

## A Comparative View on the Traditional and Complementary Medicine (TCM) Regulation in Malaysia and China

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### Abstract

The Traditional and Complementary Medicine (TCM) law in Malaysia needs to be revised to address TCM issues. The inadequacies may impact the quality of the TCM services delivery and the safety of the practitioner, patients, and the public. This study comparatively explored laws in Malaysia and China to recommend improvement on Malaysia's current legal position. The study adopts a qualitative method comprising a doctrinal study and content analysis approach on the healthcare and TCM-related legal framework. The expected outcome of this study will be significant to the government and policymakers.

**Keywords:** *Traditional and Complimentary Medicine, Healthcare, Malaysian Law, China Law*

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### 1.0 Introduction

Traditional and Complementary Medicine (TCM) is found in almost every country, and the demand for its services is increasing. It refers to theories, beliefs, knowledge, abilities, and practices founded on them based on experiences unique to various civilisations (Zakaria, 2021; Liang et al, 2021; Kim, 2017). The Malaysian Ministry of Health's Division of Traditional and Complementary Medicine describes the therapeutic notion as healing in the form of medicine or therapy that can aid in treating an illness or disability. The wellness idea refers to approaches that aid in balancing positive health in an individual, as evidenced by the quality of life and a sense of well-being. Many countries now recognise the need to develop a cohesive and integrative approach to health care that allows governments, health care practitioners, and, most importantly, those who use health care services, to access TCM in a safe, respectful, cost-efficient, and effective manner (World Health Organisation (WHO), 2013). Most researchers agree that TCM is an important yet often underestimated part of health care (Kim, 2017; Mahmud et al., 2009; Mohd Tahir et al., 2015; Remli, 2003). According to the National Pharmaceutical Regulatory Agency (NPRA), over 50 per cent of the total products registered in 2019 were natural products, equivalent to 12,139 units (MIDA, 2020).

In line with this development, Malaysia's pharmaceutical industry focuses on producing herbal products (Zakaria, 2021). The industry offers stimulating opportunities with the potential of Growth Domestic Product (GDP) contributions ranging from RM19 billion to RM28 billion by 2027. The rising cost of modern healthcare has also increased the appeal of the herbal industry as a substitute for conventional health treatments. According to the Overview of the National Traditional and Complementary Medicine (TCM) Blueprint (2018-2027),

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this could potentially reduce healthcare costs by RM13 billion by 2027(MIDA, 2020). Generally, there are six primary forms of traditional medicine practised in the country: traditional Malay, Chinese, and Indian medicines, Islamic medical practice, homoeopathy, and chiropractic and osteopathy treatments. Ancestors of modern practitioners introduced these practices as early as six centuries ago. (MIDA,2020) World Health Organization (WHO) Traditional Medicine Strategy 2014-2023 has outlined the strategy to strengthen the quality assurance, safety, proper use, and effectiveness of Traditional and Complementary Medicine (TCM) by regulating TCM products, practices, and practitioners. Consistent with this objective, the importance of controlling TCM facilities has been discussed within the TCM Division, Ministry of Health, Malaysia (MOH), resulting in the passing of Traditional and Complementary Medicine in 2016 (the Act). However, the enforcement team needed help finding an appropriate mechanism for controlling and monitoring the TCM services and products. Issues such as the absence of specific measures to ensure effective implementation of the TCM practice, lack of trained personnel, inadequate product regulatory system for traditional medicine products, lack of facilities to conduct residency training, the absence of suitable mechanisms for registering TCM practitioners without formal training, absence of a provision to monitor TCM premises complicates the holistic governance of the TCM industry. This situation may impact the quality of the TCM services delivery and, most importantly, the safety of the practitioner, patients, and the public. The industry also needs a single authority or body responsible for developing the sector TCM sector in Malaysia. The gaps within the current regulatory landscape of TCM in Malaysia have impeded the industry's full potential to grow and sustain. The non-sustainability of this industry denies patients rights to alternative access to healthcare and medication, which is more affordable to lower-income families. Therefore, this research aims to explore laws in Malaysia and China to recommend improving Malaysia's current legal position.

## 2.0 Literature Review

Most previous writings agree that TCM in Malaysia comprises different modalities, including Malays, Chinese, Indians, and the indigenous group, and there is a possibility of these systems either competing with or complementing one another (Goh, 2012; Goh;2018; Telles et al., 2014). Some studies highlighted that most Malaysians resorted to TCM to treat chronic illness diseases (Mohd Tahir, 2015; Yusoff, 2019; Park,2022; Mohiudin, 2021). Raja Ