Goodson & Vassar, 2011). However, although the ethnographic approach provides the flexibility to cope with emerging themes in the data collection process, it can impede attempts to derive explanations because ethnographic study can be time-consuming and costly, and thus often only allows small-scale research at a single site. As a result, an in-depth study design was needed to produce results with a wider application to similar phenomena, and to enhance the generalisability of ethnography (Morgan-Trimmer & Wood, 2016).

In this research, the specific research aim and questions were already determined according to the gaps and questions found in the literature on the development of TCM and the regulation of it in the UK. A preliminary finding to the research questions was also noticed during the preparation period of the fieldwork, in that TCM has developed rapidly in the UK local context but that the regulations may not be strong enough to govern it. As such, further methods were needed to collect more comprehensive data to enable examination of the presuppositions.

As a result, this research uses hybrid methods with the aim of guaranteeing the objectivity of the data and providing trustworthy evidence on the development and effect of the TCM regulatory system in the UK. The three methods of participant observation, semi-structured interview, and questionnaires were implemented. Triangulation was achieved through the three methods to have a comprehensive understanding of the regulatory issues of TCM in the UK, and to cover the views of as many stakeholders as possible (Carter et al., 2014).

3.2.1 Participant observation

A key component of ethnography is participant observation. Apart from watching and understanding the activities of groups in a social setting, the expectation is that researchers are included in the activities being observed and become part of the observed community (Takyi,

2015). The method of participant observation provides information on practical and theoretical principles of human activities to produce concepts and generalise the phenomenon. It also enables a faithful recording of human activities in an unfamiliar context, and maintains the integrity of the scientific data (Zhao & Ji, 2014).

In this research, when the researcher was embedded in the unfamiliar TCM industry and lacked a sufficient amount of written documentation to consult, participant observation faithfully recorded the primary data collected from the daily experience of the researcher. This method provided an entry path into the UK-TCM world. In this way, participant observation provides a holistic map of the phenomenon being studied, while also being able to measure concepts, generalise, test a hypothesis, and then construct causal explanations through qualitative description (Moser & Korstjens, 2018). This advantage of participant observation was needed in this research because, as mentioned, the research question and hypothesis were pre-defined, participant observation helped develop sampling strategies and prepare questions for the interview stage (Loraine, et al., 2020).

The participant observation site was a TCM clinic (the Clinic) located in Chinatown, London. The Clinic is based in the city centre where is a famous Chinese community gathering types of Chinese business and it also has a Chinese population, local UK residents, and tourists from all over the world. The Clinic opened in 2007 as a branch of a chain TCM business. Consent of observation was obtained from the manager of the Clinic in an oral form[44] as which would not influence normal work in the Clinic, and the business owner of the chained clinic was also aware of such academic activity was carried out here. The observation work was within the scale of the ethics approval granted by Newcastle University, involving human (also NHS users) participants, observation as method, discussion and analysis of drug use, and discussion of commercial contract and licence.

The researcher's entry to the Clinic was a recruitment advert, pasted on a window, which asked for a part-time receptionist. This job only required that the person had a legitimate right to work in the UK, and could speak Chinese and English fluently. The researcher was only asked about visa status and IELTS scores before being offered the post. Within the working time restriction of visa, the researcher was allocated two days (8 hours/ day) every week. Although it may seem

[44] The manager said that it was not necessary to sign anything. Also many Chinese people contacted in this research were hesitated to leave information, such as voice and signature, that makes them easy to be identified (see Section 3.3).

that was quite lucky and was a coincidence for the researcher to get this job, continuous recruitment is extremely common in most shops in Soho. People change jobs quite frequently and there is not only a low requirement in terms of personal ability but also low pay. However, the job at the Clinic was not easy to achieve without a medical background and proper knowledge of TCM.

The staff at the Clinic did some training for the researcher, and the researcher's daily duties of the receptionist included: 1) cleaning the reception and counter area; 2) performing simple consultations from customers' inquiries at the counter, and further consultations with the TCM practitioners (CP 10); 3) promoting and selling all the over the counter products, including single herbal ingredients (for making Chinese tea or soup); 4) promoting and selling long-term treatment packages to patients; 5) making ready-made and individually prescribed herbal remedies; 6) classifying, storing and recording the use of all the medical products; and, 7) other chores as requested by the practitioners. Besides, the researcher's working time was from 3–11pm, and before 7pm there would be a full-time and well-trained receptionist working together, so the researcher seldom served patients with serious problems alone. Such a working arrangement meant provided a great deal of time and freedom to observe.

As an active participant-observer, the researcher tried to maximise participation in the observed situation in order to obtain data and integrate own role with the others in the community. The researcher accepted the role as a staff member in the Clinic and experienced the daily work or even part of the life of the role. The researcher experienced and observed life in the Clinic both on a simple human level and also on the level planned for the research purposes, such that further data beyond the initial hypothesis of the research might be discovered. Therefore, two domains of observation work were conducted, visible and invisible, caused by the limitation of the job position and any potential defensiveness from the Clinic staff with a stranger. The visible data were collected directly by simply watching, which included: the basic staffing structure and work procedure in the Clinic; the process of treating a patient; the medical products used and sold by the Clinic; and, the making of prescribed products. Invisible data were collected through informal but in-depth communication with the staff and sometimes customers in the Clinic, including the personal stories of the Clinic staff, details of practice (given in a private room), hidden information about the supply chain, and certain grey areas of the operation of the TCM business.

Between early March 2019 and August 2019, 105 hours of observation work were achieved.

All the data were recorded in written fieldwork diaries on the day after the observation, and were later transcribed into digital form in NVivo. This reseaerch has concealed the name of the clinic and its staff to respect their privacy. Code names and basic information of the observation site and people involved in this fieldwork are listed in Table 3.1. The results of participant observation are presented in Chapter 4.

Code name	**Identity**
CP 10	Chinese, TCM practitioner working in the Clinic
Recep1	Chinese, receptionist
MT 1	Chinese, medical technician operating ultra-sound test and ECG
Masseuse 1	Chinese, doing Chinese massage
Masseuse 2	Chinese, doing Chinese massage
Masseuse 3	Chinese, doing Chinese massage

Table 3.1 People working at the observation site

The opportunity to work in the Clinic not only provided a participant observation site for my research, but also initiated my connection with the Chinese community in London, and this later expanded to other places in the UK. However, researchers who conduct participant observation should avoid relying solely on data collected from case studies without clear guidelines for data collection, and they must remember not to alter the behaviours of the people being studied (Brancati, 2018). Some of the problematic aspects of the study design were hard to avoid, and in this regard DeWalt and DeWalt (2002) suggest that the validity of participant observation is increased with the use of additional research methodologies; thus, two further methods were applied in this research.

3.2.2 Semi-structured in-depth interviews

As mentioned in Section 3.2.1, the ethnographic data generated from participant observation in the TCM industry in the UK required that foundations of trust and rapport be established. The data also supported the primary understanding and guidance on which further methodological approaches were based (O'Reilly, 2008). Using the direction and background investigation provided by participant observation, the semi-structured interview approach was selected to collect data with a clearer purpose. Semi-structured interviews allow the researcher to collect primary data based on an interview protocol, and thus the data may be collected more systematic and comprehensive, as the protocol keeps the interview focused on the desired line of action

(Jamshed, 2014). This feature of semi-structured interview guarantees the coherence of the interview data and prevents the answers from straying from the theme being investigated.

Another advantage of semi-structured interviews is that they are a flexible data collection method since they permit the follow-up of responses, based on the interaction between the interviewers and informants; in this regard, personal and sensitive issues can be probed with follow-up questions (DeJonckheere & Vaughn, 2019). In this way, more comprehensive information can be obtained, and personal attitudes can be associated with the culture, ideology and tradition of the current situation of the TCM industry. Based on the interview protocol, the researcher can then summarise themes and categories of analysis generated from the responses of informants (Jamshed, 2014). This feature helps the later thematic data analysis. Also, as an open-ended data collection method, semi-structured interviews enable the researcher to generate, challenge, reconsider and contextualise the understanding of the topics from the non-directive and potential responses (Newcomer, Hatry & Wholey, 2015). Thus, the semi-structured interview is particularly suited to little studied social fields with insufficient documentation and an unclear inner network (Adams, 2015).

In this research, the semi-structured interview tightly follows the main research question as the theme, but several non-directive questions were set to address each research objective. The literature review helped set the necessary direction of the questions (Bolderston, 2012). Consents of interview were observed from each interviewee in oral form[45], and they fully understood the purpose of interviews for academic use. The interviews were within the scale of ethics approval from Newcastle University to involve human participants and discussion of durg use

(1) Interview topics and questions

The topic of this interview therefore included multiple aspects around the theme of TCM regulation in the UK: 1) the basic personal information; 2) the personal stories of interviewees about the development of TCM in the UK; 3) the knowledge of interviewees about the TCM regulatory system in the UK; 4) the thoughts of the TCM regulatory system; 5) the problems existing in the TCM industry and regulatory system; and, 6) the future of TCM in the UK. Also, due to the flexibility of semi-structured interviews, unfixed questions can be added based on

[45] See footnote 44.

the specific interactions between the interviewer and the interviewees.

The interview questions for both Chinese and non-Chinese TCM practitioners are unified (see Part 1, Supplementary Material 1). The practitioners were asked about their personal information including practice length, length of practice in the UK, educational and training background, their registration information, their form of employment, the sources and suppliers of their products and medical tools,the therapies they use, the diseases they met during work, their interaction with patients, their feelings towards the current and future regulations.

The interview questions for industry stakeholders start from united ones asking about their own career related to TCM, their knowledge of historical development of TCM in the UK, their description of TCM in the UK, their consideration about the current and the furture TCM in the UK, their consideration about the current and the future TCM regulations (see Part 2, Supplementary Material 1). More specific and targeted questions are then added according to the identities of different stakeholders, such as enquiring curriculum from the TCM educator.

(2) Sampling and recriting process of interview

At the initial stage of designing the interview protocol, the researcher planned to recruit 15 Chinese TCM practitioners to compare TCM practised in the UK and it is in China under the regulatory impact. The include criteria are: 1) people who are ethnic Chinese, 2) people who practise TCM, 2) people who practise in the UK. Based on the researcher's personal experience and also the supportive evidence about the marginalisation of the Chinese diaspora in a foreign country (Chau & Yu, 2001), Chinese are normally cautious with unfamiliar persons and refuse to talk much about their personal affairs. Their sensitivity caused obstacles for recruiting participants for the interviews, even though they share the same culture and language with the researcher. Thus, it was almost impossible to walk into a clinic and ask for help with an academic activity without *guanxi*[46] (pulling strings) (Leung & Wong, 2001). Fortunately, the observation site functioned as the starting point to the research topic, and an existing link was then built from the staff of the Clinic. The snowballing method was then used to recruit further participants, as several staff at the Clinic referred their peers working in other clinics and business to the researcher, and these in turn referred others to expand the recruition.

[46] Guanxi: a Chinese interpersonal relationship or network deeply rooted in Chinese culture. A person can achieve their goal by taking advantage of an introducer (Zhang & Hong, 2017).

When proceeding with the research, non-Chinese TCM practitioners (NCPs) were added to enable a comparison with Chinese practitioners (CPs) and provide clearer insight into current TCM practices and TCM regulation in the UK from various perspectives. Several inclusion criteria were used: 1) people who are not ethnic Chinese, 2) people who practise TCM, and 3) people who practice TCM in the UK. NCPs do not typically state that they practise pure TCM. Instead, they often perform acupuncture or provide herbal medicine, shiatsu, or other therapies, either in combination or independently. NCPs who practise TCM, acupuncture, herbal medicine or other TCM therapies (see Section 1.2.1) were all considered eligible interview participants. Though it could be estimated that a large number of NCPs live in the UK[47] due to natural features of learning and practising acupuncture, there is no data showing the number and registered number of CPs and NCPs. This research recruited 10 NCPs to compare against CPs.

In contrast to the Chinese practitioners, the non-Chinese practitioners were normally willing to participate in the study. Nine of the ten non-Chinese practitioners were found through online searching in TCM registration accosiations, and they were contacted through public information on the pages of their registation. The "find a practitioner" function on the websites of the British Acupuncture Council (BAcC) and the Association of Traditional Chinese Medicine and Acupuncture UK (ATCM) were used to screen the practitioners. One was found and contacted through twitter as she introduced herself as a TCM practitioner on her personal page. Preliminary contacts were made by email with the non-Chinese practitioners to identify their willingness to participate in interviews and preferred way of interviewing. The email also asked if their education, training background and current practice were connected with Chinese medicine, which ensured that the final selected participants corresponded with the research topic. The code names and detailed identities of the practitioners are listed in Table 3.2.

Code Name	**Identity**
CP 1	Chinese TCM Practitioner
CP 2	Chinese TCM Practitioner
CP 3	Chinese TCM Practitioner
CP 4	Chinese TCM Practitioner
CP 5	Chinese TCM Practitioner
CP 6	Chinese TCM Practitioner

[47] The number of NCPs may be even larger than CPs according to studies like Hopton et al. (2012), who stated that some TCM registration associations are comprised of higher numbers of doctors and practitioners using Western medical acupuncture than those who use traditional Chinese acupuncture.

CP 7	Chinese TCM Practitioner
CP 8	Chinese TCM Practitioner
CP 9	Chinese TCM Practitioner
CP 10	Chinese TCM Practitioner
CP 11	Chinese TCM Practitioner
CP 12	Chinese TCM Practitioner/ Owner of a small TCM clinic based in London
CP 13	Chinese TCM Practitioner/ Owner of a small TCM clinic based in Doncaster
CP 14	Chinese TCM Practitioner
CP 15	Chinese TCM Practitioner
NCP1	Non-Chinese Practitioner from the UK
NCP 2	Non-Chinese Practitioner from the UK
NCP 3	Non-Chinese Practitioner from Israel
NCP 4	Non-Chinese Practitioner from Iran
NCP 5	Non-Chinese Practitioner from the Netherlands
NCP 6	Non-Chinese Practitioner from Japan
NCP 7	Non-Chinese Practitioner from the UK
NCP 8	Non-Chinese Practitioner from the UK
NCP 9	Non-Chinese Practitioner from Pakistan
NCP 10	Non-Chinese Practitioner from the UK

Table 3.2 The code names and detailed identities of the practitioners

Then, to understand comprehensively the TCM industry in the UK, several other stakeholders from the TCM industry in the UK were invited to interviews. These people were identified through observation and interviews with practitioners. During the observation and interview process, the researcher gradually recognise the different components needed to operate a TCM business, such as the 4Ps (products, practitioners, premises and practice). People providing these components or people who work to produce these components could then form a TCM industry, and they are identified as stakeholders. A derivation diagram of who should be relevant to the operation of TCM industry is drawn as Figure.

The possible stakeholders were also contacted through snowballing. Two owners of chained TCM business (BO 1 and BO 2) were interviewed for their experience of developing their commercial layout and their knowledge of the current UK-TCM industry. The stories of BO 1and BO 2 were compared to two owners, who are also practitioners, of small private TCM clinics (CP 12 and CP 13). Two health professionals (Prof BM and Mr MM) in the field of

TCM were consulted mainly for their views towards the development and regulation of TCM in the UK. Their names were found in the literature on the research. One TCM product wholesaler (SUP 1) was interviewed to understand the supply chain of TCM products from China to the UK. One representative of TCM self-regulatory association was interviewed to provide knowledge of the voluntary regulation of the UK-TCM beyond the literature. A TCM educator (Prof ST) was consulted to explore TCM education and training in the UK. Also, a representative of the MHRA (RepM 1) was contacted to understand further about their work towards TCM regulations as supplements to the written official documents. These stakeholders were fully arwared that their consent to participate this interview will be used for academic purpose. They have clarified that their identities were not necessarily to be anonymous as this research and related papers and thesis would need to the organisations they belong to. This research finally recruited 33 participants for interview and they were given a code name to respect their privacy and for easier identification. The code names and detailed identities of the stakeholders are listed in Table 3.3.

Code Name	**Identity**
CP 12	Chinese TCM Practitioner/ Owner of a small TCM clinic based in London
CP 13	Chinese TCM Practitioner/ Owner of a small TCM clinic based in Doncaster
BO 1	Industry Stakeholder: Owner of a chain TCM business based around Chinatown, London
BO 2	Industry Stakeholder: Owner of a chain TCM business based outside of Chinatowns
SUP 1	Industry Stakeholder: Manager of a TCM import and wholesale company
RA 1	Representative (vice-chairman) of a registration organisation
Professor ST	Health Professional: Headmaster of Shulan College (TCM training institution)
Professor BM	Health Professional: Former chairman of a registration organisation/ renowned academy in TCM
Mr MM	Health Professional/ renowned academy involved in herb issues and responsible to the UK parliament
RepM 1	Representative of the Medical and Healthcare Products Regulatory Agency

Table 3.3 Interview participants

Interviews were conducted in Mandarin with Chinese participants, including all CPs, BO1 and BO 2, SUP 1, RA 1, Prof ST and Prof BM, but in English with all NCPs, Mr MM and RepM 1.

The Mandarin interviews were transcribed into English from recordings by the researcher who has ability to speak both mandarin and English. The interviews were conducted either in person or by phone. The contents of the interviews were audio recorded and written notes used as reminders. However, some of the Chinese participants felt uncomfortable having their voices recorded (see Supplementary Material 2), and therefore the data for CP 2, 7 and 9 were recorded only as written notes. All the data collected were transcribed into digital form and stored in NVivo. The results of interviews are presented in Chapter 5.

3.2.3 Questionnaire for TCM users

A written questionnaire containing a series of structured questions was then used to collect personal data and was the third aspect of the study's triangulation of data. With regard to questionnaires in general, they enable multiple questions on the same complex topic to be asked at the same time. Responses to questionnaires are normally highly standardised and convenient for further comparison and analysis (Schofield & Knauss, 2013). Thus, a questionnaire can be distributed to a wide range of people and, in this research, it was used to reveal the views of many TCM users from inside and outside the industry.

Questionnaires with 16 standardised questions were administered to visitors and customers of the Clinic who were able to speak English or Mandarin. These respondents were invited to answer two parts of a paper-based questionnaire on personal information, including their gender, age, ethnic group and registration with NHS, and their knowledge and feelings about current TCM and its regulations, including their reasons, frequency and purposes of using TCM, the common healthcare services they use in a TCM clinic and how much they paid for these, their consideration of using TCM compared with mainstream medicine, their concerns of uing TCM, and their feelings towards the current UK-TCM and its regulations. Consents of using the questionnaires for academic research were granted from the respondents. The questionnaire part was within the scale of ethics approval from Newcastle University to involve human participants (including NHS users) and discussion of sensitive topics. Altogether, 106 valid questionnaires were completed. All the data were then counted and transcribed into digital form in NVivo. The questions and results (in bar chart form) can be seen in Appendix I. The results of questionnaires are presented in Chapter 4 as supplement to the observation data.

This research used mixed method triangulation in healthcare research so that various sources of data could be explored, multiple theoretical perspectives could be considered, and potential

errors and problems discovered at an early stage. There may be some implicit weakness in the research methods, for instance, in-depth and long-term involvement with the observed can make the observer confused about their own perspective, because their understanding and sympathy may be strengthened over time, and thus it might be possible that the observer inserts their personal feelings when recording and studying the observed (Takyi, 2015). The researcher took interventions in the study to reduce bias, such as training in interview skills, taking written notes as soon as possible, and using audio recordings, all of which are intended to reduce bias and improve the validity of data. Ezzy (2002) argued that all research methodologies may be biased if they are driven by political and capital interests. Concerns about the reliability and validity of a qualitative research study should be centred on the ability and positionality of the researcher since, if the researcher has been transparent and reflexive about the research process, their own values can be reflected and thus give the research value (Galdas, 2017). Those deficiencies which could not be resolved at the beginning of the research will be considered further in the discussion chapter.

3.3 Difficulties found during the process

At the beginning of research design, the bias that comes with subjectivity of qualitative study is unavoidable (Everest, 2014). To neutralise this disadvantage of qualitative study being subjective, triangulation is suggested (Everest, 2014) as a combination of methods to study the same phenomenon. The researcher strongly recommends mixed method triangulation in healthcare research so that various sources of data can be explored, multiple theoretical perspectives could be considered, and potential errors and problems discovered at an early stage. However, it must be noted that potential biases can remain in each method.

Bias in the mixed methods was accounted for in the following ways. For the participant observation method, bias can be caused through the observer. When proceeding with the observation, the observer may “go native”. In-depth and long-term involvement with the observed can make the observer lose their own perspective, because their understanding and sympathy may be strengthened over time, thus increasing the possibility that the observer becomes confused about personal identity and fails to perform as an outsider (Takyi, 2015). For the semi-structured interviews, these depend heavily on the personal quality of the interviewer. On the one hand, bias stems from the perceptions of the interviewer’s personal identity. Gender, age, ethnicity, social class and life experience may influence the extent of the rapport between the interviewer and interviewees, and these factors also affect how the interviewer judges the

responses received, especially responses on sensitive topics (Frey, 2018). On the other hand, bias can occur when wording questions, and so the interviewer may lead the direction of the responses toward their own preference (Salazar, 1990). For the questionnaire, these were directly handed to the participant visitors at the Clinic. With restrictions on the respondents, the researcher had to be aware that the results might be biased towards similar answers coming from the chosen group (Mathers, Fox & Hunn, 1998).

After designing the mixed methods to reduce bias in the research, the other interventions in the study also considered how to reduce bias. For example, the researcher undertook training in interview skills, took written notes as soon as possible, and used audio recording, all of which are intended to reduce bias and improve the validity of data.

Bracketing was used to reduce bias during the preconception in the research process. As a scientific approach, bracketing concerns how a researcher suspends personal presupposition, perception, assumptions or previous experiences related to a research subject (Tufford & Newman, 2012). The bracketing process requires a researcher to conduct an honest self-reflection about the subject, participants and their perspectives, beliefs and thoughts. Tufford and Newman (2012) have suggested several bracketing approaches for application in qualitative research. Some of their advice are used in this research. Notes were taken during observation and semi-structured interviews to accurately record the research process and the researcher's feeling about the research endeavour. Noting the researcher's presupposition helps to distinguish the involvement of the researcher and the data itself.

Even if, after taking all of the above into consideration, limitations in the study methods remain, the research should be still of value. Ezzy (2002) argued that all research methodologies may be biased if they are driven by political and capital interests. Concerns about the reliability and validity of a qualitative research study should be centred on the ability and positionality of the researcher since, if the researcher has been transparent and reflexive about the research process, his or her own values can be reflected and thus give the research value (Galdas, 2017). Those deficiencies which could not be resolved at the beginning of the research will be considered further in the discussion chapter.

Then as in the actual operation of fieldworl, although this research tried to distribute the questionnaires to as many different types of visitors to the Clinic as possible, the researcher was refused by many Chinese people for the reasons of being 'very busy', 'not interested in school

work' or 'bad English [ability]'. The major repondents of questionnaires were non-Chinese people who tooke up 85% of the questionnaire responses.

The greatest problem encountered during the fieldwork was the sensitivity of the Chinese participants. The Chinese do not regularly use email as a contact method. Little solid academic evidence was found about this, but several news reports exist, such as in Liang (2020), and this caused a problem for me to contact prospective participants. Snowballing was thus employed as a sampling strategy to recruit Chinese participants for interview, starting from the Clinic. The practitioners working here (CP 1, 4 and 10) participated in the interview first, and then they introduced me to colleagues working in other branches of the same company, and then their former colleagues and friends. This produced a total of 19 Chinese practitioners, 15 of whom successfully completed the interview; four refused to take part for various reasons.

Among the 15 CPs participated in interviews, CP 2, 7 and 9 refused to have their interview audio recorded, because they "[did] not want someone to recognise their voice". They did not specify the identities of the "someone", but perhaps just thought it better not to reveal too much about the secrets of the TCM industry. CP 2 filled out a paper copy of the interview questions as a survey; CP 7 and 9 spoke by themselves and I took written notes.

There were four other CPs who were initially keen to meet me after being referred by their friends or peers, but eventually refused to participate in the interview after consideration. Their main reasons for rejecting the interviews were: "[it is] dangerous to be involved in government issue (though they have been explained that regulatory researches do not equal political studies and this research did not receive official funds)", "[it is] not my duty to participate in academic work", and "my employer may not like the commercial secret of TCM to be revealed'. However, the short time spent with them was still a valuable experience in terms of gaining more comprehensive information about their ideas. This research thus made some records (mostly immediate audio recorded notes) of these less satisfactory meetings; the information of these four practitioners is listed in Supplementary material 2.

3.4 Developing an analytical approach: thematic analysis

In this research, thematic analysis was employed to understand the data and achieve the research goal. Braun and Clarke (2006) provided essential insights into the thematic analysis. The basic function of thematic analysis is to categorise rich data and interpret the data according to their

similar patterns (themes). Since the patterns or themes are closely related to research questions, thematic analysis works inductively to identify and gather data driven by the researcher's theoretical or analytic interest rather than developing new theories. Therefore, thematic analysis was considered appropriate in this study, and would bring the data to the prepared theoretical position (Chapter 2) to reach the central research goal. Although the researcher's interests may lead to critiques about the credibility of a study, Nowell et al. (2017) believed that the rigorous design and step-by-step manner with sufficient details shown to the reader would resolve this problem. Thus, this research followed the steps promoted by Rivas (2012) to conduct the thematic analysis on the data collected by the fieldwork methods of participant observation, interviews, and questionnaires.

As the initial step in any thematic analysis, coding is the primary approach to develop the concepts and categories from the collected data. Such coding gathers similar words and phrases even when the respondents do not use the same expressions, and thus does not simply involve counting the occurrences of words (Saks & Allsop, 2012). Rivas (2012) suggested that the first phase of coding work should be an open one, in which data are extracted and then grouped by the similar information they comprise. The second phase of coding work produces higher-level order or categories to collate the fragmented coded information and to guide them to themes. The next step of Rivas (2012) is to develop the categories into clear themes, and the themes can then be used to research the objectives.

To answer the research questions, data were collected and presented via thematic analysis. A coding tree was made (see Figure 3.1) according to thematic analysis principles to clarify the coding and theming of data. Keywords were extracted from the fieldwork records and were used as codes at first level to mark different groups of data (see the pink squares in Figure 3.1). The codes are derived from information in ethnography and questionnaire data, and information in interview data. Codes found in ethnograpby and questionnaires mainly relate to TCM business mode, daily operation of a clinic, products sold, therapeutical approaches used, patient group, and reasons of using TCM. Codes found in interviews mainly relate to practitioners' educational background, advanced training, common therapies, prevalent diseases, products, and insurance.

These codes were then organised into the second level of categories (see blue squares in Figure 3.1). Phrases such as people practising TM, people using TCM, therapies being practised, registration issues, modification of practice, and safety, quality, and efficacy concerns, were

employed to mark the collective categories. These categories are narrated in Chapter 4 and Chapter 5. Chapter 4 focuses on the operation of a TCM clinic and the information of TCM users indicating the general situation of the UK-TCM, whilst Chapter 5 presents the basic information of the UK-TCM stakeholders and their consideration about the industry and relevant regulations. The blue categories at the second level were then developed into themes at the third level (see orange squares in Figure 3.1).

The themes are in relation to the research aims. Themes, such as the situation of current TCM practice, the UK-TCM industry and related stakeholders, regulations related to TCM practice, safety/ quality/ efficacy concerns identified, and changes seen in TCM, were adopted. The themes manifest as summaries of data in Chapter 4 and 5 to illustrate the general situation of TCM business and TCM industry, the relevant regulations of TCM impacting the industry and the comments towards these regulations. The themes are presented in the beginning of Chapter 6 and 7. The themes were then used to reach the research objectives at the fourth level (purple ones in Figure 3.1) of mapping UK-TCM practice, and exploring the impact of the regulations. The research objectives are reached by applying the theories chosen by the research, namely ANT and responsive regulation. How the research objectives are reached are presented in latter part of Chapter 6 and Chapter 7 to answer the research questions.

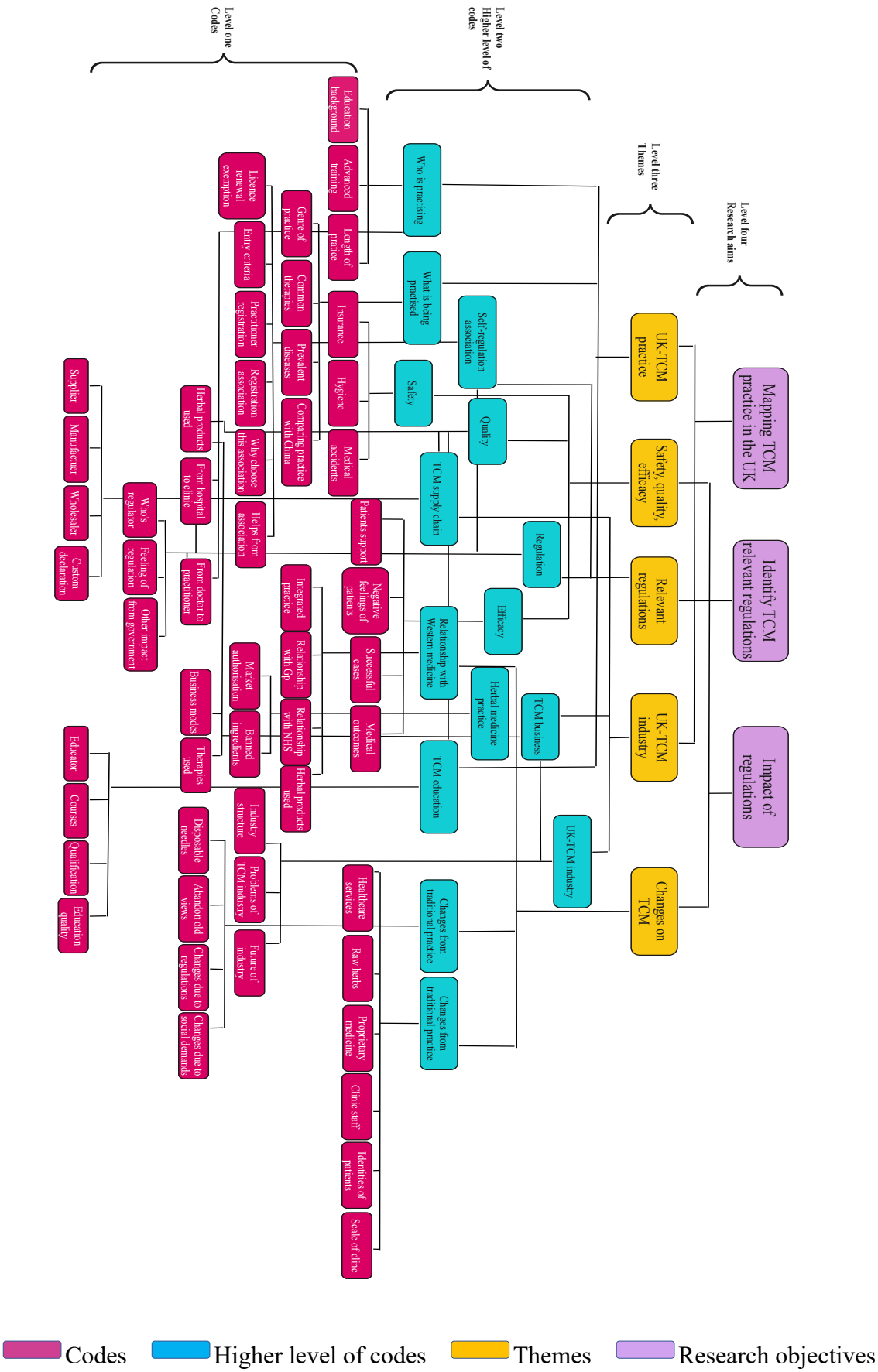


Figure 3.1 Coding tree of this research

PART III: Results

To add interpretation of the data collected according to the structure of Figure 3.1, this part of the thesis is divided into two chapters. Chapter 4 interprets the data collected through participant observation and questionnaire. This part of data describes the daily operation of a TCM clinic and its maojor client groups. Chapter 4 draws a drafted epitome of the UK-TCM industry including a brief history of the UK-TCM is then traced, identifying the key stakeholders along with their stories and experiences of TCM.

Chapter 5 interprets the interview data collected from TCM practitioners and industry stakeholders. The data collected from the practitioners is described in a layout of comparisons between CPs and NCPs. Their basic personal information, educational background, registration status, daily practice and considerations towards UK-TCM and the relevant regulations are recorded. The second part of Chapter 5 is comprised of interview data with the UK-TCM industry stakeholders. The personal information, career experience and consideration toward the UK-TCM and relevant regulations of each stakeholder are reported. Some secondary data were used to support the interpretation of results, primarily website information, literature and official reports. This part of the thesis will use the data to reach the research objectives of drawing a map of the current TCM practised in the UK, finding out the regulations influenceing TCM practice, and reflecting on the impact of these regulations on TCM.

Chapter 4 Resulte of Ethnography and questionnaires

This chapter presents the results of ethnography conducted by this research following the research topics and questions introduced in Section 1.6. And the results interpereted in this chapter is also supplemented by data derived from questionnaires. This chapter contains two parts: Section 4.1 states the daily operation of the TCM clinic being observed and its key staff, whilst Section 4.2 classifies the major TCM users identified in this research into different group according to their frequency of visiting the clinic.

4.1 Daily operation and people in the Clinic

Though it was mentioned in Section 1.2.2 that TCM was quite popular at the crossing point of 20th and the 21st century, data collected from the ethnography work revealed that a downturn of TCM was soon seen after the first decade of the 21st century. Firstly, the sharp growth in practitioners without appropriate entry standards caused medical accidents and ruined the reputation of TCM. One case of improper use of 'Longdan Xiegan Wan (龙胆泻肝丸] caused renal failure could be found . Secondly, a series of policies and regulations were issued which impacted the UK-TCM industry, especially concerning product authorisation and working visas for practitioners. These regulations restricted some TCM practice approaches and business areas. Thirdly, the 2008 financial crisis led to economic obstacles around the world, which affected the UK as well. At this time, some chain TCM businesses struggled to afford the high cost of rent and labour, and thus branches began to close and some practitioners became self-employed. Individuals or small groups of practitioners could not pay the rent in crowded and central areas, and gradually they moved to remote areas and became established in private small clinics. The surviving chain businesses and independent small clinics therefore co-exist in the current UK-TCM market.

The Clinic where this research was carried out is representative of the current UK-TCM industry. It exists at a time when TCM is experiencing a downturn in profit and a reduced number of practitioners from China. Standing in the city centre, it serves both Chinese and non-Chinese TCM users and is owned by a large chain but competes with other small clinics. The Clinic was hiring eight employees to operate its daily business. Besides the two TCM practitioners (day and night shift), there were two receptionists, a medical technician, and three masseuses.

When stepping into the clinic lobby, clients first meet the receptionist, Ms A, the full-time working receptionist. She has experience of working as a hospital nurse in Beijing, China, but after coming to the UK in 2004 and then being employed by the TCM clinic, her main job is taking care of the 'shelves' in the lobby. The shelves in the lobby of the clinic displayed all the products related to UK-TCM practice. The first shelf displayed a photograph of the owner with a UK political party member,[48] and the clinic staff believed this indicated their good relationship with officialdom and its approval, demonstrating that the clinic was trustworthy. Below this photograph, there are various types of Chinese medical artifacts, such as cupping glasses, acupuncture needles, a schematic of needling points, and moxa sticks, so that people could identify the special ethnic characteristics and services of the clinic at a glance. The medical tools were both for exhibition and sale. As Recep1 reported, buying these tools and performing some simple practices at home was a new trend, and this may be a consequence of the high cost of treatment with professional practitioners. If treatment at home did not solve the problem, Recep1 would recommend products from the other shelves.

The second shelf contained ready-made products such as externally used creams for skin problems (such as scutellaria cream 黄芩膏, psoriasis cream 牛皮癣膏), oils (such as pak fah yeow 白花油, wong to yick 活络油), balms (e.g., tiger balm 万金油, cooling balm 清凉油), plasters for body pain (such as gutong tiegao 骨通贴膏), pills and capsules for minor diseases (such as wuji baifeng wan 乌鸡白凤丸, xiaoyao wan 逍遥丸), and a number of boxes containing small bags of herbal remedies in powder form. Although after 2004 Directive came into force unauthorised proprietary medicines were no longer allowed in the UK market, this clinic still sold some Chinese proprietary medicines ordered from the headquarters of its company. The medicines in small bags were prepared according to classical TCM recipes recommended by practitioners and used to treat common mild illnesses, e.g., fever, dry cough, sore throat, or painful periods. It is interesting to note these simple remedies, which are quite different from common concepts of TCM treatment where tongue diagnosis and pulses are required to recommend individual prescriptions. People could buy these prepared remedies using their own judgement or on the recommendation of Recep1.

There was then a very large shelf, the top of which reached to the ceiling. Nearly one hundred dried raw herbs were stored here (Image 4.1). This display imitates classical TCM shops in

[48] This person was later elected as senior official of a former UK government.

China which typically have a wall of drawers containing herbs (Photo 4.1). However, clients seldom buy the raw herbs except for herbal washes or soup cooking; TCM remedies using raw herbs require long, slow cooking times in pottery utensils. Thus, to align with the market need for medicines that are straightforward to take, the clinic uses concentrated powders as a substitute for traditional raw constituents (Image 4.2). The last shelf housed numerous bottles containing the concentrated herbal powders used to make individually prescribed herbal mixtures targeted towards specific or uncommon symptoms.

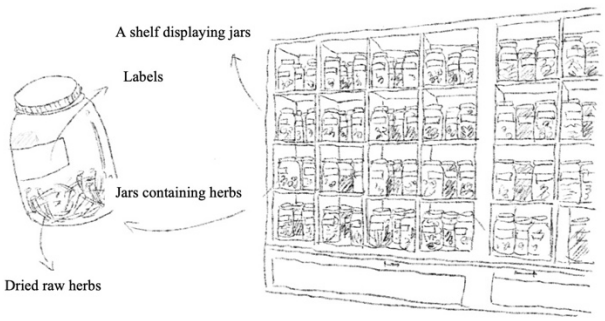


Image 4.1: Shelf displaying herbs in the Clinic

Photo 4.1: traditional drawers containing herbs in China

Image 4.2 Concentrated powder form of herbal medicine

The prescription of herbal powders was a signature service of the clinic. Normally, they were prescribed after a consultation with one of the TCM practitioners. One herbal remedy might contain many ingredients in different doses and was prepared by Recep1 with care following the instructions of the practitioner. Sometimes patients brought their prescription from elsewhere, such as a practitioner based in another clinic, a doctor in China, or from information online, and the clinic also prepared herbal mixtures according to such requests.

If a patient's symptoms cannot be addressed by the ready-made products, Recep 1 would suggest a consultation with the TCM practitioner, CP 10, for a diagnosis to inform the prescription of herbal powders or physical therapies. The TCM practitioners performed multiple essential tasks in a clinic, including consultations, body checks, prescribing oral medicine, and conducting physical therapies. CP 10 is a female practitioner who has 18 years' work experience as a TCM doctor in hospitals in China following her graduation with a PhD degree. After coming to the UK in 2005, CP 10 found herself well aligned with the local context. CP 10 reported that Chinese people prefer really old TCM doctors who seem to be well-experienced, thus (even though her was over 40 in her last few time of working in China) she was too young to be accepted as an attending doctor in China. In the UK, CP 10's age is no more a problem. CP 10's education and working experiences of integrated medicine opened up the prospect for her TCM career in the UK. Based on such experiences, CP 10even created some of her own TCM therapies to better serve the local health needs.

CP 10 has done a good job of practising TCM as a supplement to the UK mainstream medicine. She has paid attention to distress that is not prioritised by Western doctors (Xiyi, 西医, a common word used in China with literal meaning of doctors using medicines coming from the Western world to actually describe biomedical doctors). CP 10 reported that some of her clients present with issues such as heavy periods or vaginitis that 'Western doctors don't want to treat'. She considered that these problems needed long-term care to gradually strengthen the client's body as opposed to taking pain killers or anti-inflammatory medication.

To attract more clients, CP 10 has tapped into popular trends in the UK, such as using acupuncture in preparation for in vitro fertilisation (IVF) treatment for infertility. For such integrated treatment, CP 10 still uses TCM gynaecology and provides an English translation to clients to show that the knowledge of these two medical systems are compatible:

> *most gynaecological problems occur because women's bodies are weak (Xu, 虚) with the deficiencies of cold (Xuhan, 虚寒), evil hot (Xiere, 邪热) and wind (Fengleng, 风冷) which take the womb and make the blood circulation blocked, which then becomes the poison (Xiedu, 邪毒) that finally causes disease.*

Then she applies this theory to acupuncture:

needles stimulate pressure points and accelerate blood circulation […]and then drive the poison out of the body.

CP 10 claimed that bodies without '*poison*' have a higher success rate for IVF treatment.

CP 10 sometimes suggests to clients to undertake specific Western clinical tests. The results of these tests are used by CP 10 to reaffirm her judgement on the condition and to convince the client of the importance of her treatments.

In 2000, the clinic recognised the business value of providing Western diagnostic technologies to Chinese immigrants in the UK market. With the large number of Chinese immigrants entering the UK, more complex health care needs became apparent. Access to the UK NHS can be problematic for Chinese immigrants, some are not registered, others are not used to Western medical treatment alone, and some cannot speak fluent English. Thus, the clinic bought Western scanning equipment and invited MT 1 to work as a medical technician. Before coming to the UK, MT 1 had several years' experience working as a sonographer in a hospital in China. She is now performing ultrasound tests and electrocardiograms in the clinic.

In recent years, the clinic has also started to cooperate with a laboratory located in Harley Street for blood and urine tests and allergy testing performed using hair samples. MT 1's job was expanded accordingly; she accompanied clients to the laboratory and acted as a translator.

Although the clinic gradually became a one-stop health centre, the extent to which these new services helped to improve people's health is questionable. The financial costs of these tests influence people's decision. The price of the ultrasound is £65 per body part, and the prices of tests requiring laboratory collaboration are higher as the clinic charges an agency fee. Some people thus would not consider tests if they judged that their symptoms were less serious. Even for those having these tests, many clients refuse to consult the practitioners with their test results since that costs an additional £10. MT 1 stated that 'they [the clients] just want the test results so that they can search the terminologies and numbers online.'

4.2 TCM users identified in this research

TCM in the UK is used by both Chinese and non-Chinese. During observation, the number of non-Chinese visitors to the clinic was considerable. The clinic is in a very central and crowded area and many non-Chinese visitors walk in out of curiosity. However, the slow effects of

treatment do not really satisfy individuals who are not familiar with TCM, and they normally gave up after one try, and so most regular visitors were Chinese. In this study, the Chinese visitors were divided into three groups according to the size of the visitor base and their frequency of visiting.

The first and largest group of clinic users were those with limited access to UK public healthcare services, i.e., the elderly and illegal immigrants. Typically, the elderly Chinese people were old immigrants who had come to the UK when Hong Kong was still a colony, and who stayed after the reunification in 1997. The older Chinese cohort was a historically vulnerable group. Although they are by public health services, older Chinese have demonstrated quite a low rate of NHS service usage in previous studies (Chau, 2008; Pharoah et al., 2009). Generally, isolation from UK society caused by heavy workloads, such as long excessive working time in kitchen, and poor English ability are reasons for their unfamiliarity with UK healthcare services (Chau, 2008).

The older Chinese immigrants usually came to the clinic for common geriatric pathologies, such as pain for unclear reasons, hypertension, mild cardiovascular diseases, and gout. These Chinese patients did understand that they could have medical care on the NHS. However, the public health system proceeds slowly for many non-life threatening diseases. Thus, these individuals turned to a faster way to get medication to simply relieve rather than fully cure their symptoms. Another reason why older Chinese people visited the clinic was for post-operative care. After undergoing operations conducted in mainstream medicine hospitals, the older patients believed in the traditional Chinese manner of care which is different from post-operative care (NHS, 2018a) and recovery enhancement (NHS, 2019) recommended from a mainstream medical perspective. The Chinese approach essentially advocates avoiding certain foods (jikou, 忌口) and eating tonic (jinbu, 进补). Some of these older Chinese were observed to consult the TCM practitioners for a special diet or to receive a prescription for nourishing qi and blood.

As for the undocumented immigrants, none of the undocumented workers observed in this study said they had commercial health insurance because of being unfamiliar with the UK, having poor English language ability, and limited income. That said, they may not know about insurance related information, or they know about this but prefer not to spend money on health

insurance.[49] A TCM clinic, especially one similar to the facility being observed which provides some mainstream medical services, is their only choice. The greatest demand relating to these undocumented immigrants was for hepatic and respiratory ultrasound scans. If problems were discovered, the clinic normally advised the patient to undergo additional blood tests at its collaborative laboratory. This offer was frequently refused by these undocumented patients as blood tests would cost more money. The undocumented immigrants also hesitated when it came to treatment. TCM therapies often take a long time and have uncertain effects, so they would spend a large amount of money but not know when they would be cured.

The second biggest group of visitors to the clinic were Chinese students, partly because of the central location of the clinic near numerous Chinese restaurants and supermarkets. The student cohort is seldom considered a frequent TCM consumer and so it is meaningful to study this group. Their first reason for visiting the clinic was a misunderstanding of the UK health system. The number of Chinese students in the UK is large and growing, and their demand for healthcare services is clear (Migration Advisory Committee, 2018). However, a large proportion of them as seen in the clinic do not speak fluent English. Also, the length of the academic year in the UK, especially for taught postgraduate courses (International Unit, 2016), gives students a relatively short time to adapt to UK society. Although there should be inductions in each school introducing the NHS and general practitioner (GP) services, the student may not notice or understand such information. Many young visitors to the clinic voiced opinions such as '[I] don't know about a GP', '[I] don't know how to register with a GP', '[I] don't know how to see a doctor in hospital' or '[I'm] afraid of paying high bills to the public medical service'.

Secondly, young Chinese students have strong connections with their families in China, and so it was unsurprising that Chinese students came for acupuncture or to buy TCM products recommended by their parents. These acupuncture treatments or merchandise were normally not for serious diseases but a form of regimen (yangsheng, 养生), as parents worry that their children will be very fatigued and feel waist and back pain owing to heavy study pressure. Thirdly, some students came for a medical certificate as evidence that they needed sick leave from school. These students were normally refused the opportunity to rest at home by doctors and GPs. However, if they had symptoms such as insomnia, fever or headache, among others, their request for some days off was normally supported by a TCM practitioner.

[49] Some commercial insurance companies, such as BUPA, only pay for a GP referral to verify the authenticity of health needs. Whether an undocumented immigrant can buy commercial insurance is unsure.

The third group of clinic customers comprised people well-adapted to the UK context, typically young to middle-aged people who are identified as the second or third generation of Chinese immigrants[50] with stable jobs in the UK. This cohort frequented the clinic for relaxation. The most popular clinic service for this group was massage. Although various types of massage services exist in London, customers claim that Chinese massage 'concentrates on the pressure points and can better release fatigue'. Occasionally, some of these individuals attended for rare diseases or difficult problems like infertility. However, as CP8 stated, these people seldom fully accepted the advice from a TCM practitioner, as they 'need to consult [such advice] with their [Western] doctors first'.

As for the non-Chinese TCM users, they included both UK locals and people from other non-Chinese countries. More specific details about the non-Chinese TCM users were found in the data collected by questionnaires (see Appendix I). Figure 4.1 shows the outstanding information of TCM users identified through questionnaires. The pie charts in Figure 4.1indicates the basic information of questionnaire respondents, whilst the other circles presents the most chosen options when the respondents considering using TCM.

The non-Chinese respondents comprised 85% (the reason of why the majority of questionnaire respondents were non-Chinese people are explained in Section 3.2.3). The non-Chinese responders included 61.32% of white people, 12.26% mixed race, 6.60% Asian or British Asian, and 4.71% Black or Black British). Among all the responders, the male-to-female ratio was almost even (51.88% of female). Half of the responders were aged 21–40, and the number of those aged 40–60 (31.13%) was also considerable. They normally used herbal medicine (57.54%), acupuncture (54.71%), and massage (53.77%), which can be used simultaneously. The therapies provided by the TCM practitioners were used to maintain or improve health (62.26%), and also to provide help with long-term conditions (42.45%). The questionnaire data (see Appendix I) reflects that 65.09% of questionnaire respondents visited a TCM clinic because they had heard of or experienced effective TCM treatment; 44.33% of responders were recommended to use TCM by others. More than half of the respondents (57.54%) stated they understood the effective mechanism of TCM. As a result of the highly effective treatment, 37.73% of the responders visited a TCM clinic quite frequently at around once per week, and many (46.22%) were willing to spend around £100 per visit. The effectiveness of TCM has led to its prosperity.

[50] To differentiate generations of Chinese immigrants see literature like Song (2015) and Hsiao (2020).

It is noteworthy that 85.84% of the responders to the questionnaire were registered with a GP, indicating that TCM may not be the first choice for most non-Chinese users. Such information was also found in ethnography work. CP 10 reported that most of their non-Chinese patients 'know about their conditions before coming to the TCM clinics', which suggests they may have visited other healthcare providers. These healthcare providers included GPs and public hospitals, private clinics providing mainstream healthcare, and other CAM practitioners. However, 27.35% of the responders reported that their mainstream medical treatment was unsatisfactory. There are 63.20% of the respondents considering TCM practitioners could provide alternative opinions compared to mainstream doctors about their condition, and it may have given them more hope that they could be cured. CP 10 explained that the other healthcare providers could not cure the uncomfortableness and thus patients turned to them. Such healthcare options had mostly been recommended by friends or relatives (44.33%).

Concerning the problem of the current UK-TCM, the dissatisfaction about their exclusion from public insurance coverage was reported by 41.5% of questionnaire respondents, and indeed 18.86% of all the respondents stated that they might be driven away from TCM because of the high cost. The exclusion from public health insurance relates to the status of TCM which is not statutorily regulated in the UK. And as such, the percentage of respondents who considered the current TCM regulation to be good was 14.15%, barely ok was 26.41%, not effective was 30.18%, or that it meant nothing to them was 29.24%. When asked about possible improvements to TCM regulation, 59.43% of respondents expected to see more scientific evidence for the effectiveness of TCM, while 44.33% expected laws to guarantee the qualifications of TCM practitioners and safety of practice.

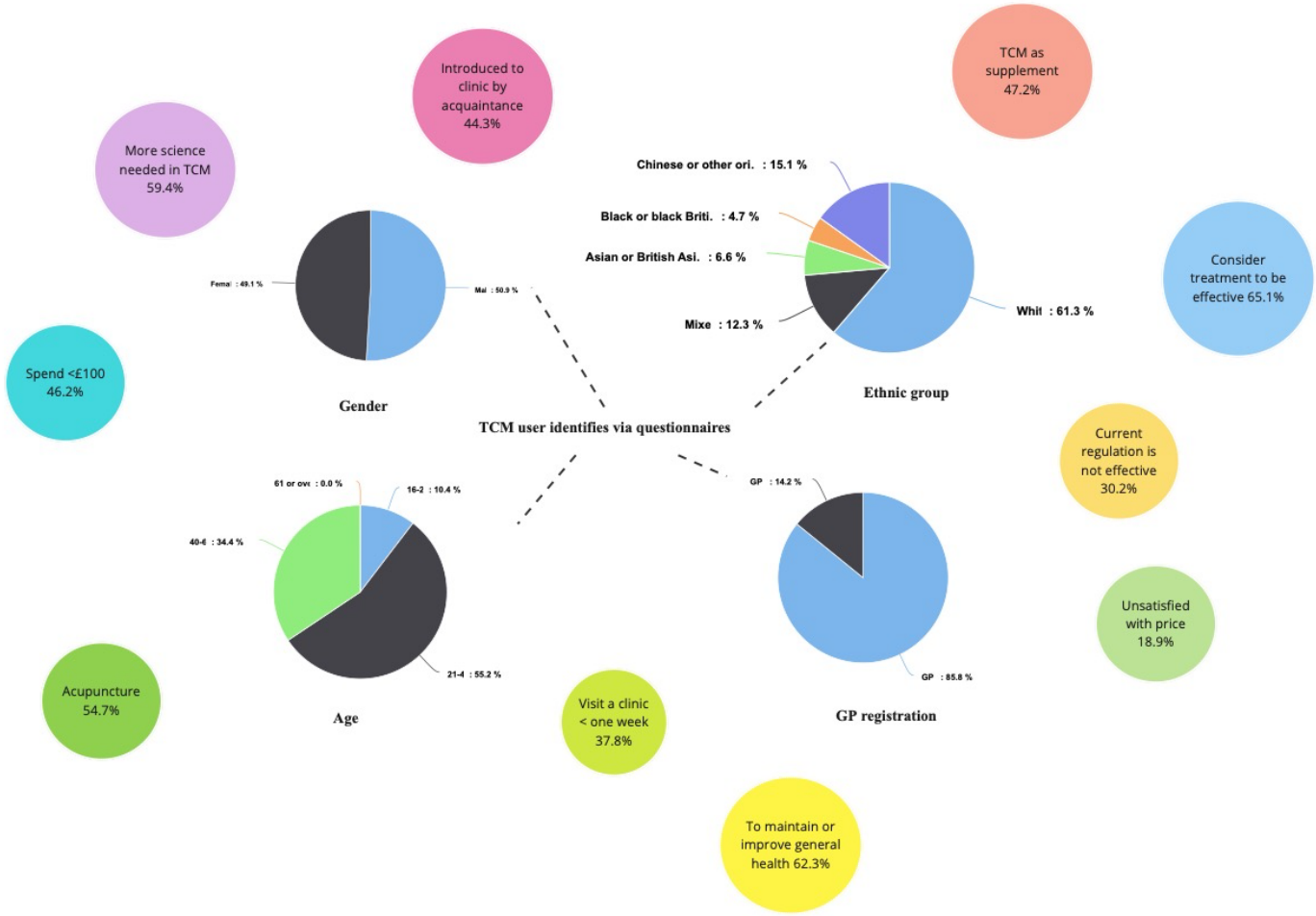


Figure 4.1: Information of TCM users identified through questionnaires

4.3 Short summary of this chapter

This chapter has combined data collected from ethnographic observation and questionnaires to understand the daily operation of a TCM clinic and its major client groups. The Clinic being observed is considered as an epitome of the UK-TCM practice and business mode. This chapter has indicated that TCM in the UK is normally practised in private clinics. Besides the TCM products and treatments, some ready-made medicinal products and biomedical diagnosis services are provided. The Clinic works as a traditional treatment provider whilst serving as a one-stop private healthcare sector. Under this condition, the biggest client group of the Client are Chinese people who have limited access to the public health sector, such as the elderly and the undocumented immigrants. A TCM site, like the Clinic, also serves young Chinese students and people seeking for relaxation.

This research has also identified a number of non-Chinese people visiting the Clinic. Their basic information was mainly collected through questionnaires. The questionnaires showed that the

major group of non-Chinese TCM users were white people aged between 21 to 40. The number of male and female TCM users are even, and their rate of using different treatments like herbal medicine, acupuncture and massage are similar. Though most of the questionnaire respondents have registered with GP, they were not fully satisfied with the diagnosis and treatment of Western medicine. Therefore, people turned to TCM, and mainly chose it through the recommendation of acquaintances. However, many questionnaire respondents were hesitant about TCM because of its exclusion from public health insurance, and they also considered the current regulations not effective or strong enough. The questionnaire respondents expected more scientific evidence about using TCM and a stronger regulation on the qualification of TCM practitioners to guarantee the safety of the therapies.

Chapter 5. Resultes of Interviews

This chapter presents the results of the interviews conducted in line with the research topics and questions introduced in Section 1.6. This chapter comprises two major parts: the interview data collected from TCM practitioners and from the UK-TCM industry stakeholders. The first part of interview data from practitioners contains their personal information and background, daily practice and experiences with patients, sources and suppliers used for practice, and thoughts about the current UK-TCM industry, its regulations and its future. The interview data from practitioners is shown in comparison form to see differences between CPs and NCPs. The second part of interview data from the stakeholders is more precisely divided into different sections for each stakeholder. Basic information and how different stakeholders work to operate the TCM industry are revealed. The stakeholders also expressed their ideas about the current state and future UK-TCM industry and its regulations.

5.1 Interview data with TCM practitioners

The information from these practitioners is a crucial part of the data in this research. This section contains data collected from TCM practitioners to give a map of the current TCM in the UK. The data collected from CPs are mainly used to indicate the differences between practising in China and in the UK; whilst the data collected from NCPs are used to make comparison with CPs to see whether ethnic group, cultural background and life experiences differentiate TCM practice.

5.1.1 Basic information of TCM practitioners

(1) Personal information of CPs

The basic backgrounds of each of the TCM practitioners were investigated, including their nationality, length of practice, education and advanced training experiences. All 15 CPs interviewed were from China and are now UK residents. Some have become British while others have kept their Chinese nationality because '[they would] finally go back to China like falling leaves getting back to the roots'. All 15 CPs had been practising TCM for around 30 years, with the longest experience being 37 years. Before coming to the UK, all had practised TCM in China; the earliest arrival was 1998 and the others came at various points up to 2006. In 2006, the new point-based system (PBS) was introduced by the Asylum and Nationality Act

2006, by which companies need a certificate of sponsorship to employ non-UK people and must pay overseas workers a high level of salary. As reported by CP1, most TCM companies and clinics stopped recruiting new staff at this point. CPs 1–2 and 4 stated that this policy seriously affected the development of TCM by preventing the younger generation of practitioners from coming to the UK. The educational background and further training of the 15 Chinese practitioners is summarised in Table 5.1.

Practitioner	School education	Further training	Training in the UK
CP1	Bachelor's degree in a medical university in China	One-year advanced study in hospital in Beijing	Self-study via books and videos
CP2	Bachelor's degree in a medical university in China	No	No
CP3	Master's degree in TCM university in China	Exchange study programme in Japan for twice	No
CP4	Bachelor's degree in TCM university in China	No	Self-study
CP5	Bachelor's degree in TCM university in China Master's degree in Shanghai University of TCM	No	Workshop held by registration organisations; sometimes lectures were given in these workshops
CP6	Bachelor's degree in Faculty of TCM, Capital Medical University	Exchange study programme in Tokyo University, Japan as visiting scholar	Workshop and conferences held by registration organisations Submitting to journals held by registration organisations
CP7	Bachelor's degree in TCM university in China Attended master's programme but no degree obtained	No	No
CP8	PhD of the China Academy of Chinese	No	Short courses, lectures and workshops held by registration organisations

	Medical Sciences		
CP9	Bachelor's degree in Shanghai University of TCM	Advanced study programme by national health department	No
CP10	PhD in TCM university in China	Short courses held by hospitals where the practitioner worked One year of surgery training in tumour hospital Advanced study in Shanghai Medical University	No
CP11	Bachelor's degree in TCM university in China	One year of advanced study for 'Western medicine' in China-Japan Friendship Hospital, Beijing Three-year apprenticeship with famous TCM master	No
CP12	Bachelor's degree in Chengdu University of TCM	Advanced study in hospitals in Chengdu and Chongqing	Workshops held by registration organisations
CP13	Diploma in acupuncture college	Three-year programme funded by Chinese government	No
CP14	Bachelor's degree of Clinical biomedicine in Capital Medical University, Beijing	Learning TCM from family member	No
CP15	Adult self-study programme to obtain bachelor's degree of TCM university in China	No	Self-study

Table 5.1 Education and training background of CPs

Each of the 15 Chinese practitioners had a formal qualification from a higher education institution. Learning TCM in China is as formal and systematic as studying biomedicine, because it is a part of national higher education (Hua, et, al., 2017). Thus, although these CPs graduated from different institutions, they learned quite similar content. During the three years of diploma study or five years of undergraduate study, they learned both TCM and 'Western medicine'. When the CPs continued their studies to master's or doctoral level, they gained more detailed knowledge in specific areas like paediatrics or gynaecology. After their study at a medical institution, each practitioner had the opportunity for advanced study in different hospital departments. One common form of advanced training is two or three years of standardised clinical training as residents in a hospital, where they practised independently after such training. Some were trained in different ways, including apprenticeship learning allowed by the Chinese government as a legitimate form of formal TMC education (*the Law of the PRC on Medical Practitioners*), and a student exchange programme.

Compared to their advanced learning experience in China, there were fewer opportunities for further training in the UK, and so the CPs normally chose workshops held by the TCM associations as an advanced training approach; however, these training activities did not help them very much. As CPs 4, 8 and 10 reported, these activities are 'very short', 'do not contain much new knowledge', 'are held only in London', and 'are held only on weekdays'. Still, the CPs tried to improve their professional knowledge and skills in their own ways. This normally included self-study using resources available on the internet or video courses and short-term training courses, workshops or academic conferences. CP6 praised the workshops and conferences as having an important role in their career by maintaining their knowledge and skills, while also providing a platform to communicate with peers and build a professional network.

(2) Personal information of NCPs

Demographic data were gathered on the NCPs. The nationality of the ten NCPs was diverse as they were from the UK, Netherlands, Pakistan, Israel, Japan and Iran. Only NCP7 had kept her Dutch nationality, while the other NCPs had become UK citizens. Their length of practice varied from 5–35 years. Only two interviewees reported overseas practice experience before coming to the UK: NCP9 had practised for two years in Pakistan, and NCP3 for three years in Israel. The ways the NCPs learned TCM are summarised in Table 5.2.

Practitioner	Educational background	Advanced training	Training in the UK
NCP 1	Short courses of herbal medicine, acupuncture and Tuina (unable to remember the names of the courses)	No	No
NCP 2	Joint honours degree in biology and chemistry	Six-year part-time osteopathy in a osteopathy college; Four-year full-time acupuncture courses in international college of integrative medicine	No
NCP 3	Four-year diploma in Tel Aviv University associated with the academy of TCM in China	No	No
NCP 4	Five-year bachelor programme in Middlesex University	Exchange study programme in hospitals in Beijing	CPD
NCP 5	Master's degree in Psychology	Four-year acupuncture training in Japan Six-month programme held by WHO Collaborating Centre for Traditional Medicine in Beijing	CPD
NCP 6	Three college diplomas in Japan Master's degree in Middlesex University	Seminars of Japanese Meridian Style acupuncture twice a year Visiting study in acupuncture clinic in Boston, US	CPD
NCP 7	Diploma in London School of Acupuncture and Traditional Chinese	Exchange study programme in Nanjing, China	No

	Medicine (now a part of Westminster University)	Training course of Japanese acupuncture One-year acupuncture programme in the Netherlands	
NCP 8	Diploma in London School of Acupuncture and Traditional Chinese Medicine (now a part of Westminster University) Herbal medicine programme in London Academy of Oriental Medicine (now a part of Reading College of Oriental Medicine)	No	CPD
NCP 9	Acupuncture training courses in Pakistan	No	CPD
NCP 10	Three-year diploma courses in an acupuncture college (preferred not to say the name)	Six-month clinical practice held by the college	CPD and other workshops held by the registration organisation

Table 5.2 Education and training background of NCPs

Compared to CPs, the NCPs interviewed in this research had a much lower rate of attending formal TCM education at degree level. NCP4 considered the quality of TCM education should not simply depend on degrees or length of study, as he had met some very good practitioners with a poor school education. NCP4 insisted that experience helps a practitioner to be professional. Nevertheless, the NCPs had a higher participation rate in systematic advanced professional training in the UK, or CPD (Continuing Professional Development). Early formal documentation on CPD requires NHS staff to maintain their performance during their daily practice as part of the clinical governance programme (Zahir, 2001). Although CPD requirements do not expand to the private health sector, some CAM therapies (such as osteopathy being regulated by the *Osteopaths Act 1993* and chiropractic by the *Chiropractors Act 1994*) do make similar requests of their members for life-long safe practice and skill competence training to cope with the changing health needs of the public (Lee-Treweek et al., 2020).

However, for most other CAM therapies, CPD is not compulsory but decided by professional bodies, regulators, or employers (CPD Standards Office, 2021). As such, there is much freedom and discretion when participating or choosing CPD. There are various forms of CPD and practitioners can choose that which is helpful for professional career development, including workshops (it is possible that the above CPs also attended CPD but did not recognise this term), conferences, learning programmes, and even idea sharing (CPD Certification Service, 2020). Also, I did not find unform standards of CPD among the UK-TCM associations via a brief internet search.[51] Each association has its own requirement for participation, hours, and credibility assessment towards the training for its members to take part in CPD.

5.1.2 Current practice

The type of other therapies used by CPs and NCPs are summarised in Table 5.3.

Practice	**Practitioner**
Cupping	CP 3, 4, 6
Osteopathy	CP 7, 8, NCP 2
Tuina massage	CP 2, NCP 1, 2
Guasha	CP 4
Moxa	CP 12, NCP 10
Facial acupuncture	NCP 5
Reflexology	NCP 2
Shiatsu	NCP 4, 6

Table 5.3 Other therapies used by CPs and NCPs

(1) What CPs pratcise

All 15 CPs reported that they practised acupuncture and herbal medicine. CPs 1 and 8 spoke about acupuncture as a broad concept with various branches, and they sometimes used Fu

[51] The CPD requirements were searched on the website of some big TCM associations: 1) The ATCM requires CPD for members but does not specify hours; 2) The BAcC requires a minimum 30 hours per year and an annual declaration is needed; 3) The FTCMP requires CPD for members but does not specify hours; and, 4) the British Acupuncture Federation requires at least 36 hours of CPD every three years.

needling,[52] electroacupuncture,[53] and retention needling.[54] As well as herbal medicine and acupuncture, more than half of the interviewees stated that they also practised 'other traditional and classical therapies'. All the CPs reported their treatments to be effective for various diseases. All the practitioners declared their treatments, especially acupuncture, worked effectively on types of pain including muscle, bone, shoulder, back, joints, migraine, and pain without clear cause. CP6 described how the TCM clinic played a similar role to hospitals for the ethnic Chinese population in the UK. CP6 also reported that Chinese patients visit a TCM clinic for all kinds of health problems, and TCM works effectively on these problems, including: disorders such as stress, anxiety and insomnia; skin problems such as eczema, psoriasis and fungal infections; and, gynaecopathia, including period problems and infertility.

The CPs reported that other chronic diseases were also improved by TCM treatment like arthrosis and hypertension. In addition, CPs claimed that TCM can cure diseases more thoroughly than hormonal medicine and pain killers, and thus they could treat problems that could not be solved by doctors. Successful practice promote the effectiveness of TCM and attract others to try it. CP7 reported that patients came to the clinic because they had heard about successful TCM cases from friends or family. CP11 reported that some of his patients were recommended by private insurance companies because patients normally have good outcomes from his treatment, and therefore the insurance companies compensate less.

Compared with practising in China, CPs 1, 10 and 14 reported that they were excluded from the public health sector in the UK. The CPs reported that their greatest obstacle with TCM practice comes from the NHS. CPs 3, 8–9 and 12 reported that there is no official mechanism within the NHS for GPs to refer patients to TCM, and sometimes NHS practitioners even prevent patients from using TCM because it may affect the outcomes of mainstream medication.[55] CP3 thought the NHS only considers the risks of interaction between TCM and mainstream medication, which may not even exist, and ignores the effect of TCM needed by many patients. CPs 9 and 12 stated it was not incomprehensible that the NHS appears very cautious about TCM, as many doctors and GPs know little about its mechanisms. The CPs also thought the NHS would not alter this attitude and strategy because 'they (the mainstream medical workers) never communicate with us'. When in China, TCM is a part of China's

[52] A therapy whereby a trocar needle is inserted into the subcutaneous layer around the afflicted spot, mainly for painful musculoskeletal disorders (Fu & Shepherd, 2013).
[53] A therapy whereby needles are inserted into the skin and then connected to an electro-machine to stimulate the point (Wang, 2009a).
[54] 皮下留置针疗法 is a therapy using special needles inserted and left under the skin for some time (Wang, 2009b).
[55] The NHS notes on its web page that herbal medicines may cause problems if people are taking other medication.

national health system, and CPs used to work for different medical departments in public hospitals. They thus always saw and treated patients with similar symptoms in their departments. By contrast, in the UK they treated people with different problems because they now worked in private clinics.

Besides the attitude of the NHS, CP6 reported that the exclusion of TCM treatment from public health insurance impacted her practice. UK People are used to free healthcare services, and so expensive costs makes people hesitate about using TCM. In addition to the subsequent influence on CP6's business income, she also worried about the potential risks to medical outcomes caused by high costs. CP6's patients sometimes chose to suspend long-term treatment or used cheaper products, even though the effects might be reduced accordingly. For example, the price of individually prescribed herbal medicines costs £63 for one week's supply, and some patients would only try one or two weeks' treatment; this dosage and period were sometimes considered by CP6 to be insufficient. Other patients would rather use ready-made remedies that cost £12 per week, but CP6 stated these are less effective because they do not target specific symptoms and body conditions.

Thirdly, CPs 5 and 8, who modified therapies when practising in the UK due social preference and needs. CP5 considered TCM to be closely linked to traditional Chinese culture, which is less accepted among other ethnic groups. They thought that people from other ethnicities could not completely accept orthodox TCM, and this affected the medical outcomes. CP5 stated that he gave up their occupational habits and sometimes even the effects of treatments to pay more attention to people's feelings when practising in the UK. He stated: 'I don't expect foreign people to understand the bitter taste of herbal medicine and the pain of acupuncture. In China, Deqi (得气[56]) is a principle of acupuncture, but this may cause panic [to the foreign patients]. I […] abandoned Deqi'. To further improve patients' experiences, CP5 changed his acupuncture needles. He reported using thinner casing pipe needles which cause less pain instead of the non-casing ones that he used in China. CP 4 aggreeded that even the 'pain of injecting needles would scare the foreigners', he normally explained that any possible pain from acupuncture is unavoidable if patients expect good outcomes of treatment, and 'once patients see the effects, they do not think any more about safety'.

Also, undue expectation of the efficacy of TCM may make patients disappointed and impact

[56] Feelings of needle injecting as a signal response of acupuncture (Yuan et al., 2013).

the application of treatments. CP6 stated that people in the UK are used to fast-acting 'Western' medication. However, TCM practitioners always prescribe long-term treatment, because therapies work slowly and need time for slight adjustments to achieve the expected outcomes. People who cannot instantly comply with practitioner advice or who give up treatment halfway through will not see its efficacy. Also, this long-term treatment means higher costs, and so people who expect quick effects from treatment may consider TCM a waste of money

As a result, besides the above traditional therapeutical approaches, one trend of TCM practice is to cooperate with mainstream medicine. CP7 said the way of practising in China is a combination of TCM and 'Western medicine', which guarantees the high accuracy of diagnosis and high efficacy of the following treatment. Besides tongues and pulse diagnosis, TCM doctors also consult the results of mainstream medical tests and scan technologies. Although CP7 could 'still figure out the problem' when practising in the UK, limited access to mainstream medicine tests in the UK still influenced the speed and accuracy of diagnosis. Thus, CM practitioners in the UK appealed for cooperation with mainstream doctors. CP5 shared his experience of cooperative treatment of a tongren jiaoxiao (瞳仁焦小)[57] case. In his description, the GP tested the patient and diagnosed the symptom as iritis. However, the medication from the GP did not work as effectively as expected. When the patient turned to TCM and found the herbal medicine worked, the GP and the TCM practitioner decided to work together to share medical records and discuss the use of medication. CP5 described this case as an ideal TCM-mainstream medicine relationship. Though he did not meet another GP who was willing to try such a different approach.

Forthly, besides the changes of practice made by CPs themselves to align with the system and social needs, CP 12 expressed her worry that some changes to TCM practice may lead to unexpected situation. CP12 stated that in these days some TCM practitioners had been trained only by short courses, many taught by Western people. CP12 did not consider the outcomes of short training courses to be equal to years of degree awarding university education in TCM in China. CP12 explained that TCM is a complex discipline, especially when learning acupuncture, as one needs a long time to understand the angle, depth and points of injecting the needles. She thus did not believe that the graduates from short courses would be able to practise properly, and this could cause severe risks to public safety.

[57] A disease in which pupils become extremely small and cannot be dilated (Fu [Ming] *Shenshiyaohan*).

Some CPs, however, denied changed to their practice in the UK. CP1 said that to work outside of the mainstream health system caused no problems. CPs were educated and trained to treat all kinds of diseases in medical schools, and this education (see Chapter 4), which even included the combined use of TCM and mainstream medicine. Thus, they were well adapted to the general conditions of UK patients who presented with various disorders and had a history of using biomedicines. CPs 2–3 and 13 agreed that the change of working places and mode did not affect their practice, and they did not make changes to concrete therapies. CPs 12 and 15 also stated that '(they made) no changes' to general practice. They explained that the most important theory of TCM is to treat every patient individually, so they continued to follow its theory on personalised treatment according to the body condition of each patient, regardless of ethnic or geographic impact factors.

(2) What NCP practise

All ten NCPs practised acupuncture. NCP10 especially mentioned that her form of practice genre was 'five elements acupuncture', while NCPs 5 and 7 used 'Japanese-style acupuncture'. NCP2 said his osteopathy therapy was 'Daoist style'. The facial acupuncture conducted by NCP5 was also a newly created service which first became popular among famous TV stars for its beauty effects to tighten skin and reduce winkles. Later, the beauty effect of acupuncture was approved by the National Institute for Health and Care Excellence (NICE),[58] and acupuncture then attracted more people wanting to try it. NCPs 2, 4 and 5 used to practise Chinese herbal medicine, but now they reported '[it is] not allowed in the UK' after the coming into force of EU Directive 2004. They now only recommend patients try some herbs but do not prescribe these themselves.

The NCPs also agreed that they could solve certain health problems better than mainstream doctors. NCP2 reported his treatments were effective on cancer, but he did not state the details of the prognosis of his treatment. Several studies have been done on TCM treatment of cancer, indicating that TCM may effectively modulate the tumour microenvironment and reduce cancer cells (Xiang et al., 2019), to improve the life quality of cancer patients (Liu et al., 2021), and reduce the side effects of mainstream medical treatments for cancer, such as chemotherapy and radiation therapy (So et al., 2019).[59] However, all these studies also indicate that the working

[58] There is no general guidance on using acupuncture produced by NICE; it just gives separate information on the effectiveness of acupuncture for treating chronic pain, chronic tension-type headache, and migraines etc. (for relevant information see NHS，n.d.)

[59] None of these three studies were clinical trials. Xiang et al. (2019) reviewed the literature of molecular and cellar mechanism underlying the chemopreventive and therapeutic activity of TCM. Liu et al. (2021) interpreted the TCM principles treating

mechanism of TCM on cancer is unclear and further research is needed. NCP10 reported that TCM can boost the effect of psychotherapy. She took the some victims of the Grenfell Tower fire[60] as an example, as they used acupuncture to help recover from PTSD after the fire.

In contrast to the CPs, the NCPs did not consider the attitude of the NHS to be a problem. First, as NCP1 stated, his understands that the NHS is responsible for public safety, and it is essential for the NHS to publish some instructions. Although these instructions may be negative towards TCM, such as highlighting the lack of robust evidence supporting the safety and efficacy of herbal medicine,[61] patients should know about possible risks if they use the non-mainstream therapies. NCPs 5 and 6 considered that TCM does not need to be involved in the mainstream medical system. Although the NHS official information is not so supportive towards TCM, NCP6 still cooperated with some GPs who sent their patients to TCM when necessary. Thirdly, NCP8 thought the negative attitude from the mainstream medical society could not be changed at present due to the large amount of research needed; therefore, all TCM practitioners could do is to maintain its current practices.

NCPs 4, 7 and 10 agreed that TCM practice is related to practitioners' habits and patients' preferences as well. They did not think there is a fixed mode of practice, and they adjusted therapies only when treating different diseases.

But modification to practice, especially for acupuncture, was also seen among NCPs. NCPs 1–2, 5–6 and 8 reported that they disagreed with the Chinese view that a needle injection should have obvious feelings. NCP 5 had experienced Deqi during her study of TCM in China. She said, the Chinese acupuncturists 'told me "Deqi, Deqi". If patients feel more Deqi, they [the Chinese acupuncturists] consider the outcomes of treatment to be better'. NCP5 considered that the habit of using thick needles producing strong feeling is because of Chinese traditions rather than the efficacy of the treatment. The CPs thus naturally inherited this way of injecting needles, but the NCPs did not necessarily follow this habit, as NCP5 stated: 'At that [early] time, most people [in the UK] learned acupuncture in Nanjing or Shanghai style from their first textbooks. Over the last decades, people were interested to learn new things, so Japanese acupuncture became very popular. They [Japanese acupuncturists] use very fine needles, just touch the skin. They don't even penetrate'. The NCPs were more frequently asked about hygiene and safety

cancer in modern language and based on new evidence. So et al. (2019) reviewed the current some trials of TCM treating cancer.

[60] A serious fire that damaged a building in London in 2017 (BBC News, 2020).

[61] The NHS notes on its web page that herbal medicines are not well regulated and lack scientific evidence to support their safety and efficacy; it also notes that adverse effects and unexpected interactions with biomedicine can appear.

risks with acupuncture. NCPs 2 and 4 normally displayed their disposable needles to dispel worries. The practitioners also reported that real safety issues are irrespective of any possible pain from treatment or hygiene conditions, as they all took care of these.

After making above changes, some NCPs (NCP 1, 3, 5 and 7) found their practie became more attractive and some of their patients came to them directly. NCP 3 described how this means that 'TCM is not always the last option' for some patients. Still, NCPs 1 and 7 did not consider that the trend of choosing TCM as a first medical option was entirely good. They recommended that their patients visit a mainstream doctor first for some necessary tests and scans, and then inform their GPs about their choice to try an alternative therapy. If they did not do so, the two NCPs considered that risks could arise.

Some other NCPs also admitted that the outcomes of TCM are not always as effective as expected. NCP2 stated the final effect of treatment varies from person to person due to individual body condition and the patient's compliance with treatment. And the practice and related outcomes are highly related to the ability of each practitioners. Firstly, the efficacy of TCM relates to the ability of the practitioner. NCP10 took the popularity of TCM treatment on infertility as an example, stating that 'there do exist some specialists who are really good at treating infertility. Now there are more and more acupuncturists claiming to be experts in infertility […] just to attract patients. Practitioners were attracted by the big marketplace'.

NCPs 1–3 and 5 considered the unsatisfaxctory outcome of TCM practice related to education and training. NCPs 1–3 identified the importance of understanding ancient TCM theories, stating that short courses do not allow enough time for a comprehensive study process from theories to practise. NCP3 specifically mentioned her training experience in China, when she took a masters and obtained a great deal of clinical practise opportunities. Due to the time limitation, students educated by short UK programmes miss both the deeper theoretical content and the practical experience. Thus, although these students obtain a certificate from a registration association, they are not very qualified practitioners, and their practice is at risk. NCP5 had heard of two acupuncture accidents caused by inappropriate operation of needles in the back, leading to serious damage to the heart and lung. The perpetrators of these two cases were both non-Chinese who had only attended short training courses in acupuncture. Moreover, as reported by NCP5, there are many TCM schools in the UK providing various courses without setting a core curriculum and standards for graduation. As such, further safety issues may arise due to the lack of standardisation of TCM education in the UK.

A small group of practitioners represented by NCPs 3 and 9, had not ever considered if there had been changes to therapies used in China. These practitioners were educated and trained outside of China, and so they did not know how TCM is practised in China or learn the traditional ways from their teachers; neither did they have opportunities to talk about such information with their Chinese peers due to the language barrier.

5.1.3 Source of TCM products reported by practitioners

Most of the CPs interviewed were employed by a TCM business. The TCM businesses have their own import channels for medicinal goods, such as China European TCM Ltd. (华欧, CE), which used to be part of BO1's TCM business and is now an independent TCM supplier, and Shulan UK Ltd. (SL). CPs also reported that the market is dominated by large established wholesalers such as Changcheng (长城, CC), Shizhen (时珍, SZ), and Phoenix (凤凰, PM). There are also some other suppliers who are partners of TCM associations, and would thus be recommended to the association members, such as Donica Health Ltd. (DH), which is a recommended supplier of ATCM.

The NCPs acquired information about product suppliers from various sources. They all considered these suppliers to be properly qualified according to the standards of their registration associations. Only NCPs 2–3, 5 and 8 could clearly remember the names of their suppliers, while the other NCPs just mentioned a 'company owned by UK people' or 'from China' as they normally called to order so they only had contact numbers of suppliers. Their statements are summarised in Table 5.4.

Practitioner	Source of Product Suppliement	How Supplier was Located
NCP 1	A company based in Newcastle and Darlington	Recommended by the registration association
NCP 2	1. Needles from Natural Health (owned by non-Chinese people) 2. Herbs from some Chinese people 3. Self-made almond oil	Recommended by friends
NCP 3	Herb Prime (Chinese owned)	Recommended by colleague and searching online
NCP 4	Japanese-style fine needles from a colleague	

NCP 5	1. Herbs from East West Herbs, No.1 Herbal Company and a friend who is a Chinese TCM practitioner 2. Needles from Acu Medic in Camden Town 3. Japanese style fine needles from Japan	Recommended by friends
NCP 8	Balance, Oxford	Recommended by friends
NCP 9	A company owned by non-Chinese people	Recommended by registration association

Table 5.4 TCM suppliers reported by NCPs

5.1.4 Registration of TCM practitioners

(1) Registration status of CPs

The CPs reported a preference for ATCM because it is a large association that provides targeted services and registration type for TCM practitioners. Alternatively, they chose the FTCMP, as it recruits mainly Chinese members and thus provides a better communication platform for the CPs without language barrier. CP13 reported that he chose organisations providing rich academic resources, especially those organisations involving TCM research as part of their daily work. Besides the basic registration of practice in the UK, he also joined the academic TCM organisation of the European Association of Jing Fang TCM, which is composed of TCM experts from the UK, Switzerland, and Germany among others, focusing on research with old and classic TCM formulae.[62] In addition, he joined the World Federation of Chinese Medicine Societies, which is a committee providing information concerning TCM regulation in different countries.[63] CP2, 3 and 8 claimed they could not remember the names of their registration associations. They tasked their employers with registering with a partner association, and thus the practitioners themselves were unclear about the detailed information.[64] CPs 1–3 and 7 also reported that their employer helped them to choose specific registration associations. CPs 11 and 15 preferred not to disclose this information. The registration information of the CPs is summarised below (Table 5.5):

[62] Jingdian Fangji, 经典方剂, in narrow definition means the 100 formulae selected by the National Administration of TCM (2018) from the ancient TCM books published before 1911, but which comply with the medicine standards of the 2015 China Pharmacopeia; in broad definition, it means ancient and widely used TCM formulas (jftcm.org, n.d.).
[63] See wcprtcm.org (n.d.)
[64] They did not specify the reason for having others do the registration, but as mentioned in the contents of UK Tier 2 visa in 4.1.1, Chapter 4, some Chinese practitioners speak less fluent English and are paid less than the standard legal salary. These Chinese practitioners may not know UK society and regulations well and have to rely on others (such as employers) to sort work-related issues.

Practitioner	Registration association
CP1	ATCM
CP2	Cannot remember the exact name of the association, just roughly call it an association[65]
CP3	Cannot remember the exact name of the association
CP4	Traditional Herbal Doctors Association
CP5	FTCMP
CP6	FTCMP
CP7	ATCM
CP8	Cannot remember the exact name of the association
CP9	ATCM
CP10	ATCM
CP11	Preferred not to say
CP12	ATCM
CP13	FTCMP European Association of Jing Fang TCM World Federation of Chinese Medicine Societies
CP14	ATCM
CP15	Preferred not to say

Table 5.5 Registration information of CPs

Most CPs considered the current voluntary regulation work concerning practitioners carried out by professional associations to be helpful and effective. The basic and first function of voluntary regulatory associations is to ensure registered practitioners are qualified personnel. CPs 5–6, 9, 12–13 and 15 reported that the regulatory bodies provide the practitioners with certificates verifying that they are legally qualified to practise TCM in the UK. CPs 5–6 specifically mentioned that because they had chosen an approved regulatory body, they would be empowered with an 'exemption right to practice acupuncture (they call it 针灸豁免权)'. This 'exemption right' allows the practitioners to practise acupuncture throughout their career, since members of TCM associations approved by district councils are exempt from having to renew their licence annually (see the 1991 Act on exemption of licence renewal for members of specific acupuncture bodies in Section 1.3.1).

[65] CP2 reported that he had registered with a TCM association (一个中医师协会), but he could not say its full name. CPs 3 and 8 said similar words.

The second important function of 124anodermaons is organising academic activities, so that the voluntarily regulated practitioners have a route for advanced education and training. CPs 9–12 highly praised the academic activities including workshops, conferences and internal academic journals.

Thirdly, CPs 7, 12 and 14 reported that the protection provided by the associations was of great importance to them. The associations provide the practitioners with insurance. CP12 stated that membership of organisations is normally bound with business insurance to compensate for the possible cost of medical accidents. Although insurance is not a compulsory requirement for TCM practitioners (see note 74), CP12 considered that practising without insurance is risky when injuries happen.

Besides insurance, CPs 7, 12 and 14 praised the post-accident mechanisms provided by the TCM associations. However, these three CPs reported that they had never caused a medical accident and did not know the details of how their association would help them in such a case. Moreover, CP6 reported that the association made regular inspections of the daily practice of its member practitioners and checked for the use of banned or restricted herbal ingredients.

However, some CPs doubted the performance of the associations. CP4 thought that the fact that there are the different lists of approved associations is indicative of the district councils having different criteria to empower the exemption privilege. As such, CP4 believed the qualifications of practitioners and the quality of their practice cannot be guaranteed as there are no unified standards for association inclusion and practitioners can choose to register with an association with lower entry criteria. CP4 thus questioned whether the existence of different approval lists means that practitioners have different levels of qualification across the boroughs. Besides geographic location, practitioners also considered other issues when choosing an association, and which held risks.

CPs preferred associations with entry criteria that are easier to reach. CP5 considered the requirement of English ability as an entry criterion of the BacC to be unreasonable. Many CPs were too old to learn a new language, and were up against a closed door with associations like BacC. CP5 admitted that those associations lacking English ability as a solid requirement were more popular among the CPs, although this went against suggestions in the regulatory reports (see Seection 1.3.1). Indeed, the less restricted entry standards may not only focus on language

fluency. CPs 5 and 12 reported that some associations do not carefully check the background of their prospective members. CP5 said of his experience with TCM practitioner registration that,

There are two major associations, the ATCM and the BacC. They have English requirements. The smaller ones [associations] are easier… When I attend their interview, the interviewer had little professional knowledge about TCM, and they didn't even know what to ask in the interview. The interview only took about five minutes. Everyone can pass it. They [the small association] just want to recruit more members to earn membership fees.

CP12 specifically mentioned that some associations do not rigorously check the background of applicants and even grant masseurs a practice certificate, even though most do not have a TCM education background. Although the associations may give masseur members a different tier of certificate, CP12 worried that it is still hard for the public to distinguish their qualifications. CP1 therefore commented that this series of verification and registration procedures is less meaningful than the association claims. CP1 considered that the UK public would still regard TCM practitioners differently to 'real' doctors based on their educational background, work place and typical therapies, and stressed that their hesitations over safety will not be eliminated by certificates from associations that are established in law.

CP4 shared another case, saying that:

The TCM association can provide very limited help with medical incidents, which is different from their promotion [… in the] case of longdan xiegan wan (龙胆泻肝丸), medicine that was supplied for a long period […] caused harm to the patient's kidney. The association didn't take any useful action like investigation, but just removed the name of that doctor from their member list.

The remaining four CPs (CP 1–3 and 8) had no special comments about the work of the associations.

(2) Registration of NCPs

NCPs have different considerations when choosing an association compared with CPs whose choice is related to being part of a Chinese cluster and overcoming the language problem. As a large association, ATCM also attracts NPCs. NCP6 reported the institution where she did the master programme is connected with ATCM, and her supervisor and other teachers all belong to ATCM. She was automatically registered with ATCM. As an association closely connetcetd to TCM education institutions, ATCM was highly praised by NCP 6 because of its academic activities including workshops, conferences and internal academic journals. NCP8 is also currently registered with ATCM. She used to be a member of BacC but found it concentrates more on acupuncture, and she also practises herbal medicine. However, NCPs 3–4, who are currently ATCM members, expressed a willingness to transfer to BacC despite the high membership fee. NCP3 explained she felt that communication with her peers in ATCM was unsatisfactory because the association contains many Chinese members and this causes language and cultural barriers for her. The high membership fees prevent her and possibly many other practitioners from joining BacC. Also, she doubted the high payment would in fact help her. NCP5 explained that the high membership fees relate to the high price of insurance. Previously, NCP5 had joined the British Acupuncture Association and Register, which later came under the umbrella of BacC, and she had not considered transferring her membership. She explained that the premium for TCM practice goes up every time medical accidents related to TCM practice happen and there are more than ten cases in the UK each year. Insurance companies have no choice but to increase the premium to cover their compensation costs. NCP5 felt that a large and renowned organisation like BacC would always use reliable and qualified insurance companies and so the high fee was unavoidable. The registration information of the NCPs is summarised in Table 5.6.

Practitioner	**Registration association**
NCP1	Acupuncture Therapy Council
NCP2	ATCM
NCP3	ATCM
NCP4	ATCM
NCP5	British Acupuncture Association and Register* and BacC
NCP6	ATCM
NCP7	Preferred not to say
NCP8	BacC* ATCM

NCP9	Preferred not to say
NCP10	BacC

Table 5.6 Registration information of NCPs

*No longer a member

The necessity of registration and the current registration process were also agreed and praised by NCPs (NCP 1–5 and 9). NCPs 1–3 stated that the organisations provide them with a certificate and acknowledgement as practitioners through entry exams and interviews, so that the public can know they have chosen a practitioner who can practise safely. Then, as reported by NCPs 5 and 9, the organisations have guidelines and instructions on safe practice to avoid accidents. NCP3 reported that patients are not likely to know many details of the working modes of registration organisations, and can only recognise a practitioner as reliable through insurance.

NCP4 specifically said that these academic activities are open to all TCM practitioners, whichever association they belong to, so that a great number of practitioners could meet to demonstrate their working outcomes and communicate with peers. NCPs 5, 9–10 then praised the CPDs provided by the association, as the training programmes of CPDs were important for improving their professional skills and prolonging their career. The importance of insurance was also emphasised by NCPs 1–4, 6 and 10, who stated that insurance is a prerequisite for working as a TCM practitioner in close contact with patients.

In addition, NCPs 5, 7 and 10 considered that the associations represent TCM practitioners or even the whole industry, to strive for their benefit. The three NCPs stated that the associations have much wider influence than individuals, and thus the associations promote TCM widely to the public, and also represent their members to the regulator. Neverrtheless, how the associations worked on behalf of the UK-TCM industry was unclear. NCP8 felt that the associations need to negotiate more with the regulators on accelerating statutory regulation to provide further protection of title and functions to TCM practitioners. He stated that ‘the only problem is we are still not really recognised by the [mainstream] medical professionals, because we are not statutorily regulated as professional healthcare providers […] we need to do a lot with them [the government]’.

Besides, NCP 10 reported huge unfairness among different associations. NCP10 reported his experience that patients having TCM treatment could not have a blood transfusion until four

months after treatment[66] because the NHS considers that TCM treatment may influence blood circulation. However, the patients of the practitioners registered with BAcC are not restricted by the four month rule, which NCP10 attributed to the fact that BAcC members benefit from the good relationship and frequent contact between BAcC and the mainstream medical society. He considered BAcC to be connected closely with mainstream medical professionals and thus had recognition from these medical professionals. Although everyone offers similar TCM treatments, the ones provided by BAcC member practitioners are regarded to have 'no impact' regarding blood transfusion. Till now, there has not been progress towards statutory regulation of TCM (see Section 1.3.1). No CPs ever mentioned that associations work on behalf of practitioners to deliver their appeals to the regulators.

5.1.5 Impacts of regulations reported by TCM practitioners

Official regulations are expected to compensate for the deficiencies of voluntary regulation, but outcomes can sometimes be unsatisfactory. For CPs, restrictions on using certain ingredients influenced their practice most (see Section 1.3.1). CPs 4, 6–7 and 11 reported that the restriction on the use of animal and mineral ingredients caused obstacles for their practice. CP4 stated that CPs choose to remove or replace the restricted ingredients, or they prolong the medication courses or double the dosage of some herbal ingredients to achieve a similar effect. The outcomes of such removal or replacements are uncertain[67], described by CP4 as 'decided by practitioners' personal experiences and knowledge'.

The second most regulatory issue that did impact CPs is the working visa system. CPs 1–2 and 8 reported that most of the CPs in the UK are quite elderly (see Section 5.1.1 (1); since all the CPs had practised TCM for a long time, this indicates their ages). CP1 thought even the youngest CPs were older than 40. He believed practitioners educated and trained in China have more solid knowledge and skills than those educated in the UK. However, many TCM business owners are unwilling to spend time and money sorting out visa issues, so the employers started to hire graduates from UK-TCM schools. CP1 regarded these young graduates as 'bare foot doctors' as they were educated in English. And can only translate and explain a superficial

[66] No reference has been found to support the four-month restriction on herbal medicine users who wish/need to have a blood transfusion. NHS (2018b) has suggested patients inform doctors about taking any herbal medicines before undergoing surgery, as some herbal medicines may interfere with anaesthesia and other medicines related to surgery; also, some herbal medicines may interfere with blood clotting and blood pressure and may increase the risk of bleeding. As a result, doctors may suggest patients stop taking herbal medicines in the weeks leading up to surgery.

[67] Studies have indicated that unstandardised use of herbal medicines may be toxic (Stournaras & Tziomalos, 2015), and unreasonable use of herbs can damage organs (Amadi & Orisakwe, 2018).

TCM knowledge. CP1 went on to say that these graduates had never been trained clinically in hospitals, and predicted that if the visa issue is not resolved then, 'TCM in the UK will die'. Though the working visa issue is ineed need to be resolved, as CP12 said that 'no one really knows if the TCM associations have ever endeavoured to achieve these demands'.

The third impact of regulations reported by CPs relates to local authoritis and private acts they apply. The three regulations (the 1982, 1991 and 2000 Acts) were frequently mentioned. Although the participants did not know these specific regulations, they did understand that their business and practice activities were under the control of the local authorities as empowered by law. The TCM practitioners were aware of the registration demands for legal practice in the UK. The TCM practitioners choose an approved association with which to register.

Firstly, the local authorities examine and approve the registration associations within their precincts. Secondly, local councils approve the exemption privilege of an annual licence renewal. Every council publishes its own list of approved associations, and if acupuncturists register with these associations, they are empowered with the legal right to practise within the area of the authorising borough without renewing their licence annually. Thirdly, CP13, who is also the owner of a small TCM clinic, reported that the council examines the eligibility of their clinics and the qualifications of practitioners when a new TCM clinic opens. The qualification review usually indicates a check on certificates granted by the TCM associations. CP13 reported that some councils also check the educational backgrounds of practitioners to guarantee their professionalism to provide healthcare services. CP4 and 5 reported that the practitioner's eligibility to work relates to the requirements of local councils but did not state whether councils check the eligibility of individual practitioners. CP5 also reported that once a medical accident occurred, the council warned the practitioners and used enforcement to close the clinic if necessary.

Comapring with the work conducted by local authorities, the MHRA was less mentioned by CPs. CP5 reported that the MHRA does regular inspections on TCM clinics, concentrating on the use and stock of banned or restricted ingredients. Another function of the MHRA operates when medical accidents happen, CP5 has reported:

They (the MHRA) would warn you when you cause medical accidents, and they can close your clinic according to law. The information of your problematic practice would then be shown to the public.

Some CPs reported to know the YCS, but they were not impacted by any submitted reports related to herbal medicine. The CPs always emphasised that their treatment was safe. CP13 stated that he was well educated and trained, and had been working as a TCM practitioner for years without accident. If patients questioned about the adverse effects of some herbs shown in the YCS database, CP13 stated that he would convince the patients with his knowledge and experience of the use and dosage of herbs. He was able to select safe herb species and precisely control the dose of each herbal ingredient in his prescription to eliminate potential harm.

The impact of GMP seem to be even less than the yellow Card Scheme. Although all the CPs and NCPs said they only used high quality products, they could not describe clearly how such 'high quality' was achieved. They just roughly stated the products were 'ordered from the head company' or 'bought from a qualified supplier'. The practitioners were found to be unfamiliar with GMP requirements, and nor did they how to control product quality. CP13 suggested a rigorous examination and close inspection of the quality of TCM products and the qualifications of the wholesalers. However, he did not state in detail how such examinations and inspections were conducted.

For NCPs, the 2004 Directive stopping their use of proprietary medicines was identified to affect practice most. Mainly, the NCPs who were unable to practise with individually prescribed herbal medicines turned the focus of their practice more towards acupuncture. NCP2 reported that the directive had impacted his practice, as he used to prescribe pills containing herbal ingredients to speed up the effect of acupuncture, but stopped after 2011.

5.1.6 Practitioners' consideration about the current and future UK-TCM

(1) Problems existing in current UK-TCM

The biggest concern reported by CPs is about the TCM business mode. The current UK-TCM business is operated by large chain companies and small private clinics. As for the chain businesses, CP5 said the branch clinics are controlled by businesspersons rather than TCM practitioners and that the former only wish to maximise profit regardless of the health demands of patients. Many branch clinics prescribe unnecessary medicines or prolong the length of treatment. CP5 thought such behaviour severely damaged the reputation of TCM. The decline of the reputation of TCM has led to fewer customers and many large TCM companies have

gradually withdrawn from the market. As for the small clinics, CP3 reported that their owners could hardly afford the high rent of a city centre and had moved to smaller or remoter places. Also, as CP8 reported, the small TCM clinics normally do not obtain support from commercial insurance companies, and this made it hard for them to attract non-Chinese customers. Both types of business mode face the crisis of a loss of customers, and thus the UK-TCM market will shrink.

As for NCPs, they thought the dominance of biomedicine has marginalised TCM, and if TCM is not admitted into mainstream medicine it cannot develop. NCPs 2 and 6 explained that TCM is a historical system born long before modern science. If TCM needs to prove its safety and efficacy in mainstream medical standards, such as with RCT data, the related research should be designed very carefully by researchers with both mainstream medicine and TCM backgrounds. In this regard, NCP6 pinned his hopes on academic organisations such as universities. However, insufficient attention has been paid to TCM even in universities providing TCM courses. NCP4 spent years in a UK university studying TCM, only to be told that TCM is not a science: 'TCM is taught in the university, so it should be a science. If it's not, why do we learn it at university? The whole thing becomes questionable. We spend so much time and money on this, but we don't receive fair treatment from Western doctors'. Until now, NCP4 has found no answers to this question.

Some other NCPs related the slow progress of TCM research to the mainstream pharmaceutical industry. NCPs 2 and 8 believed that some large pharmaceutical enterprises manipulate doctors and nurses so that they only support mainstream medicines to maximise their profits. However, the TCM manufacturers do not have the power to drive the voice of the public healthcare system. As the market share of TCM is squeezed by the mainstream pharmaceutical enterprises, NCPs 2 and 8 considered that very few funds would be invested in TCM to support its research.

(2) Expectation for the future UK-TCM

Optimistic views are related to beliefs in the efficacy of TCM. CPs 6, 11, 13–14 were confident about the efficacy of TCM in solving health problems which cannot be addressed by 'Western' medicine. They felt that people would always seek out effective medicine regardless of the external impacts from regulation or social change. CP6 agreed with this view by emphasising the issues with mainstream medicine, such as the resistance to the overuse of antibiotics, which could encourage more people to use natural medicines. Also, CP6 said that TCM has already

succeeded in treating epidemics such as SARS in China[68] and malaria in Africa.[69] However, there must be more successes in the future to show the safety and efficacy of TCM treatment. CP12 stated that the UK social political environment is naturally suitable for TCM, because TCM practice 'is influenced a lot by the social and political factors in China, the research and other academic things are restricted by the national conditions and official instructions. The real change to develop TCM is in the foreign countries where we have more freedom to practise and research'.

Apart from the existing social political environment in the UK, further change in the political environment, leading to changes for UK-TCM after Brexit, were expected by some research participants.

(3) The UK-TCM in post-Brexit era

CP10 supposed that the UK government would ease restrictions on importing patent medicines required by the 2004 Directive as the country may need more tax revenue from various industries. Medicines used in the UK may not necessarily need to meet EU standards, and TCM practitioners may have more freedom in their practice, such as using currently unlicensed proprietary medicines.

However, Brexit has also brought negative effects, the most obvious one is the reduction in patients or customers. CPs 1–3, 5, 7, and 9–11expressed similar ideas that EU citizens would leave the UK after Brexit and that customer numbers would fall, affecting their business income. For the CPs especially, having clinics based in city centres or high streets meant they normally saw more tourists as customers than local British people. CPs 3, 5, 8 and 14 predicted another influence following Brexit which would be harmful for the UK economy. CPs 3 and 8 thought Brexit would cause inflation and that the value of sterling would be affected. They considered the cost of importing medical products from China would be higher, but they could not increase the price of treatment because people would limit their expenditure if the national economy were in a downturn.

[68] Studies such as Lau et al., 2008) found that the use of *Houttuynia cordata* extract may activate cell-mediated immunity to prevent viral infection. A review by Leung (2007) confirmed the use of Chinese medicine, but he called for more caution with the independent use of TCM in treating diseases rather than just being used as adjuvants.

[69] Studies such as Liao (2009, p.5363) have mentioned the use of artemisinin combination therapy that 'impressively reduces the intensity of malaria in Africa due to its anti-gametocyte activity. The leading scientist Tu (2004) found that artemisinin is a compound isolated from *Artemisia annua L.*, which is a sesquiterpene lactone.

Unlike the CPs, most of the NCPs reported at the time that they 'don't really know about Brexit' or that it was 'hard to predict' or they were 'not sure' if Brexit would happen. NCPs 1, 3–4, 6, and 8–10 thought that if there were any change after Brexit, the national economy would be worse. However, the extent to which a bad economy affects people's expenditure for visiting the private health sector is uncertain, as NCP1 said that 'people would always use real effective medication'.

Regarding future regulation, NCPs 1 and 5 indicated that the EU legislation acts more like general guidelines, and each member State has the right to decide detailed approaches. In the UK, practitioners are more empowered by the Common Law to provide healthcare services. They thus predict no special changes would happen after Brexit, if Brexit did not make things even worse. One stated that, 'It would be very expensive to regulate a medical system and the UK would not have money to do this'. To the NCPs, the main influence on the future of TCM is the qualifications of practitioners and the relationship with the UK mainstream medical system. They considered that a synergy of knowledgeable and skilled practitioners with more research into TCM would make it a scientific discipline recognised by mainstream medicine. NCP8 said that if TCM were recognised by the UK public health system, it might be included in the NHS and covered by public insurance, and thus more patients would use it.

5.2 Interview with stakeholders identified in the UK-TCM industry

Besides the practitioners (discussed in Section 5.1) and TCM users (discussed in Section 4.2), this research identified other five key stakeholder groups in UK-TCM: regulators, TCM associations, educators, suppliers, and TCM business owners. In the following sections, each of these stakeholders is discussed, one representative of the stakeholders was interviewed to talk about the history of the UK-TCM, their own stories, their thoughts about the current UK-TCM industry and relevant regulations.

5.2.1 The regulators

The first stakeholder is the regulators who develop and implement the rules applied to the UK-TCM industry. They govern the actions of all the stakeholders listed below, with the aim of ensuring safety and other benefits, such as access to qualified healthcare services, of the TCM users described later; these regulators work independently but sometimes also cooperate with each other on complex regulatory demands. Some regulators involved in UK-TCM issues have

experienced re-organisation with new names and working responsibilities.

Established in 1989, the Medicines Control Agency (MCA) was empowered by the Medicines Act 1968 to control the licensing, regulation and surveillance work of the UK pharmaceutical industry. Before its work ended in 2003, the MCA had successfully guaranteed the sale and supply of high-quality licenced medicines on the UK market and helped to build a successful pharmaceutical industry, but it failed in some respects. For example, the MCA had not effectively protected public health, and this limited success was seen in health professional reporting of adverse drug reactions, the poor quality of leaflets and labels in respect of describing potential risks, and the insufficiency of prescription monitoring for children's medicine. The MCA had not performed well as an information provider as it had failed to fully inform both the public and some health professionals, and thus data collected by the MCA was inadequate (National Audit Office, 2003).

Since 1995, the market authorisation of herbal medicine in the UK has been the responsibility of the European Medicines Agency (EMA), which has a duty to protect public health and secure the free movement of safe herbal medicinal products in the EU (EMA, n.d.a). The EMA has a centralised market authorisation procedure for medicines[70] that is valid for the whole EU (Drug and Therapeutics Bulletin, 2009). To coordinate with the market authorisation procedure, namely the requirements of the 2004 EU Directive, the Herbal Medicinal Products Committee (HMPC) of the EMA was established in 2004. The HMPC aimed to harmonise the procedures and provisions related to herbal medicines in all EU member States, and address other issues concerning the integration of herbal medicines into the EU regulatory framework, such as the establishment of EC herbal monographs and lists of herbal substances (HMAC, 2020; EMA, 2021).

At the beginning of the twenty first century, the work of the MCA was expanded as the new EU legislations were applied to herbal medicines. The MCA merged with the Medical Devices Agency (MDA) to become the MHRA in 2003, and the latter assumed the responsibilities of the Medical Control Agency to regulate medicines, medical devices and blood components in the UK. In parallel with the establishment of the HMPC in the EMA, the MHRA developed an advisory body, the Herbal Medicines Advisory Committee (HMAC), responsible for giving advice on safety and quality issues for herbal medical products that: 1) are eligible for

[70] Centralised authorisation procedure is applicable for well-established use marketing authorisation and Stand-alone or mixed application to bring herbal medicinal products to market, but this two routes are not practical for most (if not all the) TCM products.

Traditional Herbal Registration (THR) under the Human Medicines Regulations 2012; or, 2) are unlicenced but used in the UK (Gov.uk, n.d.a). The MHRA worked closely with the EMA on issues of the market authorisation of herbal medicines within the UK.

Although the EMA has now moved out of the UK because of Brexit, the UK government expects to maintain a close partnership on issues of medical safety, inspections, and information exchange (Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community; HM Government, 2017). Supplementary information can be found on the EMA (n.d.b) website regarding future planning on pharmaceutical regulation after Brexit. This includes: a trade and cooperation agreement to recognise GMP inspection of medicines carried out by both the EU and UK; the application of EU pharmaceutical laws as 'acquis 135anoderma135ire' to the UK during the transition period;[71] performing information support to prevent medicine shortages after Brexit; and, the re-distribution of UK work missions (such as medicine assessment for market authorisation) to other EU countries.

In 2007, there were significant developments in the regulation of massage therapy, which is also used in TCM. The General Regulatory Council for Complementary Therapies (GRCCT) was established to work as a profession-led voluntary federal regulator for different CAM therapies and their practitioners. The GRCCT follows the government recommendations in the white paper titled *Trust, Assurance and Safety–The Regulation of Health Professionals in the 21st Century*, which encourages different self-regulation organisations to collaborate. As well as massage, the GRCCT covers reflexology, reiki and other therapies listed in group two of the House of Lords report (2000), and it also agrees the standards and requirements for each complementary therapy. The GRCCT regulator works with the NHS to check whether its members meet the NHS criteria for patient safety (see grcct.org, n.d.).

Of all the above regulators, the fieldwork participants were only knew about the influence of the MHRA and local authorities on UK-TCM.

(1) The MHRA

The MHRA has been contacted through its general enquiry option on its website for their work

[71] After the transition period, most EU laws were transferred to the UK (except for Northern Ireland) and domestic legislation 'retained EU legislation'. In Northern Ireland, EU laws was laid out as 'acquis comunautaire'.

related to TCM regulation. RepM 1 replied by email and corrected a misunderstanding by the practitioners about the work of the MHRA, which relates to TCM in three parts:

a. The MHRA regulates some products supplied by TCM practitioners;

b. MHRA inspects products from non-EEA countries for compliance with GMP, as a criterion for granting market authorisation. This includes a series of processes for market authorisation, homoeopathic registration and herbal registration;

c. The MHRA conducts the work of the YCS.

Sometimes a herbal product falls into a borderline category, which means it is hard to distinguish from a medicine; before its status is decided, the product is labelled a borderline product[72] and MHRA may liaise with other departments, such as UK Customs and TCM-related stakeholders such as TCM associations, in instances where there is a question about the regulatory status of a herbal product. However, this liaison does not equal official cooperation. In addition, the MHRA does not inspect for illegal practices in TCM clinics because there are only responsible for products rather than practice.

Enquiries were also made to the MHRA customer service about changes to its work after Brexit. The MHRA is unlikely to abandon the 2004 Directive as the THR will continue following the departure of the EU as part of the Brexit agreement. The MHRA still provides hope and more opportunities to the UK-TCM industry, and it plans to expand the list of countries from which herbal medicines for traditional use can be accepted. In addition to EEA countries, the MHRA plans to accept evidence of the traditional use of a herbal medicine from a country that has a level of pharmacovigilance equivalent to that in the UK,[73] to ensure that any safety issues have been properly identified to support the traditional use of the product.

(2) Local authorities

Compared to the MHRA, the TCM industry reported a more frequent connection with local

[72] Types of products may fall into borderline category include: herbal products, cosmetics, biocides, machinery/laboratory equipment, and food supplement (MHRA, 2021).

[73] The MHRA did not specify a definition of equivalence of pharmacovigilance in the UK, or how they would accept evidence from non-EEA countries after Brexit, although the Good Pharmacovigilance Practice (GPvP) may be helpful in this regard. The MHRA conducts GPvP inspections on other EU/EEA countries, Japan, the USA, and India etc., where an agency-level agreement is in place to enable discussion of mutual interests related to medicine safety concerns (gov.uk, 2014). However, whether the GPvP criteria would be applied to herbal medicine is unknown.

authorities. These include district councils, London boroughs councils, and the Common Council of the City of London, all of which are empowered to regulate acupuncture by the 1982 Local Authorities Act and the 1991 and 2000 London Local Authorities Acts. In their work, they may sometimes collaborate with police forces (the Metropolitan Police) and the fire authority (the London Fire Brigade) on special treatment premises licence issues, including: a copy of a licence application being submitted to both the police and fire brigade; the police checking if the applicant and staff have any previous convictions; the fire brigade checking if the prospective licence application meets fire safety standards; and, the police and fire brigade having the right to object to the licence application.

Westminster Council has been contacted via freedom of information request for detailed information and data on inspections the council conducted towards TCM practices during the last five years [*The Freedom of Information and Data Protection (Approriate Limit and Fees) Regulations 2004*]. Westminster Council was frequently mentioned in the observation work, as the London Chinatown is within its jurisdiction. The council's reply confirmed the role of local authorities involved in TCM regulation through inspection, stating: '[the council] holds the information I requested', but the council did not provide detailed information on the grounds of the cost of counting the inspections and synthesising their detail.

Besides, as is reported by practitioners (see Section 5.1.4), they preferred those which allowed their members to be exempt from annual licence renewal because the associations were approved by district councils. The bodies with licence renewal exemption rights can be found on the website of each district council. The councils claim that they follow Section 4 of the 1991 Act (see Appendix II), to exempt practitioners registering with specific associations from annual licence renewals. The researcher has searched the 'acupuncture exemption list of councils' on the internet, but the names of exempted associations were slightly different on the websites of five randomly selected London borough councils of Richmond, Barking and Dagenham, Lambeth, Southwark and Bexley. (137anoderm.gov.uk, 2021; Ibbd.gov.uk, n.d.; 137anoder.gov.uk, 2014; southwark.gov.uk, 2021; Bexley.gov.uk, 2022). Richmond Council claimed it uses the list of exempted bodies provided by the London Special Treatment Group, because adopting an existing list is simpler than creating their own according to the 1991 Act. This list provided by the London Special Treatment Group has also been adopted by the London boroughs of Merton and Wandsworth. If practitioners wish to register with associations not on the list, they need to have their licence renewed annually.

The other councils do not specify the details of how they decide on exempted associations, and this may cause problems for practitioners. Once the practitioners decide to register with a specific association, they can only practise within the scale of a specific council; if they wish to move to another place in the future, they face a great deal of red tape.

5.2.2 TCM associations

The second stakeholder involved in the network of the UK-TCM industry is the registration associations (the association). Some regulations and rules are applied to separate TCM issues, such as acupuncture premises and the registration of historically used herbal medicinal products. TCM as a medical system is currently under voluntary regulation in the UK. The TCM associations thus monitor the behaviours of the practitioners under the instruction of the regulators above, as well as performing other functions, such as providing insurance, linking qualified suppliers with practitioners, and organising advanced occupational training. This research thus considered using the associations as a central point for developing a map of the UK-TCM industry.

RA 1, the vice-chairman of the Federation of Traditional Chinese Medicine Practitioner (FTCMP), was interviewed as the representative of the TCM association. The researcher met RA 1 at his home to talk about the development and operation of this association. Established in March 2002, the FTCMP was also a product of the prosperous development of TCM in the UK. The website of the FTCMP shows that its official location is in Kent, RA1 stated that the FTCMP was registered with Kent council, but it has no physical head office there. All the council members of the FTCMP work part-time and communicate by phone or email.

The main functions of the FTCMP at its initial stage were dealing with voluntary registration and related issues, including purchasing insurance, hygiene checks, and providing qualification certificates. At the current moment, the FTCMP has added academic activities to its working focus. After nearly 20 years' of development, the FTCMP has hundreds of registered members, publishes an internal academic journal (*Journal of Chinese Medicine in the UK*)[74], and holds an annual conference and summer workshop each year. One working task of the FTCMP is to ensure safe practice condicted by professional practitioners. RA1 said that the FTCMP requires perspective members to have a qualification recognised by the National Health Commission of the PRC (originally the Ministry of Health) as one entry criterion. RA1 considered that this

[74] An internal journal of the FTCMP, which is not peer-reviewed.

requirement guarantees the solid knowledge and skills of the member practitioners have been taught in formal higher education organisations rather than on short courses, proving the ability of the member practitioners in China to practise safely. The FTCMP also holds entry examinations based on UK laws and the market situation to screen and select eligible members further. To guarantee safe practice by members, the FTCMP (n.d.) published its *Code of Standardised Practice* to guide their members on the legal procedure for starting a TCM clinic, the legal rules on safe practice, the actions to resolve simple problems in the clinic, and the assistance which the association can provide to handle medical incidents.

For its existing members, the FTCMP can take a series of actions to guarantee further that its members practise safely. The FTCMP publishes and annually revises its *Code of Practice and Professional Conduct* to warn about high risk treatments (FTCMP, n.d.), such as possible contaminants during acupoint injection therapy that may cause cross infections of mycobacteriumtuberculosis (Sha et al., 2016). The FTCMP has repeatedly promoted and called for its members to pay more attention to safety, and has also made the purchase of insurance a compulsory requirement for its member practitioners. Besides the compensation paid by the insurance, the FTCMP has a special team to help practitioners and patients by providing professional advice once a medical incident happens.

Concerning the association's ability to provide post-accident help, RA1 admitted that this requires highly professional staff to resolve the various complicated issues of a medical accident. Moreover, the FTCMP was once removed from the council's approved list of licence exemption bodies because one of its post-accident advisors 'made an inappropriate suggestion' and failed to settle the accident. RA1 emphasised that this incident was soon resolved and the FTCMP regained the exemption privilege.

Besides the internal work of the association, RA1 stated that the FTCMP also connects with other associations. For example, in 2017 a cooperative conference was held with other TCM organisations, product suppliers and educators to promote communication between the UK-TCM associations and other industry stakeholders (reported in the news. See China Minutes, 2017). In addition to this communication, RA1 mentioned that the associations also have various connections with government (for more detail about the relationship between regulators and TCM, see Chapter 4). It is a responsibility of the FTCMP Council to help member practitioners through frequent contact and negotiation with official departments.

RA 1 then spoke of the general situation of the various associations and gave details about the two largest and most renowned associations, the Association of Traditional Chinese Medicine and Acupuncture UK (ATCM) and the British Acupuncture Council (BacC). Basic information on these three associations was given by RA 1 and via an internet search, as shown in Table 5.7.

Name / Condition	Federation of Traditional Chinese Medicine Practitioners (FTCMP)	Association of Traditional Chinese Medicine and Acupuncture UK (ATCM)	British Acupuncture Council (BacC)
When established	2002	NI	NI
Location	Kent	London	London
Working aim	Inherit and promote TCM Support TCM education Help practitioner Improve health of people in the UK	Engaged in academic and ongoing clinical research Working with the Department of Health for statutory regulation	NR
Management structure	Board of directors Council Academic committee Secretariat Management of finance Supervisory board	Council	Council
Entry criteria	Recognise the purpose of FTCMP Appropriate TCM educational background and practise ability Passed the entry exam	Currently practise TCM in the UK (Equivalent) qualification of 4 years' full-time training in university of TCM or biomedicine but with TCM training Passed the entry interview	Three years degree level training Currently practising in the UK Eligible premises English speaking ability

Exit criteria	Voluntarily withdraw Default membership fee Criminal behaviour or under investigation of such behaviour	NR	NR
Registration type	TCM (full membership) Tuina (associate member) Acupuncture Herbal prescription	Able to practise acupuncture, herbal medicine and Tuina (full member) Able to practise acupuncture and Tuina (Ordinary A) …acupuncture only (Ordinary B) …acupuncture, Tuina, patent herbal medicine (O…C) …herbal medicine (O…D) …Tuina (associate member)	Acupuncturist
Number of members	Roughly described as 'hundreds' (actual number unknown)	Over 700	Around 2,200
Other works	Frequent meetings Member network Workshops Internal journal CPD	Courses (including CPD) Internal journal Frequent meetings	Support and promote practice Media, magazine and journal Marketing support CPD Insurance and related support Lobbying
Code of practice	Clinic environment, facilities, health, safety, workplace, privacy (record)	Premises Equipment	Safety of practice of: Workplace

	Provision of retailing Practitioner record, title Price Advertising and media Research	Hygiene Disposal Dispensary Mobile and home visit Patient records Working health and safety	Equipment Duty of care Responsibility of performance Disposal Compliance with legislation
Educational partner	Lincoln College (exempt from exam) Middlesex University (Exempt from exam) Shulan College (provides courses)	Asante Academy College of Naturopathy Medicine Glyndwr University Lincoln College Manchester Academy of TCM Middlesex University Phoenix Academy of Acupuncture and Herbal Medicine The Acupuncture Foundation	British Acupuncture Accreditation Board
Supply partner	NI	Donica Health Ltd. Phoenix Medical Ltd. Shizhen TCM UK Ltd. Shulan UK Ltd.	NI
Other partner	NI	NI	Member of the Professional Standards Authority (PSA)

			Cooperation with All-Party Parliamentary Group for Integrated Healthcare Cooperation with the European TCM Association Insurance partners on website

Table 5.7 Information on the three representative associations [75]

[75] Source: interview data of this research, and the website of ATCM (n.d.), BacC (n.d.a)

Although it is not specified in Table 5.7, RA 1 reported that the most distinguishing feature of the FTCMP is that all its members are ethnic Chinese with valuable qualification:

Yes, we only recruit Chinese doctors. They (Chinese practitioners) all graduated from medical universities and qualification working as doctors recognised by China's National Health Department. ... There are some members studied through apprenticeship in China, but they were also qualified by Chinese government.

The ATCM cooperates with many UK educational organisations, and a large proportion of its members are graduates. The BacC mainly recruits acupuncturists, as acupuncture is more popular in the UK than herbal medicine. Therefore, a large proportion of members in these two organisations are non-Chinese practitioners. RA 1, however, considered that setting English ability as an entry criterion is unnecessary and may limit the career development of Chinese practitioners and the promotion of real TCM. The FTCMP therefore does not emphasise fluency in English as a threshold. Also, the FTCMP does not require a particular educational background of its prospective members. This is also due to the situation of TCM in China, where graduates who learn from medical universities and practitioners who learn TCM through an apprenticeship are both eligible to practice. In addition, the FTCMP uses the work experience of its prospective members as a reference. Because TCM practitioners in China normally have clinical experience in hospitals and this guarantees their ability, '[we can] recognise him [or her] as a qualified person in our association' reported by RA1.

Besides conducting voluntary regulation towards registered practitioners and their practice, the FTCMP is also under management of official department. RA1 reported that the MHRA occasionally checked the daily practice and insurance status[76] of association member clinics. Sometimes, the MHRA consults TCM associations about related regulatory issues, such as the banned list of herbal ingredients.

Concerning the current regulation, RA1 said that their TCM association is finding it difficult in the current situation to address further expectations on statutory regulation. Although various strategies for improving TCM regulation were published by regulatory sectors, no real action

[76] The TCM associations (see Section 5.2.2), such as the ATCM, provides medical malpractice and public/product liability insurance to its members. Some associations, such as the Acupuncture Society, also provide professional indemnity. No reference was found to whether the MHRA checks the insurance status of TCM practitioners. A regulation of the *Health Care and Associated Professions (Indemnity Arrangements) Order 2014* required a 'person who holds a licence to practise as a medical practitioner' to have an indemnity arrangement as a pre-condition of registration with the General Medical Council. The internal caseworker guide of gov.uk (2008) says medical practitioners are normally known as doctors or consultants, and TCM practitioners are thus not classified as medical practitioners and are not required by the 2014 Order to have insurance.

was taken after the 2012 Regulations, until now. This situation must last for some time due to the complex political affairs and possible economic downturn after Brexit. RA1 expressed that the wish of the FTCMP is to help accelerate the statutory process of TCM, but the voice of only one association is insufficient. RA1 admitted that '(there is) still a long way to go […]. The only thing we can change for now is to unite all associations and even all the stakeholders of the UK-TCM industry […] to cooperate to improve the current registration mechanism'.

RA1 considered that the most urgent issue for the cooperation of associations and stakeholders was to conduct more research to show the safety and efficacy of TCM. Only if these are ensured will TCM have a better reputation and gain support from the public and the government, enabling more steps to be taken towards statutory regulation. Some endeavours have improved the research of TCM in the UK. As mentioned before, some academic journals were established within the UK-TCM industry, such as the FTCMP's internal journal (in Section 5.2.2) and the TCM product supplier, Balance Healthcare, being the partner of the *Journal of Chinese Medicine* (in Section 5.2.4). However, neither journal is peer-reviewed and they only publish Chinese articles. CP13 also mentioned that the European Association of Jing Fang TCM (mentioned in Section 5.1.4) is reported to conduct TCM-related research. The latest academic information on the website of the Jing Fang TCM Association described how the Third Conference of the Jing Fang TCM Association had successfully been held in London in 2018, but no other academic news or research outcomes had been updated since.

5.2.3 Educators

TCM educators are the third stakeholder in the UK-TCM network. Nowadays in the UK, formal higher education in TCM co-exist with short programmes. Four education institutions were selected to present a snapshot of UK-TCM education (Table 5.8)[77]. Two of these (Middlesex University and the University of Westminster) are formal higher education providers in the UK and the others are private organisations (Shulan College and Manchester Academy of TCM).

[77] Middlesex University was selected as it was education provider of NCP 4 & 6, Westminster University was seletcetd as it was education provider of NCP 8. Some information could be derived from their interview data. Shulan College was selected as its principal Prof ST was one interview participant of this research reached through snowballing. Manchester Academy of TCM was selected as it was ranked high in internet searching (such as using Google) when looking for learning TCM in the UK.

	Middlesex University/ Northern College of Acupuncture	**University of Westminster**	**Shulan College of Chinese Medicine**	**Manchester Academy of Traditional Chinese Medicine**
Location	University in London; Northern College in York	London	Manchester	Manchester
Course name	BSc in Acupuncture MSc in Chinese Herbal Medicine	BSc Chinese Medicine: Acupuncture/ Herbal medicine MSc Chinese Medicine: Acupuncture/ Herbal medicine	Diploma TCM Bachelor/ Master/ PhD	Postgraduate Diploma in Chinese Herbal Medicine/ Tuina/ Traditional Acupuncture
Degree award	BSc & MSc	BSc & MSc	Bachelor/ Master/ PhD	Diploma only
Length of study	BSc: three years MSc: three years (or two years for PGDip)	BSc: three years MSc: one year	Bachelor: five years full-time Master: three years part-time PhD: three years part-time	2 years part-time (Tuina courses for one year)
Entry requirement	BSc: UK students with adequate A level scores MSc: Acupuncturist registered with professional body with language requirement	BSc: same as all undergraduate courses MSc: 2:1 in appropriate complementary medicine, with professional qualification and working experience with language requirement	Bachelor: waiting for further information from the college Master: Bachelor degree, registered with a professional body with insurance PhD: Master degree or 6 years' experience in this field registered with a professional	Herbal medicine: Recognised qualification in acupuncture including undergraduate degree, PG diploma, and must have studied the 8 principles of TCM and have knowledge of TCM diagnosis Tuina: no special requirements

			body with insurance	Acupuncture: graduate qualification in a health-related displine
Accreditation body	British Acupuncture Accreditation Board	British Acupuncture Accreditation Board	Diploma courses accredited by FTCMP and the Complementary Medical Association; Degree courses accredited by Nanjing University of Chinese Medicine	The Traditional Chinese Medicine Accreditation Board (TCMAB)
Core curriculum	BSc: Foundations of Clinical Practice, Foundation of Chinese Medicine, Biomedicine for Acupuncturists etc. MSc: Herbs and Formulae, Managing Diseases and Conditions etc.	BSc: Acupuncture: Chinese Medicine (concept, context, points, theory), Anatomy and clinical skills, Pathology etc./ Herbal medicine: Materia medica, Botany, Biochemistry, Pathology etc. MSc: Acupuncture specific module: Chinese Medicine: a living tradition course/ Herbal medicine specific module:	Bachelor: waiting for further information from the college Master: Huangdi Neijing, Shang Han Lun, Advanced Diagnostics, Acupuncture Scientific Research etc. PhD: TCM prescription, diagnosis, dermatology, Integrated Basic/ Clinical TCM & biomedicine, TCM Rehabilitation	Diploma in herbal medicine: Herbal formula, application of herbal medicine Diploma in Tuina: digestive system condition, respiratory system condition etc. Diploma in Acupuncture: acupuncture points and needling techniques, acupuncture for common diseases and symptoms etc.

		Advanced Herbal Medicine Materia Medica and Therapeutics		
Partner association (automatically given membership)	FTCMP	BacC	FTCMP	ATCM
Other	Master courses online for weekdays, on site for weekends			Tuina course is not accredited

Table 5.8 TCM education institutions in the UK

As seen in Table 5.8, Middlesex University and Westminster University specify their programmes as degrees of acupuncture or herbal medicine. The Manchester Academy also clarifies which therapies can be learned in its programme, while Shulan College just calls its programmes different levels of degree in TCM. The two formal universities educate up to master's degree, Shulan College to PhD level (awarded by a university in China), and Manchester Academy to diploma level. The length of study varies across the institutions. Shulan College has the longest duration because it follows the curriculum in China. As for entry requirements, all the institutions ask for knowledge and experience of TCM-related fields when applying for a master's or higher education and herbal medicine training. Also, it is noticeable that Middlesex University, Westminster University and Shulan College require prospective master's (or higher) degree students to register with a professional body, as clinical observation and practice are included in their courses.

The courses of all four institutions are accredited by professional accreditation bodies, which set the standards for the required curriculum. Of these accreditation bodies, the British Acupuncture Accreditation Board (BAAB) and the Traditional Chinese Medicine Accreditation Board (TCMAB) work independently. BAAB states its accredited courses are recognised by the UK Department of Health and reviewed by the Quality Assurance Agency (QAA). TCMAB states its courses are accredited by TCM professionals but does not specify their details; the courses are also reviewed by the QAA. The core curricula of Middlesex and Westminster Universities combines some biomedicine courses with TCM courses and practice. The core curriculum of Shulan College involves many ancient TCM books from China. The core curriculum of Manchester Academy focuses more on the application of TCM therapies. All four institutions have partner TCM associations, and their graduates automatically become a member of these associations.

Professor Shulan Tang (Prof ST), the principal of Shulan College of Chinese Medicine in Manchester, was interviewed as a representative of TCM educators in the UK. Prof ST also works as a TCM practitioner and has a master's degree from Nanjing TCM University. The researcher met Prof ST in her office in Manchester. She came to the UK at the beginning of the 1990s, a period which she described as heaven for TCM. At that time, the number of TCM clinics increased sharply to cater to demand. Prof ST also opened a clinic as her first career in the UK. While practising, Prof ST noticed many people were interested in learning TCM after experiencing the magnificent treatments. However, no one was willing to open a TCM school at that time, because educators would spend time teaching and might not earn as much money

as when providing treatment. Still, the enthusiasm of Prof ST's supporters and her own aspiration to help more patients through TCM encouraged Prof ST to start a small TCM training programme in 1993. The programme was conducted under the name of Shulan College, which later became a large scale TCM education institution. The initial students involved in this training programme were patients wishing to cure themselves through TCM, and housewives who hoped to find a new career. Still engaged in the clinic, Prof ST only taught students at the weekend in the early 1990s.

Although Prof ST was only 30 years old when she taught her first course, no one doubted her ability as a good practitioner and teacher, and this is quite different from the situation in China:[78]

In China, people normally choose those who are old and looks well experienced; people in the UK don't care about your age.

Also, when practising and teaching in the UK, Prof ST emphasised the importance of learning both acupuncture and herbal medicine, which is quite different from the later TCM schools in the UK which focus only on acupuncture. Compared with herbal medicine, acupuncture is easier to understand because people can see how needles work. However, Prof ST insisted on the importance of herbal medicine which represents the 'real TCM' as it is deeply entangled with traditional Chinese culture and philosophy.

As Shulan College grew, its course design became more standardised. Prof ST developed a textbook called *The Chinese Herbal Patents Handbook*[79] for learning herbal medicine knowledge in English (see Photo 5.1). Prof ST explained that this textbook was a basic introduction to the ingredients and functions of the mass-produced and commercially packaged TCM, localised to align with the UK context, such as the body condition and prevalent diseases among Caucasians.

[78] Similar information was also reported by CP10 (see Table 5.6). Although CP10 has a PhD, she was still not trusted by patients during her early career because she was so young and looked inexperienced.
[79] This in-house textbook by Prof ST is used only in Shulan College. Further information is available on the website of Shulan College. The word patents may be a mistranslation, as it actually means proprietary medicine.

Photo 5.1 The textbook used in Shulan College (Source: Xia, 2020)

Although after the tightening of regulations (such as EU Directive 2004/24/EC and the increasing number of banned herbal ingredients) the use of unauthorised Chinese proprietary medicine was firmly restricted, Prof ST maintained that the textbook still effectively explained basic herbal medicine for local UK students. After learning from this handbook, students can engage in more advanced study of herbs from the textbook *Formulas* (*Fangjixue, 方剂学*, Wang, 2009), which is used in TCM universities in China and Shulan College. When students learn *Formulas*, they are considered to have a similar ability as university students in China.

The development of shulan College highlights the prospects for TCM education and training outside China, and this attracted the attention of higher education institutions in China. Shulan College later became affiliated with Nanjing TCM University as its overseas higher education site[51]. From then on, students of Shulan College could obtain formal degrees (from bachelor to PhD) granted by Nanjing TCM University. Moreover, distance learning was added to the teaching module of Shulan College. By the video teaching approach, more teachers and students based outside of the UK can study, and thus the scale of Shulan College was successfully expanded. Prof ST reassures a positive learning outcome of participating in her online distant course, which especially benefit students who cannot come to Manchester in person:

Our teachers and students are based in different countries and cities. We (the Shulan Collage)

teach both online and onsite, so that we can have excellent teachers based outside of the UK to join our team and teach knowledge to everyone who wants to know it. Also we have close cooperation with the Nanjing TCM university, which also provides online courses for our students.

In the first place, she explained that all her students are adults who can fully understand the course contents even via video. Second, her college requires actual practice of knowledge and skills. The practice sites can either be in her clinic in Manchester or hospitals attached to Nanjing TCM University in China.[80] As for the future development of TCM, Prof ST mentioned the promotion of TCM through the *One Belt One Road*[81] global plan, and Xi Jinping's visit to the UK, which has improved Sino-UK relations (National Administration of TCM, 2017; BBC News, 2015). These events are optimistic signs for TCM in the UK, and hopefully will help TCM out of its downturn since the 2008 financial crisis, as well as easing the pressure caused by the working visa limitation. Prof ST and RA1 expected that a renaissance in TCM, with political help, could encourage more people into TCM higher education and academic research activities. Professional education and the establishment of an evidence base would be promising for the further development of TCM in the UK. Thus, the UK social political environment is thought to be beneficial for TCM.

5.2.4 Suppliers

The fourth stakeholder in the UK-TCM world is product suppliers. Both chain businesses and independent practitioners need a qualified and trustworthy supplier to support and guarantee the safety of their daily practice. Information on these representative suppliers reported by CPs, including the China European TCM Ltd. (华欧, CE), Shulan UK Ltd. (SL), Changcheng (长城, CC), Shizhen (时珍, SZ), Phoenix (凤凰, PM) and Donica Health Ltd. (DH) were obtained through online searching and are summarised in Table 5.9.

[80] Prof ST introduced in her interview with the Xia (2020) that Shulan College started to cooperate with Nanjing TCM University since 2016. The core programme of the cooperation was to build the Europe TCM Centre and recruit students for higher education. However, no further detail about how students could receive education and training from Nanjing TCM University was found.

[81] Yidai yilu, 一带一路, the strategy of China to build a trade channel from China through Middle Asia, Russia, and finally to Europe (OECD, 2018b). The National Administration of TCM in China (2022) announced improved cooperation between governments to promote TCM overseas and help it integrate into local public health systems as a part of the OBOR strategy for 2021–2025. This strategy has emphasised the cooperation with G20, of which the UK is a member.

Company / Conditions	China European TCM Ltd. (CE)	Donica Health Ltd. (DH)	Phoenix Medical Ltd. (PM)	Shizhen TCM UK Ltd. (SZ)	Shulan UK Ltd. (SL)	Changcheng (CC)
Nature of business	Other human health activities–wholesale	Non-trading company	NI	Retail sales not in stores, stalls or markets Wholesale of pharmaceutical goods	Specialists medical practice activities	NI
Information sources	Found during observation fieldwork	Found during observation fieldwork	Recommended by practitioners interviewed	Recommended by practitioners interviewed	Recommended by practitioners interviewed	Recommended by practitioners interviewed
Established	1998 in London		2011	1997	1993	
Relationship with other TCM organisations	Member of Chinese Medical Association (CMA) and FTCMP	Recommended supplier of ATCM and Register of Chinese Herbal Medicine (RCHM)	Recommended supplier of ATCM and RCHM In partnership with the University of Southampton	Recommended supplier of ATCM	Recommended supplier of ATCM Supplier of Shulan College	Recommended supplier of ATCM
Services	Herbs Herbal power External use medicine Facilities Tea	Herbal medicine of Full Composition Granules (FCG) and standard formulas Food supplement External cream and oil Tea Acupuncture needle TCM related books	Acupuncture products Herbs Nutrition Moxibustion Physiotherapy Clinic supplies Topical Products Other tools Books and posters	Herbs Acupuncture supplies Skin treatment	Herbal granules Acupuncture needles	Herb Acupuncture needles
Partners in other countries	Shenlu (Hefei) Ltd. Zhongxin (Tianjin) Pharmeceutical Ltd. Tongrentang (Beijing) Ltd. Huqingyu Tang Ltd.	TCMAGES Pharmaceutical Co. Ltd.	Hebei Huadu Pharmaceutical Co. Ltd. Jiangtin Tianjiang Pharmaceutical Co.	NI	Ko da (Taiwan) Pharmaceutical Co. Ltd.	NI

	Guangzhou Pharmaceutical Co. Qizheng Pharmaceutical Ltd. Haerbin Pharmaceutical Ltd. Sanjiu Medical & Pharmaceutical Co. Ltd. Yingte (Zhejiang) Pharmaceutical Ltd. Kangenbei Ltd. Huatuo (Suzhou) Ltd. Farlong (US) Pharmaceutical Ltd. Willy's Pharmacy					
Notes	NA	NA	NA	Purchase is available on Amazon	NA	No website, information only found in Chinese yellow page

Table 5.9 Information of representative TCM suppliers reported by CPs

Three of the above suppliers (CE, SZ and SL) were established in the 1990s, which was also the 'golden time of TCM in the UK', as mentioned before. All the suppliers above were approved by TCM registration associations, although their partner organisation varies, and the selection criteria remain unclear. Two of the suppliers (PM and SL) are in a cooperative relationship with educational institutions. The founder of SL is also Prof ST, and the products sold by SL are naturally recommended to students of Shulan College. It is noteworthy that PM is involved in TCM-related research, and its website shows it supports TCM clinical studies conducted by the University of Southampton.[82]

It is worth noticing that the PM is a partner of a UK university for NHS-supported research. All the suppliers sell herbal medicines and products for acupuncture. All the suppliers have specified that such products are supplied as raw herbs and granules (or powders); acupuncture needles are supplied in different sizes. Four suppliers (CE, DH, PM and SZ) sell external products for muscle and skin problems. Two suppliers (CE and DH) sell medicinal products, such as lucid 156anoderma as a nutrition and food supplement. Two suppliers (DH and PM) also provide TCM-related books, mannequins and posters for teaching and learning demands. Although a manufacturer and wholesaler licence is required for medicinal products on general sale (see 2012 Regulations in Section 1.3.1), none of the above companies were found in the list of manufacturing and wholesale dealer licences produced by the MHRA (2021, version 2010, 2014 and 2021), suggesting that the number of unlicensed suppliers is substantial.

All the suppliers cooperate with or purchase goods from partners based in other countries. All their business partners based in mainland China have the China GMP certificate (the certificate of Guangzhou Pharmaceutical Co. had expired and was pending a new application due to a merger issue).[83] The partner of SL, the Ko Da Co., has a GMP certificate from Taiwan (source: Taiwan Ministry of Health and Welfare). The partner of PM called Jiangyin Tianjiang Pharmaceutical Co. Ltd was granted with C-GMP certificate from the US as a complied dietary supplement supplier (source: FDA Dashboard inspection classification database). Supplier CE

[82] Three areas of research with the University of Southampton are introduced on the PM website: 1) PM works with the Centre for Evidence-Based Chinese Medicine at Beijing University of Chinese Medicine, Southampton Clinical Trials Unit (SCTU) at the University of Southampton and Anhui Jiren Pharmaceutical Company to investigate the effects of herbal formulae, and with Shufeng Jiedu for Chronic Obstructive Pulmonary Disease (COPD); this study is funded by Innovate-UK and the Chinese government's Ministry of Science and Technology; 2) PM works with Dr Andrew Flower of the University of Southampton to study Chinese herbal medicine treatment of recurrent urinary tract infections (RUTIS). PM is the distributor of Jiangyin Tianjiang Pharmaceutical Co. Ltd., a TCM manufacturer claiming to have a GMP certificate. However, according to the web information of Tianjiang Co. and the MHRA-GDMP database, this manufacturer does not hold a UK GMP certificate and only has GMP in China and the US (C-GMP dietary supplement); 3) PM works with Prof George Lewith, Dr Michael Moore, Dr Andrew Flower and Dr Lily Lai at the University of Southampton to study herbal medicine for female polycystic ovary syndrome (PCOS) (Lai et al., 2017).

[83] Source: database of China National Medical Products Administration.

cooperates with two pharmacies in the US, but details of such cooperation is unknown. None of these partners were found to have manufacturing and import authorisation, GMP or GDP certificates, and registration of the manufacture, import, and distribution of active substances (source: MHRA-GMDP database; on the legal framework, see the GMP, GDP and the 2012 Regulations in Section 1.3.1). This may suggest that the number of suppliers breaching the requirements of the 2012 Regulations GMP and GDP is substantial.

Information on these representative suppliers reported by NCPs, including the Herb Prime Co. Ltd. (HP), the East West Herbs (EW), the AcuMedic Ltd. (AM), and the Balance Healthcare Ltd. (BL) were obtained through online searching and are summarised in Table 5.10.

Company Names / Conditions	**Herb Prime Co. Ltd. (HP)**	**East West Herbs (EW)**	**AcuMedic Ltd. (AM)**	**Balance Healthcare Ltd. (BL)**
Nature of business	NI	NI	Manufacturer and supply of acupuncture equipment accessories and clinic services	Non-specialised wholesale trade
Basic information	Established in 2006	NI	Operated for more than 40 years	
Relationship with other TCM organisations	Approved supplier of RCHM and ATCM Claimed to support NHS trails (no details found)	NI	NI	Approved by RCHM Partner with the Journal of Chinese Medicine Academic activities held by Simon Y Mills and Kerry Bone
Services	Clinical accessories External skincare Tapes and patches Tea Herbs	Packaged herbal medicinal pills	Acupuncture and other physical therapy tools Herbal granules Skincare	Acupuncture tools FCG Oil Phytotherapy oil

	Pre-recorded educational lectures		Tea Medical books Medical courses	Nutrition TCM books
Partners in other countries	Sole distributor of Sun Ten Pharmaceutical (顺天堂 Taiwan)	Wellness Works Inc. (US)	NI	TCMAGES Pharmaceutical Co. Ltd.
Notes	NA	Purchase is available on Amazon	NA	NA

Table 5.10 Information of representative TCM suppliers as reported by NCPs

Two suppliers (HP and BL) were approved by TCM associations according to approval schemes.[84] The BL company is a partner of the *Journal of Chinese Medicine*.[85]

All the suppliers sell herbal medicine products as ready-made packaged pills and granules, except for the EW company which only sells ready-made pills. Three suppliers (HP, AM and BL) sell products for acupuncture and other physical therapies, such as massage oil, skincare cream and aromatherapy essential oil. These three suppliers (HP, AM and BL) also sell educational products including courses, videos and books.

None of these suppliers were found in the list of manufacturing and wholesaler licences (version 2010, 2014 and 2021. MHRA, 2021. On the legal requirements, see the 2012 Regulations in Section 1.3.1). This may suggest that more attention is needed on the number of unlicensed suppliers.

Three suppliers (HP, EW and BL) mentioned cooperation with partners based in other countries. BL's partner is based in mainland China and has the Chinese GMP certificate (source: database of China National Medical Products Administration). The partner of HP has the GMP certificate of Taiwan (source: Taiwan Ministry of Health and Welfare). The EW company does business online via Amazon using the product information of a US based company, but no accurate information was found about this provider. No partners were found to have manufacturing and import authorisation, GMP or GDP certificates, or registration of

[84] The ATCM approval scheme found on its website specifies the association's requirements regarding personnel, premises and facilities, storage and the dispatch/transportation/return/recall process to suppliers. The RCHM scheme does not mention any detailed requirements.

[85] This is not a peer reviewed journal.

the manufacture, import and distribution of active substances (source: MHRA-GMDP database, legal requirements see contents of GMP, GDP and the 2012 Regulations in Section 1.3.1). This again suggests that the number of suppliers breaching the requirements of the 2012 Regulations GMP and GDP is substantial.

SUP1 was interviewed as a representative of TCM products suppliers. SUP1 is the manager of CE, which was initially built as a product supply office of a large TCM chain company that distributed products to clinics. Later, due to the increasing demand for TCM products in the UK market at the beginning of the twenty first century, this logistics office registered with Companies House as an independent medicine import and wholesale company. Located in Rainham, the CE company occupies a whole building with both offices and warehouses. The location means CE can deliver products to clinics in London quickly, which helped them to make a name in London. Taking the reputation among the London-TCM, CE then developed clients, both Chinese and non-Chinese practitioners or clinics, in other places in the UK and even to other European countries. At the peak of business at this time, SUP1 reported that CE had over 30 mass-purchase clients all over Europe. However, along with the downturn of UK-TCM in recent years, the business shrank as many customers withdrew from the market.

When asking about the products provided by CE, SUP1 guaranteed that his products are of proper quality. For raw herbs, the CE company cooperates with agent partners in China who buy raw herbs from eligible farms (for example, farms using soil with low contaminant levels), conduct quality checks of these raw materials, and package and transport them to the UK. For the concentrated herbal powders, the CE company orders from Shenlu Ltd. in Anhui, China, also reported by SUP1 to have reasonable qualification and manufacturing facilities for TCM products.

However, one part of CE's business, Chinese proprietary medicine, has been severely impacted by regulations. This influence mainly came from the restrictions of the 2004 Directive (this also relates to the 2005 Regulations and the THR scheme, see Section 1.3.1):

Yes, we do feel impact especially after 2011 (the 2004 EU Directive coming into force). We are not allowed to sell the proprietary medicine anymore. Now there are still clinics selling pattern medicine, because actually no official department really inspects and checks this. The proprietary medicine is now a grey area. We import propietary medicine as food or nutrition supplement.

SUP1 is fully awareb of the requirements of GMP and understands that the products used in the UK should comply with the requirements of GMP. However, SUP1 stated that no TCM product fulfils the requirements of the THR scheme for scientific data and reports[86], because the manufacturers are unwilling to spend money and time on research. Although the laws restrict the use of Chinese proprietary medicine in the UK, SUP1 stated that the proprietary medicine business now exists under the counter. SUP1 reported that the real department deciding whether a TCM product can be used in their business and practice is UK Customs. The MHRA has limited connection with Customs (see Section 5.2.1[1]), so how these two departments cooperate with the GMP inspection remains unclear. SUP1 described the importation of proprietary medicine as a 'grey area' in the written law. As SUP1 noted, wholesalers import unlicensed TCM medicinal products for internal or external use in three ways: 1) in very small amounts each time; 2) as food supplements; or, 3) as cosmetics.

SUP1 explained that the wholesalers succeeded in importing the products because 'no one really inspects'; sometimes, they face problems, especially when importing external products, the legal scope of which is quite hard to be define. SUP1 said:

… not sure about this [law]… it depends on luck. If the customs office says it's ok to import, we can import a batch of medicine; if … not ok this time, we have to send back the containers. We imported the wanjin balm (万金油) for years…never met any problems. From the end of 2018, the customs office suddenly decided to recognise the balm as medicine, so we had to stop transporting it to the UK.

5.2.5 TCM business owners

The fifth stakeholder in the UK-TCM industry is the TCM business owners. When the graduates of TCM schools (in China and the UK) start their careers, they need to contact business owners first. Four Chinese TCM business owners were contacted as representatives of the business operators in this research. BO1 is the owner of a chain TCM business located mainly around Chinatown, London. He was inspired to enter this industry by reports of the success of TCM treatment. BO1 started his first TCM clinic in Belfast in 1992 and described the 1990s as the golden time of the UK-TCM. The opening of mainland China and its pursuit of financial

[86] Having checked the *Guidance of Herbal Medicines Granted a THR* (MHRA, 2019), the researcher did not find any registration holders based in China or any product names containing Chinese.

development urged an increasing number of Chinese to go abroad. ‘Where there are Chinese, TCM is needed’, said by BO1. Moreover, since the later regulations restricting the use of proprietary medicines had not yet been issued (see the 2012 Regulations in Section 1.3.1), TCM practitioners had more freedom to use different TCM methods. BO1 seized the opportunity to develop the market for TCM in the UK and moved his business to London, where there are many Chinese immigrants. BO1 said that the reputation of TCM leaped in 1998, that the media kept reporting the miraculous effects of TCM and this attracted a great number of people. BO1 soon expanded his business into a chain by opening branches and merging the existing clinics with a good reputation. BO1’s business became a small monopoly, such that people visiting a TCM clinic in central London are highly likely to step in BO1’s properties.

BO2 is the owner of a chain TCM business spread across England. Having begun his business at a similar time to BO1, he considered that TCM is not only for the benefit of the Chinese but should “also help people from other nations”. BO2 found the attraction of TCM to the UK locals was not limited to its medical effects but also its charm as a manifestation of Chinese culture. His business revolves around serving ‘foreigners [the UK people]’. BO2 had chain shops in Kensington Olympia and Wembley, where various ethnic groups intermingled at first and gradually migrated to other cities in England.

Both BO1 and 2 experienced the peak of their chain business before 2006, and they estimated that the number of TCM clinics in the UK at that time was much more than in any other European country. However, the turning point of the UK-TCM came suddenly when many owners were still immersed in plans of sharing the wealth of a large TCM business. As mentioned in Section 4.1, the synergy of new regulations, a damaged reputation caused by industry chaos blind expansion of business, unregulated practitioner registration and medical accidents, and the global financial crisis seriously affected the UK-TCM business. BO1 attempted to cope with this situation by adding massage to his clinic services, but this somehow made his TCM clinic lose advantage and competitiveness. BO1 said massage is much easier to learn compared with other TCM knowledge and skills such as herbal medicine, which has a complex knowledge system.

BO2 chose another way to develop his business. BO2 has noticed that the most severe quality concern with TCM products is that several formulas co-exist claiming to have the same effects. Patients are usually prescribed different prescriptions when they visit different TCM practitioners, even for the same disease. BO2 considered this to be normal in China and due to

the experience of practitioners influencing their decisions on which herbs to use. However, for non-Chinese people, BO2 described TCM as 'a mysterious thing like fortune telling', in that many different ingredients are mixed, making both the quality and efficacy of treatment uncertain. BO2 had been focusing on this problem and aimed to solve the quality concern; he explained that the number of patients suffering from rare and severe diseases is small and the dialectic[87] way in TCM of treating patients individually is less necessary for mild symptoms. People with similar symptoms can just use the 'same medicine (i.e., medicine with the same ingredients)', and the quality control of medicines with the same ingredients is much easier than a specific prescription for an individual.

BO2 then became a manufacturer himself, and his company reviewed, synthesised and adjusted 37 varieties of classic TCM formulae to standardise ready-made medicines with fixed ingredients. The 37 medicines can be used to treat 50 different minor ailment, such as coughs, colds, or irregular periods. The practitioners hired by BO2 diagnosed symptoms from unified criteria and then recommended one formula. BO2 considered that the unified ingredients and dosages reduced the requirement for knowledge and skills in the person preparing the formula. Thus, it would be much easier for BO2 to recruit eligible manufacturing personnel, even in a foreign country. There was also the possibility of moving the production line to the UK in the future (at the time of the research it was in Taiwan).

In addition, BO2 said that, if many people take the same medicine, a possible adverse effect can soon be identified. However, this concept can be doubted as the adverse effects of a drug may become obvious immediately, even if the data can be collected from many people using the drug. For example, thalidomide affected 1,000 embryos for four years after it came on the market as an OTC medicine (Miller, 1991). Also, the differences in and severity of the side effects of a drug are more likely to be decided by its treatment dose and duration rather than just the type of medicine (Ghobrial & Rajkumar, 2003; Zhang, et al, 2013). Besides the unified ingredients for product manufacturing, the whole distribution process of BO2's medicines had been standardised. BO2 reported that he tightly controlled the hygiene conditions for transport and storage of products in standardised environments. By this means, BO2 was confident that he could avoid any pollution and deterioration during transportation and storage caused by inappropriate operations. BO2 believed that his quality-controlled medicines would soon occupy the market, owing to their superior advantages.

[87] Bianzheng (辨证) in Chinese, which means that TCM doctors can differentiate and classiy diseasses according to patients' syndrome (Huang, et al., 2022).

Lastly, BO2 stated that no one can guarantee that different prescriptions have the same effects, and some may even cause side effects as there is no united standard for measuring the medical outcomes. Patients thus may worry about which prescription to trust.

However, not all the TCM business were able to develop new services or production line. Facing such hardship, many other large TCM businesses bailed out of the industry. The TCM practitioners started to be self-employed by operating smaller businesses, and small independent TCM clinics emerged. There is no information on the number of TCM practitioners who are self-employed, and it is unclear what the advantages are of having this status. Practitioners normally become self-employed for their own reasons, such as earning more than a fixed salary or having more freedom of practice, as introduced below.

CPs 12–13 were interviewed as Chinese representatives of small TCM businesses. CP12 used to work for a chain TCM company named Herbal Medic till 2005, and then she started her own business with two other TCM practitioners. Her small West London clinic is close to the crowded shopping mall. This location guaranteed a considerable number of visitors. Also, unnecessary expenditure is avoided because of the simpler business structure compared to large companies. CP12 reported an even higher income than when she was still employed by Herbal Medic. However, not every TCM practitioner can afford the high rent of a place near a shopping centre or on a high street and these practitioners moved their business to more remote places. CP13 was also employed by Herbal Medic, but after some time he moved to Doncaster because of the high living costs in London. Although he tried to operate a clinic in a shopping mall of Doncaster, the number of customers was not optimal in such a small city. Now, CP13 has reconstructed the ground floor of his home into a clinic, and he has accumulated a considerable number of regular patients who admire his good TCM skills and reputation. Both CP12 and 13 reported that they felt much more freedom compared to working for large companies. They emphasised their identities as TCM practitioners rather than businessmen, and thus they could pay more attention to patients and their diseases rather than profit and recommending improper treatment (such as unreasonably long treatment courses).[88]

Except for NCPs 2 and 6, the other eight of the ten NCPs own their businesses. The freedom of practice type and time were the main reason that the eight NCPs chose to be self-employed.

[88] Studies such as Fatima and Nayeem (2016) and Phua, Zosel and Heard (2009) state that the toxicity of herbal medicine may appear at some dosage or in overdose.

Although customer numbers may be a problem, the NCPs resolved to promote their businesses via online social media, gain recommendations from regular customers, or cooperate with larger organisations. NCP1 reported working with some gyms or yoga studios when their members suffered accidental sprains. NCP3 had a contract for her clinic with Nuffield Health as a part of the healthcare services of a university in London to treat injuries incurred during sports. NCP8 cooperated with drug treatment services to supply acupuncture treatment for drug or alcohol addiction.

Concerning the current regulations, BOs all reported being inspected by district councils. The BOs opened clinics and shops in premises with eligible hygiene and fire safety as required by local/district regulations. The BOs also stated that if they took any inappropriate actions, i.e., caused medical accidents or sold restricted products, the council would call the police and take sanctions, but they did not express negative attitude towards the actions of district councils.

The first obstacle reported by BOs is caused by TCM products registration. All four BOs reported that they had to reduce the variety of their products to obey the law as they mainly used products imported from China. The restrictions on proprietary medicines have thus impacted TCM business, because as BO1 explained, non-Chinese customers are used to taking pills or capsules, and they thus naturally resist individually prescribed herbal medicine even in powder form. However, during the fieldwork, some Chinese proprietary medicines and external medical products were seen in the clinic (see Section 4.1). BO1 stated that no TCM product fulfils the requirements of the THR scheme for scientific data and reports, because the manufacturers are unwilling to spend money and time on research.

Tight regulations may also force some stakeholders to take advantage of loopholes. Since the 2004 Directive prohibited the use of unlicensed Chinese proprietary medicines in the UK, the TCM business has sought another way to obtain these products as there are profits to earn. BO1 bought TCM products imported as food supplements and tore off the product labels indicating medical functions to avoid ‘trouble’ (from patients’ enquiries or regulator inspections). When asked if such actions could cause harm to public safety, BO1 emphasised the regulations on food were more rigorous than medicines:

There are extremely rigorous checks on heavy metal residues on foods imported to the UK. However, soil for herb planting in China is normally not restricted, and thus heavy metal

residues and pesticides are commonly found in herbs imported from China. The amount of heavy metal residue is even higher when […] made into concentrated powder form, so we have to select the suppliers of herbs and related products in China very carefully.

Nevertheless, to wrongly declare medicines for importation releases medicine far away from the legal requirements on the market and may have unexpected consequences.

The second concern of regulation reported by BOs relates to products importation. BOs 1–2 agreed with SUP1 that the UK Customs actually controls whether a TCM product could entre the UK market. Under the impact imporation control from the Customs, BO1 experienced a similar situation as he could not always access the products he had ordered. Sometimes his supplier had to return the products to China because of 'bad luck' in that the customs office had suddenly decided a TCM was medicine and forbad its importation.

The third obstacle for BO1's product supply came from the decision makers' unfamiliarity and misunderstanding of TCM knowledge. He mentioned the restriction on mutong as an example (see Table 4.3), as all species of mutong (木通) were on the banned and restricted herbal list of the MHRA. Nevertheless, mutong has a sub-species called guan mutong (关木通) which is an aristolochic acid with adverse effects, but the sub-species used by TCM practitioners is chuan mutong (川木通) (see Qiao, 2006), which does not contain aristolochic acid. BO1 complained that the restriction list of the MHRA does not understand the slight difference between sub-species of Chinese herbs, and BO1 thought that the list had unreasonably banned some herbs from UK-TCM prescription.

Fourthly, concerns over the quality of products exist. BO1 complained about the difficulty of controlling production in China. Because of the long distance, it was hard for BO1 to know the real production procedure of the manufacturers by making a visit to the factories or storehouses. BO1 had experience of a manufacturer secretly adding chemical substances to products claimed to be 'pure herbal medicine' to enhance the medical effects. The manufacturer did not inform BO1 about the added ingredients, but people buying these products reported that BO1's business was selling unauthorised drugs, resulting in his company receiving a penalty.[89] Also, when purchasing some expensive herbs, such as ginseng and 165anoderma, BO1 had been cheated by shoddy or even fake products. BO1 told the truth that very few TCM products meet

[89] BO1 did not state details of the sanctions imposed on him, but selling unlicensed proprietary medicines breaches regulations such as the 2012 Regulations, leading to fines such as sanctions (see Section 4.2.4).

UK-GMP requirements because raw herbs are grown and manufactured in China. The manufacturers mainly supply products to the Chinese market, and do not spend money on reforming the production line according to UK regulations.

BOs 1 and 2 had a similar view that several factors which are currently negative for TCM may be reconsidered as the UK government may need to 'make some changes'. They felt that the emigration of EU citizens could provide more working opportunities for people from other countries, and thus the restrictions on working visas may be eased. Also, the two BOs thought that leaving the EU could indicate the abandoning of some EU-UK mutual regulations, with the possibility that TCM business owners could establish businesses in proprietary medicines. During Brexit, they had already tried to achieve this by meeting different political party leaders and writing letters to the national authorities like the prime minister.

In the future, BO2 believed the efficacy of TCM would be proven in time and by successful cases rather than simply data from lab experiments. As time passes, more TCM products will fulfil the 'long tradition of use' criterion in the 2004 Directive, and these products will be licensed for use in the UK market. 'The promised future of TCM in the UK is bright and hopeful', and BO2 also believed that more and more non-Chinese patients would be willing to try TCM that is as convenient as mainstream medicine but with fewer side effects. And BO1 hoped that the future of TCM practice would focus more on disease prevention to improve quality of life, in addition to curing illness. This trend would focus more on the needs of UK people who prefer a healthy lifestyle, and this would promise TCM new opportunity to develop in the UK.

5.2.6 Health professionals

The sixth stakeholder is health professionals whose knowledge and concepts were used to supplement the ideas of previous stakeholders and to complete the map of the UK-TCM industry. The first health profession, Prof BM, has a master's degree in TCM in China, and has been a visiting scholar in Cambridge University. Prof BM has rich knowledge and experience in TCM. He has written books reviewing the history of TCM, has established TCM research institute and has taken the role as chairman of TCM association. Prof BM is the member of the Herbal Medicines and Practtioners Working Group led by D Walker (see Section 1.3.1).

Prof BM has contributed the popularity of TCM in the UK to its suprising effects. One very

famous successful case of early TCM treatment in the UK was Dr Luo's treatment of a child with eczema. She claimed her medicines had no hormonal component (a steroid) to cause an adverse effect, such as a steroid addiction.[90] This case, as noted by Prof BM, was reported in the *Independent* newspaper (Coverley, 1994), greatly promoting the reputation of TCM in the UK. Against such a background, a chain business appeared and the total number of TCM clinics increased rapidly to '*2,000 or even more*'. These were first located in Chinatowns, but then started to occupy high streets and shopping malls. The figure of 2,000 was reported by interviewee Prof BM, but other sources speak of 3,000 clinics, as referred to in Section 1.2.2. More and more TCM practitioners were invited by TCM business owners from China to fill career vacancies and meet market demand.

As for the voluntary regulations, Prof BM stated that the current voluntary regulation of TCM is fragmented as it is conducted by various independent associations:

Currently, every department of the UK-TCM is fragmented and independent (has own standards). For example, the ATCM now reduces the frequency of holding academic activities, which means they paid less attention to the development of professional knowledge and skills. Meanwhile, some influencial people who can lead the establishment of unified standards don't want to be involved in any association. … this is the habit of Chinese that we seldom cooperate with others, and everyone wants to be the leader ….This is not good for the industry. We need to be familiar and united with each other

On the one hand, Prof BM was worried that every organisation has its own focus of work, and it is difficult to get all the organisations to participate in the acceleration of statutory regulation as some only concentrate on academic activities rather than political affairs. On the other hand, some important people, like health professionals and large wholesalers, do not wish to be involved in any organisation. Prof BM attributed this to the habit of Chinese people, as 'everyone wants to be the leader rather than cooperate with others'. And concerning the official regulations, Prof BM reported that there are no Chinese proprietary medicines with a 30-year utilisation history in the EU. However, Prof BM also reported that no official actions were taken to solve this predicament of TCM. As such, Prof BM thought the policy makers from both the MHRA and the NHS do not really understand TCM.

[90] This is a direct translation from interview data. The interviewees mean topical corticosteroid addiction as a side effect of applying steroid to the skin (Ghosh et al., 2014).

Mr MM works as a herbalist and acupuncturist for over 30 years. He has rich knowledge and experience in herbal medicine, and he has launched the first UK school of Chinese herbal medicine. Mr MM is the former president of a herbal medicine institute and current chair of a TCM association. Mr MM is also the member of the Herbal Medicines and Practtioners Working Group led by D Walker (see Section 1.3.1).

Mr MM said that currently the TCM industry is far from being effectively regulated. During his 30 years' experience working for on CAM-related issues, he said the greatest obstacles to statutory regulation have come from mainstream medicine, as the mainstream medicine industry remains opposed to TCM and most other CAM because of the lack of scientific evidence:

Because doctors are the bosses, . . . They don't believe TCM is scientific. I mean the problem is, nowadays, everything has to be proved with the trail (RCT). So evidence-base is the most important thing, ... The evidence of TCM is insufficient... it is impossible to prove the efficacy of the treatment. The theory of Chinese medicine is not understood by Western medical professionals... If TCM is statutorily regulated, it means we (TCM practitioners) are also recognised by law and can be regarded doctors. They (the Western doctors) don't want this to happen.

Moreover, there are not enough scientists or funding to support research in this area. At the same time, medical accidents happen because the sources, quality, standardised practice and quality of practitioners are not strictly controlled (see Yang et al., 2018). To address these concerns, local UK governments need policies like that on GMP in China. In short, Mr MM thought there are too many issues waiting to be addressed for now under voluntary regulation, and so it is impossible to place TCM under statutory regulation at the moment.

5.3 Short summary of this chapter

This chapter contains interview data with TCM practitioners and industry stakeholders. The TCM practitioners were divided into groups of CP and NCP for comparison. The 15 CPs interviewed in the research all practised for over 30 years; they all had degree from formal higher educational institutions; most of them registered with ATCM or FTCMP. Some of the CPs considered that the current voluntary regulation works effectively, so that they have freedom to practise as they wish. At the same time, they can access the training and academic

communication activities held by their registration association. However, some of them still call for statutory regulation, because they think statutory regulation can protect their title as doctor and make TCM more recognised by the UK mainstream health system. The practice length of NCPs vary from 5 to 35 years, their eductioanl backgrounds are different as well. Some NCPs were educated through short programmes. Most NCPs registered with ATCM or BAcC. Many NCPs have no special feeling towards current regulations, but some NCPs considered that introducing further regulations to set standards could bring more fair among different TCM associations.

Six other industry stakeholders were interviewed, their stories, expeiences and views towards the current TCM industry and regulation were reported. These stakeholders were found to be inter-related. The two regulators, the MHRA and local authorities, mainly impact the TCM associations and TCM business. The TCM associations often cooperate with TCM educational organisations whose graduates could directly register as members; the TCM associations also cooperate with suppliers to recommend products supply to TCM business and practitioners. Two health professionals were interviewed as well to provid their understanding to the current industry. They expressed that the scale of UK-TCM is shrinking, an the current regulations are fragment.

PART IV: Analysis of Results

This part of the thesis analyses data in results part (Part III), and which is distributed into two chapters. Chapter 6 explains the transformation and adaptation of TCM in the UK first using Gidden's modernity and globalisation concept; Chapter 6 then uses ANT to understand the establishment process of the UK-TCM industry and its regulatory system. Chapter 7 evaluates the performance of the regulations of the UK-TCM thorugh respeonsive regulation theory and a evaluation framework design and explained in Section 2.2.3. After data analysis, Part IV will be able to answer the research questions of the current practice of the UK-TCM, its relevant regulations and the performance of these regulations.

Chapter 6. The Transformation and Adaptation of TCM in the UK

As shown in the previous Chapter 4 and 5, information collected from various sources has roughly answered the research questions on the form of UK-TCM, relevant TCM regulations, and the impact of these regulations. This chapter aims to provide an understanding of the broad concept of UK-TCM, as follows: Section 6.1 draws a map of the current TCM industry to understand its structure and operation; Section 6.2 contains Gidden's view of modernity concerning the definition of UK-TCM; Section 6.3 looks at TCM to open the black box and understand the formation and operation of the UK-TCM industry; and, Section 6.3.2 (2) focuses on the organisation of the UK-TCM regulatory system. From an understanding of these three aspects, an explanation is formed of: 1) the transformation of TCM from an ancient Chinese medicine to the current UK pattern; 2) the reasons and process of how TCM found a foothold in the UK; and, 3) the current operation of the broad concept of TCM under the impacts of the regulations. In so doing, the first part of the research aim is achieved concerning how TCM adapted to the UK social and regulatory contexts.

In this chapter, the researcher extracts and analyses: the changes in practitioner management, method of practice, and use of products; the reasons that caused such changes; and, the synergy, cooperation and competition of various stakeholders involved in the UK-TCM industry. These issues are analysed through the theoretical prisms of modernisation and globalisation as well as ANT (see Chapter 2).

6.1 The structure of the UK-TCM industry in a networked form

With the interpretation of the data produced by the literature review, ethnographic observation, interviews and questionnaires, the stakeholders in the UK-TCM world have been identified and a map of the current UK-TCM industry developed. The UK-TCM industry experienced prosperity in the first decade of the twenty first century, but soon faced a downturn caused by publicity around harmful treatments, tightened regulations, and the financial crisis. In the last ten years, UK-TCM has stabilised through the interaction of regulators, registration associations, educators, suppliers, business owners, practitioners, and TCM users (or patients).

The stakeholders of the UK-TCM industry were introduced in this chapter from the top down. At the top, the regulators seem to have had the strongest impact on the UK-TCM world. With the domestic and social changes in the UK, some of the regulators identified in the literature re-

organised, took on new names, and re-worked their missions, while others left the UK regulatory system. The two regulators found to influence the UK-TCM most are the MHRA and the local authorities, with other stakeholders having been impacted by these regulators to varying degrees. The MHRA and the local authorities are thus actants at the top of the TCM world. The MHRA directly impacts: 1) TCM associations, by consulting on regulations such as the use of restricted products, influencing how the associations set standards and codes of conduct for their members; 2) TCM product suppliers regarding imports and wholesale in the UK, and sometimes by liaising with Customs and Excise; and, 3) TCM business owners, concerning which products are permitted. Indirectly, the MHRA not only influences educators, for example by cutting some teaching content according to changing regulations, but also practitioners by reducing the type of medicines they can prescribe. Also, the MHRA operates the YCS through which TCM users can report suspicious products they have received when undergoing TCM treatment.

Regarding the direct impact of the local authorities, they check, approve and inspect the qualifications of TCM associations as a listed exemption body for practitioner licence renewal; they also cooperate with police and fire authorities to check the qualifications of employees and the eligibility of business premises, which impacts the business owners. Indirectly, whether the qualifications of TCM associations are approved may influence the registration of practitioners and the partnership between educators and associations, as the graduates of some educators are automatically registered with specific associations.

Other links in the network between actants became apparent. First, the associations directly connect with TCM product suppliers, educators and some business owners via partnerships and also manage the qualification of practitioners; the latter should, therefore, relate to patient selection of whom to consult and have treatment with. Second, the suppliers import and wholesale products from China to large and small private TCM businesses, and the quality of the products they supply may impact the safety and efficacy of TCM treatments. Third, the educators train TCM practitioners, and the quality of their courses is the key to whether their graduates can fulfil the entry standards of some associations. More importantly, the education outcomes decide the safety, quality and efficacy of the diagnoses and treatments provided by these graduates. Fourth, the large chain businesses employ practitioners and their business mode may influence the practice of practitioners, leading to potential risks for patients (such as unnecessarily long treatment, see Section 4.2 and Section 5.1.2 [1]). Some employed practitioners disagreed with the business mode and this, alongside social changes, led to some

turning self-employed; somehow, this changed the pattern of the UK-TCM world. Finally, the patients or TCM users seem to be at the bottom of the TCM world, as actions by other stakeholders potentially influence their health and safety. However, they are able to obtain information from various sources, such as through ethnic customs, family influence, and friend recommendations, and they can re-spread their experiences and feeling after using TCM to the other people. This is a bi-directional relation. Also, once suspicious products are found, they can report problems to the MHRA and can report other illegal or problematic practices to the local authorities. Thus, all these actants within the UK-TCM world are interrelated, as presented in Figure 6.1.

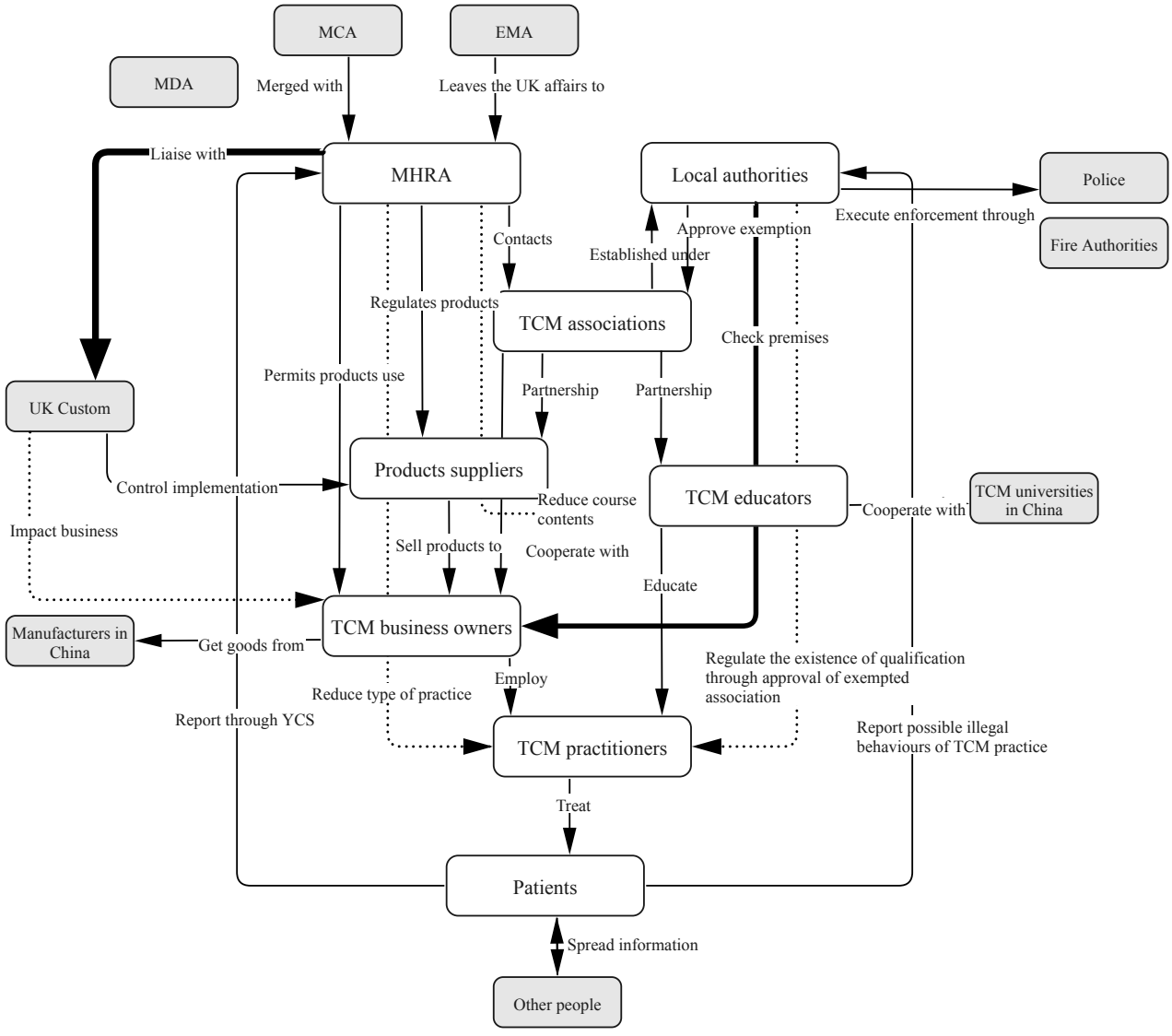


Figure 6.1 Network of the UK-TCM industry

UK-TCM world stakeholder — Other actants beyond the UK-TCM world

Direct relationship — Indirect relationship

Figure 6.1 reveals new findings that are beneficial for the deeper study of this research. First, there are stakeholders (white squares) within the UK-TCM world; other actants (grey squares) connect with the stakeholders and may impact the operation of the TCM world. For example, manufacturers in China decide the quality of products imported by the suppliers to the UK. Second, the stakeholders in Figure 6.1 form a network. The solid arrows indicate that actions by each stakeholder are multi-directional; that is, these stakeholders within the UK-TCM world are both interrelated and interactional. Third, of all the stakeholders, two are found to be of central importance. One is the MHRA, which directly or indirectly influences most of the other stakeholders; the other is the TCM associations which have connections and interactions, both upwards to the regulators and downwards to other stakeholders. As noted in Chapter 4, the MHRA controls UK-TCM product-related issues. From the role and work of the TCM associations as introduced in this chapter, we can see how it links different parts of the UK-TCM world and appears to be important for the voluntary regulation of UK-TCM. However, what needs to be analysed in more depth is how these two stakeholders are involved in UK-TCM and its regulation, and the impact of this. This will be the focus of the next chapter.

6.2 Transformation of the UK-TCM

The transformation of the UK-TCM seen in this research has gone through the stages of modernisatin, gobalisation and a new round of modernation. These stages of transformation can be understood through Gidden's view (1990 & 1991). Based on Giddens' view (1990 & 1991), a diagram of the transformation of TCM in the UK is drawn (see Figure 6.2) and is explained in the following sections.

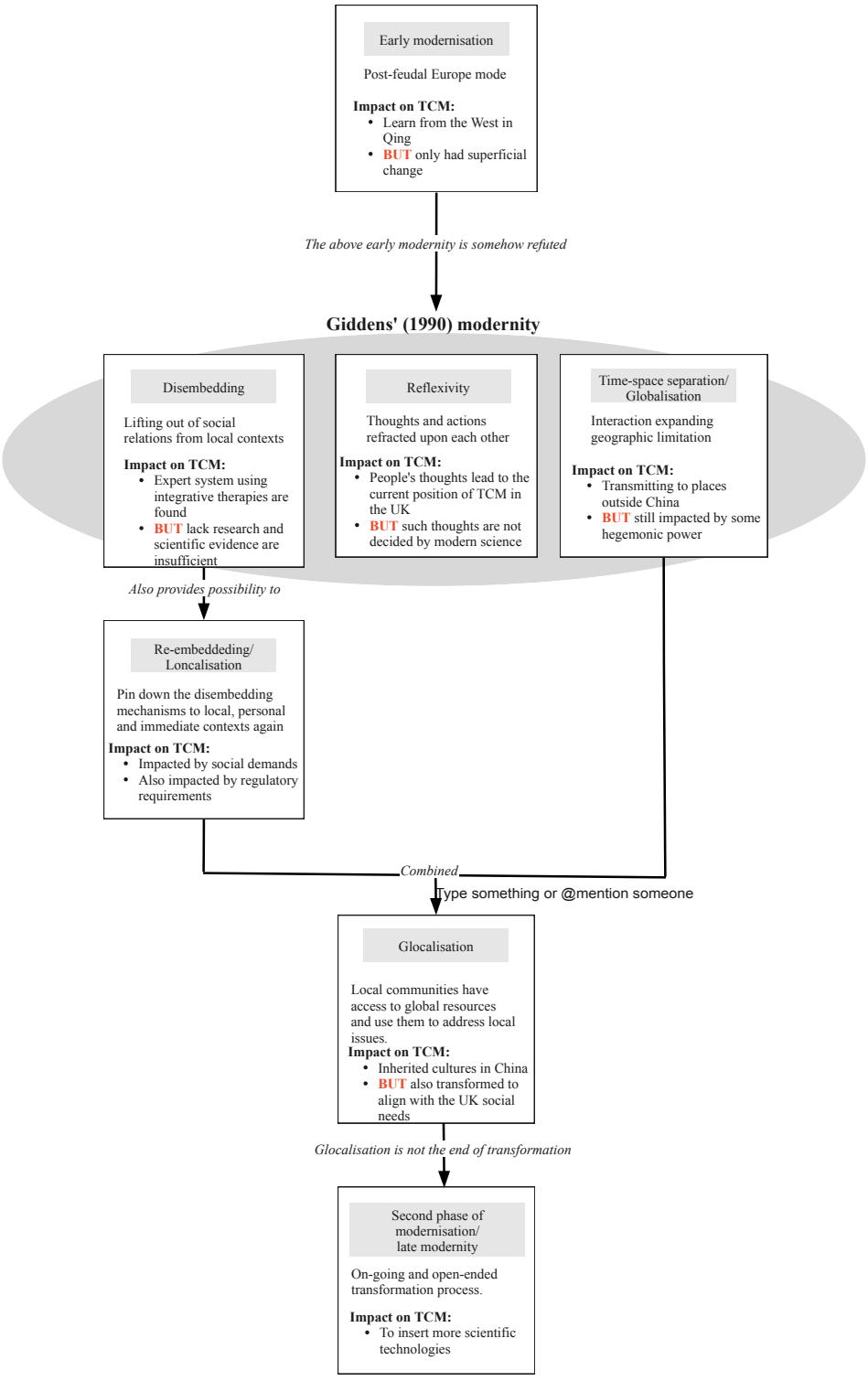


Figure 6.2 Giddens' modernity and the transformation of TCM in the UK

6.2.1 Early modernisation of TCM

Giddens (1990: 14–15) referred to ‘the intuitions and modes of behaviour established first of all in post-feudal Europe’ as modernity, and such institutions and modes contained various dimensions such as industrialism, surveillance, and information control, as well as the development of capitalism. Over many years, the West became dominant, and its ideologies, science and technologies, socio-political system and cultures spread and became a model for social development.

The early modernisation era had an obvious impact on TCM. As mentioned in Section 1.2.1, China started to ‘learn from the West’ as early as in the Qing dynasty (Tian & Wang, 2007), and it was then that Western factors were added to TCM. Following this wave, CM and later TCM were continuously integrated into the modern or ‘Western’ health system mode, despite, as Giddens (1990) stated, the ‘post-feudal Europe’ mode gradually becoming ‘world-historical’ in its impact. The implementation of ‘Western’ medical knowledge and technology was seen in TCM and led to early modernisation (National Administration for TCM, 2017; see Figure 7.1.1a). The literature reports that biomedicine knowledge and technologies were inserted into TCM in China, such as using molecular biology to analyse the active ingredients of herbal medicines (Jiang et al., 2018) and checking the residual rate of pesticides and heavy metals (Xu et al., 2013).

The impact of modernisation on TCM has also been identified in this research. One example was reported by BO1, who noted that safety procedures, such as pesticide and heavy metal testing, are used in the products he imports. Moreover, most practitioners in this research were representative of the modernised TCM. All the CPs were the new generation of TCM practitioners who had been taught both biomedical and TCM knowledge at university. All the CPs reported experience of working in public hospitals, and some especially mentioned their utilisation of integrated diagnostic technologies and treatment. When they emigrated to the UK, they retained their knowledge and working habits. This was also seen in the observed clinic, which is a modernised TCM practice with mainstream medical investigational approaches such as those used in hospitals in China. The use of mainstream medical technologies in diagnosis was not directly mentioned by NCPs, but they mentioned contact with GPs as being supplementary to their practice. NCPs also reported using proprietary herbal medicines before the 2004 Directive came into force in 2011 (see Section 5.1.2 [2]). The development of this modernised medical system confirms the view that TCM has never been immutable or stereotypical. Although TCM has ‘ancient (Gulao, 古老)’ factors, it is not ‘necessarily old and backward (Jiu, 旧)’ (Scheid, 2002).

Hsu (2009: 112) used the term ‘alternative modernity’ to describe the above form of TCM practice. The blind pursuit of integrated medicine was considered an imitation of the ‘Western’ mode and led only to superficial changes to TCM. To find the extent to which TCM has in fact been modernised, Giddens’ three characteristics of modernity, including disembedding, reflexivity and time-space separation, are referred to.

First, Giddens (1990: 21) considered disembedding as a process of modernity, which is the ‘lifting out’ of social relations from local contexts. One important type of disembedding mechanism is the ‘expert system’ (Giddens, 1990: 27–28), through which the material and social environment is organised by technical accomplishments or professionals instead of by traditions or the rule of the thumb. Although progress has been made in China with integrating TCM into the modern health system, some integrative approaches to TCM seem to be difficult to conduct in the UK. While the diagnosis and treatment of the CPs involved mainstream medical technologies (also see Section 4.1, this may be a habit inherited from their educational and work experiences in large public hospitals in China mentioned Setion 1.2.1). Seldom did the CPs in this research mention evidence or lab research as a foundation to support their practice. The basis of TCM in China is described as ancient wisdom and rich experience, and ways to improve it are through more experience obtained from practice on patients and communication with peers.

When practising in the UK, the CPs explained that their treatment was based on Chinese ideologies rather than mainstream UK medical knowledge (see Section 4.1 that CP10 explained the integration of acupuncture with IVF). The examples indicate that, even though TCM has experienced a modernisation process, such modernisation is deeply entangled with Chinese identity, culture and habits. Moreover, the CPs reported that isolation from scientific research and professional education, as well as a negative attitude from the NHS and limited cooperation with mainstream medical technologies, has prevented UK-TCM from moving closer to scientific development. For example, patients having TCM treatment cannot have an immediate blood transfusion (see Section 5.1.4), but no experts from the mainstream system have ever presented evidence to explain this. An expert UK-TCM system has been established, but it is not comprehensive and mature under the impact of Chinese traditions, cultural factors, and the attitude of the mainstream health system.

Second, reflexivity is an aspect of modernity (Giddens, 1990) which happens at both

institutional and personal levels to create and change modern systems and social organisation. Giddens (1990) described reflexivity as the basis of system reproduction in that thoughts and actions refract upon each other. Giddens denied the importance of precedent but emphasised that old things can only receive their identity from the reflexivity of the modern; that is, they prove their correctness in the light of incoming knowledge.

The current TCM thus does not completely fit Giddens' concept of modern reflexivity. On one hand, TCM users have their own thoughts about which healthcare services to use and they are aware of the possible effects of TCM as alternative and supplementary approach to mainstream medicine. On the other, the identities, cultures and habits of TCM users and practitioners caused the utilisation or even popularity of TCM in the UK, and these cultures and habits existed in the past; as such, they are not reasonable modern knowledge which explains the use of TCM. Section 1.2.1 mentioned that successive Chinese governments have modified TCM according to their needs and used TCM as a political tool. Despite years having passed since the early establishment of the PRC, Chinese, seen as the largest patient group in this research, still adopt TCM as their healthcare option (see the description of the large number of Chinese visiting the TCM clinic in Section 5.2.7), because it is part of their culture, regardless of whether it is equipped with advanced medical technologies.

Current UK-TCM has failed to reach a high level of modern reflexivity, but the attempt at modernisation has provided TCM with new possibilities for being involved and promoted in international society. When it spread outside China, alongside China's appearance on the international stage, the third and most defining feature of Giddens' modernity concept is seen—time-space separation. Giddens (1990) stated that the concept of time is unified and standardised in modern society, such as with time zones, thus facilitating interaction from different places. As such, local boundaries have expanded, as illustrated by the discussion of globalisation in the next section.

6.2.2 Globalisation and new round of modernisation of TCM

The modernisation of TCM, as stated in Section 7.1.1, set the baseline for UK-TCM in the era of globalisation. The first appearance of UK-TCM was as a hybrid Chinese medical system utilising ancient theories and therapies, and which was passively involved with biomedical knowledge and technologies. This medical system stepped onto the international market with the wave of immigration and cultural material exchange caused by the globalisation of the

economy. Although the earliest emergence of TCM in the UK cannot now be traced, its rapid development is detectable in certain studies (such as Tran, 2009 and Ye, 2016) and from the statements of the BO participants. The number of clinics and practitioners of TCM in the UK experienced a sharp increase at the end of the 1990s.

During its transmission to the UK, TCM has been impacted by various factors. First, studies such as Mikander (2016) and Mohamoud (2021) stated how marginalised places can transmit their culture through globalisation, but during the transmission process, some cultural traits still occupy a leading role despite the multi-directional process of globalisation. This process includes factors such as the superior position of the English language over other languages due to the power of countries such as the US and their cultures. Mikander (2016) and Mohamoud (2021) thus considered globalisation to be a substantial new form of colonialism, or at least that globalisation overlaps with colonialism. The hard military and economic power of some countries allows their hegemony to forcibly use culture as a soft power tool to intervene in weaker countries. For example, it has been seen in this research that some TCM glossaries were translated into English and used by the CPs to explain their diagnoses and treatment (see Section 5.2.6). There is no nationally standardised translation of TCM products, ingredients or other knowledge in China, and the English translations can only be found in non-governmental sectors [such as the observed clinic in Section 5.2.6 (2) and reportedly in the UK TCM education, seen in Section 6.2.2]. The use of English in TCM can be considered a spontaneous absorption of the leading culture, as TCM attempted to step onto the international stage. Such translation activity may only make 'changes of rhetoric (Hsu, 2009)' and the translation may be inaccurate (see Table 4.3, in which a single common name may refer to several species), affecting the identification of the right herbal products (Li, Duke & Roufogalis, 2003).

The second impacting factor is the existence of localities during globalisation, which in this research is called the localisation process. Although Giddens' core concept (1990) on modernisation lies in the disembeddedness from local relations, he stressed that it provides new opportunities for the reinsertion of previously removed social relations. Also, Gidden stated that we all exist in a 'world of strangers' and issues like facework commitment may lead to re-embeddedness, pinning down the disembedding mechanisms to local, personal and immediate, albeit temporary, contexts again (1990: 42). After entering UK society, TCM has continuously re-established itself to align with the changing local situation.

Schuerkens (2003) stated local societies have autonomy to choose the parts and the extent to

which they accept external elements. One local demand on TCM is to supplement mainstream medicine. A concrete approach for TCM to supplement Western mainstream medicine is by becoming a commodity. Friedman (1990, 1994) stated that consumption as an expression of self-definition is always local, especially when globalisation it is now multi-polar, instead of the old homogenous world pattern. The consumption mode of the UK customers in this research exactly reflected their expectation of TCM as CAM. For the practitioners, one obvious change reported by the CPs was concerned with their different position from China to the UK. TCM is part of the national health system in China, and all the CPs reported having worked in public hospitals, but having moved to the UK they found themselves in the private, complementary and alternative health sectors.

For its practice, TCM also performs an alternative role to supplement mainstream medicine. The fieldwork data showed that TCM is practised in small clinics providing various healthcare services at the patients' own expense. People do not need to go through the NHS for treatment. Most questionnaire responses showed that the non-Chinese respondents based in the UK (as mentioned in the methods chapter, these were the main respondents of the questionnaire) used TCM to maintain or improve health. A high percentage of the UK clients used massage, which is not considered a direct treatment approach, and those using TCM were normally looking to cure diseases with chronic symptoms rather than for urgent or severe situations; most used TCM to supplement mainstream medicine. The demand for complementary and alternative healthcare was also seen among Chinese patients, based on observational data, as they also used TCM to fill gaps not covered by UK mainstream medicine, although sometimes this use was driven by Chinese cultural reasons. People in the UK only accepted the parts of TCM that could not be provided in mainstream medicine. Some parts of TCM go against these patients' social needs and expectations of CAM, and so traditions such as *deqi* were considered unnecessary and thus abandoned.

Besides the social demands, regulatory factors in the UK further reinforced the role of TCM as CAM. In Chapter 5, it was seen that the UK regulatory system uses biomedical standards which require that CAM therapies are scientifically safe, qualified and effective. Therapies which do not reach these standards are not permitted into the UK mainstream health system. TCM was classified as group 3a by the 2000 Report, which indicates that TCM is far from being an officially recognised medical system and as such it was excluded from statutory regulation. Although the 2000 Report and the later 2001 Response did not require TCM to be voluntarily regulated, the TCM industry followed the precedents of the other CAM therapies in

spontaneously establishing voluntary self-registration. The UK-TCM industry set up registration associations to issue certification to practitioners. These indicate who can provide healthcare services, in the same way as other CAM therapists who may be more familiar in the UK. With the development of TCM and other CAM therapies, more regulations were established to manage CAM to protect the public from the potential harm of unscientific medicine; some of these regulations related to TCM and these have further shaped the UK-TCM. They also set and controlled the title and qualification of practitioners, market entry, TCM production processes, inspections, and the fulfilment of safety-related requirements on premises.

To combine the concept of globalisation and localisation, the term 'glocalisation' has been used to describe the synthesis of the form of TCM after it was lifted from its local context in China. This form transcends geographic restrictions to reach an international society and has been re-pinned in the UK environment, among other places. Mendis (2007) suggested that an ideal working mode for glocalisation is where local communities have access to global resources and use them to address local issues. Glocalisation is the consequence of globalisation as shaped or penetrated by local elements. Glocalisation indicates the equal weight and importance of global and local factors in a social transformation. In this research, it has been seen that the transformation process of modernisation and globalisation has made TCM in the UK into a unique entity. TCM was taken to the international market from China to spread its culture and values to the other places; then, when it entered a specific society, TCM was shaped by multiple local factors. TCM does carry at its core the culture of China regarding its theories, glossaries, and logic on diseases; these guide its special therapies that were partially reformed by medicines from Western countries.

The hybrid TCM with a Chinese cultural core and Western elements as outer decoration entered the international stage, and from here it learned from and absorbed more non-Chinese cultures.[91] Chinese are no longer the only practitioners as more non-Chinese are practising TCM and have even developed their own schools. For products, Chinese practitioners still insist on prescribing products produced and used in China, although some of these are limited and shaped by UK regulations. For TCM premises in the UK, TCM is not practised in public hospitals as it is in China. Private clinics (those owned by chain businesses or individuals) are currently the major places of TCM practice. For the patients, TCM can treat Chinese people

[91] With the development of globalisation, more places of the world connected. I use foreign cultures here indicating that TCM does not only appear in Western country, but also in other places, such Hsu (2007) has studies TCM used in East Africa and TCM also absorb the cultures in Africa.

whose disorders are not prioritised by mainstream doctors, those who require TCM to cover their culturally featured health needs, and those who have limited access to the UK mainstream medicine; TCM also provides healthcare to non-Chinese population who use TCM as a healthy lifestyle approach or who seek alternative healthcare to supplement mainstream medication.

A glocalised TCM is never its final form. In this research, it was determined that a second phase of modernisation, which Giddens (1991) called late modernity, is applicable. Giddens (1991) and other authors, such as Kumar (2020), explained that modernisation is an on-going and open-ended process without termination rather than an element of a succeeding era known as postmodernity. In China, the new modernisation strategy of TCM promoted at the 1996 PRC Health Conference stated that 'the modernisation of TCM should take advantage of modern scientific technologies to develop both theoretically and practically to protect and improve the public health' (Zhang, 2000). The further insertion of scientific technologies is also seen in glocalised TCM. As for TCM practice, communication between TCM practitioners and GPs, and cooperative practice between TCM clinics and biomedical labs, are illustrative of the attempts within the TCM industry to modernise via technical means whilst retaining its core features. As for products, ready-made products (not proprietary medicines) with united ingredients are used and it is the intention to use standardised manufacturing processes (i.e., GMP is applied).

6.2.3 The current form of TCM in the UK

The previous sections have provided a comprehensive description of UK-TCM, from its departure from China to its current status in the UK. The early modernisation from the West introduced biomedical knowledge to TCM and changed it in some respects. When TCM first stepped on to the global stage, it was a medical system that had originated in ancient Chinese culture but had already been forcibly transformed by Western medical knowledge and technologies under the will of the ruling class. Its real development in the UK was a discontinuity from the Chinese form. TCM has experienced both globalisation and localisation in the process of finding a foothold in non-Chinese societies, and it has become a branch of CAM. Nevertheless, UK-TCM is required as a supplement to the UK mainstream medical system, such as by treating disorders that are not prioritised by mainstream doctors. The localised TCM has an opportunity to develop and be prosperous, as demonstrated by the numbers of non-Chinese who have been attracted to using and learning to practise it. Moreover, TCM has further evolved under regulatory requirements, including abandoning some

ingredients, requiring market entry authorisation, and standardising manufacturing and distribution.

The current form of UK-TCM has relinquished the use of harmful ingredients to become a safer form of medicine for the wider public rather than only Chinese, and it has changed, such as by regulating practitioners and intervening in their practice so that they align with mainstream medicine in the UK. Further, it has inherited Chinese culture and theories, introducing new thoughts to modern medicine. A second round of modernisation to evolve TCM into a more scientific medical system is ready going ahead.

6.3 The network of the UK-TCM industry

In the above section, it was concluded that TCM originated from China, became involved in the international market with globalisation, and was further transformed by the UK local context. The existing UK-TCM can be understood from four aspects: 1) it is practised as a CAM synthesising traditional Chinese therapies and mainstream medical knowledge and technologies; 2) it is practised in various forms by both Chinese and non-Chinese practitioners of various educational backgrounds; 3) Chinese-style products are used but some are restricted due to UK social preference and legal issues; and, 4) it is conducted in private clinics. Based on this definition of UK-TCM, it is clear that: 1) TCM is continuously transforming under the influence of characteristics from different countries, but this transformation is not limited by geographic boundaries as regional characteristics can also be seen in TCM; 2) various actants in UK-TCM were identified as being related to its practice, practitioners, products and premises; and, 3) UK-TCM runs effectively as an orderly entity.

This research mainly analyses how TCM in the UK became a comprehensive industry, and how a regulatory system could be formed to ensure the industry is beneficial for the UK public by providing safe medicines, qualified practitioners, eligible premises, and adequate practice. In this section, ANT is used to understand the formation of TCM as an industry in the UK.

TCM is a complex system that involves various human and non-human actants, and no one sector can decide the best route for operating the industry. The contemporary unclear structure of the UK-TCM industry and how this structure formed is another black box containing TCM practice as one part of it (the current form of TCM practice explained in Section 7.1). TCM is an entity linking global and local elements, and the coexistence of the global and local within

TCM does not simply indicate that TCM transferred from one geographic area to another; rather, it illustrates that the impacts at both the national and international levels were simultaneous and produced TCM in its current form.

The TCM studied in this research displays all elements in one picture, and the translation mechanism of ANT is of great importance for studying TCM-related issues. On one hand, ANT helps to describe the natural development, or 'performative nature of quality improvement' after the interactions between the actants. In the case of the TCM industry, few statistics were identified to show the current and future development of the industry. Descriptive data work more effectively in this situation to narrate and explain the operation of the TCM industry. Also, ANT emphasises the equal position and weight of all the actants involved, which may address the insufficient voice of the practitioners by giving them (and other weak voice stakeholders) stronger participation in the TCM industry and its related regulation. Thus, ANT is an appropriate method for this field as it has enabled a description of the interactions between different stakeholders in the TCM industry to be drawn, and guided the researcher through these complex issues.

Applying the ANT device of the co-existence of simplification and juxtaposition in this research, a two-level analysis was designed to understand how the various heterogeneous elements work in the TCM world. In the first level of the network analysis, the black box of the UK-TCM industry has been opened to see how the various identified stakeholders gathered and performed different duties to establish and operate the TCM world in the UK, from the supply chain to the concrete healthcare services. The UK-TCM industry can then be simplified to a single point at which more actants participate to regulate the UK-TCM industry. Thereafter, a second level of analysis was conducted to see when the regulatory actants became involved in the UK-TCM world, and how this world was shaped and regulated into its current form.

6.3.1 Actants identified in this research based on general symmetry

Latour (2005) proposed that a major pillar of ANT is general symmetry. While symmetry indicates the involvement of both human and non-human entities, Latour also suggested a deeper role for symmetry in the refusal of any priority for causality, categorisation, or capability to act. Latour emphasised that the capacity to act, or agency, is not only a feature of humans, as it can also be ascribed to objects. In his view, humans and non-humans are equal and ontologically flat (see Section 2.1.2), meaning that all actants are on the same level regardless

of their size, force, scale and social impact. The term actant is used to unify both human and non-human actants in a network as if they are 'granted to be the source of action'. Dwiartama and Rosin (2014) further explained that the view of agency as based on ANT is that intentionality is not embodied by humans. Agency is manifest only in the relations of actants to each other, and what matters is not intentionality itself but how intentionality is shaped by the casual factors produced by the relations between all the actants, human or non-human. Within this concept, non-human actants can also exert agency just as humans can, and an agent is understood as anything modifying the state of affairs. Heterogeneous human and non-human actants were identified in the UK-TCM world, and these actents were derived from the network of practice, practitioners, products and premises (see Table 6.1).

Actants	**Identification source**	**Type**
TCM association	Practitioner, practice	Human
TCM practitioner	Practitioner	Human
Business owner	Practitioner, products, premises	Human
Educator	Practitioner	Human
Product supplier	Products	Human
MHRA	Products	Human
Local authority	Practice, premises	Human
UK customs	Products	Human
Police	Premises, practitioner	Human
Fire authority	Premises	Human
Herbs and other tools	Practice	Non-human
Clinics	Premises	Non-human
TCM knowledge	Practice	Non-human
Laws	Practice, products, premises	Non-human
Guidelines	Products	Non-human
Official reports	Practice, practitioner, products	Non-human

Table 6.1 Actants identified in this research

6.3.2 Building the UK-TCM network

(1) Level 1: Building UK-TCM from the principle actants from the industry

In applying ANT, I first identified the human actants involved in the UK-TCM world to conduct the level one analysis to see how the actants formed into a stable and well-operating system; in other words, the analysis explains the reason and process of how TCM found a foothold in the UK. To analyse the initial establishment of the UK-TCM industry, its associations, practitioners, business owners, educators, and product suppliers were included. These actants are responsible for TCM treatments, commercial activities and other related business. When considering the details of how these human actants perform these activities, non-human actants were also found to be essential to the establishment of the industry. The non-human actants include TCM substances such as herbs and needles, TCM-related premises (clinics and shops), and TCM knowledge and technologies. There is not a clear and united time point when these regulatory actors involved in the UK-TCM, but it can be predicted that their entry time relates to the issue time of relevant regulations, such as the local authorities involved in TCM regulation when the 1982 Act came into force. The actants involved in level one to understand the establishment of the UK-TCM industry are shown in Table 6.2.

Human actants	**Non-human actants**
TCM associations	Products: herbs, needles and other tools
Practitioners	Premises: shops and clinics
Business owners	Knowledge and skills
Educators	
Suppliers	

Table 6.2 Actants involved in building the UK-TCM industry

a. Problematisation

The actants identified in the UK-TCM world are presented in Chapter 4. The TCM associations are considered a principle actant in the ANT analysis. According to Law (1987), there should be an 'heterogeneous engineer' who interferes with and mediates the different actants in a world. The TCM associations were not the first actant to appear in the UK-TCM world, as it was initially organised by some early practitioners (see Section 6.1.1); nevertheless, the associations communicate and connect with other stakeholders. The associations thus shape and assimilate the various networks by translation to control the demands of the other actants. The associations aim to have the UK-TCM world operating smoothly and promoted widely, so that TCM can become established and continuously develop in the UK. However, the obstacle the associations face is achieving the cooperation of the various other sectors in the UK-TCM

world. For instance, the associations by themselves cannot make TCM work in UK society, as they need effective practice, safe products, and qualified practitioners to build a good reputation for TCM and to attract patients. Moreover, the business owners need to provide clean and safe premises and facilities, the suppliers need to sell reliable goods, and the educators need to design a professional curriculum.

Establishing a UK-TCM industry is thus considered an OPP (obligation passing point), which means there should be connections, cooperation and communication between the various actants to enable TCM to subsist. To achieve their aim, the associations act as leaders in the formation of the industry. At the level one stage, the associations determine a set of actants and involve them to enable the development of TCM in the UK. The associations then attempt to identify the actants and their interests while organising the TCM industry. These actants need to adjust their interests to pass the OPP of forming an industry to avoid obstacles conflicting with the interests of each actant, and to become actants involved in the network. The process of how these actants passed the OPP and joined the initial network is shown in Figure 6.3.

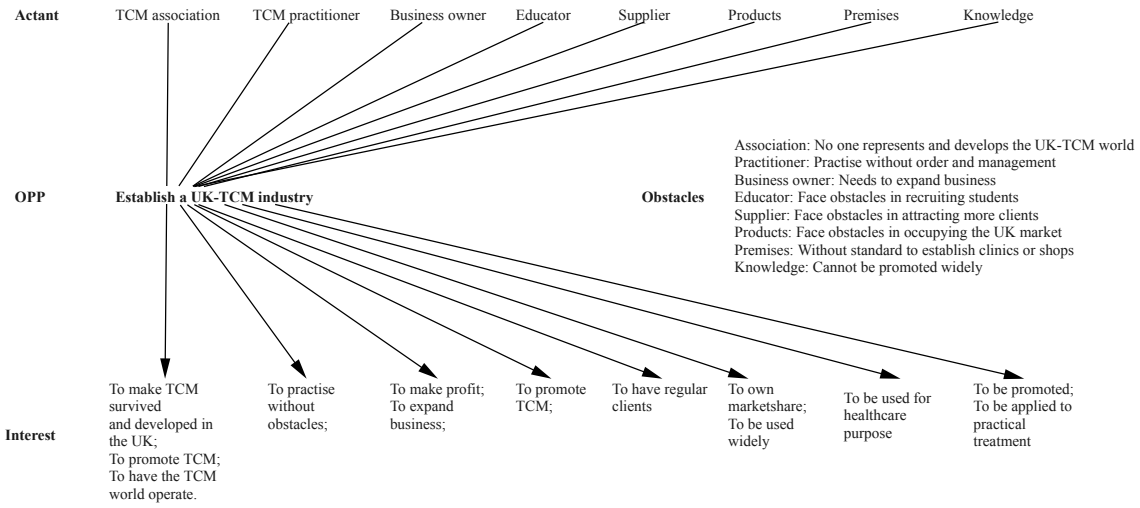


Figure 6.3 Problematisation of developing the TCM in the UK

According to Figure 6.3, the various actants all realise their interests through the UK-TCM industry. The practitioners practise with the support of the other actants, and the products, premises and knowledge are all used. The business owners make a profit through the practitioners they employ and are well supported by the industry. The suppliers find clients doing TCM business. This success attracted more perspective students to participate in TCM education. Finally, the associations have established TCM in the UK.

b. Interessement

After identifying the actants, the associations need to guarantee the actants are locked in their positions and perform their duties. To this end, devices should be adopted to lock in a commitment from each actant and minimise possible influence from other networks which may involve the promised actants of the UK-TCM world. During the fieldwork, partnerships were a common device used by the associations to lock connections with other human actants. Some NCPs joined an association because of a recommendation from their educators, who are the partners of the association, and some even automatically became a member of a specific association after graduation (such as NCP6). Such partnerships were also seen in CPs who were recommended by their employers to register with a 'friend association'. The associations thus have a fixed membership. Correspondingly, the associations conveniently recommend partner suppliers to its members.

For the non-human actants, such as TCM knowledge, products and premises, the associations used standards to lock this connection. Normally, each association has its own code of conduct to control quality of practice, entry criteria, the utilisation of products, hygiene conditions on premises, and the frequency and content of CPDs. The associations can thus guarantee the non-human actants are safe and of eligible quality for use in each part of the TCM network.

c. Enrolment

Problematisation and interessement involved and lock the actants in place, but further actions are needed to enact the set roles of these actants. Callon introduced negotiation as a common approach of enrolment. While this was not clearly reflected in the research data, it is conceivable that the associations communicate with other actants to decide what benefits are provided by partnerships and how such partnership can subsist; indeed, no conflicts were discovered between the actants in the TCM industry. Consent without discussion was predicted to be achieved.

To affirm the invisible negotiation, a gradual adjustment of the roles and relations of the actants was identified. As seen in this research, the associations may add new functions to align with the industry demands, such as the FTCMP reporting a focus more on academic activities during these years, as the practitioners and educators wished to be accepted by the mainstream health system through building a scientific evidence base.

d. Mobilisation

After enrolment, the TCM industry was formed, and the associations became thoroughly engaged in the daily operation of the industry; thus, they became the spokespersons of the industry. The fieldwork data also showed that representative members of TCM associations contacted government or influential people. Being the spokespersons of the UK-TCM industry, the associations can adjust the behaviours to stabilise the network. Within the working scale of the associations, they control the behaviours of the practitioners by setting registration criteria, holding academic meetings to promote information, organising post-medical accident follow-up mechanisms, and deciding on the existence and cancellation of practice certificates. These actions stabilise the position of the practitioners and then influence the other actants.

Within the UK-TCM industry, the various actants have achieved their general aim of finding a foothold in the UK while achieving their different personal interests. However, two problems were found in this level one actor network. First, although the TCM association (as the actant representing multiple associations) was identified as the principle actant and later became spokesperson, the association itself is broad. The registration entry standards potentially require the educators to set a reasonable curriculum and provide high quality training, update information on medicinal or herbal ingredient utilisation to influence the import activities of the suppliers, and ensure that the cancellation of practice certificate lead to dismissal. As found in the fieldwork data, there are many TCM associations in the UK, and they work independently with limited connection to each other. Of all these associations, there is no leading association or person who represents the others. Therefore, the actual mobilisation part may be problematic as it is uncertain who will represent the TCM society and lead the adjustment of other actants to stabilise the network.

In this research, the heads of different associations were found to be in communication with the UK government for various reasons. However, to what extent these appeals represent the whole TCM industry is uncertain. Second, although TCM has gained a place in the UK, its current position is not recognised by the UK mainstream health system. TCM is still removed from mainstream UK medical standards of safety, qualification and efficacy. Although efforts have been made, such as voluntary registration, setting codes of conduct, and holding academic activities, the data collected by this research still show that the TCM associations have had limited success in reducing unexpected adverse medical effects and medical incidents. The associations have failed to impose quality requirements on TCM stakeholders, and thus ensure the efficacy of TCM. No obvious progress was seen to make TCM move closer to being the

type of medical system expected in UK society.

(2) Level 2: Reforming the network under the impact of regulations

Two major problems with the TCM industry have thus been identified: 1) control over TCM stakeholders by TCM associations is fragmented and insufficient; and, 2) the work of the TCM industry has not made TCM a safe, qualified and effective medical system. Since more actants are needed to participate in the UK-TCM network to adjust the work and outputs of the TCM industry, it is not useful to continue to discuss the numbers of actants in the TCM world. In this research, the actants forming the TCM industry have thus far been simplified into a whole entity. In the second level of the ANT analysis, other human actants will be included, mainly those with regulatory power, such as the MHRA and local authorities, as well as the police and fire services (on how the police and fire brigade are involved in TCM regulation, see Section 5.2.1), and UK Customs. The non-human actants include legislation, technical standards and guidelines, and official reports. The actants in this level two analysis help with understanding the establishment of the UK-TCM regulatory system so that TCM may be reshaped or, in other words, to explain how TCM adapted to the regulations. The actants involved in level two analysis are summarised in Table 6.3.

Human actants	**Non-human actants**
TCM industry	Legislation
MHRA	Technical standards and guidelines
Local authorities	Official reports
Police/ fire brigade	
Customers	

Table 6.3 Actants involved in building the UK-TCM regulatory system

a. Problematisation

To form the expanded network involving regulatory actants, the MHRA is considered the principle actant. The MHRA implements regulations to manage TCM products in the UK. It works under the instruction of various laws and regulations and thus directly impacts the TCM industry, while also liaising with other related departments to monitor essential issues with TCM products under the Borderline Section. The MHRA is the 'heterogeneous engineer' to make TCM a safe, qualified and effective medical system. To achieve this purpose, there should be a comprehensive regulatory system involving as many stakeholders as possible and to

control as many aspects of TCM as possible. Establishing a UK-TCM regulatory system is then set as an OPP.

The MHRA's task is to identify the other actants while arranging the TCM-related regulatory work and communicating with them through the Borderline Section. The process of how these actants pass the OPP and join the initial network is shown in Figure 6.4.

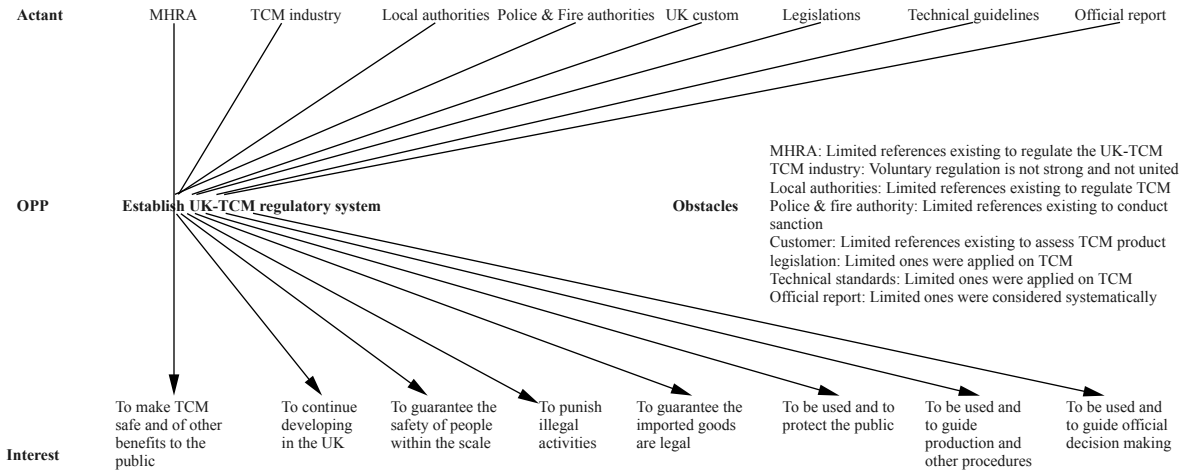


Figure 6.4 Problematisation of developing the TCM regulatory system

According to Figure 6.4, the various actants can all realise their interests through forming a UK-TCM regulatory system. Once the UK-TCM regulatory system has been built, the MHRA can guarantee the safe utilisation of TCM products; the TCM industry will be allowed to operate by official UK departments; the local authorities, police, fire authorities and UK customers can conduct their TCM-related work smoothly according to legal references; and, the legislation, technical standards and official reports will be in the right place and beneficial to the public.

b. Interessement

The MHRA used consultation and cooperation as devices to attract actants and lock in their position and role in the TCM network. As is explained in Section 2.1.1, an entity may simultaneously be an actant of different networks. When involved in a new network, the entity may be at odds due to its role, interest, and identity in the other network. When the MHRA performs as the principal actant, it adjusts the role and locks the position of the actants in the level one network to embed these actants more deeply in this expanded network. For the human actants, this research has revealed that the MHRA consults the TCM associations on regulatory

issues like decisions on restricted ingredients, and this indirectly involves the other TCM industry stakeholders as they are represented by the TCM associations in the level one network. The MHRA also cooperates with the district councils and the UK Customs on TCM products used in the UK market under the Borderline Section. For the non-human actants, the MHRA uses the legislations and technical standards as the basis on which to build the network. By these means, the MHRA can make the actants integral parts of the network.

c. Enrolment

After adjusting the positions and roles of the actants through interessement, further enrolment approaches are needed to guarantee the actants can finalise the network establishment as the principal actant predicts. For the human actants, the MHRA enrols them by regulating them. For example, the MHRA regulates banned or restricted use TCM ingredients, and it was reported by the MHRA that there were consultations with the TCM associations on some banned or restricted herbal ingredients. For the non-human actants, the MHRA enrols them by implementing them. The MHRA implements: the 2004 Directive, the 2005 Regulations and the 2012 Regulations on herbal medicine licensing, the 2004 Directive and the 2012 Regulations on pharmacovigilance, and GMP and GDP by inspecting the manufacturing and distribution of TCM products. The implementation of these regulations shows that the regulations are well suited and operating in the expanded TCM network.

The enrolment by regulation of human actants and the implementation of non-human actants can thus effectively test the positions and roles of these actants decided in interessement.

d. Mobilisation

The MHRA is regarded as a representative of the TCM regulatory system, and it is thus the spokesperson of the level two network. The MHRA normally works to stabilise the network in two ways: first through the enforcement mechanism of the legislations, to guarantee that the TCM industry causes no harm to the public; second, through producing the intermediaries, such as the profile database of medicine ADRs, as referenced in Table 6.1, and passing these intermediaries up to the other actants by publishing online or delivering through freedom of information requests.

Up to this point, with more actants involved in the UK-TCM world to set rules to reduce the possible harms, TCM was on the way to becoming the type of medical system expected by UK society. It is notable here that I used the words ‘on the way’, indicating that the later regulatory

actants reshaped the broad concept of the UK-TCM into its current form. This shape is an evolution of the initial TCM world described in the level one translation, but which is not the final form permitted by UK society and authorities. This is because concerns still exist, and one large problem seen in the level two translation is the limitation of the working scale of each regulatory actant. Although the MHRA is considered the principal actant in the level two network because of its regulatory authority and connection with most TCM stakeholders and regulatory actants, its working scale is restricted to issues with products. For other aspects such as the regulation of practitioners and premises, it is the local authorities which perform most of the regulatory work. However, each local authority, such a district council, has its own standards of regulation. Also, the frequency and actual situation of the connection and cooperation between these actants on TCM regulatory issues remain unclear. Other concerns, including TCM-related legislation as an actant, have not been updated for some time, and official reports discussing TCM issues are seldom adopted and applied to practice. As a result, further exploration of how TCM could be regulated to satisfy UK social and regulatory demands is required.

6.4 Short summary of findings in this chapter

This chapter has explained the transformation and adaptation process of TCM from an ancient Chinese medical system to the current branch of CAM in the UK, providing an answer to the first research aim of understanding the current practice of TCM in the UK. The ancient therapy was forcibly shaped by medical knowledge and technologies from Western countries in the early modernisation period, when value led world development. Such modernisation endowed TCM with some scientific elements, but failed to transform its inner culture. In the late twentieth century, with the rise of Asia, the world pattern changed again. Some more marginalised places and their cultures found an opportunity to enter Western society. During its globalisation process, TCM was again modified to cater better to foreign preferences, including those in the UK. Here, TCM further transformed its practices, practitioners, products and premises to become a CAM system based on the UK's local social and political demands.

Even though it was a non-mainstream medical system, TCM still gained a foothold in the UK. In this regard, ANT was employed to analyse how TCM achieved its current status. ANT opened the black box of TCM's appearance and development in the UK by revealing four elements in the translation process. UK-TCM experienced two levels of translation. First, it first formed a comprehensive industry with product suppliers, educators, practitioner registration,

and business activities. However, this industry was far from being the type of medical system which would meet UK standards. TCM also had no spokesperson responsible for adjusting and stabilising the UK-TCM world, and nor did the industry provide reasonable practice, products, practitioners and premises at that former stage.

More actants were then involved in the UK-TCM, transforming it into a more beneficial system for the public. The level two translation explained how the current broad concept of UK-TCM was formed under regulations. Referring back to the research aims, the process of the adaptation of TCM to the UK context was first understood through the transformation of its medical practice, through early modernisation involving Western elements, globalisation which added an international element, and localisation and alignment with the UK market. Finally, there was glocalisation, combining the traditional form of TCM in China with the international impact, such as using English, and local UK demands. This medical practice then found a foothold and fixed its position in UK society by forming an industry. On one hand, this industry should satisfy the UK market demand to establish a comprehensive supply chain and service network involving multiple actants in its operation; on the other, it should also involve regulatory actants who reshape it to provide beneficial healthcare services, or at least who cause no harm to the public. The adaptation of TCM to the UK context is a process of transforming its content according to specific social demands, forming an industry to stabilise its position and develop further, and shaping the medicines and the industry to satisfy the regulatory requirements and achieve the regulatory goal.

Although TCM spontaneously made endeavours to align with the market, it can only be beneficial to the public through the reshaping of regulations. However, some problems were noticed, such as the regulatory actants working independently, the legislation not being updated for a long time, and the suggestions of official reports seldom being put into use.

Chapter 7 The Performance of the UK-TCM Regulatory System

In Chapter 6, the essence of UK-TCM was discussed as a broad concept, including the nature of TCM as a medical system, the formation of the UK-TCM industry, and the basic operation of UK-TCM under regulations. Although UK-TCM seemed to involve establishing a relatively mature network, TCM is still far from being an eligible medical system in line with UK social expectations and scientific standards. In this chapter, the aim is to explore the practical operation of the current UK-TCM regulatory system, assess its performance, and suggest possible improvements for the provision of satisfactory practice, products, practitioners, and premises. To this end, the theory of responsive regulation is utilised to understand the regulation of the UK-TCM world in the following aspects: 1) the reasons and feasibility for adopting responsive regulation; 2) two basic responsive regulation approaches which can be used to understand UK-TCM; 3) an evaluation of the current UK-TCM regulatory system; and, 4) suggestions for the future improvement of the existing regulatory system.

7.1 Impact of regulations

7.1.1 General review of the existing regulatory system

Seeing the fast development of TCM in the UK at the end of the twentieth century, CP5 felt that the UK government and regulatory authorities knew little about TCM at that time, and the government had not established an effective way to manage the different therapies used by TCM and its practitioners. CP5 recalled that some TCM practitioners established professional autonomy bodies for self-regulation, and these bodies later became voluntary regulatory associations. In this situation, CP5 described the 2000 Report as the first attempt by the UK regulator to progress specific legislation for TCM (and other CAM) practices. The researcher summarised some regulatory directions for the UK-TCM from the contents of the 2000 Report as: 1) practice, including issues related to therapy classification, regulation routes, and improvement of safety and efficacy; 2) practitioners, including the concerns of training and education; and, 3) products, including the establishment of an evidence base, and the promotion of information and healthcare delivery. However, twenty years have passed since the 2000 Report, and the participants in this research reported that limited progress in the improvement of TCM regulation, which is still fragmented. During these years, conflictions were seen.

Among different associations, CPs reported that a 'leader'[92] was urgently needed to regulate the chaos in the TCM (details see); between stakeholders, their consideration about a better to regulate the industry vary; between the bigger associations and the others, unfair treatment from the mainstreat health sector was reported (examples see the dispute about blood transfusion in Section 5.1.4). However, the progress of improving regulation was slow. As NCPs 3 and 6 reported, agendas for establishing statutory regulation came out frequently during the first decade of the twenty first century, but few actions were taken. NCP6 reported that there has been no new information on TCM statutory regulation for some time, and he supposed that the government has other affairs to attend to, and unimportant and less urgent items such as TCM are put aside.

Some practitioners (such as NCP10) complained about this slow progress in statutory regulation that created obstacles to their practice. First, practitioners who were not statutorily regulated could not register with any of the 12 health and social care statutory regulators (see footnote 17) as medical practitioners and be protected for specific titles and the proprietary right to practice[93] (see the 2000 Report in Section 4.1.1). Second, NCP10 found that because there is no official standard to evaluate the safety and efficacy of TCM, the mainstream health system may treat practitioners registered with different associations differently (see Section 5.1.4 about the case of blood tranfusion).

Some stakeholders in the TCM industry are attempting to accelerate the regulation process to promote TCM in mainstream society and thus expand the industry. Prof BM had tried to use his personal network; for example, he had met Prince Charles, who is in favour of CAM, and Jeremy Hunt, whose wife is Chinese, to promote TCM and gain for support from influential people. However, these attempts were met with limited success, as currently UK-TCM still faces a downturn. As Prof BM reported, 'the number of TCM clinics has reduced from its peak[94] to only around 300'.

Although some practitioners canvassed for statutory regulation, some, such as CPs 1–2, 10, 12 and 14, felt much less impact from the current regulatory situation. Some regulations and laws restricted parts of TCM practice, such as using animal ingredients, but they still have a great

[92] This word was directly translated from the word 'lingdao 领导' reported by CP5. 'Lingdao' can mean leader, representative or regulator (officer) in Chinese.
[93] For example, osteopathy is statutorily regulated; it is against the law for anyone who does not register with the General Osteopathic Council to call themselves an osteopath. The General Osteopathic Council prosecutes individuals who practise as osteopaths when they do not register with the Council.
[94] Section 1.2.2 mentioned that 3,000 TCM clinics existed in the UK, according to a 2006 study.

deal of freedom to practise as they wish as they are voluntarily regulated. The changes of TCM practice caused by regulations were mentioned but not seriously contradicted. The TCM business owners expressed a similar idea, in that it is better to keep the current situation. BO2 stated that statutory regulation is unnecessary for UK-TCM, and it may to some extent bring restrictions and 'discrimination'. In this regard, BO2 said, 'Legislation sometimes aims to limit a career only to the local people. It is exactly because there is no legislation on TCM in the UK, we Chinese people can practise TCM here'.

7.1.2 Literal ssessment of existing regulations

This assessment of the regulations is classified according to the type of regulatory instrument: EU directives, UK acts of parliament, private acts in the UK, SIs, and technical standards.

(1) EU Directives

The 2001 Directive was officially assessed by the European Parliament and the Council of the EU as incomprehensive, and thus it was replaced by the 2004 Directive, which forms the basis of the current EU legislative framework. For the 2004 Directive, literature (such as Chinou, Knoess & Calapai, 2014) evaluated it as a powerful regulatory model for the marketing of scientific medicinal products. The 2004 Directive requires data on safety and efficacy, especially for product labelling, so that reliable information is provided for both healthcare workers and patients using registered herbal medicines. Also, the monographs and guidance required by the 2004 Directive has facilitated the harmonisation of standards of traditional herbal medicine licensing work in the EU. After the UK's exit from the EU, official legislation records (legislation.gov.uk) show that the contents and requirements of the 2004 Directive were transferred into UK domestic law.

However, the validity of long-term use as a form of evidence is somewhat doubted in the literature. Although study suggested the utilisation of a medicine for long time could provide evidence of its lack of carcinogenicity (Moreira et al., 2014), there are also suggestions that thirty years' history of use is unequal to clinical trial data which provide rich knowledge about the safety and efficacy of medicine (McCartney, 2014; Cox, 2014). Additionally, the performance of the Directive can be further improved by learning from herbal medicine regulations outside the EU, keeping updated monographs, and combining data on traditional use from outside the EU (Peschel & Alvarez, 2018; Qu et al., 2018).

(2) Assessment of UK acts of parliament

Critiques of the acts of parliament were found in both the literature and fieldwork data. The 2005 Medicines Regulations, through which the 2004 Directive has been implemented in the UK, was assessed in the Explanatory Memorandum produced by the MHRA as being influential on all aspects of the pharmaceutical industry. The 2005 Regulations, like the SIs of the 2004 Directive, urged pharmaceutical companies to develop appropriate premises, facilities and manufacturing systems to ensure quality products. However, the 2005 Regulations did not require proof of actual work and no assurance of effectiveness (Barber, 2014). As an implementation tool of the 2005 Regulation, the THR Scheme failed to include many products and lacked a guarantee of efficacy (Dickinson et al., 2019)

(3) Assessment of private acts

No literature assessing the 1982 Act was found. The 1991 Act was amended and extended by the 2000 Act, as the 2000 Act deemed that the 1991 Act should be strengthened in respect of improved provisions to strengthen local government services in London, and to be beneficial for people living in the area. The local authorities are empowered by the 1982, 1991 and 2000 Acts to regulate the TCM associations for licence authorisation and exemption, the healthcare services of practitioners, and the business activities of TCM clinics. The associations are under close inspection by district councils which grant and cancel the licence exemption right (see Section 5.2.2).

Alaso, as is identified in fieldwork, all the identified practitioners worked in places registered as clinics. The observed clinic fulfilled the requirements of the 1982 Act in registering to provide special treatment, displaying its registration certificate, and satisfying hygiene and fire safety rules. The clinic is a member of an exempt TCM association approved by local authorities, which satisfies the 1991 and 2000 Acts; it also fulfilled the 2012 Regulations in being private, able to be close to exclude the public if necessary, and in being open for investigation.

(4) Assessment of SIs

The 2012 Regulations were officially assessed by the MHRA (2017b) as part of a wider exercise

within government to test regulations five years after implementation through evidence collected from organisations impacted by the regulation. The MHRA (2017b) considered the overall work of the 2012 Regulations on pharmacovigilance to be satisfactory for the protection of patient safety, and this regulation had a neutral impact on the UK pharmaceutical industry. The MHRA (2017b) found that the 2012 Regulations had reduced the number of regulations and statutory instruments that had to be consulted, as it was the single reference for most aspects of medicine regulation in the UK. However, problems may remain as the regulations are long and difficult to understand; many rules remain the same as the 1968 Act and need further assessment, while some licensing procedures (such as for controlled drugs) are correlatively expensive. Moreover, the MHRA (2017b) did not particularly mention the operation of the 2012 Regulations on the exemption of herbal medicines from registration. We thus do not know the official stance on the performance of the 2012 Regulations on CAM.

(5) Assessment of technical standards

Studies such as Gouveia et al. (2015) and McLoughlin (2020) have assessed the EU-GMP. In their view, GMP is effective as a harmoniser of quality standards in the EU by requiring manufacturers to establish their own quality control system to meet GMP standards. At the UK level, the MHRA has been producing annual GMP inspection deficiency reports to review the GMP deficiencies for drug products since 2015. The main inspection deficiencies relate to quality risk management, contamination control strategy, environment monitoring, overall attention to quality systems, and appropriate investigation.

Concerning GDP, the requirements of EU-GDP (version 2013) were assessed as having a limited contribution. Medicine distribution is an international issue and coordination among EU member states is needed, but certain situations, such as keeping the same transportation temperature along the whole medicine supply, can hardly be unified as each State has its own considerations concerning distribution requirements in its own domestic conditions (Cold Chain IQ, 2013). At the UK level, Krasteva and Brown (2020) presented in the MHRA Inspectorate blog that there was potential risk caused by the publicity of all GDP certificate information online, in that ‘false impersonation, phishing and scamming’ can happen. Herbal medicine distribution issues were not specifically mentioned in these assessments.

The MHRA (2020) has affirmed the contribution of the Yellow Card Scheme in providing information on the risks and harm of medicines, and thus it is beneficial for healthcare

professionals and patients when choosing treatment. This contribution was also reported in the literature, although some problems were also identified, such as the low number of completed reports and the weight assigned to healthcare professionals and normal patients when reporting (Blythe, 2000; Avery et al., 2011).

The researcher searched the published interactive drug analysis profiles (iDAPs) containing complete data for all spontaneous suspected adverse drug reactions or side effects reported and all licensed drugs for which the MHRA had received reports of suspected adverse reactions since 1964. Up to 31 May 2021, 173 herbal ingredients were identified among the thousands of items in the iDAPs database. These 173 herbal ingredients include raw plants or herbal substances that have been simply processed, such as by cutting or drying, and the researcher elected to scan their detailed information because the 1968 Act only permitted herbal ingredients which had been simply dried, crushed or comminuted to be added to unlicensed medicines; and, on the other, as reported by the BOs and SUP1, no TCM product has been granted a THR certificate and no TCM practitioners are allowed to use Chinese proprietary medicines (see Section 5.2.4).

Among the 173 herbal ingredients, 108 species were found to be used in TCM (see Appendix IV). The 108 ingredients were identified through a literature search, online information, checking the stocklist of the observed clinic, and consulting the *Pharmacopeia of PRC (2015 & 2020 ed.)*. Of the 108 TCM herbs in Table 7.1, 41 were used alone, and 67 were added to multiple constituent formations. Altogether 8427 cases of adversed effects after using TCM ingredients were report. The herb hypericum received the largest number of adverse effect reports at 266, ephedrine received 200, and cannabis sativa received 122. For 78 herbs, females reported adverse effects more than males. People whose age was not reported had adverse effect in 32 ingredients, and people aged between 60–69 were the second largest age group reporting adverse effects from 24 herbs. The largest number of adverse effect reports were submitted to the YCS in 2017. The largest number of adverse effects concerned the cardiac system, seen in 27 ingredients, while skin and subcutaneous tissue disorders were seen in 18 ingredients, and further investigations were reported as essential for 18 ingredients. Some 25 herbs were reported to have fatal impact on organs, and 13 were reported after using multiple constituent formulations. Altogether 85 fatal cases after using these ingredients were reported. Death because of hepatobiliary disorders was seen with seven herbs, and damage to the cardiac or respiratory system, or thoracic and mediastinal disorders, were also important factors leading to fatal cases (each was seen with six herbs).

Total number of TCM herbs reported to YCS	108
Number of herbs used in multiple constituent formulations	67
Total number of adversed effects cases	8427
Largest number of reports received	Hypericum (Guanye Lianqiao/贯叶连翘): 266 Ephedrine (Mahuang/麻黄): 202 Cannabis Sativa (Huomaren/火麻仁): 122
Largest number of side effects reported in population (sex)	Females: reported in 78 ingredients
Largest number of side effects reported in population (age)	Unknown age group: reported in 32 ingredients 60–69: reported in 24 ingredients 30–39: reported in 23 ingredients
Largest number of side effects reported by year	2017 2018 2010
Largest number of adverse effect reactions by organ class	Cardiac system: reported in 27 ingredients Skin: reported in 18 ingredients Investigation: reported in 18 ingredients
Number of herbs with fatal reactions	23 (13 reported to happen on multiple constituent formulations)
Largest number of fatal reactions in organs	Hepatobiliary: reported in 7 ingredients Cardiac system: reported in 6 ingredients Respiratory: reported in 6 ingredients
Total number of fatal cases	85

Table 7.1 Summary of the iDAPs of YCS reports

Among the 108 TCM ingredients, 46 were not included in the *Pharmacopeia of PRC* (2015 & 2020 ed.) but mentioned in other TCM books (i.e., Summary of Chinese Herbal Medicines of the Whole Country writing group, 1975). The profiles of 23 ingredients do not give detailed instructions for use, and TCM only uses parts of the plants (i.e., the fruit, seeds or leaves); the

profiles 43 ingredients are written in genus names, and TCM only uses one or some species of a plant's genus. That said, the reports of adverse effects of herbs do not necessarily connect to TCM practice. However, no more detailed information about where and how people obtained these ingredients is available. In the researcher's enquiry to the MHRA about the operation of YCS, the MHRA considered that the reports received by the YCS do not reflect the true number of adverse effects of herbal medicine in the UK.[95] One reason causing the insufficient report of herbal medicine was that unlicensed medicines, such as herbal medicine, do not include a reporting process on its package.

7.1.3 Accessment of existing regulations derived from fieldwork

Both regulatory factors and social factors were found to impact TCM in the UK. The regulatory impacts were interpreted following the pattern established in Section 1.3.2 to reflect clearly the comments on the existing regulatory system (see Table 7.2). Although there were some positive comments on the current regulatory system from the industry, problems remain, and the largest of these is the fragmentation of the regulatory system.

From the perspective of regulatory instruments, the EU Directives were found to have an obvious impact on UK-TCM because they prohibit the import and use of unlicensed medicine, causing obstacles for TCM businesses and practitioners using Chinese proprietary medicines. No TCM product was reported or found to have been granted the THR certificate by BOs and SUP 1. Also, the THR scheme itself has been criticised in the literature for ignoring the importance of the efficacy of medicines. The impact of private acts (the 1982 Act, 1991 Act, and the 2000 Act) operated by local authorities were frequently mentioned by the practitioners. However, they did not clearly know what constitutes the legal basis for empowering local authorities to regulate them. This confusion was also seen in other regulations related to TCM in the UK. GMP and GDP were assessed as effective in the literature, but reported to work less effectively by the industry as insufficient inspection on product importation exists.

For the four Ps of regulatory objectives, the regulation of practitioners was mentioned most in interviews. TCM practitioners in the UK are under voluntary regulation operated by TCM

[95] A report of the HMAC (2014) found only around 60 YCS reports involving herbal medicines were submitted each year between 2006–2014, and 40% of these were submitted by the general public. A study by Booker (2006) reported that the rate of reporting adverse effects of TCM is low. Booker studied practitioners in the Register of Chinese Herbal Medicine, a TCM association, and found only 3% of practitioners of this association had ever completed a YCS report. However, these two studies were written several years ago, and no recent detailed data was found reflecting the rate of reporting adverse effects of herbal medicine or TCM through YCS.

associations, rather than being statutorily regulated. The practitioners reported that the associations provided them with certificates of practice, insurance, academic activities, and advanced training programmes. However, problems were also reported regarding the existence of too many different associations with different standards, working procedures and codes of conduct, causing chaos in the whole TCM industry. As for the products, regulations work less effectively. Wholesalers were found to take advantage of the 'grey area' by importing medicines as food supplements because no rigorous inspections are conducted. The regulations of practice did not impact most of the CPs, but NCPs reported they had to focus more on practising acupuncture due to the restrictions on unlicensed medicines by the 2004 Directive. The regulations on premises were not reported to impact the TCM industry.

For the regulatory targets, safety concerns were mentioned most in interviews. Although all the participants of this research reported they had not ever been involved in medical accidents, they still felt that problems are caused by inadequate education from short courses leading to inappropriate practice, chaotic registration entry criteria for selecting eligible practitioners, and ineffective post-accident help from associations. Quality concerns came from the handover with manufacturers in China, where few manufacturers or production procedures fulfil UK GMP. Efficacy concerns were mentioned less, as both practitioners and patients reported TCM to be helpful for various diseases.

The data on regulatory enforcement were interpreted in the working of the local authorities and the MHRA. Inspections and enforcement by district councils were frequently mentioned by the participants, who reported that the councils check their compliance with private acts and decide on the eligibility and cancellation of certificates of associations, businesses and practitioners. Inspections by the MHRA were less often mentioned by the industry. CP5 reported his experience of an inspection by the MHRA, which, 'checked my clinic, warehouse and the office of the head company to see whether I use animal ingredients or other restricted ingredients. After the inspection, the MHRA publishes the result, and patients in this area can see [any incompliance]'.The researcher enquired with the MHRA about inspections, and it replied that they do inspect TCM-related products, mainly through the YCS.[96] It further stated that the YCS receives more than 40,000 reports of suspected adverse reactions of medicine each year. However, fewer than 100 of these are associated with herbal medicine. When checking the adverse effects of herbal products reported to the YCS, the total number of such reports was

[96] Although practitioners reported that the prohibition on animal ingredients is controlled by the MHRA, this research finds that animal ingredients are mainly regulated by importation rules.

limited, and the extent to which the adverse effects were caused by TCM practice is unclear.

Regulatory impacts discussed in 4 aspects	**Sub-level of aspects**	**Comments**
Regulatory instruments	EU Directives	Reduced the availability of products
	Private Acts	Important to the industry but confusing
	GMP& GDP	Important to wholesalers but less effective
Regulatory objectives	Practice	Reduced practice of herbal medicine
	Practitioners	Regulated by voluntary regulation but problems exist
	Products	Regulations restrict the type of ingredients and their quality, but acceptable ingredients are less effective
	Premises	No special comment
Regulatory targets	Safety	Problems exist in education, registration and protection
	Quality	Regulated by GMP but needs cooperation with other actants
	Efficacy	Claimed to be effective but less evidence exists
Regulatory enforcement	Local authorities	Has a close connection, but insufficient details were available
	MHRA	Work was seen but has less connection to TCM specifically

Table 7.2 Impacts from the regulatory system

Additionally, the impacts of non-regulatory factors on TCM were also mentioned in this resear. These impacts came from patient preference for reducing some traditional Chinese cultural elements, the unsupportive attitude of the UK mainstream health system, the immature education system, and deterioration in TCM business. Although TCM has re-shaped itself under the impact of these factors, most of the research participants felt that TCM is being marginalised in the UK.

For the future of the UK-TCM, Brexit may be a watershed. The research participants from the UK-TCM industry expected some EU laws setting barriers to TCM would be abandoned, while

some of the participants feared that Brexit would lead to an economic downturn with a negative influence on the TCM market. The official information conveyed by the MHRA shows no huge change would happen to TCM-related laws after Brexit, but it plans to relax the restriction on accepting traditional evidence from EEA countries only to a wider range of places. Besides the expected changes of regulation, the research participants from the UK-TCM industry hoped that the current voluntary regulation could be more united by selecting a leader or representative for the industry, and accordingly standards for education, registration and practice could be established, with more attention to, and investment in, scientific research to make TCM more accepted in the UK mainstream health system.

7.2 The implementation of responsive regulation on UK-TCM

7.2.1 Pyramidal escalation using tit-for-tat strategy in TCM regulation

As stated in Section 1.3.2, UK-TCM is currently regulated by various means, from cooperative approaches (self-regulation or partly self-regulation) to deterrents. According to the tit-for-tat (TFT) strategy (see Section 2.2.2), in TCM regulation the 'big guns' are held by the national government, which can apply legal sanctions via prosecution to breaches of law. Having the law and nondiscretionary sanctions as a backup force, other regulatory approaches were allocated to moderate behaviours within the TCM industry.

Two types of pyramid were discussed in Section 2.2.2, and both can be found in UK-TCM regulation. The first is the enforcement pyramid which happens between the regulators and a single entity. In this research, this pyramid manifests in how each regulation manages its regulatory targets according to the motivation to achieve the regulatory objective. Section 1.3.2 shows the enforcement mechanisms of each TCM regulation in the UK. These enforcement mechanisms have routes of escalation, moving from 'informing the responsible entities and the public' to 'information collecting mechanisms' to 'investigation', and finally 'enforced sanctions' (Figure 7.1).

In the pyramid in Figure 7.1, the most deliberative approaches are placed at the bottom and these include various approaches to publishing regulations for awareness; if the regulated fail to comply voluntarily with regulations, the reporting mechanism begins to collect suspicious information, such as with GMP and an inspection. After collecting the suspicious information, an investigation could be conducted, such as through the YCS and its professional investigation

process; the outcome of the investigation would then lead to sanctions, seen at the top of pyramid. The regulatory goal can be achieved after each step or by escalation through all of them. In addition to the core of the pyramid, the small circles at the side of each level illustrate the common regulatory approaches.

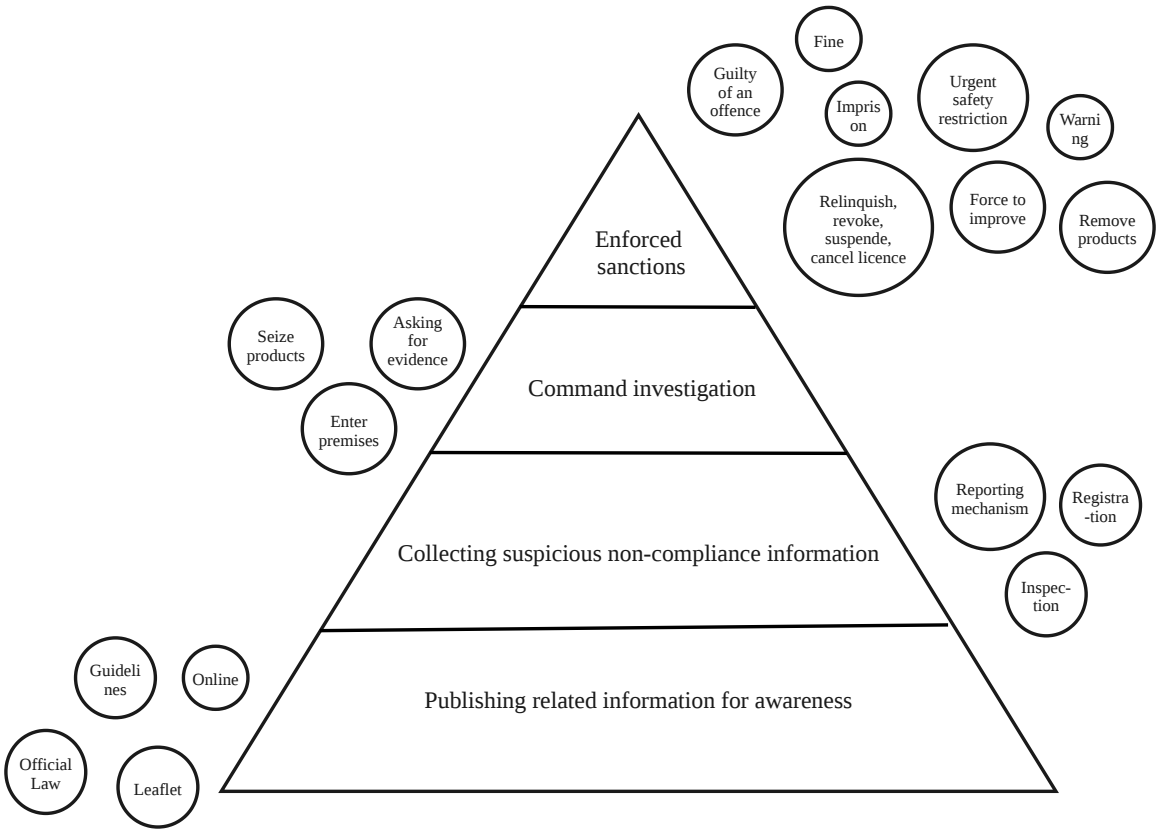


Figure 7.1 Enforcement pyramid for UK-TCM regulation

Three relatively comprehensive regulations: GMP (GDP has almost the same regulatory escalation route), THR, and YCS; these will now be discussed to explain the escalation route within the enforcement pyramid as applied to UK-TCM.

GMP has an official escalation process (gov.uk, 2020) which is targeted at manufacturers but also involves other stakeholders, such as wholesalers and business owners. These stakeholders are motivated to have TCM products used in the UK (Figure 7.2). The GMP enforcement mechanism is never too harsh to apply direct sanctions to the regulated, and instead follows a TFT strategy which gradually ensures products are eligible for the market. The MHRA inspectorate[97] performs various types of inspection (see Section 1.3.2 and 10 in Appendix II)

[97] The MHRA Inspectorate conducts inspections to protect public health by ensuring that medicines are available and are of

of medical products in the UK, including herbal medicines. If non-compliance is identified, the inspectors will meet the related entities to outline the consequences of continued non-compliance and then begin regulatory escalation by closely monitoring for improvement in non-compliance levels. If the non-compliance is resolved, the regulatory escalation stops. The de-escalation process or forgiving process returns the activities of the inspected entities back to basic inspection; however, if the previous deficiencies are not improved to an officially satisfactory level, the inspectorial group proceeds to the Inspection Action Group (IAG), which can refuse or suspend the related licence (MHRA, n.d.).

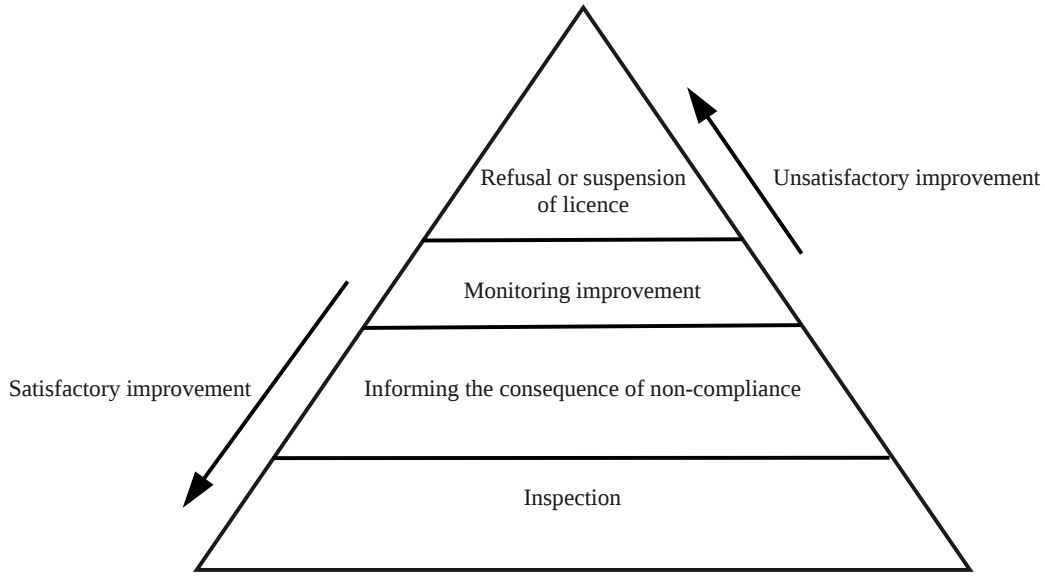


Figure 7.2 Enforcement escalation in GMP

Pyramidal enforcement mechanisms were also found in THR and the YCS (Figures 7.3 & 7.4). THR targets applicants who wish to place traditional medicinal products on the UK market, including manufacturers, wholesalers, business owners and practitioners. The YCS targets products to achieve appropriate safety levels, and thus also involves manufacturers, wholesalers, business owners, practitioners and others who wish to keep their products accessible in the UK. The two regulations contain the three stages of publishing regulatory information to ensure the regulated are made aware of requirements, the collection of data on suspicion of non-compliance, and investigation. When these three stages do not prevent continuous non-compliance, discretionary punishments will be issued. THR changes the status of a licence or registration as its main deterrence, while the YCS has more varied sanctions, but

the right quality, and that appropriate standards of regulation are being applied. The work of the MHRA Inspectorate is achieved by licensing and inspecting related stakeholders. The work is conducted by the departments of inspectorate operations, inspectorate strategy and innovation.

all aim to inform the public about the harm of non-compliance. At the top of each pyramid, an offence under THR can produce a guilty sentence, but the YCS deploys discretionary punishment and only removes products in ‘rare circumstances’.

Figure 7.3 Enforcement pyramid of THR

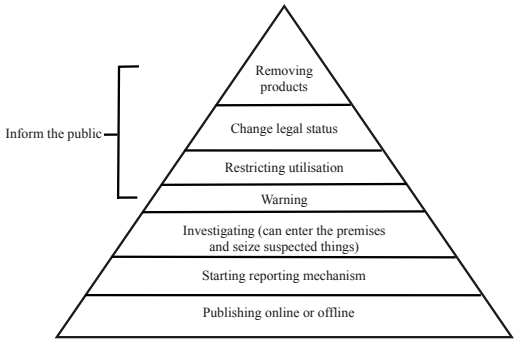


Figure 7.4 Enforcement pyramid of YCS

The second type of pyramid transcends the scale of the single entity to target industry-wide regulatory issues. The base of the industry’s regulation pyramid is self-regulation, escalating to enforced self-regulation, to command regulation with discretionary punishment, and then to command regulation with non-discretionary punishment. An industry regulation pyramid for UK-TCM as motivated by the aim of developing in the UK can be seen in Figure 7.5. This pyramid is a very similar to that of Ayres and Braithwaite in their 1992 publication. Some examples found in UK-TCM regulation are shown as they correspond to each level of this pyramid.

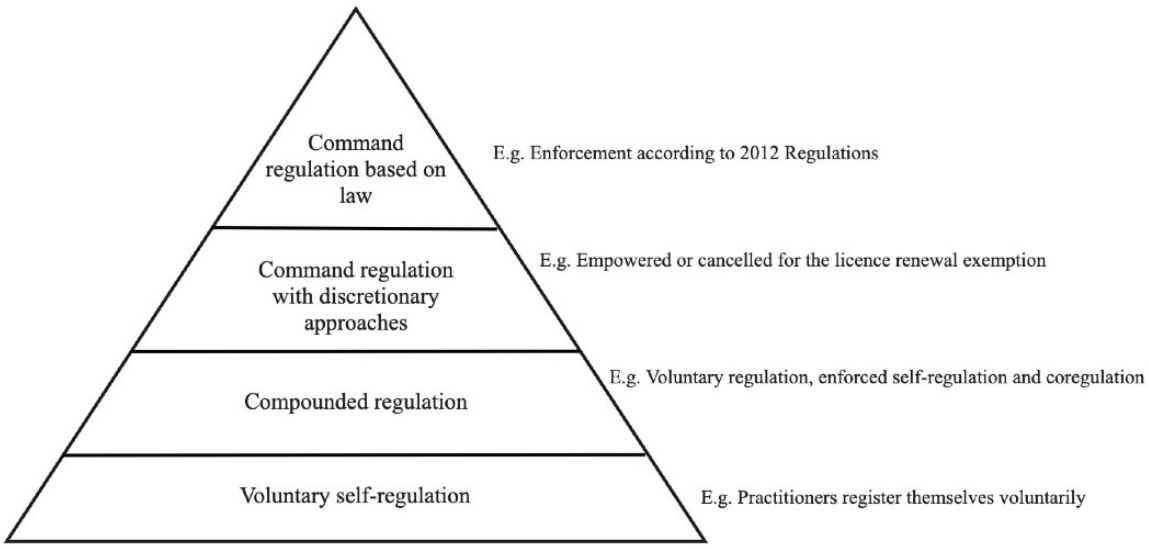


Figure 7.5 The regulation pyramid of the UK-TCM and some examples

The base level of this pyramid is that the current UK-TCM is under voluntary self-regulation. Although there are upper levels in the pyramid, these higher regulatory routes only cover parts of the TCM industry. Section 7.2 contains an explanation of how various actants gathered to form the TCM industry and maintained its operation according to their unwritten orders. This study has seen that the TCM associations regulate their registered practitioners, and connect with educators, TCM companies and product suppliers via partnerships or recommendations for placing UK-TCM under voluntary regulation. However, as noted under the discussion of the level two translation of ANT in Section 7.2.2, purely voluntary regulation was still considered insufficient to protect and benefit the public, and so more regulatory actants with their different regulatory approaches were later involved.

One role of the regulators is to keep the voluntary regulation of TCM consistent with legal requirements and ensure that the operations of the industry align with the regulatory goals. For example, TCM companies establish their own rules to operate the business and control their employed practitioners, and these rules are not completely disengaged from the restrictions set by the official regulators. Company owners still need to be aware and follow documentation, such as restrictions on animal and mineral ingredients, and request that their employees also obey these rules. This is explained later as enforced self-regulation. Also, each TCM association has its own mechanism for practitioner registration and the empowerment of practice certificates. Many practitioners preferred to be registered with associations that have strong management mechanisms and abilities, and which therefore are entrusted with an exemption of annual renewal of special treatment premises licence. These inner mechanisms are observed by the authorities (such as district councils, in this research). If the associations behave inappropriately, their exemption privileges are cancelled (see Section 5.2.2—the exemption of licence renewal of the FTCMP was withdrawn once because the association did not resolve medical accidents caused by its member properly). This is regarded as a manifestation of coregulation.

Similarly, inspections and changes to licence status conducted by the MHRA also show the close attention and intervention by official powers. As mentioned in Section 5.2.1, although the MHRA does not directly control issues such as product importation, it does inspect the products afterwards. Accordingly, the MHRA can revoke, suspend or vary licences and registrations. Besides these relatively free regulations, legal powers can also be identified in UK-TCM. Acts of parliament on herbal medicine can authorise highly deterrent sanctions (normally being found guilty of an offence, fined or imprisoned) if necessary.

7.2.2 Delegation

Delegation strategy in responsive regulation involves private actants who share regulatory tasks and functions at the same level within the market (see Section 2.2.2). Delegation mainly contains approaches of tripartism, mixed self-regulation and partial industry intervention, application of these approaches can be found in the UK-TCM.

(1) Tripartism

Ayres and Braithwaite considered that cooperation is much easier to achieve when the same inspector is repeatedly dealing with the same entity being regulated, or when the same regulator only manages a small number of regulated entities in a single industry. In such a situation, capture and corruption become a problem, and so tripartism is recommended by Ayres and Braithwaite as a solution. A PIG (public interest group) is a common form of tripartism, which normally works in three ways: 1) accessing information available to the regulators; 2) sitting at a negotiation table between the regulators and the regulated; and, 3) being empowered to work in a similar fashion as the regulators. No matter how the PIGs work, their basic effects are to punish directly the regulated or work as a mediator to punish the regulators who failed to modify their noncompliance. PIGs should be able to accelerate decision making, prevent conflict by leading the negotiation to a win-win solution, and help implement laws.

When selecting the PIGs, Ayres and Braithwaite considered the simplest model of tripartism is sufficient for a health-related industry in which a single PIG is selected by the State power. The selected PIG should compete to win the role as a third party in regulatory negotiation to accomplish its working task; within the PIG, actants should compete to become the PIG's representative. The performance of the PIG may be influenced by the personal preferences of its internal members, but this is not a problem as the essence of regulation is to understand the needs of as many participants as possible and to deliver a solution at reasonable cost to fulfil the wishes of all.

In this research, the TCM associations are considered a third party participating in regulation. The associations work by being empowered by the real regulators to work in a similar fashion as the regulators in the voluntarily regulated parts of UK-TCM. As is known from the level one analysis of ANT, the associations can coordinate the multiple stakeholders of the UK-TCM industry. Firstly, the associations set rules to select eligible education providers and product

suppliers. Secondly, the associations inspect the behaviours of the practitioners and their clinics. Most importantly, once medical accidents happen, the associations have a mechanism to deal with the possible aftermath to protect patients and punish practitioners. Also, as reported in the fieldwork data, the associations work to negotiate with the regulators by writing open letters or participating in official consultations.

Besides the associations, health professionals such as Prof BM and Mr MM, who participated in this research, were also seen to negotiate with or lobby the regulator and other influential people to strive for improvement in UK-TCM regulation. Compared with how the associations may depend on the personal willingness of their management groups, the health professionals work more independently to avoid unnecessary conflicts of interest. Correspondingly, the health professionals may not know about the TCM industry as deeply as the associations, which are entangled in the daily operation of the industry.

(2) Mixed self-regulation

Ayres and Braithwaite introduced enforced self-regulation as an intermediate approach between totally voluntary regulation and strong command regulation. Enforced self-regulation happens at the middle level of a regulatory pyramid, to avoid either unnecessary implementation of command law or the failure of a completely laissez-faire (free) market. The most common enforced self-regulation appears between the State and a single entity in an industry (such as an individual company). Each entity proposes its own regulatory standards under the request of the State, referring to its unique contexts and conditions. The entity making its own rules should spontaneously take up the related enforcement duties, costs and inspection jobs (such as forming an inspectorial group). During this process of making and applying the private rules in enforced self-regulation, actants such as the PIGs and formal regulators are also involved. The role of the regulators is to: approve the rules as consistent with the minimum legal requirements or reject weak ones; ensure the independence of the internal inspectorial groups and audit their efficiency and toughness; monitor those entities which are too weak to afford an inner compliance system; publicly enforce privately made rules; and, punish violations of private or public regulations. The PIGs comment on the proposed private rules, and are sometimes represented in the inspectorial groups of the regulated entities.

The organisational stakeholders within the UK-TCM industry, such as companies, clinics, and wholesale companies, all have their own operational rules. No regulations directly set rules to

regulate the daily activities of these entities. However, once problematic behaviours happen, regulators such as the MHRA act. In this regard, one case was found in the fieldwork data on the rules of using ingredients in medicinal products, according to the report of CP5 in Section 5.2.1. Although the MHRA does not control ingredient purchases and the use of each clinic, it does periodically check if restricted herbal ingredients are used by inspections and YCS reports, and can restrict product usage or remove products and publish the related information in a leaflet or fact sheet (see Table 1.9). TCM associations, such as PIGs, should also be involved in such issues, and TCM associations do inform their members of non-compliant behaviours and monitor the operations of member practitioners and corresponding clinics.

Besides the enforced self-regulation, Ayres and Braithwaite also mentioned a similar type of intermediate level of regulation: coregulation. While enforced self-regulation occurs between the regulators and a single entity, coregulation normally happens between the regulators and the industry associations which make the industry-wide rules ratified by the regulators. PIGs can also be involved in coregulation, when inspection and the role of a third party is needed in the regulatory mechanism.

Compared to enforced self-regulation, coregulation may be a more appropriate definition of the current UK-TCM regulation. Enforced self-regulation normally happens between specific councils and associations. As noted in the above analysis, the TCM associations set their own codes of conduct to regulate their member practitioners, but the implementation of the codes is under the inspection of local councils. On the other hand, the associations can also work as a PIG to approve and inspect the rules of lower-level entities such as the TCM clinics. If the behaviours of the clinics and their employees harm the patients, the associations take action to reveal non-compliant behaviours.

Ayres and Braithwaite also noted that the implementation of enforced self-regulation does not mean the elimination of voluntary self-regulation. The latter is still applicable in industries with less economic competition and potential to harm the public when chasing profit. In an industry which lacks the ability to confront the regulator, voluntary self-regulation is the cheapest option. Even though proposals to strengthen the regulation of TCM have been published, the overall UK-TCM is still voluntarily self-regulated. One feature seen in the TCM voluntary regulation is ‘learning’. TCM was classified in the 3a group of the 2000 Report, and so no requirement for regulation was made by the UK regulator, but the TCM industry learned from the regulatory route of other CAM therapies in being ‘recognised by the UK public’, performing practitioner

registration, providing insurance, and holding CPD programmes. These three representative regulatory approaches moulded TCM practitioners in a similar way as other healthcare practitioners in the UK. We can thus conclude that UK-TCM is under the synthesis of voluntary regulation, enforced self-regulation, and coregulation.

（3） Partial industry intervention

The three aforementioned forms of regulation (the pyramid, tripartism, and mixed self-regulation) all impose regulation in a binary situation; that is, the regulators control either all members of an industry or none. A fully regulated industry may breed corruption (the abuse of power for benefit)[98] and capture,[99] which impacts more on political decision making; an unregulated industry produces an oligopoly (a small group of large sellers)[100] or even a monopoly (a single seller).[101] Whichever situation occurs, consumers are likely to be harmed. Corruption leads to a long-term corrosive impact on economic growth, quality, quality of governance, and an institutional environment (Anti-Corruption Helpdesk, 2014); capture leads to a monopolistic structure supported by powerful interests (Hellman, Jones & Kaufmann, 2000); oligopoly leads to anti-competitive coordination and has negative welfare effects (such as one firm setting prices with other producers and harming the consumer) (OECD, 1999); and, a monopoly may make the prices of goods exceed a rational level (Miller, 2006). Ayres and Braithwaite thus suggested an alternative path, that of partial regulation, which controls part of the industry while leaving another part unregulated. As a result, competition happens inside the industry and can enhance public welfare by helping to produce competitive prices and prevent collusion between the regulators and the regulated.

Partial regulation also maintains a structure of ‘checks and balances’, with regulators driving the regulated entities which in turn affects the whole industry and ensures the compliance of the unregulated, because they are forced by competition to match the offers of the regulated. If, occasionally, regulatory failure happens (such as a mistaken or captured government decision), the unregulated entities are not affected by the mistaken regulatory decision or capture.

[98] Corruption is defined as the intentional misuse of (either public or private) power to gain someone’s own benefit (Bahoo, Alon & Floreani, 2020).
[99] Capture is widespread corruption, but it acts more on political structures in that corrupt actors influence the State’s decision-making process to pursue their private goals to the detriment of other public goods (Fazekas & Tóth, 2016).
[100] An oligopoly is a market form within which an industry is dominated by a small groups of powerful actors (Leahy & Neary, 2010).
[101] A monopoly is simply that one seller produces all the goods, and this seller can set both the prices and quantity of goods (Miller, 2006).

Moreover, the unregulated can act as a PIG to check whether capture happens and blow the whistle when necessary. Partial regulation is thus regarded as a useful tool for correcting various market failures.

A regulatory pattern similar to partial regulation has been identified in the UK-TCM industry. This partial regulation controls the activities and behaviours of some of the actants in the industry and leaves others uncontrolled, rather than imposing general regulations on the whole industry. An example of this is the market authorisation restrictions applied to medicinal products (in the UK this indicates THR under the 2005 Regulations).

Although the market authorisation requirements only target product licence applicants or holders (normally the manufacturers), this regulation also influences other stakeholders. Practitioners cannot prescribe medicinal products without a licence and this forced some (normally NCPs) to stop practising herbal medicine in favour of physical therapies (see the statement of NCPs 2, 4–5 in Section 5.1.2). There were other impacts: business owners reduced the scope of their service content (see Section 5.2.5); educators removed related information from their course design (see Section 5.2.3); wholesalers stopped importing these ingredients (see Section 5.2.4); and, the associations had to understand these regulatory requirements and set related standards or codes of conduct for their members (see Table 5.7). Also, once the legal status of a product changes, the licence holder should inform other stakeholders (including practitioners, patients, and retailers. See 7, Appendix 1). Another example is the restrictions on using animal, mineral or banned herbal ingredients. Paractitioners are the group affected most (see Section 5.1.5), but the other stakeholders are also affected, alongside the types of services provided by business owners, product importation, and the practice standards written by associations. In turn, this may impact patient safety as the practitioners have to use alternative ingredients without testing them (see how practitioners change restricted ingredients in Section 5.1.5).

7.2 The level of performance of the current UK-TCM regulation

7.2.1 The gap between the existing UK-TCM regulation and a well-operated responsive regulation

Gaps remain between the existing TCM regulatory system and the comprehensive responsive regulation suggested by Ayres and Braithwaite. The first gap is in the escalation strategy,

although the overall design of the UK-TCM regulation is moderately acceptable. Nielsen and Parker (2009) explained that desirable responsive regulation should prevent non-compliance in the future. The three lower levels of the TCM regulation enforcement pyramid (Figure 8.2-4) take quite soft approaches in announcing the existence of a regulatory mechanism and the potential for severe sanctions.

When analysing the details of the enforcement escalation, I selected the three examples of GMP, THR and the YCS because their pyramids are visible and describable; however, some other regulatory rules, such as the 1982 Parliament and 1991 and 2000 private acts, often omit stages which rise directly to legal sanctions without compromise. That said, the use of a TFT strategy has not been expanded to cover many detailed regulations in the TCM regulatory system. Most TCM-related activities are still regulated by rules with unreasonable concepts that roughly class these activities as legal or illegal. Among the three selected regulations, only GMP has a mature pyramid with both escalating and forgiving mechanisms; the pyramids of THR and the YCS only have uplifting mechanisms and lack an explanation of how sanctions can be de-escalated. Also, for the THR and YCS pyramids, although I have clarified the upwards process of the sanctions after investigation, the relevant laws and official introductions of these two regulations do not clearly indicate their severity. THR is the implementation of the 2005 Regulations and the 2012 Regulations, and thus the most serious sanctions (at the apex of the pyramid) punish being guilty of an offence with fines or even prison sentences. However, for the YCS, a single closely related law is missing to show the consequences of breaching legislation. Its official instruction juxtaposes the sanctions from warnings to the higher levels, and the removal of a product is only applied in rare circumstances; thus, this is at the apex of the pyramid. The designs of these two pyramids are therefore incomplete.

In addition, data obtained from the fieldwork reported loopholes with all three regulations when applied to TCM. No eligible TCM manufacturers or wholesalers were found in the GMP database, and the wholesaler interviewed in this research admitted that manufacturers in China cannot meet UK-GMP standards and so wholesalers seek alternatives when importing TCM products. No TCM proprietary medicines have a THR licence, but many products were still found in the market, as observed at the clinic, and some products are exempted in the 2012 Regulations. A limited number of reports concerning herbal medicines had been received by the YCS over the years, and the real situation is considered worse than the superficial data shown in the e-portfolio of the YCS.

As for the TCM regulatory pyramid (Figure 8.5), this is also acceptable. The base level voluntary self-regulation is solid and has been working smoothly for years to cover every aspect of the UK-TCM industry. However, when the pyramid escalates, there is no regime which involves all the stakeholders of the industry. Each regulation or legislation only partially regulates one or some aspects of UK-TCM. According to Sections 1.3.2, most regulations focus on safety and quality issues, especially of products. Also, the MHRA, the principal actant in the level two ANT analysis, only regulates some TCM products. The regulation of targets—efficacy, practice and practitioners—is insufficient. Once voluntary regulation fails, there is no command regulatory approach as a backup to continue to protect the public, and again there is no clearly defined forgiving mechanism.

More problems were seen in the delegation strategy used in the UK-TCM regulation. Ayres and Braithwaite had already identified the possibility that the PIGs would also be captured, but they considered that capturing both the regulators and the PIGs would cost much more than the benefit a business entity could achieve. The capture of PIGs is not likely to happen. However, as I noted, since the TCM associations are an appropriate third party, the capture may be easier than Ayres and Braithwaite believe. There are too many associations in the UK, and some smaller ones, as reported in fieldwork data, prioritise profit as their real goal. If one association uses low entry standards and unprofessional interviews to attract prospective members so that it can earn membership fees, it may also make other immoral deals for profit. Members of PIGs might also compete to be representatives, as the representatives sit at the negotiation table with the regulators; thus, separating the personal interests of the PIG representatives and the public interests to guarantee the fairness of the negotiation becomes a problem.

An example of this is that the member practitioners of the association BAcC were reported to enjoy certain privileges as their association has a closer friendship with the mainstream medical system. BAcC may thus be more attractive to some practitioners. A bigger association is also more likely to be selected as the lead parent. However, the extent to which they can perform as a PIG with little conflict of interest is uncertain. I have also suggested that health professionals could act as one PIG. Individuals such as Mr MM, who has been deeply involved in herbal medicine issues within the UK parliament, would seem to be a reasonable choice. Yet, the extent to which they can be involved in all aspects of the TCM industry is uncertain. It must be hard for a single person or small group to realise the demands of so many actants with respect to TCM regulation.

For the alternative types of self-regulation, I have already discussed the effectiveness of voluntary self-regulation and co-regulation. For enforced self-regulation, the example of regular inspection of special ingredients by the MHRA should work effectively. However, it is noticeable that the TCM industry involves multiple actants. The use of restricted ingredients is a globalised chain business from herbal planters and manufacturers in China, to international importers and wholesalers, to TCM companies and practitioners and single clinics. Whether the MHRA could inspect every entity in each node of this chain and immediately intervene when self-regulation fails remains unclear.

Lastly, for partial regulation, mutual containment among the different sectors of the TCM industry was seen. Once the regulator controls one sector of the industry, the other sectors of the industry are also impacted. However, the example given of the partial regulation of the different sectors of the TCM industry does not exactly relate to the thoughts of Ayres and Braithwaite, in that governments aims to accomplish regulatory goals by controlling one (or a few) firms to affect the competitive performance of the entire industry. Some of the TCM industry stakeholders found in this research (i.e., the TCM product manufacturers who must register their products) were regulated and others (i.e., practitioners wishing to prescribe these products) were impacted accordingly. No competition was found between these stakeholders from different business sectors. An ideal partial regulation should be implemented inside each business sector of the UK-TCM industry or collusion may occur inside the unregulated sectors. For example, although the manufacturers should have their products registered for use in the UK to prevent unregulated prescription of these products by practitioners and companies, the latter can still collude with product importers to escape the registration regulation and obtain the products they want.

7.2.2 Practical problems with responsive regulation and its implementation in TCM regulation

Problems can be seen with the escalation approaches applied to TCM regulation according to Section 2.2.2. These are summarised next. First, the spontaneous compliance with regulation mentioned by Baldwin and Black (2008) is seen in the UK-TCM. As analysed in the level one translation of ANT in Chapter 7, the various stakeholders of the TCM industry have a common goal to win a foothold in the UK. Despite the regulations causing obstacles for TCM practice in the UK, I have seen little resistance. For example, stakeholders yielded to the regulatory requirements of the banned ingredients, although the practitioners reported their need to use

animal and mineral ingredients (in Section 5.1.5), and BO1 explained the difference between the two types of mutong (in Section 5.2.5), in that both guan mutong and chuan mutong are prohibited). Thus, these stakeholders choose to align to continue to develop in the UK. In the same way, the Chinese custom of obeying the government can be detected in the continuous transformation of TCM according to the wishes of the Chinese government (in Section 6.2). However, such compliance may cause TCM to lose its cultural features and advantages and even cause potential safety problems, as described in Section 5.1.5.

Second, the weak over-generalisation of the role and components of the regulators and the regulated, as suggested by Baldwin and Black (2008), is also reflected in TCM regulation. While the MHRA reported that its function is to contact other regulators such as councils or Customs under the Borderline Section if necessary (see Section 5.2.1), the frequency of such contact and the definition of 'necessary' are unclear. As several regulators work independently, the regulated may feel confused about whom they should contact and what to listen to, especially when many of the regulated in the TCM industry are Chinese who have difficulties with English and understanding the social and political mechanism.

Third, the slow reaction towards the catastrophe of responsive regulation is seen in the case of Longdan Xiegan Wan (龙胆泻肝丸) (see Sections 4.1 and 5.1.4), in which a gradual and soft approach was unable to provide the necessary protection for the patients. Fourth, as I analysed before, the existing regulations cover parts of the UK-TCM world, but the support of the legislature for TCM regulation is insufficient. GMP has clearly introduced its de-escalation mechanism (forgiving process) (for the case of GMP, see Section 7.3.1, and GDP has the same de-escalation mechanism), but a proper de-escalation mechanism is not mentioned in other TCM regulations.

Problems are also seen in the delegation approaches of TCM regulation. Besides the possibility that the TCM associations as PIG may be captured as mentioned above (see Section 7.2.2) due to the defects of tripartism, the enforced self-regulation or co-regulation may also sometimes fail. As indicated in the introduction to this thesis, there are medical accident concerns and these regulatory approaches are unable to cover all the nodes of the TCM business chain. Due to the high demand for information from any industry when conducting partial regulation, the regulators are not likely to find sufficient information in a marginalised area like TCM.

Some resolutions have been proposed to the above problems. Baldwin and Black designed a

regime called ‘really responsive regulation’ that is responsive to the attitudinal settings of the regulated, the institutional environment, the interactions of regulatory strategies, and changes to all elements involved in the regulation. However, real responsive regulation itself has potential problems, such as the cost of designing and operating such a sensitive system, and thus better ways to regulate the UK-TCM need further discussion.

7.3 An evaluation of the UK-TCM regulation from broader perspectives

Table 8.1 was compiled according to information from these three major documents and other supplementary literature suggested in Section 2.2.3 and information given in Table 2.3 for the assessment of the performance of the UK-TCM regulatory system from a broader perspective. The regulatory approaches are listed according to their legal or regulatory resources, their positions in responsive regulation mode, their regulatory objectives, targeted regulatory problems, whether and the extent to which they addressed or improved the regulatory problems (non-attributional relationship between the regulatory approaches and their outcomes), and the reason why they resolved or not these problems (attributional relationship between the regulatory approaches and their outcomes).

Regulatory functions	Regulatory approach	Legal resource	Position in responsive regulation	Regulatory objective	Regulatory target	Improved or not	Improvement level	Reason for (non-)improvement
Products registration	Products registration	THR (guided by 2004 Directive, 2005 Regulations, 2012 Regulations)	Command regulation (undiscre..), but also partial regulation of the whole industry	Products	Safety, quality	✓	Very low	The industry knows about registration, but very few (almost no) TCM products have THR certificates, and many TCM products are exempted from regulation
Licensing	Manufacturing licence	2012 Regulations, GMP	Command regulation (undiscre..)	Products	Safety, quality	✘		Chinese manufacturers only have licence in China rather than in the UK
	Importer licence	Mentioned but not controlled by the 2005 Regulations	Command regulation (undiscre..)	Products	Safety, quality	✓	Low	Medical products are sometimes imported as other goods
	Retail licence	Mentioned but not controlled	Command regulation	Products	Safety	✘		TCM products are sold as combination of

		by the 2005 Regulations	(undiscre..)					clinic treatment rather than OTC in pharmacies
	Wholesaler licence	2005 Regulations	Command regulation (undiscre..)	Products	Safety	✓	Low	Same as importers
	Premises licence	2012 Regulation, 1982 Act, 1991 Act, 2000 Act	Command regulation (undiscre..)	Premises	Safety	✓	High	Premises for special skin treatment is regulated and regularly inspected
	Practice licence	Voluntary regulation, but also co-related by local authorities	Coregulation	Practice	Safety	✓	High	Only registered practitioner has the certificate for legal practice
	Practitioner licence	Voluntary regulation	Voluntary regulation	Practitioner	Safety, quality	✓	High	All practitioners registered
Inspection	Manufacturing inspection	GMP (guided by 2004 Directive)	Command regulation (discre..)	Products	Quality	✓	Middle	Chinese manufacturers attempted to comply

								GMP, but progress is limited
	Distribution inspection	GDP	Command regulation (discre..)	Products	Safety, quality	✓	Low	The hygiene and safety of distribution were reported but do not strictly follow GDP requirements
	ADRs inspection	YCS	Command regulation (discre..)	Products	Safety	✓	Middle	ADRs about herbal medicines were reported but the number was insufficient
Control in other aspects	Insurance	Voluntary regulation	Voluntary regulation	Practice	Safety	✓	High	All practitioners have insurance
	Advertisements	2012 Regulations	Command regulation (undiscre..)	Products	Safety	✘		Chaos caused by unregulated importation, and packages destroyed
	Prescription	Information from Department of	Enforced self-regulation, partial	Products, practice	Safety	✓	High	Animal, mineral and banned and restricted ingredients are no

		Environment, Food & Rural Affairs (2014) and Department for Business, Innovation & Skills (2012)	regulation					more in use
	Education and training	Voluntary regulation, information of General Medical Council	Voluntary regulation	Practitioner	Safety, quality, efficacy	✓	Middle	The short courses are not well recognised; CPD is good
	Information awareness	YCS, NHS website	Command regulation (discre..)	Products, practice	Safety	✓	High	Information is highly accessible

Table 7.3 The performance of the existing TCM regulatory system

Altogether 16 regulatory approaches (see the column on regulatory approaches in Table 8.1) were identified among the ten different regulations of the existing TCM regulatory system (see the column named legal resources in Table 8.1). Seven of the 16 regulatory approaches are at the highest level of the responsive regulation pyramid of the UK-TCM as command regulations with non-discretionary sanctions based on law to regulate products on premises; four stands at a slightly lower level of the pyramid as command regulations with discretionary sanctions imposed by the regulators to regulate products and practice; two restrictions on ingredients used in prescriptions and the practice certificate (licence renewal exemption) are at the third lowest level of the pyramid as compounded types of self-regulation of products; three, as well as parts of the practice certificate (for therapies besides acupuncture), are at the lowest pyramid level as voluntary regulation of practitioners and their practice (see the column named reason for (non-)improvement in Table 8.1). These 16 regulatory approaches are discussed according to their regulatory targets (see regulatory targets in Table 8.1), to: 1) determine if they have improved compliance with these targets (see column named improved or not in Table 8.1); and, 2) find the extent to which compliance has been improved (see column named improvement level in Table 8.1), and the reason for such improvement or why regulations have not improved compliance (see column named position in responsive regulation in Table 8.1).

Fifteen of the regulatory approaches were aimed at reducing problems with safety concerns. Three of these failed to make any improvement compared with the baseline of TCM set in this research, which means that the regulation of TCM manufacturing and retail licences as well as advertising controls remained unchanged from the old Chinese form or had moved away from the regulatory goals. One of these approaches, the THR registration, promoted only a very low level of improvement even though the TCM industry stakeholders were aware of regulatory requirements; none held a certificate and this situation is not likely to change soon as insufficient inspections were reported and some TCM products enjoyed the exemption privilege, and so TCM practice was not severely impacted by the THR requirements. Three of these safety-targeted approaches to medicine manufacture and distribution achieved little. The improvements in manufacture and distribution were caused by the wishes of the regulated to comply rather than the solid requirements of the regulations. Two approaches achieved mid-level improvement, as the reporting system of the YCS and the curriculum design of TCM education operate smoothly in their current form but need further improvement. The remaining five safety-targeted approaches improved from the TCM baseline to a highly satisfactory status.

All of the following are under effective regulation: the licensing of the premises of TCM clinics;

the registration of practitioners and their practice certificate; the insurance of TCM practice; the control of ingredients used in prescriptions; and, public access to TCM-related information. Regarding reduced quality concerns, the approaches of THR registration, distribution and education were assessed before as they are more or less also used as safety-targeted approaches. The manufacturing inspection procedure is barely acceptable. As is reported in the fieldwork data, the manufacturers in China wished to enlarge their market by exporting products to the UK, but restructure their manufacturing facilities would cost too much and thus many TCM products are imported to the UK under the name of other goods. The efficacy target of TCM was identified as being achieved through improving education. However, according to the TCM practitioners interviewed, they considered the current TCM education in the UK, which is mainly by short courses, to be insufficient from the perspective of the practitioners to provide highly effective healthcare.

7.4 Summary of findings in this chapter and a conclusive assessment of the existing TCM regulatory system in the UK

I have discussed how the baseline of the initial form of UK-TCM is a hybrid medical system involving both ancient Chinese culture and theories and modern biomedical knowledge and technologies. Although TCM transformed to suit international preferences and then transformed again to fit UK social and market demands, it has not been accepted by the UK mainstream medical system and thus is not statutorily regulated. As a result, TCM has become one of the many CAM therapies in the UK. To develop continuously in the UK, the people involved in TCM gradually formed an industry by which to operate it, from purchasing to importation and finally practice. This industrialised TCM is regarded as a stable network and has further attracted more patients. With this expansion, official powers became involved in guaranteeing that TCM would provide safe medicines, qualified practitioners, hygeian and safe premises, and effective practice. Several regulators and regulations participated in and then enlarged the UK-TCM network, thus structuring UK-TCM into a kind of responsive regulation mode.

To analyse the responsive regulation applied to TCM, both escalation and delegation strategies were discussed. The overall enforcement pyramid of TCM is well designed to take preventive approaches first, with the higher levels of sanctions existing as a backup to threaten those who do not comply. If non-compliance continues, the highest level of legal sanctions can be exercised. The single enforcement pyramid of GMP in TCM regulation works well, while the

other enforcement pyramids either escalate too sharply or do not clearly define the severity of their sanctions. The regulation pyramid of TCM has a strong base of voluntary self-regulation but, if this fails, the higher-level regulatory approaches can only control parts of the industry.

Some delegation strategies were identified in UK-TCM regulation, but further exploration of the delegating regulation is needed. One problem is the selection of a PIG which can participate in all three forms of delegation. If the TCM associations are selected as a PIG, they may be captured, while if the health professionals are selected, they may be restricted by the personal abilities. Besides these comments, the responsive regulation mode used in TCM regulation may face other practical problems such as the slow reaction of the pyramid in emergencies, the lack of eligible regulatory agencies, and costs, among others.

Further assessment of the existing TCM regulation was conducted based on the regulatory tool documentation produced by the OECD and WHO, and the WHO's TM strategy. Thirteen of the 16 regulatory approaches have improved UK-TCM compared to its baseline (see Figure 7.6). Six of the 13 were highly satisfactory at reducing the safety problems in TCM regulation. Three of the six were highly successful approaches contributed by voluntary self-regulation. Two of the 13 working approaches can be continuously improved in terms of the improvement of production facilities and modification of educational curricula. The remaining problems for consideration are centred around safety concerns, especially how to urge the regulated to abandon the loopholes they have found and to participate and comply with regulations.

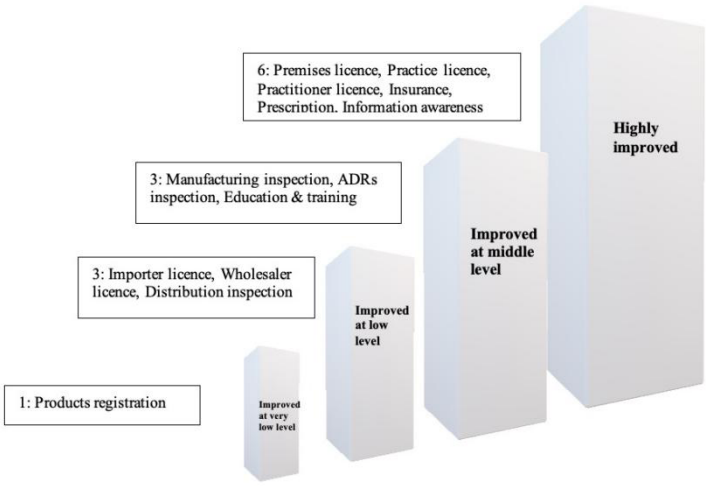


Figure 7.6 13 areas of the UK-TCM industry which have been improved by regulation

To conclude, the performance of the overall UK-TCM regulatory system is presented in an

overall escalation pyramid (see Figure 7.7), which lists the regulatory resources, concrete regulatory actions, regulatory objectives, and regulatory targets and problems seen in the implementation of regulation. A short general assessment is then provided.

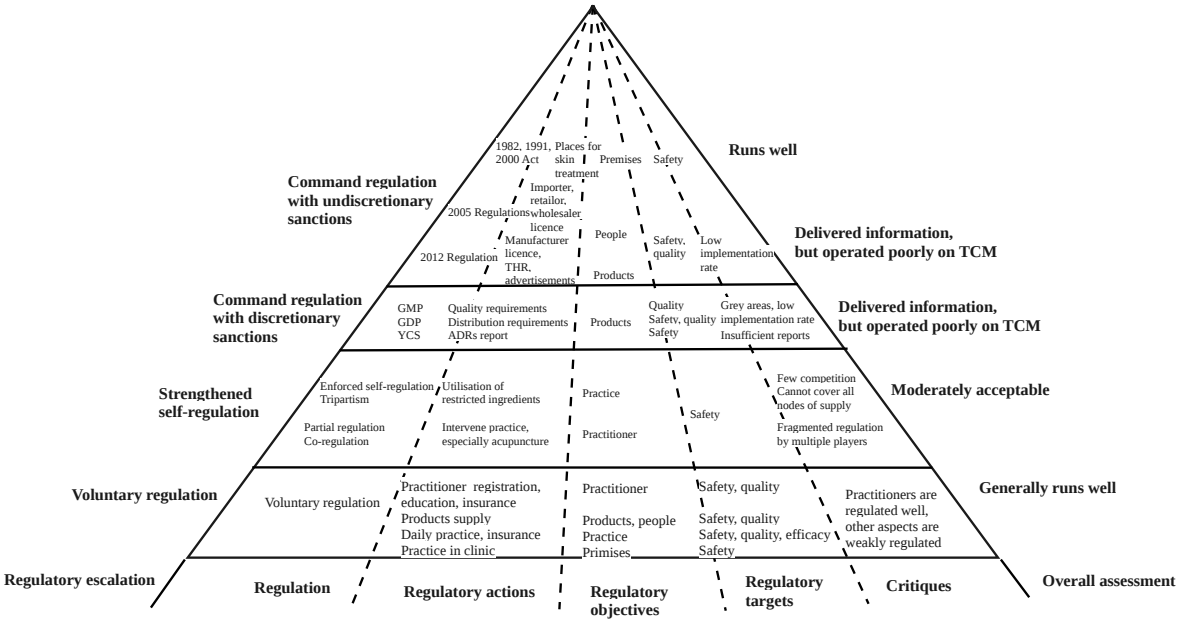


Figure 7.7 Assessment of the performance of the UK-TCM regulation

The overall performance of the base level of voluntary regulation is good. From the ANT analysis, the various stakeholders of the UK-TCM had a self-contained system to control issues related to the operation of TCM. The overall performance of the base level of voluntary regulation is good. The voluntary regulation initiated by the TCM industry naturally covers all aspects and participants of the industry. According to the results interpretation part of this research (especially Chapter 6) and Table 8.1, the functions of voluntary regulation related to practitioner management, including practitioner registration, related practice certificates and accompanying insurance (also related to practice) are highly praised for reducing safety risks and guaranteeing the identities of practitioners.

The education function is considered acceptable for reducing the safety problem and helping with the quality and efficacy of practice. However, the other people involved in TCM industry, such as manufacturers, importers, wholesalers and other staff in the clinic, are just in place to keep the TCM industry in operation. Voluntary regulation has paid much less attention to these people. Moreover, voluntary regulation has attempted to manage all aspects well, but the regulatory aspects of practice, products and premises were not frequently mentioned in fieldwork, and I believe that this voluntary regulation could not control these areas well; thus,

TCM regulation was thus escalated to a mixed type of strengthened self-regulation.

The regulatory strategies of tripartism, enforced self-regulation, coregulation and partial regulation were identified to control TCM practice and practitioners so as to reduce safety problems. Both partial regulation and enforced self-regulation serve to control the use of restricted ingredients well by adjusting the behaviours and business activities of other stakeholders. Similarly, what also works well is the coregulation to empower privilege of acupuncture practice and the associations working as a third party to intervene in the details of practice by setting entry standards, writing codes of conduct, and providing post-accident follow-up mechanisms. However, problems were also seen. For the ingredients regulation, the MHRA should cooperate with more regulatory actants to cover more nodes in the whole supply chain. The extent to which partial regulation is practically effective is uncertain as there is a lack competition between the regulated and unregulated. One large problem concerns the role of the councils and TCM associations. As is seen in the UK-TCM, the 'local authority' and 'association' are not just general concepts, but ones which are constituted by multiple different organisations and associations. In the fieldwork, the regulatory work of the local authorities and associations was reported to be fragmented, as each council and association has their own criteria for conducting practice-related regulatory work. For the associations particularly, these are considered a third party, and no inner representatives were found because 'everyone wants to be leader' (see Section 5.2.6); as such, captures may happen as each small association puts their own interests first.

Tougher but discretionary measurements were seen at a higher level of regulatory pyramid to control products and related people if applicable. GMP, GDP and the YCS are the representative regulations at this level. GMP is considered a strong regulatory approach for medicine quality in the literature, and it did inform the TCM industry on the quality requirements as they differ from TCM in China, particularly since the industry wishes to develop in the UK. However, there are loopholes when implementing GMP on TCM. The TCM manufacturers are in China and do not want to change their production mode for cost considerations; the importers, wholesalers and TCM company owners thus seek grey areas to sell and use products at odds with GMP, as 'no one really inspects' (see Section 5.2.4). The related licences of these people are unverifiable. The MHRA has various inspection means, but it is Customs which in fact controls imports. GDP was assessed as being of little contribution in both the literature and in practice, according to the findings of this research. Little fieldwork data reported attention to GDP from the TCM stakeholders. One TCM business owner mentioned his wish to control

product transportation (see Section 5.2.5), but no concrete progress was seen. The performance of these two regulations on quality issues was considered unsatisfactory.

The YCS was evaluated as an effective information checking system in the literature. A large number of reports were found when I searched for them, meaning that pharmacovigilance information is well delivered. However, as reported by the MHRA, the numbers of ADR reports related to herbal medicine must indeed be lower than the actual situation. When I was searching and checking the work in the YCS portfolio, I found the existing information on ADR reports to be too general. The extent to which these received reports relate to TCM is unknown, since: 1) TCM may use another name in the database (e.g., in Chinese pinyin or hanzi) for the ingredients rather than the botanical name; 2) TCM only uses some parts, such as the seeds or leaves, of the herb/plant as medicine; or, 3) TCM only uses one or more species of the herb/ plant. The observation data also identified readymade small batch of medicines, medicines without proper packaging, and complex remedies with too many ingredients. Access to safety information for TCM needs improvement. Also, the ADRs of some ingredients were reported even in 2020 and 2021, suggesting the enforcement may not work so effectively.

The highest level of TCM regulatory control is still for products and premises. The regulations at this level involve deterrent sanctions based on law. The 1982 Act, 1991 Act and the 2000 Act controlling the premises of acupuncture practices have not been assessed in the literature but were highly praised in the fieldwork as fully in control of the safety and quality concerns of TCM clinics, although I came across problems when requesting detailed information from the local council. The two regulations concerning the safety of TCM products were praised in the literature. The 2005 Regulations on medical products were assessed as being influential on all aspects of the pharmaceutical industry, and the 2012 Regulations (guided by the 2004 Directive) were assessed by one reference as covering many medicinal aspects. As is seen this research, the 2005 Regulations controlling the import and wholesale licences set requirements for the related stakeholders, but due to the difficulties of applying UK-GMP on products from China and the chaos of inspection, the actual implementation of the 2005 Regulations is ineffective.

According to the information obtained in this research, the 2004 Directive, 2005 Regulations and 2012 Regulations controlling herbal medicine registration (THR) provided legal requirements for the related stakeholders, but the implementation of THR on TCM is extremely unsatisfactory. Although some stakeholders may face issues due to the lack of market

authorisation (see Section 5.2.4 and 5.2.5), this situation is unlikely to change soon. The stakeholders, due to their consideration of saving money and the fact that no TCM products fulfil the 30 years' use history, seek loopholes for selling proprietary medicines by using old storage, destroying packages, or claiming fake classifications for medicinal products. No TCM products in the UK market hold a THR certificate. The regulators are not taking any action to plug the loopholes in importing due to the uncertain connection between the MHRA and the UK Customs. Stakeholders such as practitioners have not rushed to change the situation either. For the CPs, they can still practise individually prescribing herbal remedies that are exempt from the 2012 Regulations. For the NCPs, herbal medicine is not the only therapy they practise, and so they can switch to acupuncture. Moreover, no improvements in the safety concerns over the manufacturing licence (2012 Regulations), retail licence (2005 Regulations) and advertisement requirement (2012 Regulations) were seen in the UK-TCM compared to its baseline.

Referring to the research aim, the extent to which the regulatory system ensures the rights and benefits of the public when using TCM is answered. The regulations ensuring eligible premises work best with a high level of compliance and no obvious critique. The performance of the regulations ensuring qualified practitioners are considered suboptimal with problems remaining in the quality of outcomes of short courses. The work of the regulations ensuring adequate practice is moderately acceptable because there are too many actants with different standards to intervene TCM practice. The regulations related to practice are actually fragmented. The regulations to guarantee the safety of TCM products are considered problematic. Although the overall regulatory controlling the UK medical products were assessed as comprehensive and contributory, delivery of these regulations to the UK-TCM industry was unsuccessful. Loopholes and grey areas were found. The number of harm reports was underestimated; the inspection conducted by a single department was somehow barely able to cover all nodes of the TCM products supply, sale and utilisation chain; also, some TCM products are under exemption and a THR licence is less necessary to TCM.

Chapter 8 Concerns for discussion and further exploration

In the results chapters, answers to the research questions were presented concerning how TCM has developed in the UK, what the relevant regulations are, and how the regulations have impacted UK-TCM. The chapters in the analysis part discussed the process of how TCM has transformed into its current UK situation, the rationality of forming a networked TCM world, and an assessment of the performance of the existing UK-TCM regulatory system. During the analysis, loopholes were identified in the regulatory system, mainly indicating the chaos for product importation, and the possibility of using TCM to expand health coverage to immigrants.

This chapter first focuses on the appearance of these loopholes and the possibility of plugging them, before considering the TCM health needs of Chinese immigrants and making the case for necessary access to TCM. Considering these two points of discussion and the previous comments on the performance of the existing TCM regulatory system, the suggestions are also made on the further development of the regulatory system by transforming it into a networked responsive regulation with more regulatory actants which can share the huge and complex task of regulation.

8.1 A comparison of UK regulations for medicine, herbal medicine, food and cosmetics

One big loophole in TCM regulation found in this study is the way some TCM products enter the UK. As reported in Section 5.2.5, some TCM products enter the UK as food (those taken orally) or cosmetics (those used externally). In this section, the regulations for importing and using food and cosmetics in the UK market are compare with the regulations related to importation and utilisation of medicines and herbal medicines, to explore if there are grey areas which could be utilised for the importing of TCM products. Some regulations were amended after Brexit. These amendments are applied in the UK, with the exception of Northern Ireland (NI) which still follows the EU rules. However, since the amendments do not distinguish clearly between the situations in the UK and NI, this section also contains a discussion of the common regulatory situations for medical products, food, and cosmetics in the UK. These regulations are discussed according to definitions of products, importation requirements, safety requirements, and enforcement measures (see Appendix V, and summarised in Table 9.1).

Type	Medical products	Herbal medicine	Food	Cosmetics
Definition	Proprietary products: ready-made, under special name, in special pack. Medical product: substance(s) for treating or preventing diseases, making diagnosis or restoring, correcting or modifying physiological functions for human or animal. Exclude human (blood) component. (Human Medicines Regulation 2012) Substance: can be originated from human, animal, vegetable, chemical. (Council Directive 65/65/EEC) Homeopathic medical products: according to the European Pharmacopeia or other member stated pharmacopoeias. (Council Directive 92/73/EEC)	Traditional herbal medicinal products: use without supervision of practitioner for diagnosis, prescription or monitoring; with strength and posology; oral, external, inhalation; with sufficient evidence; fulfil the traditional use, but can supply under authorisation or supply when ingredients reduced. Herbal medicinal product: herbal ingredients as active substance. Herbal substances: whole, fragmented, cut plants, plants parts, algae, fungi, lichen in unprocessed form, not for specific treatment. Herbal preparations: subjecting herbal substances to treatment to be other forms, i.e. extraction, distillation and etc.. (EU Directive 2004/24/EC, Human Medicines Regulation 2012)	Food: for human ingestion/ includes water and chewing gum/ excludes feed/ live animal/ live plant, exclude narcotic or psychotropic substances, control residues and containments. [Regulation (EC) 178/2002]. Food supplement: to supplement normal diet, with nutritional or physiological effect, not intended treat or prevent diseases (EU Food Directive 2002). Herbs and spices: advices from Health Protection Agency, but no legal clarification (FSA). Novel food: not used by large number of people in the EU before 15 May 1997 (Regulation 2015/2283).	Have the functions of: clean/ perfume/ change the appearance/ protect/ keep in good condition/ correct body odours; Apply in: epidermis/ hair/ nails/ lips/ external genital organs/ teeth/ mucous membranes of oral cavity; In permitted form (Appendix 4), such as cream/ emulsions/ lotion/ oil/ gel/ tinted bases (liquids, pastes, powders)/ hair products [The Regulation (EC) No 1223/2009]
Importation requirements	Comply with GMP, the active substances should be used as staring material and should also comply with GMP. (Human Medicines Regulation 2012)	Traditional herbal medicinal products: comply with THR requirements (2012 Regulations), and other provision (2005 Regulations); Other herbal medicinal products: following the UK custom importing goods procedure with special procedure with regulated labels (gov.uk, 2012).	Comply with Community Law (178/2002 Regulation), or importing food supplements and health foods, or importing herbs and spices (FSA). Selling food should register as a Food Business Operator (FBO). Novel food could apply as a general novel food or through traditional food notification (2015/ 2283 Regulation)	Comply with the UK (EU) safety requirement (including importer as responsible person), fulfil the safety assessment and related test, fulfil the labelling requirements, register with the Cosmetic Products Notification Portal (CPNP) (1223/2009 Regulation).

Safety requirements	Acceptable safety: advantages>disadvantages, good>harm for most people, acceptable side effects (House of Lords, 2019)	THR certificate: long-term of use to guarantee the herbal medicines are not harmful	Food: not unsafe, not injure health, comply with community provisions (178/2002 Regulation). Food supplement: comply with labelling requirements (2003 Food Supplements Regulations). Novel food: scientific/ historical safety data, as safe as the ones in market, not harmful than the previous ones to be replaced (2015/2284 Regulation)	Safety for use, not confused with food, responsible person ensures compliance, comply with GMP (1223/2009 Regulation, 2019 Regulations).
Enforcement	Infringement notices, guilty of an offence when breaching a provision or pharmacovigilance regulations, misleading information, penalties apply (2012 Regulations)	Non-compliance with the THR, labelling, advertisement cause guilty of an offence, fine or imprison (2012 Regulations and other regulations in Appendix II).	Guilty of an offence when rendering harmful substances, violating demand nature, falsely describe (Food Safety Act 1990). Notices and orders of hygiene regulation, guilty of an offence with fine or imprison (2013 Regulations). Penalty rules exist (2015/2283 Regulation)	Competent authority makes responsible person ensure the compliance, takes action to prevent further distribution, informs other authorities, follows GAP procedure, takes provisional actions (2019 Regulations).

Table 8.1 General regulations of medicine, herbal medicine, food and cosmetics in the UK

8.1.1 Definitions of herbal medicines, food and cosmetics

The definition of medical products, including proprietary medicine, medical products and medical substances, was identified through the *Council Directive 65/65/EEC* and the 2012 Regulations. The definition of homeopathic products was identified in the *Council Directive 92/73/EEC*. According to these regulations, medical products should be used to diagnose, prevent or treat symptoms, and they can originate from various substances. The definition of herbal products, including traditional herbal medicinal products, herbal medicinal products, herbal substances, and herbal products, was identified through the 2004 Directive and the 2012 Regulations (see Section 1.3.1 and Appendix II). According to these regulations, herbal products should include herbal substances as active ingredients to treat symptoms under the guidance of practitioners or for other use, rather than treating specific diseases. As traditional herbal medicinal products must be supplied to the market with sufficient evidence and under

authorisation, TCM products should be classified as herbal medicinal products.

Although the UK left the EU, many regulations concerning food safety have been retained. Among these, Regulation 178/2002 (see Appendix V) set the definition of food based on non-animal origin. Food as a broad concept is constituted of various substances and appears in different forms, but anything defined as food should not have medical effects. Within the UK regulatory scope of food, the sub-classification of food supplements, herbs and spices, and novel food was identified. These sub-level definitions all include oral products originating from herbs or plants, and they overlap with the definitions of herbal medicinal products/substances/preparations, which also originate from plants and do not have medical effects. The gov.uk (2021) admitted there is no clear boundary between some medicines, especially herbal medicines, in contrast with food supplements in the guidance notes on legislation implementing Directive 2002 on food supplements. The manufacturers or importers should consult the MHRA for ultimate explanations of the category of a product. The FSA (2020) indicated in their web information on importing herbs and spices that UK law does not define standards for spices. Although the FSA (2020) recommended a list of common culinary herbs and spices for cooking as used in Europe compiled by the Seasoning and Spice Association (2013), this list has no legal or regulatory effect, is not comprehensive, and has not been updated since 2021.

In some Asian grocery markets, herbal medicinal products and spices are displayed on the same shelves (according to fieldwork data, see Figure 9.1.2). 'Novel food' is an even more confusing concept as so many kinds of food were used in the UK or EU before 1997, with the impact of globalisation. The Commission Implementing Regulation (EU) 2017/2470 has provided an EU list of novel food according to the rules set by the 2015/2283 Regulation. On this list, authorised novel food, including Crataegus pinnatifida (Shanzha, 山楂) in dried fruit form, Lippia citriodora (Gouqi, 枸杞) in dried extract form, and Medicago sativa (Muxu, 苜蓿) in lucerne leaf extract form, are also used in TCM as medical ingredients (*PRC Pharmacopeia,* Li , Ming).

The definition of cosmetics was identified through Regulation (EC) No 1223/2009, which regulates the function, application area, and form of cosmetics. According to the definitions in the 1223/2009 Regulation, externally used TCM products somehow overlap cosmetics. These products fulfil the functions of changing the appearance of body parts and protecting and keeping body parts in good condition; they can be applied to the epidermis, external genitals, hair, and mucous membranes of the oral cavity. They normally appear as creams, emulsions,

lotions, oils, gels and tinted bases.

8.1.2 Importation, sales and utilisation procedures of different goods

The importing of raw herbs or the extracted herbal powders such as those seen in the fieldwork clinic should be unproblematic if the importers comply with the 2012 Regulations (see Section 1.3.1) and follow UK customs procedures (gov.uk, n.d.b). Importation issues mainly concern proprietary medicines from China. As discussed in the previous chapters, few Chinese proprietary medicines comply with UK GMP or GDP requirements, and nor do they hold THR certificates (see Section 5.2.4 and 5.2.5). As such, there is a possibility that some enter the UK as food or cosmetics.

The importation of most food stuffs falls under Regulation (EC) No. 178/2002 (see Appendix 4) and requires that the imported food is compliant with the UK domestic safety regulations in being 'not unsafe' and 'not harmful for people's health'. As for the importation of food supplements, the Food Supplements Regulation 2003 (see Appendix V) requires that most types of food supplement comply with labelling requirements. Such requirements seem to be softer and easier to fulfil compared with the GMP and THR requirements for medicines. For some special types of food, Regulation (EU) 2015/2283 of the EU Parliament and of the Council control the operation of novel food, and Regulation 2019/1793 controls the importation of special foods (see Appendix V).

To obtain authorisation in the UK, the 2015/2283 Regulation permits two routes: 1) general application or 2) traditional food notification for novel food from third countries.
At the same time, increased controls affect high risk food imports from China. The 2019 Regulations manage foods from certain places into the EU, to check pesticide residues in tea and goji berries (wolfberries) (Lycium barbarun L.), control salmonella in sweet peppers (Capsicum annuum), and control aflatoxins in groundnut and its related products. Besides the 2019 Regulations, the Retained Commission Decision 2011/884/EC specifically controls the contaminants of genetically modified organisms in sauces and preparations, mixed condiments, and seasonings. These foods can only be imported through assigned Border Control Points (FSA, 2021)[102] and need to be lab tested to check the level of aflatoxin and pesticide. The

[102] Also referred to as UK Border Control Posts (BCP) and previously as Border Inspection Posts (BIP) (Animal and Plant Health Agency and Department for Environment, Food & Rural Affairs, 2019), which includes ports, airports and harbours where imported products are checked.

existing EU list of approved novel foods authorises Crataegus pinnatifida (Shanzha, 山楂) in dried fruit form, Lippia citriodora (Gouqi, 枸杞) as a dried extract, and Medicago sativa (Muxu, 苜蓿) in lucerne leaf extract form for the UK market. For other special foods found in this research (see Section 5.2.4) , BO1 stated that controlling and reducing contaminants is still easier and cheaper than restructure the manufacturing facilities of medicines in China.

Regarding cosmetics in the UK market, whether made or sold by companies or individuals, these must comply with *EU Cosmetic Products Regulation 1223/2009 (CPR)* as amended by the UK Product Safety and Metrology Regulation 2019 and applied in GB. The regulations for importation and safe use of cosmetics in the UK are stronger than those on food. Cosmetics importers are normally marked as responsible persons under the requirements of the 1223/2009 Regulation and 2019 Regulation, and the responsible person should ensure that the cosmetics fulfil the standards of the safety assessment and related tests, comply with the labelling requirements, and are registered with the Cosmetic Products Notification Portal (CPNP). Cosmetics for the GB market should comply with cosmetic GMP and daily use cosmetics should not be confused by the public with food.

From the perspective of legal enforcement, regulations impose corresponding enforcement upon medicines, herbal medicines, foods, or cosmetics. The 2012 Regulations set provisional actions towards non-compliant activities, such as sending notices and sentencing offences with penalties for medicines breaching provisions, as well as setting pharmacovigilance regulations, information, and labelling requirements (see Section 1.3.2). The 2012 Regulations can apply penalties up to imprisonment for non-compliance concerning traditional herbal medicinal products breaching the requirements of THR, labelling, and advertisements (see Section 1.3.2). There are also inspections and related enforcement of GMP, GDP and other regulations, as discussed in Section 1.3.2 on herbal medicines.

The Food Safety Act 1990 sets the following behaviours as offences: rendering harmful substances in making food; selling food violating its required nature; falsely describing or presenting food; and, other offences causes by unexpected harmful consequences after the consumption of food. *The Food Safety and Hygiene Regulations 2013* set a series of reactions for breaches of food hygiene regulations. These include: hygiene improvement notices stating non-compliance with hygiene regulations, requiring improvement within 14 days; hygiene prohibition orders imposed by the court; hygiene emergency prohibition notices and orders; and, remedial action notices and detention notices.

Also, the 2013 Regulations can impose fines or prison sentences for other food regulation related non-compliance. The 2015 Regulation on novel food enables the government to set penalty rules for possible non-compliance. As for cosmetics, *the Cosmetic Products Enforcement Regulation 2013* prohibits: the supplement of cosmetics causing damage to humans under appropriate use; the use of some substances in Annex II of 1223/2009 Regulation; the use of specified risk material, i.e., products derived from certain animals carrying a risk of BSE. It also restricts the use of certain substances, e.g., fragrances, colouring agents, and UV filters. Moreover, cosmetics are required to have specific labels and information held by the responsible person; otherwise, the authorities can take measures to withdraw or recall products and prevent their further distribution.

To summarise, there are loopholes by which TCM products could be declared as other products so that they can enter the UK and avoid the evidence requirement of THR. First, the definition of oral TCM products is easily confused with food, food supplements, and some novel foods if these products are non-animal in origin and containing unrestricted substances, as well as not claiming to have medical effects. Also, external use TCM products are somehow conflated with cosmetics as they fulfil the functions of changing the appearance of body parts, and protecting and maintaining various body parts through the application of creams, emulsions, lotions, oils, gels and tinted bases to the epidermis, external genital organs, the hair, and the mucous membranes of the oral cavity. Second, the TCM business owners in this research reported declaring TCM products as food to take advantage of a simpler importation route, because controlling contaminants is easier than remodelling manufacturing facilities built in China. However, although there is a requirement in the UK to register food business (FSA, 2018), the proportion of TCM product importers holding such registration is unclear.[103] Similarly for the importation of cosmetics, the rate of TCM products importers registering with the CPNP is unclear.

Moreover, as is summarised in the previous chapters, many TCM products are self-regulated or unregulated by the existing regulatory system; the issues here are not only that the relevant rules fail to cover comprehensively all aspects of TCM practice, but that the system receives very limited inspectorial feedback. When considering the enforcements made with food and cosmetics laws, incorrect declarations on product types may place TCM in a harder position if

[103] At least, the six TCM suppliers listed in Table 5.2.4 and discussed in 5.2.4, Chapter 5, were not found in the list of Approved Food Establishment until March, 2002 (FSA, 2002).

tougher regulatory enforcement arises. That said, there is the possibility that loopholes in regulations can be exploited by declaring TCM products as food or cosmetics, but such declarations may involve multifarious procedures and place TCM products under even tougher controls. The necessity of and advantages to declaring TCM products as other products are not obvious, and the actual rate of doing so needs further exploration. In addition, the TCM business owners reported in Chapter 6 that TCM products are sometimes imported only in small amounts and pass through customs by luck. Such close shaves relate more to the work and responsibility of the UK customs, and further contact and cooperation between the customs and health department to prevent small scale non-compliance is expected.

8.2 Immigrants' health needs

A second consideration for the current TCM regulatory system should be how this system protects the health demands of immigrants, both documented and undocumented. Although the UK NHS provides free healthcare services, there are still many visitors to the TCM clinic. Chapter 4 has identified that most visitors to the clinic were ethnic Chinese, and analysed in Chapter 7 that these visitors use TCM to supplement the mainstream healthcare. Nevertheless, some of these patients use TCM because of their unfamiliarity with the UK health system or the long waits caused by the heavy load on the NHS (O'Dowd, 2021). The vast percentage of Chinese use TCM because of their cultural habits, such as for customary regimens, special diets for illness, and care for the aged. As the WHO (2013) explained in its 2014–2023 TCM strategy, TM concerns types of healthcare close to people's homes and this TM is culturally acceptable and reliable. The WHO (2013) emphasised culture as an important factor influencing healthcare options, and thus the regulation of TM should consider cultural beliefs in TM.

Besides, problems caused by Chinese culture exist with the provision of high quality TCM treatment, such as: practitioners' insistence on using Chinese theories (without an accurate English translation see Section 4.1) rather than there being an evidence base for their treatment; a lack of coordination between the PRC Pharmacopoeia; the habits of CPs; and, the names of herbs used in the UK (i.e., in the YCS database, see Table 4.3) leading to a misunderstanding of the names of the herbs in English. Therefore, it is necessary to balance the requirements of TCM practice between inserting Western scientific medical standards and retaining the traditional cultural elements.

Moreover, TCM provides access to healthcare for undocumented Chinese immigrants and, in

so doing, provides a valuable service for them (Legido-Quigley et al., 2019). The undocumented immigrants had mostly come to the UK with the aspiration of earning money in a more developed place and then taking their wealth home to China (Zhuang, 2006). Such an opportunity is attractive but comes with well documented health risks for illegal immigrants (Bakhtiari, 2018). They go back to the very beginning of the immigration process. Some diseases are inherent problems specific to a group of people, such as the high prevalence of hepatitis B and tuberculosis among Chinese (Liu et al., 2019; WHO, 2020). However, many illegal immigrants use fake documents on their journey to avoid being examined for certain health conditions before their visa application,[104] so that their original health problems were not discovered. Alternatively, they switched from one country to another. Such migrants are discussed by Bloch, Sigona and Zetter (2009), who found that they travelled to Romania, Germany and finally the UK. During their journeys, they travelled over long distances in crude vehicles and stayed in poor accommodation, often changing companions; these are all risk factors for illness.

Their working environment could additionally exacerbate this situation. When these immigrants came to the UK, they worked in labour-intensive industries such as restaurants, massage parlours, and manicure stores. Long working hours are common among undocumented immigrants, and workload relates to pathologies. Although they may work diligently, illegal workers are not covered by the employment law to obtain overtime pay (Bloch, Sigona & Zetter 2009). Under this situation but without appropriate insurance, the unducomentted immigrants have high demand using TCM. However, TCM services are limited compared with UK mainstream medicine. The health of undocumented immigrants is not guaranteed and their health problems, e.g., communicable diseases, may impact the health status of non-immigrants (Castañeda et al., 2015).

In relation to the health needs of Chinese immigrants, as well as the involvement of UK customers in the development of UK-TCM, it can be suggested that patients' needs and actions affect the operation of the medical industry; these patients also play important roles in the network of health regulations (Zavestoski et al., 2004). In some cases, patients hope to self-diagnose problems and negotiate the diagnosis and treatment with health professionals. Once they are dissatisfied with the diagnosis of their customary health service provider, they may seek help from alternative medical sources. Davis and Abraham (2011) emphasised the

[104] According to web information on tuberculosis tests for visa applicants, people who apply for a short stay visa of less than six months (such as a travel visa) do not need tests for tuberculosis.

importance of patients as free market consumers whose perspectives and wishes drive regulatory change. Early Chinese immigrants brought TCM with them, helped it become established in the UK, and were themselves the consumers of TCM products and healthcare services. Later, when official controls began to impact TCM, people expressed the will to become involved in health regulation, especially when government policies do not meet public expectations on access to health (Vahdat, et al., 2014).

The TCM market and its contribution to health coverage should be recognised and, thus, policymakers should guarantee access to such medical services as an approach to improving health coverage. Referring to the data collected in the results sections of this thesis, some suggestions from the industry and the public offer advice on the future regulation of TCM, to allow it to develop sustainably in the UK and provide access to those in need of its services. To keep supporting TCM and help it grow further in the UK, TCM business owners suggested easing some restrictions on applying for working visa sponsorship and providing working visas to TCM practitioners from China. The announcement of the Migration Advisory Committee (2012) in the report titled 'Limit on Tier 2 (General) for 2012/13 and Associated Policies' increased the skill requirements for working in the UK, and the current sponsor licence system seems to be complex and costly for the TCM business owners, as they reported that the TCM market is shrinking. They are expecting the UK government to lower the immigration points requirement for TCM practitioners and reduce the sponsor licence application fee, so that more and younger TCM practitioners can be hired from China. If the working visa system does not change, the TCM practitioners who participated in this research suggested improving the TCM education quality to train practitioners with a more standardised perspective to fill future career vacancies.

Then, to enlarge access to TCM services, the practitioners and questionnaire respondents appealed for wider health insurance coverage. A list found on the ATCM (2015) website contains nine private health insurance companies who recognise the services provided by ATCM-registered practitioners, including Simplyhealth, Medisure, and Sovereign Healthcare and etc.. Some other health insurance companies (such as AXA and BUPA[105]) recognise members of BAcC (n.d.b) but only for acupuncture treatment, while others, such as Aviva (aviva.co.uk, n.d.)[38], need GP referral just for acupuncture. The different polices of insurance coverage for TCM may cause problems for patients, such that they might not choose the

[105] When searching online for 'best/ biggest health insurance company in the UK' these companies are listed. The insurance recommended by ATCM, however, was not shown in the search results.

practitioner they prefer if there is no insurance coverage.

8.3 Possible ways to improve the regulatory system

The previous chapters suggest that several problems exist in the current UK-TCM regulatory system, which are presented as follows: 1) fragmented coregulation that each TCM association and local authority follow their own standards and working mechanisms; 2) poor execution of superior command regulation (e.g., GMP and YCS with a low rate of coverage on TCM products); 3) regulations with command sanctions (e.g., THR) tackled the issue of TCM, whereas loopholes were found. Improvements of the existing regulatory system are expected, and the health demands of the public should be considered, and the access to TCM should be ensured. Next, this section suggests the possible route to optimize the current UK-TCM regulatory system with the concerns above. Braithwaite (2017) extended the proposed responsive regulation concept by developing and classifying different types of responsiveness, and the networked and nodal responsiveness (N&NR) are considered to be applicable to the UK-TCM. Braithwaite (2017) explained that networks have superior coordination and complexity management capabilities when a former regulator lacks power to get all things under control; nodes are actants within a network or organisational products to some networks which are tied together for a united purpose. Subsequently, N&NR concept place a focus on the role of nodes to connect networks to create concentrations of power to exercise governance (Drahos, 2004). The present section will start from the discussion of feasibility of networked regulation based on the Drahos (2007)'s research to gain an easier insight into the application of N&NR in the UK-TCM regulation.

Drahos (2007) suggested that soft regulatory mode, such as agreement (treaty), is considered more appropriate for an area without sufficient scientific measurements. The UK-TCM industry is voluntarily self-regulated under the coordination of stakeholders. Along with the increasing use and development of TCM, simple self-regulation may lack robust capacities and power to control the entire TCM field. Subsequently, this research suggested that official regulatory actants are involved to form a classic regulation pyramid (see Figure 8.5). However, the upper-level work of this pyramid is a fragment that the respective regulator can only take charge of one or some aspects of TCM practice. The current regulatory pyramid is a dendriform pattern, whereas it is not an ideal triangle shape (Figure 8.1). Also, this research found that the monitoring mainly taken by the MHRA on TCM industry stakeholders' compliance is not strong and sufficient, and the industry stakeholders sometimes seize grey areas to escape from

legal responsibility. From Drahos (2007)'s perspective, the fragmented regulation is caused by insufficient regulatory capacity.

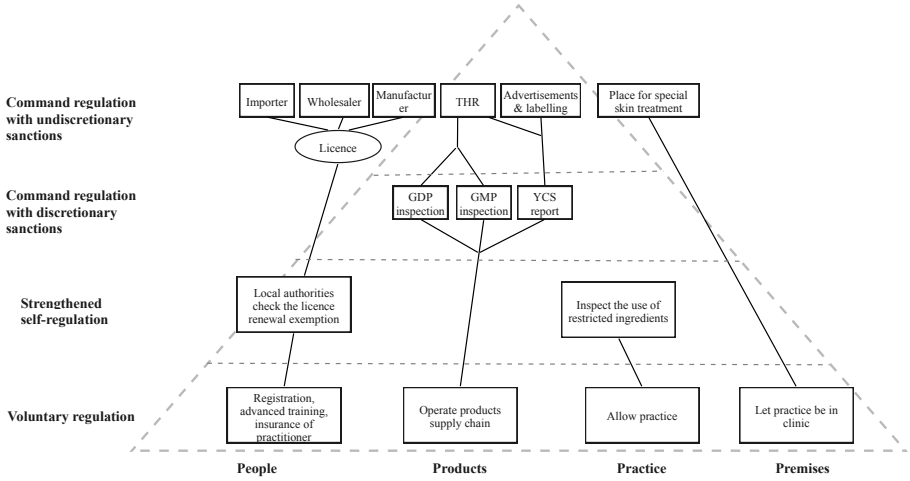


Figure 8.1 Dendriform regulation inside the pyramid

Besides, Braithwaite (2017) admitted one defect is lack of consideration about tactics for de-escalation, as also mentioned in Section 7.2.2. Once the enforcement is lifted, the regulated can hardly be forgiven and go back to the lower level of regulation. Braithwaite (2017) considered a pyramid should not escalate up until all possible horizontal solutions failed to improve non-compliance. Drahos (2007)'s networked responsive regulation is feasible to enlarge effects of lateral regulation. The networked responsive regulation involves multiple agencies to deliver enforcement response within the scale of one level of the pyramid. The above agencies will have sufficient capacity to regulate a small network, and all the small networks compose a big aggregative network. The state regulator at the apex of the pyramid are coordinators of other actants, instead of the traditional regulator controlling the whole. The networked responsive regulation should look for all potential network partners with fresh resource to increase the regulatory capacity and resolve problems within single level of pyramid as much as possible.

The networked pyramid (Figure 8.2) was modified based on the regulatory pyramid of Figure 8.5 to apply the networked form of responsive regulation on the UK-TCM. The base of this new pyramid still starts from the voluntary regulation that operates well in the current regulatory system while providing the industry with laissez-aller to meet the market needs and leave access to TCM for patients. At this bottom stage, the stakeholders of the UK-TCM industry have established a network and controlled the operation of the industry in the network. When the voluntary regulation fails to make TCM, more actants are involved at the second stage of the

pyramid. The second stage is set to primarily conduct inspections to deter the regulated parties about the potential consequence of non-compliance. Besides the local authorities (i.e., the district councils) that only inspect the practice of acupuncture, the other competent actants are identified to join the above inspection network. The TCM associations and influential health professionals are considered ideal participants since they normally gain more insights into TCM, thus allowing them to expand the inspection from acupuncture to more therapies. The participation of TCM health professional takes on a special significance as they are independent personnel to provide comprehensive and fair opinions regarding TCM development and regulation. Some issues (e.g., the coverage of insurance) can be delivered to the regulators via health professionals.

If some non-compliance is not deterred by the regulatory network at the second level, the pyramid escalates to a higher level. More official power will be involved at this third stage. To place the MHRA, custom and higher-level councils[106] at the same network, they can negotiate unified standards of non-compliance to cover as many aspects of TCM as possible and incapacitate those breaching the standards by investigation, cancelling registration, suspending qualification, withdrawing products from the market, etc. The apex of the pyramid serves as the state regulator to take sanctions in the light of laws. The state regulator are primarily capable of altering the consequence of non-compliance and coordinating the other networks. The state regulator can sponsor the cooperation of tier 3 network to prevent the enforcement escalate to be offence with fine or imprison; set code of conduct for the tier 2 network (including district councils, associations, and influential people) to guide this level of network to formulate criteria of inspection and determination of suspected non-compliance and inspect the operation of the industry.

[106] Higher level of councils, such as county councils and unitary councils, cover the social fucntions of large geographic areas. Especially the responsibility of district councils relates more to premises safety, but higher level councils also work for social care (Local Government Group, 2010). The higher level councils are reasonable to be involved in N&NR framework.

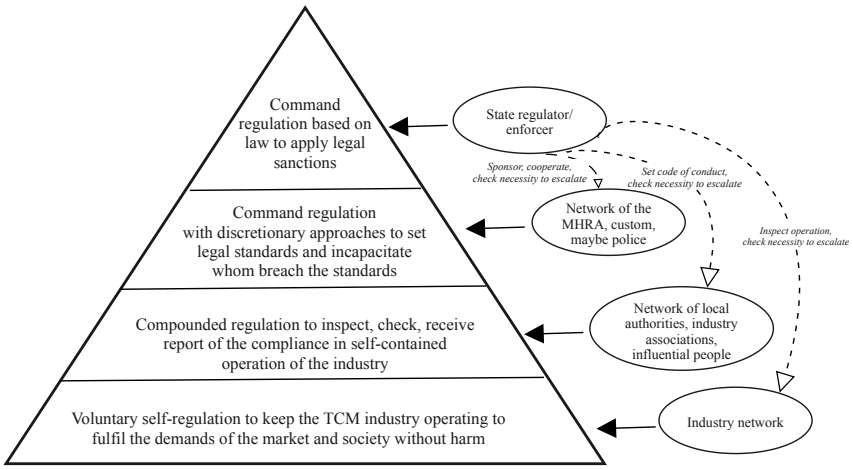


Figure 8.2 Networked regulatory pyramid of the UK-TCM

To further increase the capacity and effectiveness of networked regulation, Drahos (2004) emphasised the role played by nodes in networked responsive regulation. Notably, nodal regulation is suitable for the network containing sub-level of networks that are linked to create concentration of power to exercise governance. Regulation of massive or complex issue requires intermediate information, whereas information is currently dispersed to be held by multiple independent smaller networks against the globalisation background. The response from the state regulator based on the classic responsive regulation mode may not react duly, which can be appropriately resolved by the nodal approach.

Nodal regulation does not bring information omniscience to actants, whereas it provides resources to make actants centre of governance. Nodes work as organisational centre where regulation can flow during a specific period. Nodes can be either human or non-human actants or ‘super-structural’ nodes, which is the command centre of regulation, that bring together actants representing networks to concentrate resources to research a common regulatory goal. The above concept has been extended later by Holley and Shearing (2017) that public authorities are not the only regulatory power, and there also exist private ‘auspices’ and ‘providers’ to control part of the world. Moreover, human is not the only actants in regulation, non-human actants are also to be involved. Such idea was derived from Latour (2007) that the world is made up of both human and non-human actants, and politics is naturally applied in the above world. Holley and Shearing (2017) summarised this concept as ‘power comes from everywhere’. On that basis, regulations can have multiple resources and forms and works based in different sites. Nodes are sites of regulation, and the respective node operates in a relatively independent manner from other nodes.

Subsequently, Holley and Shearing (2017) incorporated the concepts of nodes and network as twin elements and explained their role in N&NR. As mentioned in the last paragraph that nodes operate quite independently, network provided a platform that nodes can be linked into 'horizontal partnerships' through proper coordination. Some nodes can regulate the others since there is no restriction of composition of nodes that individual, groups, organisations, and states can all perform as nodes. No matter whom the nodes are, they work separately or jointly to support or supply governmental actions.

In practical use of N&NR, the coordination amongst nodes should be considered carefully. First, when selecting nodes, Drahos (2004) specially stressed the feasibility of nodal regulation is strengthened by the overlapping identities of nodes that one node might be member of multiple networks, so the node can more effectively connect and communicate with different other actants. Second, for the arrangement of nodes, the aspects of mentalities (the logical relationship between regulation and outcome), technologies (the methods of supporting or supplying regulation), resources (the means deployed when proceeding regulation), and institutions (the structures used to mobilise the previous aspects to achieve the regulatory goal) should be considered (Holley & Shearing, 2017[107]).

If the N&NR regulation of TCM are to be established, the state regulator, the MHRA, district councils, and the TCM associations in full line circle are first selected as nodes. This study suggests that the above three nodes are deeply involved in TCM regulation. The county councils, custom and health professionals in dash circle are identified as the potential nodes who are currently not considered to play vital roles in TCM regulation, but should be contributory as if they are involved in the regulatory system. Table 8.2 lists their desirability, technologies, resources, and institutions.

	Desirability	Technology	Resource	Institution
TCM association	Good operation of the industry	Voluntary registration and partnership	Close contact with industry	Lead voluntary regulation
District council	Acupuncture safety	Inspection	Local regulatory power within smaller	Conduct inspection on

[107] Concepts were derived from Johnston & Shearing (2003), and Burris, Drahos & Shearing (2005).

			area	acupuncture
Health professional	Good operation of the industry	Experience and observation as third party	Knowledge and understanding to TCM	Promote TCM to obtain support from the UK society
County council	Acupuncture safety	Empower district council	Local regulatory power within larger area	Set regional standards for safe acupuncture practice
The MHRA	Medicinal products safety	Inspection, registration, and report	Broad regulatory power	Lead medicinal products standardisation, registration, inspection
Custom	Eligible products	Importation examination	Broad regulatory power	Lead importation declaration, examination
State regulator	Protect and benefit the public	Legal sanction	Law	National level of regulation

Table 8.2 Investigation of nodes selected

The nodal coordination of the UK-TCM regulation is presented in Figure 8.3.

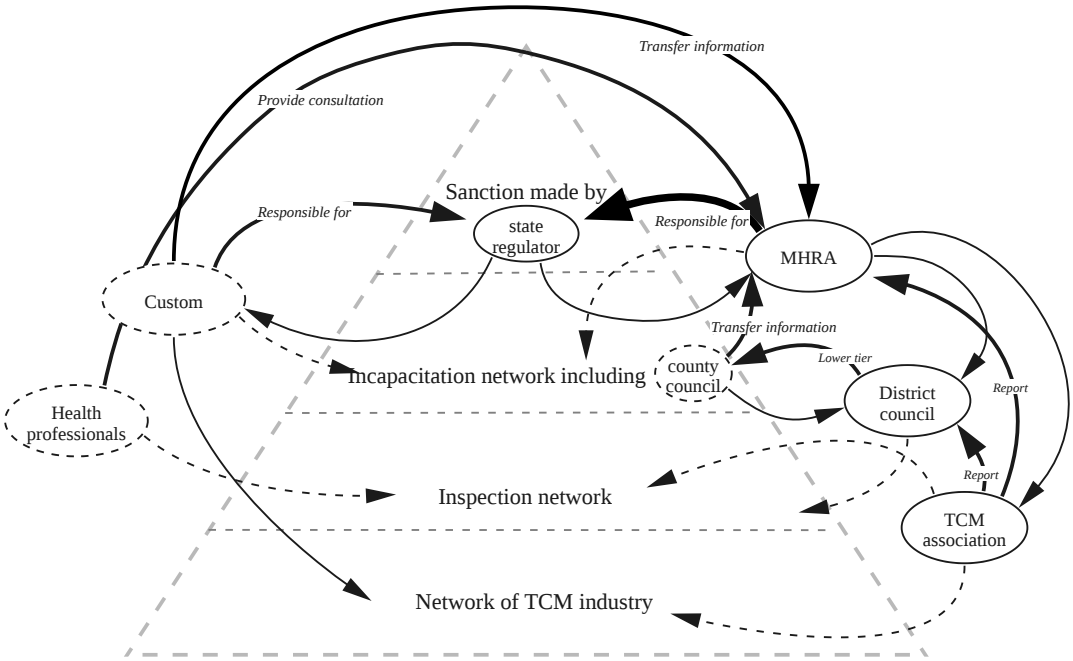


Figure 8.3 Representing nodes in the N&NR mode of TCM

In Figure 8.3, the dotted arrows represent the membership of the above nodes. Notably, the TCM associations have dual membership of both the voluntary regulatory network and the inspection network, thus helping communication and information exchange between the TCM industry and the primary regulators.

The full line arrows represent the coordinating relationship among the nodes. The state regulator (government) empowers the departments (e.g., the MHRA and Custom) to regulate TCM-related issues. The Custom can coordinate the standards, licence, declaration of products importation to affect the industry. The MHRA connects with district councils and provides guiding information for TCM associations.

The thick line arrows represent how the above nodes work to contribute to the N&NR regulatory system. First, the TCM associations stand at the cross place of the network of the TCM industry at the bottom level and the inspection network at the second level. The TCM associations are the principal actants analysed in level one translation of ANT, thus suggesting that the industry network is self-contained at the first stage without much intervening from the official regulators. TCM associations, as a representative of the industry and voluntary regulation, should collect the timely compliance information of operating TCM therapies. TCM associations keep the information of herbal medicine for its own inspection purpose, while reporting the part of physical therapies to district councils for inspection purpose. TCM

associations report non-compliance about TCM products to the MHRA at the level two of inspection regulation.

Second, the district councils stand at the cross place of the inspection network at the second level and the incapacitation network at the third level. As is mentioned in Section 5.2.1 that the respective district council has own criteria of coregulating acupuncture practice, the inspection work conducted by district councils would be fragmented. This research hereby suggest involving higher tier of councils to set relatively united standards of authorising acupuncture practice permission and licence renewal exemption. Subsequently, the district councils can submit their inspection results to county councils. Besides, the health professionals stand at the same level, and they can provide advisory opinions to the MHRA based on their experience and knowledge regarding the UK-TCM industry.

Third, the custom, the county councils, and the MHRA represent at the third level of incapacitation. They are responsible for ensuring the eligible products importation, so as to guarantee safe practice of acupuncture and safe use of herbal medicine. The custom, the county councils, and the MHRA each regulate part of the UK-TCM, and they should regularly exchange information. Furthermore, the above three nodes are empowered by the state, and they should account for the state regulator and decide whether to escalate non-compliance to the highest legal sanctions. Among all the nodes in this pyramid, the MHRA plays the critical coordinating role since it is the principal actants in ANT analysis with history and experiences of regulating TCM. For this reason, the MHRA is expected to lead the cooperation with nodes at same level and to guide nodes at lower levels to operate this N&NR pyramid.

N&NR has again proved the complexity of regulatory issue and provided many valuable thinking to this study about how the current UK-TCM regulation can be improved. Although there are defects of N&NR (e.g., its overestimation of the significance of horizontal regulation that weaken and denying the contribution of state institutions and vertical regulation (Holley and Shearing, 2017), N&NR mode can solve the three major problems of the current regulatory system mention in the beginning of this section.

The N&NR mode starts from voluntary regulation by empowering the industry network with freedom to meet the market demands, thus suggesting that market needs and adequate access to TCM are the preconditions of the following regulations. The N&NR mode involves the fragmented parts of TCM by setting different tiers of regulatory networks to inspect and alter

various aspects of non-compliance. This can avoid some industry stakeholders from seizing the loopholes of some less focused areas. Also, since the fragmented organisations, especially the local authorities and TCM associations, are gathered to form an inspection network, they are expected to think about some unified standards and working mechanism. Moreover, the nodes selected provide more flexibility to TCM regulations. In fact, the different parts of the regulatory system do not become an entity, and it may cost money and human resource to remould the whole regulatory system. Since regulatory power can originate from every node, the respective aspect of TCM regulation can be precisely targeted, while the information of each regulatory aspect can be exchanged and delivered to a higher level of regulators timely.

The N&NR mode plans to involve some nodes that have been seldom considered before as part of regulation to facilitate information change. For instance, the custom can be involved to provide TCM products importation and supply data, and the TCM health professionals should be involved to indicate the voice from inside of industry (e.g., the difficulty to apply GMP on products imported from China), as well as to explore the route to operate the regulations more effectively. The nodal regulation can avoid some regulations lacking execution since the higher level of regulators may not know the actual situation and delay in reaction. The N&NR mode, a combination of networks and nodes, should optimize the current regulatory system to a certain extent.

Though this research has suggested possibility to improve the UK-TCM regulation, there is a further consideration that the impulse to regulate the UK-TCM is actually a Red Herring (a false clue, Breyer & Lorenz, 2021). For example, in Section 5.2.5, BO2 stated that statutory regulation may somehow lead to restrictions and 'discrimination'. BO2 worried that regulation may actually limit the freedom and autonomy to practise and then cause TCM to shrink. Also, this research has identified TCM has changed some features to align with the regulatory requirements and such changes may not always be beneficial for people's health. Therefore, the necessity and actal benefit of regulating the UK-TCM will needs further exploration and discussion.

8.4 Short summary of this chapter

In this chapter, the loopholes found in TCM products importation are first discussed by comparing the definition, importation requirements, domestic safety requirements and enforcement of breaching amongst medicine, herbal medical products, food, and cosmetics.

From the definition perspective, herbal medicinal products, herbal substances, and herbal preparation may overlap the definition of food (especially food supplements), and cosmetics to a certain extent. Thus, the TCM product importers may wrongly declare the type of their goods when importing. For importation requirements, to import TCM products as food is feasible as if the level of contaminant is controlled. However, to import TCM products as cosmetics needs registration with CNPN, and to which level the TCM importers owning such registration is unknown. Moreover, the business activities of food require registration. Subsequently, breaching the regulation of either medicine, herbal medicine, food, or cosmetics face guilty of offence and other sanctions for the enforcement. In other words, some TCM products may seize loopholes to be declared as food or cosmetics to enter the UK. However, such importation is not cost-effectiveness. One possibility is that some products have been imported in very small quantities that escaped from careless examination. The cooperation between the MHRA and the custom is appealed to ensure that only eligible and legal products enter the UK.

Second, the contribution of TCM in satisfying health demands of immigrants who are either documented or undocumented is confirmed. To ensure the access to TCM, some demands from the industry may should be considered to keep TCM continuously existing, including simplifying the working visa for TCM practitioners from China, and standardising the TCM education in the UK to train the next generation of local practitioner if considerable Chinese practitioners cannot come to the UK from China. Besides, the coverage of insurance is problematic during the opening of the access to TCM.

The N&NR regulatory mode is suggested to address the above discussions and to solve the defects of the existing regulatory system analysed in the previous chapters. The N&NR mode first emphasises the significance of vertical regulation to avoid unnecessary escalation and fragmented regulation. Four sub-level of networks are considered to regulate TCM at different stages of voluntary regulation, compounded regulation for inspection, command regulation for necessary incapacitation and command regulation with legal sanctions. Dividing TCM regulation into smaller parts is conducive to delivering enforcement. The responsive regulatory strategy is suggested to use cooperation and kindness to produce higher compliance since the connection between sub-level regulators and the regulated is tighter. The concept of nodes is introduced to link the smaller networks to create concentration of power to exercise governance. The TCM association, district councils, health professionals, county councils, the MHRA, the UK custom and the state regulator are identified as the possible nodes. The participation of the nodes forms the networked responsive regulation to be a N&NR mode. The N&NR mode leaves

freedom to the industry by selecting TCM association as the node of the industry voluntary regulation network.

Subsequently, the N&NR mode designs inspection network to check whether there exists non-compliance in self-regulation. The higher level of regulatory network containing the nodes of the MHRA, custom, and county councils can incapacitate the regulated once non-compliance happens. This N&NR pyramid does not escalate sharply, it provides autonomy to the industry and let the official regulators just inspect at the initial stage. Otherwise, the third level of the pyramid can take actions to target more aspects than the existing regulatory system. Also, the apex node of state regulator can take not discretionary actions empowered by law if severe sanctions are needed. The N&NR mode can gather the fragmented actants/parts of the TCM regulation to be involved in different small networks with the same working aim and urge the above fragmented actants/parts to unify their working standards and mechanism. The N&NR mode can involve some actants less focused before (e.g., the Custom) to cover more aspects of TCM regulation to avoid loopholes. N&NR mode set nodes to precisely target the respective regulatory aspect and relevant information of non-compliance can be solved more quickly. Furthermore, the delivery of regulation can be delivered more effectively under the supervision of nodes.

Conclusion

This study has attempted to gain insights into the integration of TCM in the UK, with a strong focus on regulatory perspective. The development of TCM throughout the long history in China has been reviewed in the beginning part of this study. Under the effects of various social and political factors, the position of TCM in China has been progressively reinforced as a critical part of China's national health system. When it was transmitted to the UK, though there have still been numbers of clinics and shops existing everywhere and visited by people everyday, we saw the position of TCM diminished to a just branch of CAM therapies. Gaps and deficiency have been found in existing literature (see Section 1.5), and speculation arose thereafter about how TCM has been shaped in the UK, what the current form of TCM practice in the UK is, as well as whether the regulation can guarantee appropriate 4Ps to be served to more TCM users in the UK. Furthermore, this study sets the aim to understand the above two speculations.

This study has collected the data from literature and fieldwork using a combination of methods (see Chapter 3) to answer the research questions asked in Section 1.6. First, to answer the research question (1) regarding the UK-TCM relevant regulations, the historical TCM-related regulations and influential documents have been reviewed in this study. A total of 12 regulations and 10 influential documents have been found from the 1968 Act to 2017 Government Response to the advice on herbal medicine regulation. There are 10 existing regulations, which were studied in four aspects, including their regulatory instruments, regulatory objectives (4Ps), regulatory targets and enforcement. The above regulations pertain to various regulatory instruments (e.g., EU Directives, UK Parliament Acts, and private acts) work simultaneously on the UK-TCM. The above regulations pay the most attention to medicine safety.

Subsequently, quality and much less significance were attached to efficacy. These regulations have been primarily designed to control products issues, and no regulations have specially mentioned concerns regarding TCM practice. The above regulations all set enforcement mechanism to prevent non-compliance (see Chapter 4). This has been a comprehensive chronological review of TCM-related regulations in the UK for the first time, thus providing unique contribution to TCM field as a reference to present the timely changes and development of TCM regulations.

Second, to answer the research question (2) regarding the form of TCM practice in the UK, this

study has drawn a portrait for the UK-TCM field. Seven stakeholders were found in the UK-TCM industry (see Chapter 5). The above stakeholders take up the work (e.g., regulation, education, products importation, running business, and providing healthcare services). The above stakeholders form a network to operate the UK-TCM together. In this network, this study suggests that two stakeholders (including the MHRA and the TCM association) should be paid special attention to. MHRA directly or indirectly affects most of the other stakeholders, whereas the TCM associations have connections and interactions both uphill with the regulators and downhill with the other stakeholders. Besides, this network is expandable that some other actants (e.g., the UK Custom and manufacturers in China) can be involved. This has provided a novel insight into the practice of TCM in the UK. TCM is not merely a medical system containing herbal medicine and acupuncture, it is more an industrialised field involving a full set of products supply chain, a wide variety of business, practitioners with various backgrounds and complex therapies with modified appearance while retaining Chinese cultural factors inside more or less. TCM serves a wide range of people either to supplement the deficiencies of the UK mainstream medical system, to provide one-stop healthcare services combining biomedical diagnostic technologies and TCM treatment, or to meet the culture-oriented needs of Chinese immigrants.

Third, to answer the research question (3) regarding the effect of the regulatory system on TCM, this study has collected views from stakeholders of the UK-TCM industry (answers to research question 2) and from previous research to see the effects of regulations in accordance with the themes of the four aspects to investigate the existing regulations (answers to research question 1). It has been suggested that the overall UK-TCM regulations are fragmented, and the implementation of regulations cannot effectively match the actual situation of the industry. The most significant concerns include insufficient implementation of GMP. More attention should be paid to insufficient attention practitioners since practitioners control the practice and products given to patients. Insufficient regulations are applied on efficacy of TCM. The exact number of inspections and following enforcements issued are unclear. Accordingly, work and outcomes of the existing regulations have been directly indicated based on the opinions from inside of the industry and from the public.

By answering the three research questions, some vital points were extracted for deeper analysis. Since the UK-TCM providing biomedical services and using ready-made medicines in form of pills and tablets (see Section 5.1), it is argued that the UK-TCM is not simply an ancient medicine originated from China. It has been added with biomedical knowledge and

technologies and experienced an early form of modernisation process by absorbing elements from Western societies (Chapter 6). TCM has not transcended the geographic scale and entered the other countries though it has failed to achieve an expert system, and its reflexivity is affected by traditional Chinese culture. TCM has been further transformed to align with local social and political needs when stepping into foreign countries (e.g., the UK). In the localisation process, two vital actants (identified in answer to research question 2) were found to take up essential works of building the current UK-TCM field. The TCM associations connect other stakeholders to coordinate the operation of the TCM industry. Though the UK-TCM industry seems to be self-contained and well-operated. Safe medicine, qualified practitioner, eligible premises, and adequate practice were not ensured as no rule to restrain the behaviours and activities of the actants of the TCM industry. The regulators and regulatory actants (i.e., laws) participated into the second level of translation (see Section 6.3.2). The MHRA has been considered a central actant to introduce the regulations and the other regulators into the UK-TCM network. The enlarged network makes the UK-TCM closer to the medical system having safe medicine, qualified practitioner, eligible premises, and adequate practice, whereas further evaluations are required.

During the evaluation work towards the performance of the regulatory system, the working mode of the UK-TCM regulatory mode is understood in accordance with the responsive regulation theory. Defects have been identified in the current TCM regulatory system. First, the UK-TCM regulation is not fitted in with a perfect responsive regulation mode. For instance, the regulation pyramid failed to involve all the industry stakeholders and all the enforcement pyramids, except for GMP and GDP, do not have de-escalation mechanism when compliance increases. Furthermore, the TCM regulatory system faces some implicit shortage of responsive regulation (e.g., slow response to catastrophe).

Further evaluation was conducted using the specifically designed framework of this study (see Section 2.2.3). The overall performance of the TCM regulatory system is acceptable. Satisfactory performance is identified in the voluntary regulation of practitioners and command regulation of practice premises, and sub-optimal performance is identified in products regulation with set rules and mechanisms but insufficient actual implementation on TCM products.

In this study, ANT was used to explain the establishment of the current UK-TCM industry and regulatory system, which has provided a novel concept to the TCM research field that the

development of the TCM industry can be intended rather than being completely spontaneous. Subsequently, this study responsive regulation was adopted to analyse TCM regulation to extend the existing studies on applying responsive regulation to health regulation and decision-making. This assessment of the overall performance of the current regulatory system is acceptable and can still be used in the future.

Compared with the existing literature related to this research field (see Section 1.3), this study has made contributions. First, the current TCM system in the UK has not become fully consistent with Scheid's (1999) three consumptions. The contemporary UK-TCM system has had many of its therapies adopted to be medical tools, but its theory has been transformed to involve a different culture and UK local preference rather than become destroyed. UK-TCM has not been standardised nor institutionalised, but it has aligned itself to UK regulations and become somehow acceptable to UK society and mainstream medicine, such as using acupuncture in the NHS. Some people have realised the efficacy and value of TCM, and some studies of TCM exist, but there is still a long way to go to develop TCM into a new tradition.

Second, this research has given an up-to-date definition of TCM practised in the UK. The integration of TCM in the UK has experienced a modernisation-globalisation-localisation process to align TCM to the UK's social and political contexts. This study has confirmed the function of TCM to supplement mainstream medicine in the UK and the unique significance of TCM in providing culture related healthcare. The UK-TCM system has provided healthcare access to a wide range of people living in the UK in accordance with ones' special needs. The UK-TCM industry has been a case for in-depth studies on other ethnic culture-related CAM therapies to recognise their contribution as complementary and alternative approaches to mainstream medicines and as a source where immigrants can receive culturally oriented healthcare services.

Third, in the process of regulating TCM to a safe, effective medicine with high quality, this research has given a comprehensive review and evaluation of the UK-TCM regulations, a first in this field. Also, this research has tested the regulatory direction in Section 1.3 and found that current TCM is still distant from scientific medicine, but it does fulfil healthcare demands for different groups of people. This research indicated that the current TCM regulation in the UK allows access to TCM, but the recognition of professional value in TCM practice is insufficient. This research has also reconfirmed concepts in Section 1.3 that TCM regulation in the UK is fragmented, some of its regulatory requirements cannot guarantee TCM to not be harmful for

people, and the current regulation does not improve the modernity of TCM.

However, there are some constraints of this study. This study has been conducted at a relatively small scale, at a single site, as well as by a single researcher. There may be more possibility and findings if ethnography research is conducted in a multiple-sited contexts, especially to include views from mainstream medical site (e.g., practitioners providing acupuncture in hospitals).

Also, the findings of this study cannot fill in some gaps mentioned in Chapter 1. First, the current regulatory system of the UK-TCM is still fragmented. The current regulatory system has not push the UK-TCM closer to science. Theoretically, the existing UK-TCM does not have modern reflexivity nor an expert system to decide and explain things scientifically. In practice, it has only involved some superficial modern technologies to help with diagnosis, instead of making more endeavour into scientific research for medicine safety and efficacy. Moreover, there has been no change though there are doubts about the existing regulations (e.g., the validity of long-term use as entry criteria). Furthermore, there has still been no united education and training standards in the UK-TCM industry, and sufficient attention has been paid to the professionalism of TCM. Other loopholes are found in regulation of importation, and it is necessary to address the concerns of the health coverage of undocumented immigrants to further expand access to health. The above points should be studied in depth.

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Appendix I Questionnaire for Traditional Chinese Medicine Users

Number of total questionnaires collected: 106

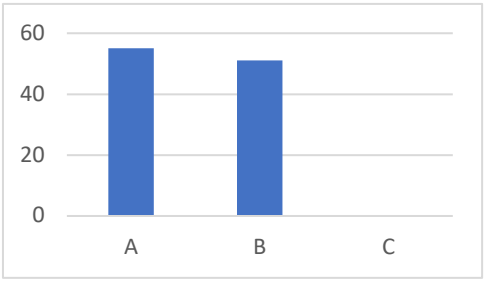
1. The following questions will provide the researchers with your basic information.

(1) Are you

A . Female

B . Male

C . Other



A 55/51.88%
B 51/48.11%
C 0/0.00%

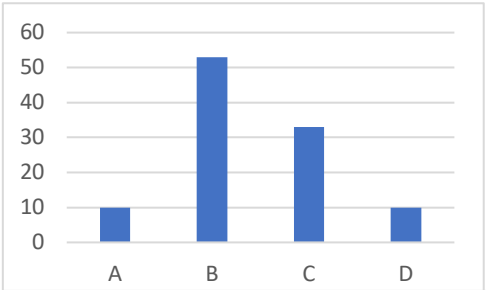
(2) Age

A. 16-20

B. 21-40

C. 40-60

D. 60 or over



A 10/9.43%
B 53/50.00%
C 33/31.13%
D 10/9.43%

(3) Are you

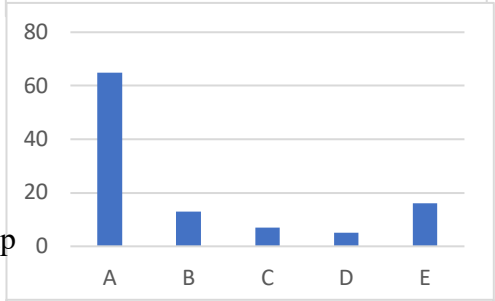
A. White

B. Mixed

C. Asian or British Asian

D. Black or black British

E. Chinese or other oriental ethnic group

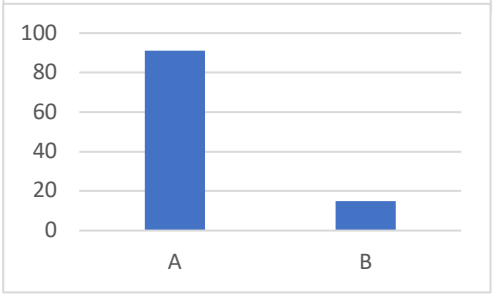


A 65/61.32%
B 13/12.26%
C 7/6.60%
D 5/4.71%
E 16/15.09%

(4) Are you

A. registered with GP

B. not registered with GP



A 91/85.84%
B 15/14.15%

2. Please answer the following questions based on your experiences. (Multiple choices)

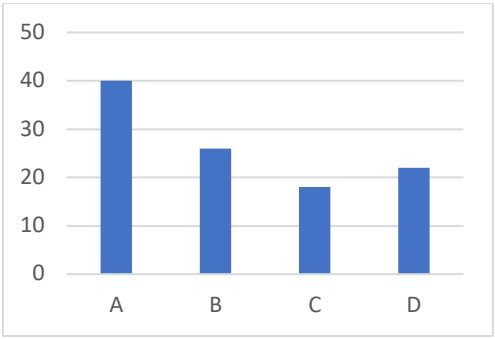
(1) How often do you usually visit a Chinese Medicine clinic?

A. Less than once week

B. Less than once month

C. Once in about half a year

D. Once in a year or longer



A 40/37.73%
B 26/24.52%
C 18/16.98%
D 22/20.75%

(2) What is your purpose when visiting a Chinese Medicine clinic?

A. To seek help for a long term health condition

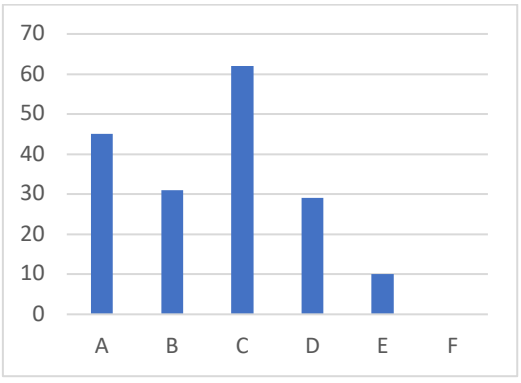
B. To seek help for a sudden health condition

C. To maintain or to improve your health

D. To seek an alternative health opinion from GP or other Western medicine doctors

E. To know about Chinese culture

F. Other (please write in)



A 45/42.45%
B 31/29.24%
C 66/62.26%
D 28/26.42%
E 10/9.43%
F 0/0.00%

(3) What services do you normally receive in a Chinese Medicine clinic?

A. Herbal medicine

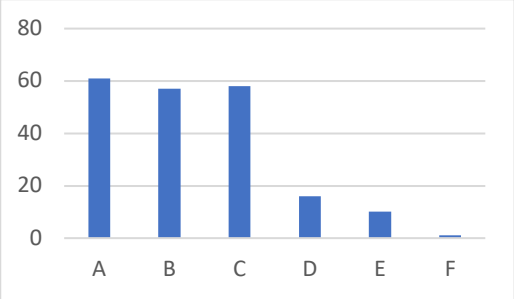
B. Massage

C. Acupuncture

D. Cupping

E. Ear candling

F. Other (please write in)



A 61/57.54%
B 57/53.77%
C 58/54.71%
D 16/15.09%
E 10/9.43%
F 1/0.94%

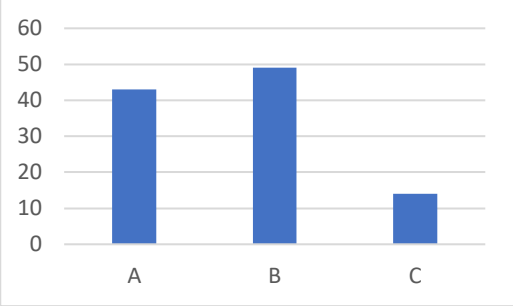
*Other: Just consultation

(4) How much do you normally spend when visiting a Chinese Medicine clinic?

A. Less than £50

B. Less than £100

C. More than £100



A 44/41.50%
B 49/46.22%
C 14/13.20%

(5) What is the attraction when visiting a Chinese Medicine clinic?

A. I believe the knowledge and skills of the TCM practitioner

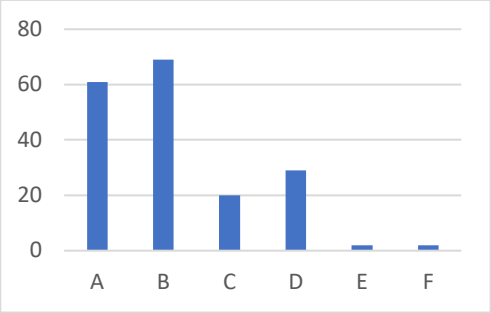
B. The treatment or medicinal products is effective

C. I feel it is part of my culture

D. Dissatisfaction with Western medicine doctor

E. Can not see Western medicine doctor for different reasons

F. Other (please write in)



A 61/57.54%
B 69/65.09%
C 20/18.86%
D 29/27.35%
E 2/1.88%
F 2/1.88%

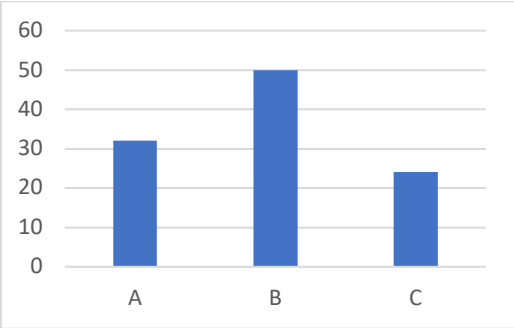
*Other: It was recommended/ Holistic care

(6) How do you approach Chinese Medicine and modern medicine?

A. Use these two medical system equally

B. TCM is used to supplement modern medicine

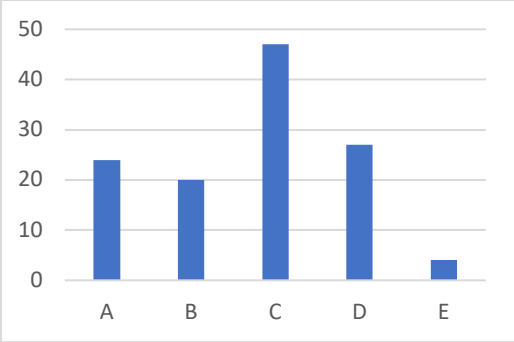
C. Use TCM more



A 32/30.18%
B 50/47.16%
C 24/22.64%

(7) How did you hear about the Chinese Medicine shop or clinic?

A. Through the internet searching
B. Through advertisement
C. Introduced by relatives or friends
D. Occasionally passing by
E. Other (please write in)

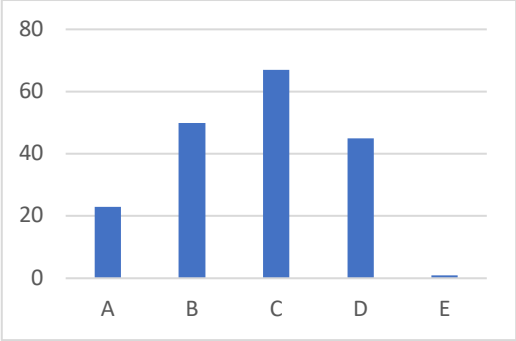


A 24/22.64%
B 20/18.86%
C 47/44.33%
D 27/25.47%
E 4/3.77%

*Other: Books/ Books and documents/ Introduced by a friend/ My girlfriend is Chinese

(8) What is the attraction of a Chinese Medicine practitioner?

A. Qualified certificate and educational background
B. They have rich experiences
C. They provide supplement or alternative opinion from Western medicine
D. Specific and individual diagnosis and treatment to my condition
E. Other (please write in)



A 23/21.69%
B 50/47.16%
C 67/63.20%
D 45/42.45%
E 1/0.94%

*Other: I thought it would provide a better treatment but it didn't

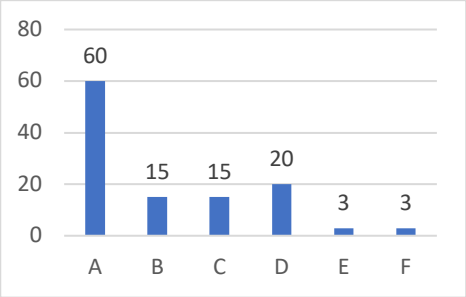
(9) Do you have any dissatisfaction about visiting a Chinese Medicine clinic?

A. No
B. Insufficient scientific evidence for the treatment
C. Treatments take a long time

D. Price is high

E. Negative opinion from NHS or other Western medicine doctor

F. Other (please write in)



A 60/56.60%
B 15/14.15%
C 15/14.15%
D 20/18.86%
E 3/2.83%
F 3/2.83%

*Other: The medical practitioner could not speak English well enough. I doubted the diagnosis and the practice and so I didn't take the herbs. In an other case, the cupping and acupuncture didn't work. / Lack of regulation or certification./ Language barrier.

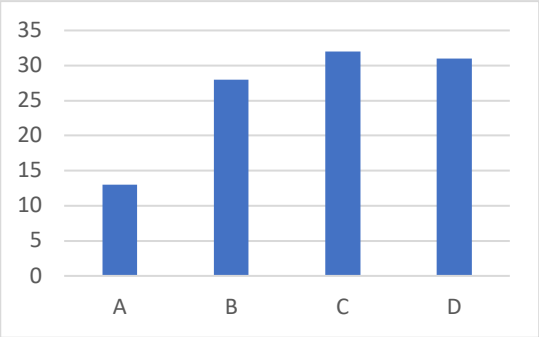
(10) What do you think about the current regulation of Chinese Medicine in the UK?

A. Strong and effective

B. Works barely

C. Not effective

D. Do not know about this



A 15/14.15%
B 28/26.41%
C 32/30.18%
D 31/29.24%

(11) What do you think is essential to improve TCM industry?

A. Scientific evidence to prove the effectiveness of the treatment

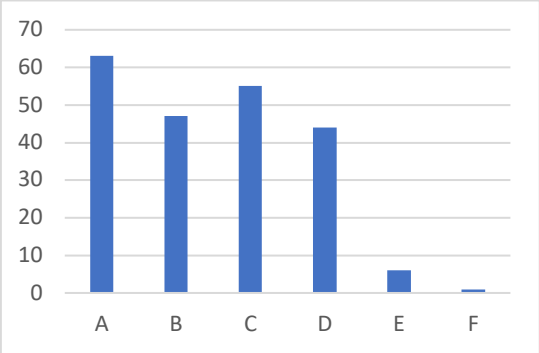
B. Stronger regulation for the education and qualification of the practitioner

C. More products and therapies to be permitted by the UK

D. Treatments covered by NHS or private insurance

E. Stronger legislation to limit the use of TCM treatment and products

F. Others (please write in)



A 63/59.43%
B 47/44.33%
C 5551.88%
D 44/41.50%
E 6/5.66%
F 1/0.94%

*Other: Practitioners should speak English, prove their qualifications, be licensed and a register before being allowed to advertise for business and/ or practise, and should have a complementary UK medical qualification as well.

Appendix II Historical regulations concerning TCM practice in the UK

1. Medicine Act 1968 (Part II, Section 12)

Current situation: Not in use

Regulatory instrument: Statute law (Act of Parliament)

Regulatory body: Licensing worked is in the charge of the independent of jointly work of the Minister of Health, the Secretary of State concerned with health in Scotland and the Minister of Health and Social Services for Northern Ireland; the related work of exempted sections was not mentioned

Objective: Safety/ quality

Target:

(1) Product (exempted from "product licence"): only through drying/ crushing/ comminuting; name of the products only specifies the plant and would not be changed after these manufacturing process; without written instruction on the use.

(2) Manufacturer/ practitioner (exempted from "manufacturer's licence")/ Wholesaler (exempted from "wholesale dealer's licence"): person could sale/ supply/ manufacture/ assembly herbal remedy under the request of a specific person and under the presence of this person to use his own judgement on the necessity of the treatment.

(3) Premises: person doing the business is the occupier of the premises/ premises could be closed to exclude the public.

Process/ Enforcement/ compliance mechanism: Enforcements/ compliance mechanism concentrate on holders of the licences and certificates rather than products/person/premises exempted from the Act.

Recent assessment: Reviewed in the 6th report of the House of Lords that permission of unlicensed herbal medicine produces potential harm. Reviewed in the 2001 Government Response that the regulation on unlicensed herbal medicine is weak. Replaced by the Human Medicines Regulation 2012 as the result of the MHRA's consolidation and review of the UK medicines legislation.

2. Local Government (Miscellaneous Provision) Act 1982 (Part VIII)

Current situation: In use

Regulatory instrument: Statute law (Act of Parliament)

Regulatory body: Local authorities (district council/ council of London borough/ Common Council of the City of London) of England and Wales.

Objective: Safety of acupuncture

Target:

(1) Practitioner: person should register with local authority/ the cleanliness of person and assistant is required/ the copy of registration certificate and byelaws should be kept. The requirements do not extent to practice under supervision of registered medical practitioner.

(2) Premises: premises should register with local authority is the only place for practising acupuncture (but sometimes home visit under request is allowed)/ the cleanliness of premises is required/ the cleanliness and sterilisation of business instruments, materials and equipment are required/ the copy of registration certificate and byelaws should be displays in the premises/ authorised officer of a local authority could enter the premises if necessary with warrant, and the occupier who refuse the authority of entry would be guilty of an offence and fine (given by the court). The requirements do not extent to premises under supervision of registered medical practitioner.

Process/ Enforcement/ compliance mechanism:

(1) Local authority should issue a certificate of registration to person and premises.

(2) Local authority could require the information of the premises of practice when assessing the applicant person, any other information may also be required except for information about individual people receiving treatment.

(3) Registration fee maybe applicable.

(4) Failed person/ premises/ requirements on cleanliness shall be guilty of an offence and liable on summary conviction to a fine;

(5) Failed person may be ordered for suspension or cancellation of registration by court in additional to fine, and such suspension or cancellation could be extend to related premises;

(6) The order of suspension or cancellation could be appealed to suspend;

(7) If the order of cancellation is finally determined, the cancelled certificate should be deliver up to the local authority within 7 days, otherwise guilty of offence and fine would be issued; the person could not be registered again without the consent of the court giving order.

Recent assessment: This Act was later partly amended by the London Government Act 2003, but the amended contents does not affect the regulations on acupiuncture.

3. London Local Authorities Act 1991 (Part II)

Current situation: In use

Regulatory instrument: Private acts

Regulatory body: London borough council, Common Council of the City of London, and may involve Police of the Metropolis and London Fire Authority.

Objective: safety of acupuncture

Target:

(1) Premises: licence is required for premises providing special treatment (including acupuncture)/ licence is exempted for premises belonging to or under supervision of a registered medical practitioner/ member of specific body of health practitioner approved by borough council (see Part II section 4, [b] [ii])/ a person registered under Professions Supplementary to Medicine Act 1960.

Process/ Enforcement/ compliance mechanism: guilty of offence and fine maybe applied to occupier of the premises intending to conduct special treatment without licence/ if the services provided out of the permission of the licence, licence holder or the premises occupier would be guilty of an offence and fine (not mentioned given by whom)/ licence could be revoked by council if premises is under offence (by the borough council).

Recent assessment: A few refinements and amendments on the come-into-force, expiry date, appeal of licence in *London Local Authorities Act 2000*.

4. London Local Authorities Act 2000 (Part IV, Section 27)

Current situation: In use

Regulatory instrument: Private acts

Regulatory body: London borough council, Common Council of the City of London, and may involve Police of the Metropolis.

Objective: safety of acupuncture

Target:

(1) Premises: Inserted, amended some requirements of the 1991 Act

5. EU Directive 2001/83/EC (Section 5 【1】 & Chapter 2a)

Current situation: Partly in use

Regulatory instrument: Regulation

Regulatory body: The European Parliament and of the Council

Objective: Safety, efficacy, quality

Target: Products

(1) General:

a. Member states of the EU shall require a manufacturer authorisation to medicinal products, and this authorisation shall also apply on products for export and import from a third country.
b. The 2001 Directive requires implementing measures on the quality system for the performance of pharmacovigilance activities (Article 108);

(2) Traditional-use registration is applicable for:
a. Products could be used without supervision, nor purposes of diagnosis and prescription, nor monitoring of treatment;
b. Products administrated with specified strength and dosage;
c. Products for oral/ external and/or inhalation use;
d. Products fulfil the period of traditional-use;
e. Products with sufficient data of traditional-use, the data is particularly required to prove no harm and acceptable effects.
f. Products containing safe whilst ancillary vitamins or mineral ingredients.

(3) Products that are not eligible for registration could be supplied to individual patients under personal request by an authorised health-care professional

(4) Well-established use marketing authorisation*:
a. Scientific literature exist supporting the active substances utilisation has been well-established within EU for 10 years with acceptable level of efficacy and safety.
b. Assessment for mostly bibliographic safety and efficacy data exist.

(5) Stand-alone or mixed application*:
a. Company's own (or combination or bibliographic) studies provide data of safety and efficacy

*are routes to bring herbal medicines to market but not really suitable for TCM products

Process/ Enforcement/ compliance mechanism:

(1) A Committee for Herbal Medicinal Products is established. The Committee should establish monographs as references for the registration work (established already).
(2) The applicant and registration holder would be recorded in the community (EC).
(3) The applicant submit application to the authority of EC member states.
(4) The application should contain the materials and documents of:
a. Documents required by the Directive for general market authorisation;
b. Results of pharmaceutical tests/ summary of products characteristics/ active single or combined ingredients;
c. Application history;

d. Evidence for efficacy of a products in medicinal use for 30 years and 15 years within the Community (EC);
e. Evidence for safety.

(5) The results of application should be given within 210 days, and during the process, the manufacturer and importer should be verified and allowed for necessary presence.

(6) The application would be refused if:
a. The product does not fulfil the requirements of general market authorisation of this Directive;
b. The qualitative/ quantitative composition is not clear;
c. Harmful under normal use;
d. Data of efficacy is not sufficient;
e. Pharmaceutical quality is not satisfactory.

(7) After gaining the market authorisation, the product should:
a. Has label stating the identity as traditional-use of medicinal product; (so as advertisements)
b. Has instruction asking for consultation with doctors if the product does not work well.

Recent assessment: Herbal medicinal products part was amended by the EU Directive 2004/24/EC.

6. EU Directive 2004/24/EC

Current situation: In use

Regulatory instrument: Regulation

Regulatory body: The European Parliament and of the Council

Objective: Safety, efficacy, quality

Target: Products

(1) Definitions of 'traditional herbal medicinal product', 'herbal medicinal product', 'herbal substances', 'herbal preparations' were moved to the beginning of the 2004 Directive.

(2) The Article 16 (g) of the 2004 Directive requires to adopt Article 3(1 & 2) about exemption for individually prescribed medicine, 4(4) about leaving legislation freedom to member states, 6(1) about market authorisation, 12 about documentation need for market authorisation applicant, 17(1) about the processing time of market authorisation, 19 about the work responsibility of competent authorities in member states, 20 about measures needed to ensure the work of competent authorities, 23

about the responsibilities of the market authorisation holder, 24 about the valid period of market authorisation, 25 that market authorisation should be within civil liability, 40 to 52 about the regulation of manufacture authorisation, 70 to 85 about the classification of medicinal products,101 to 108 about pharmacovigilance, 111(1& 3) about competent authorities conducting inspection, 112 about documentation for the manufacture process, 116to 118 about cancelation & revoke of authorisation, 122 about communication and information change among member states, 123 that all decision on authorisation should have reasons and inform the EMA, 125 that decision on authorisation should open to the public, and 126 that no decision to refuse, revoke and suspend the authorisation should be made except on the grounds of the 2001 Directive to traditional-use registration.

(3) required by the 2001 Directive on traditional-use registration.

(4) The 2001 Directive requires to apply the principles and guidelines of Commission Directive 2003/94/EC for GMP in respect of (investigational) human medicinal products on traditional-use registration; the 2004 Directive requires to apply the Commission Directive 91/356/EEC. The 91/356/EEC has been repealed since the issue of 2003 Directive, but the 91 does not involve regulation on investigational medicine.

Further and detailed modification see EU Directive 2010/84/EU.

Process/ Enforcement/ compliance mechanism:

(1) The 2004 Directive added Article 2 to require member states take measures to comply with this Directive, and the measures should include the reference of this Directive (the 2001 Directive did not require fully adoption of its articles, though articles related to traditional medicine should be adopted as compulsory).

(2) The 2004 Directive added Article 2 to require the member states to apply provisions of the Directive for herbal medicines already on the market 7 years after its come-into-force.

(3) The 2004 Directive added Article 3 set the enter-into-force time of this Directive on the day of its publication in the Official Journal of the European Union (the 2001 Directive uses EC).

(4) The 2004 Directive added Article 4 to address this Directive to member states.

Recent assessment: assessed in literatures (such as Qu, L. et al., 2018; Chinou, Knoess & Calapai, 2014; Peschel & Alvarez, 2018)

7. The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005

Current situation: In use

Regulatory instrument: Statute instruments (Implementing measure of 2004 Directive in the UK)

Regulatory body: Department of Health

Objective: Safety, quality

Target:

Products: Can not be put in market and distributed by wholesale without the registration provision introduced in the 2005 Regulations.

Process/ Enforcement/ compliance mechanism:

(1) The application for a traditional herbal medicinal products registration should be written in English, established in EC, and comply with the relevant EC provision. The application may come with a fee. The renewal application should be before 6 months of the expiry date of the old one. The application should state the product is only for sale in pharmacy or for other places, and the method of sale or supply if needed.

(2) The licence should be in accordance with the other EC provisions and import regulation. The licence granting or other related actions should involve a procedure of hearing. The licence should be accompanied by a parallel import licence. The licence should be valid for 5 years. The licence should be cancelled if the product is not placed on the UK market for 3 consecutive years.

(3) The licence could be revoked, suspended or varied for its use, supply or marketing. The actions could be taken either by the licensing authority or EU with/ without a notice of period. Once these actions were taken, the licence holder should inform the wholesales, retailers, practitioners, patients and etc., and the product should be withdrawn from market. These actions should be accompanied by procedure of hearing.

(4) Urgent safety restriction may be applied on the product. The licence holder should thereafter implement the restriction and apply to vary the registration within 15 days.

(5) The licence holder has the obligation to comply with the EC provisions especially of updating information, making changes, varying registration, pharmacovigilance and of labels and leaflets. The licence holder should keep the documents to show awareness of suspected adverse reactions according to EC provision, and open the documents for inspection, and withdrawal or recall the product. The holder should provide information of the product has not been on the market for 3 consecutive years and

volume of sales. The holder shall be guilty of an offence when violating the regulations and provisions.

(6) The regulations work relating to *the Medicine Act 1968*, *the Trade Description Act 1968* (for application of trade description), *the Medicines Act 1971* (for fee), and *the Consumer Protection Act 1987* (for licence).

Recent assessment: Assessed to be "do not require proof of actual work and no assurance of effectiveness" by the Parliament member (Dr Sarah Barber, 2014, SN/SC/6002) in the section of Science and Environment, titled as *Regulation of herbal medicines*, and stored in *the House of Commons Library*.

8. Traditional Herbal Registration (THR) Scheme

Current situation: In use

Regulatory instrument: Scheme (Introduced by the 2005 Medicines Regulations)

Regulatory body: MHRA

Objective: safety, quality (in traditional use)

Target: Product (definition in accordance with the Human Medicines Regulation 2012, but herbal products can also be identified as food or cosmetics)

(1) THR is compulsory before market.

(2) THR is only granted for products for minor health problem without medical supervision.

Process/ Enforcement/ compliance mechanism:

(1) Application for THR should include evidence for safety and quality:
   a. Technical dossier for quality in electronic Common Technical Document format;
   b. Safety review (clinically& non-clinically) carried out by experts;
   c. Summary of product characteristics
   d. Mock label and leaflet.

(2) These evidence should prove the product has been used for 30 years and 15 years related in the EU/EEA market to apply THR in the UK or Northern Ireland/ 15 years of history in other countries (that have an equal level of pharmacovigilance of the UK) may also be acceptable if only apply for THR in Great Britain.

(3) Banned or restricted ingredients (listed) should be excluded.

(4) Fees may apply.

(5) A THR Certification Mark is permitted on registered product.

Recent assessment: assessed in literature, such as Anquez-Traxler, 2011 (established slowly, published in 2014 in the UK), Dickinson, et al., 2019 (failed to include many products, and lack guarantee of efficacy)

9. Human Medicines Regulations 2012

Current situation: In use

Regulatory instrument: Statute instruments (under the *European Communities Act 1972*)

Regulatory body:

Objective: safety, quality (?)

Target: Products (but also related manufacturer and premises)

General requirements that also apply on TCM:

(1) Labelling/ packaging/ leaflet: The label of the product should state the product is a traditional-used one and it is necessary to consult a medical practitioner when needed/ a p should be labelled when a pharmacy traditional medicine is sold by retail. (These requirements do not applied on some packing like transparent).

(2) Advertisement: advertising relating to THR should contain the words "Traditional herbal medicinal product for use in"/ statement of indication consistent with THR/ the words "exclusively based on long standing use".

(3) Part 3, section 17 (1) requires a person should have a manufacturer's licence as if this person manufacturer, assemble or import medicinal product from a state other than EEA. When doing such importing, section 38 (3) requires the licence holder must comply with GMP, and active substances used as starting materials should also comply with GMP.

(4) Part 3, section 18 (1) requires a person should have a wholesale dealer's licence as if this person distribute medicinal products by wholesale dealing. Section 43 (1) requires the licence holder must comply with GDP in accordance with Article 81 of the 2001 Directive.

Traditional-use herbal medicinal products:

(5) Apply for THR.

Exemption: "A", a person manufacture or assemble herbal medicinal products, is exempted from a manufacturing license and market authorisation

(1) Premises: occupied by A, and A can exclude the public (same as MA 1968).

(2) Manufacturer: for administration to a person (B), requested or be on half of B, in B's presence, to use A's judgement (changed) on the treatment

(3) Products:

a. The product excludes substances in Part 1 of Schedule 20 (partly overlaps but less than the MHRA Banned and Restricted Herbal Ingredients)/ restrict the use in Part 2 of Schedule 20 with the label, under the maximum use and under specified percentage for external use; the products are not manufactured or assembled in large scale or through industrial process./ A medicinal product is not subject to general sale/ or general sale outside a registered pharmacy can be sold or supplied excluding the substance in Part 1 of Schedule 20 or substance in column 1 of Part 2 of Schedule 20 (unless this substance is a corresponding entry in column 2 with label or in column 3 less than specified percentage), and the product fulfils (1)& (2).

Related requirements:

(1) Part 11 of the Regulations set rules for pharmacovigilance.

Process/ Enforcement/ compliance mechanism:

(1) For THR:

guilty of an offence will apply on:

a. Breach the provision related to urgent safety restrictions.
b. Fail to provide compulsory information for THR application, or the information is false.
c. Other behaviours related to these provisions.

Fine may be applicable. Imprisonment for not exceeding two years may be applicable.

Defence procedure may be applicable.

All these action may also be implemented on the employer or principal of the guilt person.

(2) For labelling:

Guilty of an offence may apply on:

a. The packing or leaflet breach the provision.
b. The product does not comply with the package or leaflet.

The offence applies on person doing sell or supply of the products other than registration certificate holder. However a notice of compliance relating to labelling requirements will be sent to the holder, and if the holder fails to comply, a guilty of an offence may also be applicable.

Fine may be applicable. Imprisonment for not exceeding two years may be applicable.

(3) For advertisement:

Guilty of an offence may apply on breach of the provisions.

Fine may be applicable. Imprisonment for not exceeding two years may be applicable.

(4) For manufacturer's licence:

Guilty of an offence may apply on breach of the provisions.

Recent assessment: assessed by MHRA (2017).

10. Good Manufacturing Practice (GMP)

Current situation: In use

Regulatory instrument: Regulation (a part of Pharmaceutical Quality Management)

Regulatory body: MHRA (used to be guided by EMA)

Legal framework: principles and guidelines were first laid down by the Commission Directive 91/356/EEC, as amended by Directive 91/412/EEC and Directive 2003/94/EC, emphasised by the 2001 Directive to refer to the Volume 4 GMP that includes manufacturing of herbal medicinal products in Annex 7, some particular changes were made in accordance with the 2004 Directive, updated by Directive 2017/1572 (supplement 2001 Directive) and Regulation 2017/1569 (adding rules for investigational medicine)

Objective: Quality

Target: Products (all lifecycle stage: production and quality control to ensure products consistent with intended use and requirements of market authorisation)

(1) Necessary documents exist: 1) instructions: specifications, instructions for manufacturing formular/ processing/ packaging/ testing, procedures, protocols/ technical agreements; 2) record/ report: records of action to comply with instructions, certificates of test results summary, report of exercises/ projects/ investigations.

(2) Manufacturing process is clearly defined, but changeable, written as instruction, carried out clearly, recorded (including deviation/ distribution), conducted and supervised by competent people:

   a. Materials: all in accordance with set instructions, incoming ones are checked and quarantines, be placed under appropriate condition, protect from dust and contamination, labelled.
   b. Container: investigate all damaged or problematic ones, labelled.
   c. Products: finished ones to be quarantined, intermediate and bulk ones to be handled on receipt, different products not work in same place, be placed under appropriate condition, protect from dust and contamination, labelled.
   d. Check on yields and reconciliation of quantities may be applicable.
   e. Avoid deviation.

(3) Quality control requirements: an independent Quality Control Department to assess the finished products with all relevant factors, and the related data is accessible for the

Quality Control personnel. Lab premises, equipment, personnel should all be appropriate to meet the general and specific requirements including:

a. Documentation.
b. Sampling with written procedures to selected representative samples with appropriate labels.
c. Testing with validated methods (can be transferred) approved by Quality Control including lab reagents, solutions, glassware, reference standards and culture media marked with preparation, opening date and signature of prepared person/ in-use shelf life of microbiological media/ recorded results including required data/ quarantined animals.
d. Stability programme should be monitored with written protocol applying mainly on package, sufficient data (number of batches& frequency of testing) for trend analysis, a summary of data should be written and maintained. Specification or significant atypical tends should be investigated.

(4) Outsourced activities with appropriate contract/ informed changes/ appropriate arrangement between authorisation holder and manufacturer.
(5) Has procedures of recalling and complaint: procedure to record, assess, investigate, review complaints; to recall products from distribution network
   a. Personnel: trained/ experienced/ adequate/ maybe inter-disciplinary.
   b. Procedures: written procedure of complaint process with special attention to falsification and then to facilitate a request to investigate, and to address appropriate areas.
   c. Investigation: with information recorded/ checking all related batches& products/ review of previews reports/ report risk level and non-compliance to market authorisation and GMP/ result in risk-reducing action/ inform relevant people.
   d. Analysis and correction are needed.
   e. Recall: robust and fit for use, promptly and at any time, recorded, with accessible distribution records, information about trail sites, market-specific risk-reducing actions, secure areas to store recalled products.
(6) Self-inspection: compliance with GMP.
(7) Provides necessary facilities for GMP:
   a. Personnel: adequate number; clear organisation (with people in position of quality control) to ensure people in position of quality control have clear duties (such as senior management set quality policies to manage quality control and to comply with GMP/ set key people in Head of Quality Control check EU products fulfilling

the laws and market authorisation, and non-EU products fulfilling quality analysis according to market authorisation/ set Head of Quality Assurance or Head or Quality Unit if needed); training for: 1) all personnel for production, storage and lab, 2) training and continued training on quality management and GMP, 3) hazard, 4) supervise visitors and untrained personnel; hygiene: 1) medical examination upon recruitment, 2) no infectious diseases nor open lesions, 3) protective garments, 4) no eating, drinking, smoking in specified areas, 5) no direct contact between skin and products, 6) hand wash; consultant: 1) adequate education and training, 2) keep records.

b. Premises: suitable environment and conditions, carefully maintained and designed and equipped, able to exclude unauthorised people, clearly labelled. Production area: prevent cross-contamination, designed in logical order, adequate places, exposed surface of products should be no harm and easy to clean, well designed pipework, lighting, ventilation, special weighing spaces, special packing places. Storage areas: sufficient capacity for necessary use, good condition, protect from weather, restricted quarantine and segregated area, special sampling area, place dangerous material safely, place packaging materials safely. Quality control area: separate lab, well designed lab, place sensitive instruments safely. Ancillary area: separate rest and refreshment rooms, easily accessible changing and washing places, separate maintenance workshops, isolated animal houses.
c. Equipment: well designed, located and maintained, easy to be cleaned, no harm caused by repair or maintain, prevent possible contamination, appropriate range and precision, clearly labelled, sanitised pipes, removal of defective ones.
d. Material, container, label
e. Procedures
f. Storage& transport

Herbal Medicinal Products in Annex 7 of the *Rules Governing Medicinal Products on the EU, Volume 4, EU Guidelines to GMP Medicinal Products for Human and Veterinary Use*

a. Storage: in separate areas against/exclude insects & animals to prevent fermentation or mould growth and to prevent cross-contamination; the areas should be well aerated with circulation of air; the areas should be clean and fulfil other conditions (i.e. light).
b. Production area: provisions should be made for all process of production.
c. Equipment: all equipment should be compatible with extraction solvent.

d. Audits document for herbal medicine starting materials should include: binomial scientific name of plant, source of plant, parts used, drying system, description of herbal substances and micro & macro examination, identification tests for constituents with therapies, water content, assay of constituent of therapies, methods to determine pesticide contamination in accordance with European Pharmacopoeia, tests to determine fugal/ microbial contamination/ toxic metals, foreign materials and any additional substances if appropriate, treatments to reduce contamination with details.
e. Processing instruction should: describe the operations on herbal substances (i.e. cleaning & drying), be written or records ensuring the condition of containers, describe security sieving or other methods removing foreign materials and procedures for cleaning/selecting plant material, include details of solvent, time & temperature of extraction for herbal preparation.
f. Sampling for quality control: conducted by particular personnel with special care and expertise and experience, having own documentation for each batch, having reference of sampling, should be in accordance with relevant European guidance for identity and quality.

Process/ Enforcement/ compliance mechanism:

(1) Inspections under risk-based compliance programme:
   a. Based on GMP rating: compliance report/ previous inspection history/ organisational changes
   b. Increased risk will be peer reviewed

(2) Products-related inspection:
   a. When assessing a market authorisation application
   b. Can also be requested by EMA

(3) Triggered inspections by:
   a. Whistle blower
   b. Other MHRA departments
   c. Other regulatory authority

(4) Inspection findings:
   a. Critical deficiency: significant deficiency and harmful
   b. Major deficiency: non-compliance with market authorisation/ major deviation/ failure of Quality Control/ combination of other deficiency
   c. Other

(5) After inspection：

a. A letter with decision will be sent.
b. The person should respond to confirm the actions and date.
c. When actions and due date are accepted, a GMP certificate with inspection report will be sent; if actions and due date are not accepted, compliance escalated to higher level.
d. GMP inspection asks for an interim assessment to be completed if there are changes to site.
e. Fees apply.

(6) Compliance escalation:
a. Making recommendations on close monitoring of compliance improvement work through inspection.
b. Meetings and correspondence with company senior management clearly outlining the consequences of continued noncompliance
c. Once the process finished, one could be returned to the routine risk-based inspection or referred for regulatory action if the improvement is not satisfactory.

(7) Critical deficiency may lead to refusal or suspension of licence.

Recent assessment:

(1) Reassessment of transitional qualified person assessed and acknowledged under the SI 2004.1031.

(2) Inspections performed by mutual recognition partners within the scope of the mutual recognition agreement (inspection outcomes from EEA authorties) in place are still acceptable before 1 Jan 2021.

11. Good Distribution Practice (GDP)

Current situation: In use

Regulatory instrument: Regulation

Regulatory body: MHRA (used to be guided by EMA)

Legal framework: published in 1994 (94/C 63/03), guidelines based on Article 84 and Article 85b(3) of the 2001 Directive, revised in 2013 to include new requirements in Directive 2011/62/EU for falsified medicines

Objective: Quality

Target: Products

(1) Guided by EU Commission guideline 2013/C 343/01 and EU Commission guideline 2015/C 95/01

Process/ Enforcement/ compliance mechanism: Inspection

(1) Inspections under risk-based compliance programme: based on risk score (activities taking place on site/ number and type of deficiencies)

(2) Triggered inspections by:

d. Whistle blower
e. Other MHRA departments
f. Other regulatory authority

(3) Inspection findings:

a. Critical deficiency: results in counterfeit medicines
b. Major deficiency: major deviation
c. Other

(4) After inspection：

f. A letter with decision will be sent.
g. The person should respond to confirm the actions and date.
h. When actions and due date are accepted, a GDP certificate with inspection report will be sent; if actions and due date are not accepted, compliance escalated to higher level.
i. Fees apply.

(5) Compliance escalation

(6) Critical deficiency may lead to refusal or suspension of licence.

Recent assessment: EU level assessment (Cold Chain IQ, 2013);

12. Yellow Card Scheme

Current situation: In use

Regulatory instrument: Scheme

Regulatory body: MHRA

Objective: Safety, quality (defective medicine, fake medicine)

Target: Products

(1) Side effects (adverse drug reaction).

(2) Defective medicine (not of acceptable quality).

(3) Fake medicine.

Process/ Enforcement/ compliance mechanism:

General mechanism for the public:

The MHRA, the manufacturer or medical specialist will investigate the problem, and the report will be recorded. A confirmation will be sent to the reporter and further contact may apply.

(1) For ADRs:

a. The reports will be assessed by a team of experts, and the safety profile will be looked at as well as the side effects of other medicines under the same condition.
b. The MHRA assess the risks and benefits of medicines for the time of licensing and throughout their uses.
c. The MHRA seeks advices from independent Commission on Human Medicines.
d. The MHRA takes actions of:
   -changes to warnings
   -restricting the indications of the use
   -changing the legal status of the product
   -removing the product from the market
   -communicating with medical workers and patients by updating patients leaflets, writing to doctors, updating *Drug Safety Update*, publishing fact sheet and safety alert.

(2) For defective products: Consulting with doctors or related medical workers first.

(3) For fake products:

a. The MHRA investigate the fake products according to the *Human Medicines Regulations 2012* and *Consumer Protection Act 1987*. The investigation is empowered to enter the business and seize the suspected things.
b. The MHRA takes actions including:
   -working together with the manufacturers;
   -taking formal enforcement;
   -offenders may be fined or imprisoned under other regulations;
   -Civil injunction maybe applicable

Recent assessment: assess by the MHRA (latest update in 2020) and in literature (such as Blythe, 2000).

Appendix III Key documents identified impacting TCM regulations in the UK

1. House of Lords Selected Committee on Science and Technology- Sixth Report

Author: House of Lords Selected Committee on Science and Technology

Time: 2000

Objective: To protect the public interests (do not harm, effective beyond placebo, adequate quality of remedies)

Target:

(1) Practice grouping and regulation for public safety:
   a. Classified TCM in the group 3a with less scientific evidence to support its complex framework. No special recommendation for regulation though somehow self-regulation applied.
   b. However, acupuncture and herbal medicine in group1 (professionally organised). Therapies in this group should strive for statutory regulation.
   c. Massage and reflexology in group2 (often used without diagnosis skill). Single regulatory body is in need for each therapy.

(2) Practice effect:
   a. Has pleasing effect.
   b. Scientific evidence on efficacy is weak (few research/ low weight of existing researches).

(3) Practitioner training and education: standardised education and training should be investigated by each regulatory body of single therapy.

(4) Products: researches are needed to build evidence base (but the researches on products should not be separate from which on practice).

(5) Practice and products information: Attention needed on information channel.

(6) Practice delivery: GPs and doctors as gatekeepers.

2. Government Response to the House of Lords Select Committee on Science and Technology's report on Complementary and Alternative Medicine

Author: Department of Health

Time: 2001

Objective: Safety, efficacy, quality

Target:

(1) Practice grouping and regulation:

a. For therapied crossing boundaries of grouping, statutory regulation or professional regulation could be applied for the parts of the therapies within their group (like herbal medicine and acupuncture, which are allied with TCM, in group1 could be regulated first).
b. Single regulatory body is needed for each therapy.
c. Statutory regulation on acupuncture and herbal medicine is expected, but representatives and other materials and documents and procedures are required.

(2) Practice effect:

a. Research on diagnosis procedure is as important as treatment.
b. Evidence for CAM efficacy beyond placebo is missing, but one mostly accepted function of CAM is relaxation.
c. Practitioner should make realistic claim on treatment, and related code of practice is needed from regulatory bodies otherwise consumer protection law is applied.

(3) Products safety (herbal medicine):

a. MCA (former MHRA) would advocate the development of European legislative framework for safe traditional medicine.
b. The Section 12 of Medicine Act 1968 is weak, the EU framework is expected to replace Section 12.
c. Government is on the way to forbid the use of some toxic ingredients.
d. To ensure the safety and quality of herbal medicine is as important as respecting the independent features of different genre of herbalists.

(4) Practitioner education and training:

a. Registration association should ensure the qualification of practitioners, and should provide lifelong advanced training.
b. Accreditation board is a route for standardised education.
c. Competence is a concern in CAM education.
d. National occupation standards for CAM is needed.

(5) Practice and products information: healthcare professionals in the UK health system should by familiar with CAM at different level, and the public should have access to adequate information of CAM.

(6) Practice delivery: there is a scope for integration of CAM and Western medicine, and GPs play an important role here.

3. Key Recommendations on the Regulation of Herbal Practitioners in the UK (A Summary Report)

Author: Herbal Medicine Regulatory Working Group

Time: 2003

Objective: Safety, quality

Target: Herbal medicine

(1) Practitioner:

a. to be regulated under professional body of either a Herbal council or a CAM Council

b. only herbalists under statutory regulation are allowed to practise medicine with specific dosage and ingredients that was permitted to be supplied after one-to-one consultation (change made to the SI 1977/2130 The Medicines (Retail Sale and Supply of Herbal Remedies) Order 1977)

c. only herbalists under statutory regulation are allowed to practise industrially manufactured herbal products produced by a third party to bona fide unsolicited request (changes to Section 12 (1) Medicines Act 1968)

d. those who were not regulated by any means and under any organisations should seek for either statutory or voluntary but professional and systematic regulation

(2) Products:

a. the regulatory body would ensure the qualification of its member than allow its member to prescribe unlicensed remedies including mineral and animal ingredients

b. the permission for a third party to manufacture remedies (in non-industrial way) after individual consultation should be reconsidered (change made to the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971)

e. industrially manufactured herbal products produced by a third party and supplied by a statutorily regulated practitioner should be complaint to GMP (changes to Section 12 (1) Medicines Act 1968)

f. industrially manufactured herbal products produced by a third party and supplied by a statutorily regulated practitioner should be subjected to the 2001 Directive for a market authorisation (changes to Section 12 (1) Medicines Act 1968)

g. further discussions were required on the route of proving the safety and quality of non-plant medicines

(3) Practice: work with the European Herbal Practitioners Association and the Skills for Health to develop National Professional Standards for Herbal Medicine to guide practitioners, assess the work of regulatory bodies, to assist the educators, promote and guide the utilisation of herbal medicine for the others

4. Regulation of herbal medicine and acupuncture- Proposals for statutory regulation

Author: Department of Health

Time: 2004

Objective: Quality of patient care

Target: Herbal medicine and acupuncture

(1) Practitioner:

a. to be regulated in four UK countries

b. to be regulated by granting specific titles to guarantee the competence of practice

c. to be regulated either under a single professional body or an overall CAM Council, and a CAM Council was preferred as it could:

- be a body that involves both practitioners and lay people in its decision making group; set committees of education& training, investigation, professional conduct, health; use 'grandparenting' scheme in transitional period
- do registration work: set working distinction for practitioners already registered; starts from herbalists and acupuncturists to other CAM professions; individually assess practitioners qualified overseas
- set standards of education and training: involve accreditation of education and core curriculum; operate CPD
- suggest standards of conduct: identify the needs of professional standards; emphasis the confidentiality& informed consent of patients; propose code of using herbal medicine under 1968 Act, code of professional conduct and code of safe practice; consider the fitness of practice
- administer misconduct: set sanctions for misconduct in fitness of practice; open channel of appeal
- safeguard the public
- work with other stakeholders
- consider the professions differently
- regard to the interest of the public
- inform its work

- advise on products
- promote the professions
- advise on development

5. White paper- Trust, Assurance and Safety- The Regulation of Health Professionals in the 21st Century

Author: The Secretary of State for Health

Time: 2007

Objective: Safety

Target:

(1) Practitioner: a working group was established to look into the unregulated health professionals including acupuncturists, herbalists and TCM practitioners

6. Report to Ministers from The Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK

Author: Department of Health Steering Group on the Statutory Regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK

Time: 2008

Objective: Various aspects of public interests

Target: Practitioners to be statutorily regulated under either

(1) A single profession body, which was not recommended due to the cost; or

(2) A general body, which was not recommended due to overlap with the existing bodies and possible high cost; or

(3) A group of HPC:

a. Could find sources and to devise suitable structures for different professions
b. Could distinguish different disciplines of a profession (such as traditional& medical acupuncture)
c. Could set standards of proficiency
d. Could set standards of education& training
e. Could set standards of conduct, performance& ethics

f. Could protect the titles for ‘acupuncturist’, ‘herbalist’& ‘TCM practitioner’, and permit other medical practitioner eligible of HPC registration of these three professions to practise these therapies
g. Could protect the practise function by ensuring practitioners are properly qualified
h. Could set ‘grandparenting’ for the currently registered practitioners to transfer
i. Have the function of: promote and develop, publish journal, run CPD, provide support of complaint, provide industrial relation, and other standards
j. Should consult and meet the professions frequently
k. Should set language competence
l. Should cover the four UK countries

(4) Whilst urge to reform the Section 12 (1) of the 1968 Act:
a. To set standards of training and practice
b. To accelerate statutory regulation
c. To consider smaller scale of therapies that may not be regulated
d. To distinct medicines used under 1968 Act and the other OTC medicines
e. To request proof of historically safety of medicine under 1968 Act

7. A joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK

Author: Department of Health/ Professional Standards Division

Time: 2009

Objective: Public protection

Target: Practitioner to be regulated under either

(1) Products regulation:
a. Using THR to regulated OTC medicines under the 2004 Directive
b. Using the following route to regulate practitioner prescribing the unlicensed medicine to supplement the weakness of the 1968 Act, while informing the public more about the risks of using unlicensed medicine
c. Statutory licensing scheme: granting license to practitioners with proper qualification and no records of crime
d. Voluntary licensing scheme: same as now
e. System regulation: practitioners to register with a Care Quality Commission based on their medical activities

f. Self-regulation: needs standards and corresponding sanctions in various aspects, also public information sources need to be strengthened
g. Accredited registration for voluntary regulation: needs standards of minimum governance, of investigation, of codes of conduct
h. General health or trading legislation: weak and less focusing
i. Local authorities regulation

8. Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK- An Analysis Report on the Consultation

Author: Department of Health/ Professional Standards Division

Time: 2011

Objective: Public protection

Target: A factual analysis of the public or industry response to the 2009 Consultation

9. Regulation of Herbal Medicines and Practitioners

Author: David Walker

Time: 2015

Objective: Safety

Target:

(1) Product:
a. To review and amend the current list of banned and restricted herbal ingredients
b. To review and assess the feasibility of the food lists used in other European countries
c. To invite the European Commission to review the Herbal Directive
d. To encourage the further research about: risks of herbal medicines and demanded intervention, the evidence base of such intervention, and the assurance towards practitioners to guarantee the safety of products

(2) Practitioner:
a. To consider the possibility of allowing off-site small scale of products 'dispensary'
b. To develop umbrella voluntary registration

10. Government Response to Professor Walker's advice on Regulation of Herbal Medicines and Practitioners

Author: Nicola Blackwood (from Department of Health and Social Care)

Time: 2017

Objective: Public safety

Target:

(1) Product:

   a. A review to the current list of banned and restricted herbal ingredients is proposed
   b. A review to the food lists is rejected as ‘not applicable’, instead, to increase the understanding of existing regulatory controls is expected
   c. The invitation of the European Commission to review the Herbal Directive is under discussion due to Brexit
   d. Further research is supported

a. Practitioner:

   a. Off-site small scale of products ‘dispensary’ is rejected
   b. The development of standards for education, training and conduct is supported to add accreditation to registration

Appendix IV Information of TCM related reports received by the YCS

Herbal name	Total report	Most sex (M/F)	Most age	Most year	Most organ damage	Most seriousness	Cases caused (number of fatal cases)	Also used in multiple constituent formulation
Adenophora Shashen/沙参[c]	2	F& M	60-69	1999, 2008	Nervous	Non-fatal	8	
Agrimonia Xianhecao/仙鹤草[c]	1	M	60-69	2004	Renal and urinary	Non-fatal	1	
Allium Sativum Dasuan/大蒜	31	F	70-79	2010, 2018	Gastrointestinal	Non-fatal	71	
Apium Graveolens Hanqin/旱芹[a]	6	F	50-59, 70-79	2004	Cardiac	Non-fatal	12	√
Arachis Hypogea Huasheng/花生[a]	17	M	20-29, unknown age group	2007, 2014, 2015, 2016, 2019, 2021	Nervous; respiratory, thorac and mediastinal (respiratory)	Non-fatal	73	√
Arachis Oil Huasheng You/花生油	48	M	0-9	2017	Skin & subcutaneous tissu (skin)	Non-fatal	91	√
Aralia Racemosa Cilaoya/刺老鸦[a]	3	F	30-39, 40-49, 50-59	2006, 2015, 2018	Gastrointestinal	Non-fatal	12	
Arctium Niubang/牛蒡[c]	28	F	20-29	2020	Gastrointestinal	Non-fatal	110	√
Areca Binglang/槟榔[c]	1	M	20-29	2018	Blood & lymphati (blood)	Non-fatal	1	
Atropa Belladonna Dianqiecao/颠茄草	54	F	50-59, unknown age group	1979	Skin	Non-fatal	86	√
Avena Sativa Yanmai/燕麦[a]	7	F	60-69	2005, 2010	Nervous	Non-fatal	38	√
Berberis Xiaobo/小檗[ac]	4	F	10-19, 30-39, 60-69, 80-89	2005, 2011, 2016, 2020	Gastrointestinal	Non-fatal	19	
Brassica Yuntai/芸薹[ac]	2	F	60-69, 70-79	2008, 2011	Investigation; respiratory	Non-fatal in investigation; fata in respiratory in 2011	2 (1)	√
Calotropis Niujiaogua/牛角瓜[ac]	1	F	Unknown age group	2014	Investigation	Non-fatal	4	
Camellia Sinensis Shancha/山茶[a]	65	F	20-29	2012, 2013	Nervous	Non-fatal in most symptoms; fatal in respiratory and some multiple constituent, in 201	225 (1)	√
Camphor Zhangnao/樟脑	116	F	60-69	2018	Skin	Noticeable fatal in all sex, multiple ages, single and multiple constituent, cardia and general disorder, in 1964, 1987, 2015	479 (3)	√
Cannabis Sativa Huomaren/火麻仁[b]	122	M	20-29	2019	Psychiatric	Noticeable fatal in all sex, multiple ages, single constituent, multiple symptom in multiple years	602 (31)	√
Capsella Bursa-Pastori Jicai/荠菜[a]	1	F	50-59	2018	Investigation	Non-fatal	1	
Capsicum Lajiao/辣椒[c]	77	F	30-39	2015, 2016	Skin	Non-fatal	223	√
Carthamus Honghua/红花[c]	9	F	30-39, 60-69, unknown age group	2008, 2010	Nervous	Non-fatal	35	√
Catechu Ercha/儿茶	1	F	40-49	1997	Renal and urinary	Non-fatal	1	
Caulophyllum Hongmaoqi/红毛七[abc]	1	F	Unknown age group	2006	Pregnancy, puerperium and perinatal	Non-fatal	1	
Chelidonium Baiqucai/白屈菜[c]	2	F	10-19, 40-49	2013, 2020	Skin & subcutaneous tissu	Non-fatal	3	

Cichorium Juju/菊苣	6	M	Unknown age group	2017	Nervous; respiratory; musculoskeletal a connective tissue (musculoskeletal)	Non-fatal	12	√
Cinnamomum Rougiu/肉桂[b]	23	F	60-69, 70-79	2011	Nervous	Basically non-fatal but fatal reported female, 70-79, single constituent, hepatobiliary, 201	78 (2)	√
Cochlearia Lagencai/辣根菜[b]	1	F	60-69	2003	Hepatobiliary	Non-fatal	1	
Cocos Nucifera Yezi/椰子[b]	14	M	0-9	2019	Skin	Non-fatal	65	√
Commiphora Moyao/没药[c]	12	F& M	30-39	2009, 2010, 2011	Nervous	Non-fatal	49	√
Coriandrum Sativum Yansui/芫荽[a]	1	F	20-29	1989	Skin; musculoskeletal	Non-fatal	9 (1)	
Crocus Fanhonghua/番红花[c]	3	M	20-29, 30-39, unknown age group	2009, 2014, 2015	Skin	Non-fatal	15	√
Curcuma Jianghuang/姜黄	27	F	60-69	2018	Gastrointestinal	Non-fatal	118 (1)	√
Cuscuta Tusizi/菟丝子[c]	7	M	Unknown age group	2003, 2006, 2007, 2008, 2010, 2011, 2012	Nervous; general disorder	Non-fatal	33	
Cymbopogon Xiangmao/香茅[ac]	7	F	20-29	2015	Nervous	Non-fatal	28	
Daucus Huluobo/胡萝卜[ac]	4	F	30-39	2012	Investigation	Non-fatal	19	√
Digitalis Yangdihuang/洋地黄[b]	18	F	Unknown age group	1965, 1972	Endocrine	Fatal for all sex, multiple ages, in cardiac and infection, reported death in 1970, 1974, 1976 and 1978	27 (4)	
Dryopteris Mianma/绵马[c]	2	M& F	30-39，unknown age group	1975, 2000	Nervous; hepatobiliary	Non-fatal	2	
Ephedrine Mahuang/麻黄[c]	202	F	Unknown age group	1985, 1986	Nervous	Fatal for all sex, a multiple ages, bot single and multipl constituent, in multiple organ damage, death reported in 1969, 1971, 1972, 1975, 1992, 1999, 2001, 2010	507 (9)	√
Equisetum Muzei/木贼[c]	21	F	40-49, 50-59, 60-69	2008	Hepatobiliary	Fatal found in female, 50-59, multiple constituent, hepatobiliary, reported in 2020	65 (1)	√
Eucalyptus Anshu/桉树[ab]	102	F	0-9	2021	Skin	Fatal found in female, 0-9 and 40 49, multiple constituent, cardia and general disorder, reported 1987 and 2015	381 (2)	√
Eupatorium Zelan/泽兰[c]	1	F	90-99	2005	General disorder and investigation	Non-fatal	4	
Fagopyrum Esculentu Qiaomai/荞麦[a]	3	F	20-29, 60-69, 70-79	2005, 2014, 2016	Hepatobiliary and cardiac	Non-fatal	7	√
Ferula Assa-Foetida Awei/阿魏	1	M	50-59	2004	Investigation	Non-fatal	1	
Ficus Carica Wuhuaguo/无花果[a]	1	F	40-49	2013	Skin	Non-fatal	2	
Foeniculum Vulgare Huixiang/茴香	23	F	20-29	2009	Investigation	Fatal in infection and infestation	80 (1)	√
Gentian Longdan/龙胆[b]	75	F	60-69	2017	Gastrointestinal	Fatal found in female, 80-89,	169 (1)	√

						multiple constituent, hepatobiliary, reported in 1985		
Ginkgo Biloba Yinxing/银杏[b]	94	F	70-79	2000	Nervous	Fatal found in mal 70-79, single constituent, infection, reported in 2015	237 (1)	√
Glycyrrhiza Gancao/甘草[b]	113	F	50-59	2010, 2017	Gastrointestinal	Fatal found in M&F, multiple ages, S&M constituent, hepatobiliary, psychiatric, neoplasms benign reported in 2004, 2010, 2020	281 (5)	√
Hamamelis Jinlvmei/金缕梅[ac]	49	F	60-69	2019	Eye	Non-fatal	152	√
Hazel Zhen/榛子[ab]	1	M	0-9	2018	Immune system	Non-fatal	1	
Hedera helix Changchunteng/ 常春藤[a]	2	F& M	70-79, unknown age group	2013, 2019	Gastrointestinal, general disorder, investigation	Non-fatal	5	
Hippophae Shaji/沙棘	2	F& M	30-39, 50-59	2009, 2014	Immune system	Non-fatal	3	√
Hyoscyamus Niger Langdang/莨菪	1	M	0-9	2010	Psychiatric	Non-fatal	4	
Hypericum Guanye Lianqiao/贯叶连翘[ac]	266	F	30-39	2000	General disorder	Fatal found in F, 30-39, single constituent, cardia reported in 2002	788 (1)	√
Hyssopus Officinalis Niuxi/牛膝	7	F	60-69	2020	Immune system	Non-fatal	24	√
Ilex Dongqing/冬青[ab]	18	F	20-29	2021	Immune system & general disorder	Non-fatal	74	√
Impatiens Glandulifera Fengxianhua/凤仙花[a]	4	F	Unknown age group	2015	Respiratory	Non-fatal	7	
Inula Xuanfuhua/旋覆花[c]	2	F& M	30-39, 50-59	2009, 2019	Infection	Non-fatal	9	√
Juglans Hutao/胡桃[ab]	8	F	30-39	1994, 2004, 2005, 2006, 2007, 2008, 2009, 2010	Respiratory, gener disorder	Non-fatal	13	√
Juniperus Cibo/刺柏[ab]	39	M	Unknown age group	2019	Skin	Non-fatal	102	√
Kaempferia Shannai/山奈[c]	2	F	80-89, unknown age group	2014, 2017	Cardiac, investigation	Non-fatal	8	√
Lactuca Woju/莴苣[abc]	23	F	50-59, unknown age group	2017	General disorder	Non-fatal	55	√
Laminaria Kunbu/昆布[c]	6	F	60-69, unknown age group	2009	Investigation	Non-fatal	22	√
Levisticum Officinale Oudanggui/欧当归[ab]	1	F	30-39	2013	Gastrointestinal	Non-fatal	5	
Linum Usitatissimum Yama/亚麻[b]	8	F	30-39, 70-79 unknown age group	2012	Cardiac, Gastrointestinal, hepatobiliary, skin	Non-fatal	12	√
Lithospermum Zicao/紫草	5	F	20-29, 30-39	1999, 2000, 2004, 2008, 2010	Hepatobiliary	Non-fatal	10	
Lobelia Inflata Banbianlian/半边莲	16	F	Unknown age group	1964, 1970, 1972	Endocrine	Fatal found in F, unknown age, infection, reported in 1970	26 (1)	
Lonicera Rendong/忍冬[bc]	14	M	20-29, 30-39	2011	Gastrointestinal	Non-fatal	52	
Magnolia Xinyi/辛夷[c]	6	F	20-29, 50-59	1999, 2001, 2009, 2010, 2018, 2019	Gastrointestinal & infection	Non-fatal	14	√
Mulberry Sangsen/桑葚	7	F	10-19, 20-29, 30-39	2010	Investigation	Non-fatal	11	√
Myristica Fragrans	5	F	50-59	2010, 2015	Hepatobiliary,	Non-fatal	11	√

Roudoukou/肉豆蔻[ab]					investigation, nervous			
Nasturtium Officinale Doubancai/豆瓣菜[a]	1	F	20-29	2014	Hepatobiliary	Non-fatal	5	
Nepeta Jingjie/荆芥[ac]	7	F	20-29	2004, 2010	Gastrointestinal	Non-fatal	40	
Ocimum Luole/罗勒[ab]	2	F	Unknown age group	1997, 2014	Investigation	Fatal in infections and infestation	19 (1)	√
Oenothera Yuejiancao/月见草[ac]	79	F	40-49	1992, 2006	Nervous	Fatal found in F, 40-49, single constituent, congenital disorde reported in 1994	170 (1)	√
Origanum Niuzhi/牛至[a]	2	F	40-49, 50-59	2014, 2020	Gastrointestinal, injury, investigation, musculoskeletal, skin	Non-fatal	5	√
Oryza Sativa Xianmi/籼米	3	F	20-29, 30-39, 50-59	2007, 2008, 2009	Hepatobiliary, infection, musculoskeletal, renal, skin	Non-fatal	15	
Paeonia Baishao/白芍[bc]	35	F	60-69, 70-79	2011	General disorder	Fatal found in F, 70-79, single constituent, infection, reported in 2004	128 (1)	√
Passiflora Xifanlian/西番莲[a]	77	F	Unknown age group	2017	Gastrointestinal	Non-fatal	217	√
Patchouli Guanghuoxiang/广藿香	1	M	20-29	2018	Blood	Non-fatal	1	
Pinus Changsong/长松[ac]	46	F	0-9	2018, 2019, 2021	Skin	Fatal found in F&M, 0-9 and unknown age, multiple constituent, infection and general disorder, reported in 1979, 1991	127 (2)	√
Pistacia Ayuehunzi/阿月浑子[ac]	1	F	50-59	2006	Eye, nervous, respiratory	Non-fatal	3	
Plantago Cheqiancao/车前草[c]	161	F	Unknown age group	1988, 1990, 2017	Gastrointestinal	Fatal found in F&M, multiple ages, single constituent, gastrointestinal an respiratory, report in 1970, 1977, 1979, 1993	344 (7)	√
Polygala Yuanzhi/远志[c]	4	M	20-29, 40-49, 50-59, 60-69	1999, 2010, 2011, 2018	Nervous	Non-fatal	10	
Potentilla Jinlumei/金露梅[a]	3	F	40-49, 60-69, 80-89	2006, 2010, 2017	Cardiac, hepatobiliary, investigation	Non-fatal	9	
Primula Baochunhua/报春花[ac]	1	Unknown	Unknown	2010	Congenital	Non-fatal	2	
Pulsatilla Baitouweng/白头翁[c]	5	F& unknown sex	Unknown age group	1995, 1997, 2018, 2019, 2020	General disorder, nervous	Non-fatal	16	√
Punica Granatum Shiliupi/石榴皮[b]	7	F	30-39, 70-79	2008	General disorder	Non-fatal	25	
Rhamnus Shuli/鼠李[ac]	12	F	60-69	2011	Gastrointestinal	Non-fatal	34	√
Rheum Dahuang/大黄	15	F	30-39	1999, 2011	Gastrointestinal	Non-fatal	61	√
Rhodiola Hongjingtian/红景天	23	F& M	Unknown age group	2010	Investigation	Non-fatal	63	√
Rhus Yanfumu/盐肤木[abc]	8	F	70-79, unknown age group	2016	General disorder	Non-fatal	14	√
Ricinus Communis Bima/蓖麻[b]	3	F	0-9, 30-39, unknown	1973, 1982, 2016	Gastrointestinal	Fatal found in M, unknown age, single constituent, gastrointestinal, reported in 1982	4 (1)	√

Rosa Qiangwei/蔷薇[ac]	15	F	50-59	2009	Investigation	Non-fatal	63	√
Rosmarinus Officinalis Midiexiang/迷迭香	13	F	40-49	2014	Skin	Non-fatal	34	√
Rubia Qiancao/茜草[c]	2	F& M	30-39, unknown age	1997, 2010	Gastrointestinal	Non-fatal	12	
Rubus Fupenzi/覆盆子	6	F	20-29	2008	Nervous	Non-fatal	17	√
Rumex Suanmo/酸模[ac]	3	F	50-59, 60-69, 80-89	2005, 2008, 2011	Gastrointestinal	Non-fatal	14	
Ruta Yunxiang/芸香[ac]	1	M	Unknown age	2011	Skin	Non-fatal	1	
Sambucus Jiegumu/接骨木	5	F	20-29	1997	Psychiatric	Non-fatal	9	√
Smilax Baqia/菝葜[c]	16	M	30-39, 50-59	2009, 2016, 2018	Gastrointestinal	Non-fatal	89	√
Stellaria Media Fanlv/繁缕[a]	3	F	0-9, 40-49, 60 69	2001, 2005, 2012	Gastrointestinal	Non-fatal	18	√
Swertia Zhangyacai/獐牙菜[a]	3	F, M, unknown sex	60-69, 70-79, unknown age	2006, 2014, 2017	Investigation	Non-fatal	8	√
Urtica Qianma/荨麻[a]	21	F	50-59	2021	Skin	Fatal found in F, 50-59, multiple constituent, hepatobiliary, reported in 2020	131 (1)	√
Valeriana Officinalis Xiecao/缬草[a]	231	F	Unknown age group	2016	Gastrointestinal	Fatal found in F, 80-89, multiple constituent, hepatobiliary, reported in 1985	712 (1)	√
Verbena Mabiancao/马鞭草	19	F	50-59, 70-79, unknown age	2017	Gastrointestinal	Non-fatal	58	√
Zanthoxylum Huajiao/花椒	6	F& M	60-69	1987, 1992, 1997, 1999, 2011, 2012	Gastrointestinal，hepatobiliary	Non-fatal	9	√
Zea Mays Yumi/玉米[a]	3	F	50-59, 60-69	2005, 2017, 2020	Gastrointestinal	Fatal found in F, 50-59, multiple constituent, hepatobiliary, reported in 2020	36 (1)	√
Zingiber Officinale Shengjiang/生姜	60	F	Unknown age group	2021	Gastrointestinal	Fatal found in F, 50-59, 60-69 multiple constituent, hepatobiliary, respiratory, report in 2011, 2020	208 (3)	√

[a] Not found in the *Pharmacopeia of the PRC*, but found in other TCM books in China
[b] TCM only uses some parts of this herb/plant
[c] TCM only uses one or more species of this genus of herb/plant

Appendix V Regulations concerning food and cosmetics importation to the UK

PART I Regulations for food in the UK

13. Regulation (EC) No. 178/2002 of the European Parliament and of the Council

Current situation: End of implementation after Brexit, but requirements retained in the UK

Regulatory instrument: EU Regulation

Regulatory body: EU Parliament, EU Council, European Food Safety Authority

Objective: General principles and requirements for food safety

(1) Protect human life and health/ consumers' interest/ (where appropriate) protect animal, plant and environment

(2) Achieve free movement of food

(3) Consider international standards

Target: Product (food)

(1) Definition: For human ingestion/ includes water and chewing gum/ excludes feed/ live animal/ live plant/ medical products with Council Directive 65/65/EEC (1) & 92/73/EEC (2)/ cosmetics within the meaning of Council Directive 76/768/EEC (2)/ tobacco within 89/622/EEC (4)/ narcotic or psychotropic substances/ residues and containments

(2) Importation: should comply with or equivalent to the Community law

(3) Safety requirements:

   a. Not to be unsafe: at any stage/ provide specific information (even just parts of the food)/ no contamination

   b. Not injure health and not unfit for human consumption: for both short- or long-term cumulative toxic effects or cause problem to special sensitive people

   c. Community provisions: regards food with compliance to the provisions to be safe/ could still withdraw food even though which complies/ regards food complying with member states' provision to be safe when no Community provision applies

(4) International standards: Community and member stated should contribute to/ should promote/ pay attention to developing countries to reduce unnecessary obstacles/ promote consistency between technical standards and international standards

Process/ Enforcement/ compliance mechanism: see The Food Safety and Hygiene (England) Regulations 2013

Recent assessment: Assessed in literatures: risk assessment is not strong enough, more scientific systematic assessment needed (Boer, 2019); the concept of 'placing on market' was too broad especially for exporting food that needs pre-market authorisation in EU before exportation, but this has been solved in the Brexit Agreement (Simpson, 2020).

14. Commission Implementation Regulation (EU) 2019/1793

Current situation: End of implementation after Brexit, but requirements retained in the UK

Regulatory instrument: EU Regulation

Regulatory body: EU Commission

Objective: Temporary increase of control and emergency measures governing the entry of food to the EU from certain third countries

Target: Product (food)

(1) Increased official control on (Annex I):

a. Goji berries (wolfberries) (Lycium barbarum L.) for fresh, chilled or dried to control pesticide residues
b. Sweet peppers (Capsicum annuum) for crushed or ground to control salmonella
c. Tea (flavoured or not) to control pesticide residues

Goji berry and sweet pepper are under 'ex' CN code that are subjected to examination.

(2) Special control due to mycotoxins:

a. Groundnut with(out) shell in butter, oil, flour or otherwise prepared to control aflatoxins

Process/ Enforcement/ compliance mechanism: N/A

Recent assessment: N/A

15. Food Safety Act 1990

Current situation: Amended to align with the EU regulations

Regulatory instrument: Parliament Act

Regulatory body: The Secretary of State, the Food Standards Agency or other food authorities

Objective: Food Safety

Target: Product (food) related activities would be sentenced as offences including

(1) Rendering food to be harmful for health by adding any substance, using any substances in preparation of food, abstracting constituent from food, subjecting food to treatment, with intention that food is sold for human consumption (Section 7);

(2) Selling food violating the demanding nature (Section 14);

(3) Falsely describing or presenting food (Section 15);

(4) If other person caused the offence, the other person would be guilty of an offence;

(5) An defence is applicable.

Process/ Enforcement/ compliance mechanism: N/A

Recent assessment: Amended by the 2013 Regulations

16. The Food Safety and Hygiene (England) Regulations 2013

Current situation: In use

Regulatory instrument: UK statutory instrument

Regulatory body: The Secretary of State, the Food Standards Agency

Objective: Food safety and hygiene

Target: Product (food)

Process/ Enforcement/ compliance mechanism:

（1）Hygiene improvement notices to state non-compliance to Hygiene Regulations and requires improvement within 14 days; Hygiene prohibition orders imposed by court; Hygiene emergency prohibition notices and orders; Remedial action notices; Detention notices;

（2）Guilty of an offence with fine or imprison

Recent assessment: Asking for post implementation review (results unknown) (FSA, 2020b).

17. The General Food Regulations 2004

Current situation: In use

Regulatory instrument: EU Regulation

Regulatory body: The Secretary of State, the Food Standards Agency, district health authorities (including the Common Council of the City of London)

Objective: Safety

Target: Product (food)

(1) Activities offend the requirements of the 178/2002 Regulation for safety requirement, presentation, traceability related to food business, and other responsibilities for food and food business;

(2) Punishment is sentenced when a person is guilty of an offence with fine or imprison (for no more than 6 months on summary conviction or 2 years on conviction on indictment);

(3) The district authorities can enforce any offence, whilst the FSA can enforce offence related to food safety requirements and other responsibility of food business;
(4) The activities of Section 7 (2) in 1990 Act of using substance in food preparation is replaced by 14 (4) 178/2002 Regulation; the activities of Section 7 (3) of abstracting constituent is omitted; the part of food that is unsafe is decided by Section 14 178/2002 Regulation

Process/ Enforcement/ compliance mechanism: N/A

Recent assessment: Reconsidered and amended by the European Commission in 2018 concerning the specific food chain, especially regarding the transparency of studies used in evaluation of the pesticides (ENVI, 2018).

18. The EU Food Supplement Directive 2002/46/EC

Current situation: In use, but transferred into the Nutrition Regulations 2019 and the Nutrition Regulations 2020

Regulatory instrument: EU Directive

Regulatory body: The Secretary of State (and similar authorities in Scotland and Wales)

Objective: Safety

Target: Product (food supplement)

(1) Definition: food with purposes to supplement the normal diet and is the source of vitamin or mineral or other substances with nutritional or physiological effect, and which is sold in dose form.

Process/ Enforcement/ compliance mechanism: Implemented in the UK as The Food Supplements (England, Scotland, Wales) Regulations 2003

Recent assessment: A complex legal area to distinguish medicine and food supplement (Guidance notes on legislation implementing Directive 2002 on food supplements, 2021)

19. The Food Supplements Regulation 2003

Current situation: In use

Regulatory instrument: UK SI

Regulatory body: The Secretary of State (and similar authorities in Scotland and Wales), food authorities

Objective: Safety

Target: Product (food supplement)

(1) Food supplement shall be sold after pre-packed;

(2) Vitamins and mineral substances can only be manufactured in food supplement of specific species and in specific form and with specific purity criteria;
(3) Food supplement should be labelled as 'food supplement', and cannot be delivered to a catering establishment before fulfilling the specific label requirements, and such label should state the quantities of nutrients;
(4) The label of food supplement should be clear, be clean, be in proper place of the package, be understandable, and should state related documents of compliance.

Process/ Enforcement/ compliance mechanism: Person violating the selling form, composition, making and using proper labels shall be guilty of an offence and may with fine.

Recent assessment: Further information of labelling see Food Information Regulations 2014.

20. Regulation (EU) 2015/2283 of the EU Parliament and of the Council

Current situation: In use

Regulatory instrument: EU regulation

Regulatory body: EU Parliament and the Council,

Objective: Safety

Target: Product (novel food)

(1) Definition: food that not consumed by people in the UK or EU before 15 May 1997, including new food, traditional food eaten elsewhere, food produced by new technologies and etc..
(2) Market authorisation:
    a. General rule:
        - application includes general information, scientific evidence for safety, analysis methods, labelling information; the food authority shall make public such application; the food authority could terminate such application at any stage.
        - Safety: as a comparable food already on market/ composition and condition of use do not pose safety risk/ has no nutritionally disadvantage with the existing food that the application intends to replace
    b. Traditional food notification:
        - application includes general information, composition, countries of origin, data of history of safe use, labelling information;

- Safety: data of safe use history in third country (25 years outside the UK)/ composition and condition of use do not pose safety risk/ has no nutritionally disadvantage with the existing food that the application intends to replace

Process/ Enforcement/ compliance mechanism: Member states shall lay down penalties and take measures to ensure the penalty rules are implemented.

Recent assessment: Debates found discuss the approval of CBD as novel food after Brexit (see Tatum, 2021). The 2015 Regulation made change to the old approval mechanism of novel food, better protected the consumers and the competitivity of the domestic market. However, balance needs to be considered when facing the safety legislation gaps between the EU and the third countries (Zarbà, Chinnici & D'Amico, 2020)

PART II Regulations for cosmetics in the UK

1. The Regulation (EC) No 1223/2009 on Cosmetic Products, amended by the Product Safety and Metrology (EU Exit) Regulations 2019, and the Cosmetic Products Enforcement Regulations 2013

Current situation: In use, but amended to apply in GB

Regulatory instrument: EU Regulation

Regulatory body: The Secretary of State, the local authorities in GB

Objective: Safety

Target: Product (cosmetics)

(1) Defined to have the functions of: clean/ perfume/ change the appearance/ protect/ keep in good condition/ correct body odours; to apply in: epidermis/ hair/ nails/ lips/ external genital organs/ teeth/ mucous membranes of oral cavity; to be in permitted form (Appendix 4): (seen in TCM products) cream/ emulsions/ lotion/ oil/ gel/ tinted bases (liquids, pastes, powders)/ hair products

(2) Importation: comply with the UK (EU) safety requirement (including importer as responsible person), fulfil the safety assessment and related test, fulfil the labelling requirements, register with the Cosmetic Products Notification Portal (CPNP).

(3) Safety requirements:

a. Safe for human use (manufacturers should foresee the average possible usage);
b. To comply with The Food Limitations (Safety) Regulations 1989 to prevent person confuse the cosmetics with food, or related actions that cause death or injury;

c. A responsible person should ensure the compliance. This person could be manufacturers or importers based in the UK, or a nominated third party based in the UK.
d. Manufacturing of cosmetics should comply with GMP or other applicable documents available from trade association.

Process/ Enforcement/ compliance mechanism:

(1) Provisions:

a. Do not supply cosmetics causing damage to human when reasonably using;
b. Do not use prohibited substance;
c. Restrict the use of some substances, i.e. fragrances, colouring agents and UV filters;
d. Do not use prohibited 'specified risk material', i.e. products derived from certain animal carrying risk of BSE;
e. Specific label;
f. Certain information is required to be held by responsible person.

(2) Enforcements:

a. A competent authority ensures the responsible person to ensure compliance or withdraw or recall products within time limit;
b. A competent authority takes action when immediate measures are needed to prevent further distribution of the products;
c. A competent authority taking any actions should inform other competent authorities;
d. A competent authority taking any actions should follow the procedure of the Good Administrative Practices.
e. A enforcement authority can take provisional action for serious risk, such action should be allowed by the safeguard clause but determined by the Secretary of the State.

Recent assessment: N/A

Supplementary material 1-Interview questions

Part 1: TCM Practitioners Interview questions

1. How long have you been practising as a TCM practitioner or doctor?
2. How long have you been practising TCM in the UK?
3. Can you tell us something about the professional education and training of TCM that you had?
4. Did you attend any other training after graduation?
5. Do you practice TCM through your own business or do you work for a company?
6. What kind of therapies do you use?
7. Do you modify the therapies you use when practicing in the UK?
8. Are your patients concerned about safety?
9. What are the most prevalent sicknesses you experience during your practice?
10. Are sicknesses here different from China?
11. Have your patients been to see other medical practitioners before coming?
12. Do you make your own medicine?
13. Where do you get the medicine or the medicine ingredients?
14. Why do you choose the supplier for these medicines and medicine ingredients?
15. Have you ever registered with any TCM registration organizations in the UK? How did you do this?
16. How do you feel about the current registration and regulation system?
17. Apart from the TCM regulation system you know, is there any other impact you feel from the UK government regulations?
18. Do you think your work and the TCM industry will be influenced by Brexit?
19. What do you think is the most urgent and important change needed in the current TCM regulation system?
20. Is there anything else you want to share about this topic?

Part 2: TCM industry stakeholder interview questions

1. Can you tell us something about the historical development of TCM industry in the UK from your own point of view?
2. Can you introduce us something about how you developed your TCM related business in the UK?
3. What are the advantages and attractions of TCM in the UK?
4. Do you think there are problems existing in this industry?

5. How do you apply the requirements of GMP in the manufacturing and import of TCM products?
6. How do you think about the future of TCM industry in the UK?
7. How do you think the current stage of the regulatory system of TCM industry in the UK?
8. How do you think the current TCM regulatory system can be improved?
9. What are the major differences between the practice of TCM in the UK and China?
10. What are the similarities and differences between how TCM is regulated in the UK and China?

Supplementary material 2-TCM practitioners finally refused to participate in this research

During the recruiting process of the interview method of this research, there were 4 Chinese TCM practitioners agreed to take part in but finally regrated according their own consideration. They were labelled as RP 1, 2, 3 and 4. The information obtained from them are very limited, but which exactly reflected the sensitivity of Chinese people. The following data may contributed to further researches in this field.

RP 1 was a female practitioner employed by the chain TCM company which owns the Clinic. She was aged around 55. She did not confirm her participation in the interview but instead invited me into her consulting room for a chat. When I explained the details of the interview, she refused because "taking part in academic activity is not her responsibility". As a TCM practitioner, her only job is to treat patients rather than chatting, and this is what her employer pays her for. Then she further explained that she had even refused students from famous academic institutions like the Universities of Cambridge and Oxford (i.e., Dong [2011], who studied the phenomenon of Chinese people's fascination with top universities). RP 1 also said she had agreed to meet me because she felt embarrassed to refuse her friend, who was also my referrer.

RP 2 was another female practitioner employed by the same company, and she appeared to be aged over 70. Before agreeing to participate, she hesitated and wondered for a period and kept asking me for my personal details. Her greatest concern was my organisation. Although I explained that this interview was part of an academic study of my university programme, she was worried the programme had a government connection. She rejected being audio recorded, because she didn't "want [her] voice to be recognised"; neither did she want me to take any written records, because I might misinterpret her words, although she did agree to answer the printed interview questions on paper, starting with the first two questions. Finally, she considered that exposing her handwriting was also a risk and she destroyed the paper. I repeatedly explained that this interview would not be harmful for her, and it was completely unrelated to any governmental issue. RP 2 still considered that anything different from her daily work might cause her trouble.

RP 3 was a female practitioner aged about 50 employed by a small private clinic based around Mayfair, London. I was referred to her by a staff member who had previously been her

colleague at the Clinic. Although she first agreed to take part in the interview and said she was very willing to “do this little favour for a student”. She finally refused to participate because “saying too much may annoy my boss”.

RP 4 was a male self-employed practitioner based around Shepherd’s Bush, London. I was referred to him by his friend, a staff member at the Clinic. I talked to RP 4 several times through Wechat (a popular Chinese social app, similar to Whatsapp, where people can only communicate after adding the contact), and he took time to read my interview questions in advance. However, in the end I did not meet him. RP 4 was promoted as a very renowned TCM practitioner who can “soon reduce blood pressure by injecting two needles”. RP 4 explained he was too busy to rearrange patients waiting for him, and he could not spare any more time for me.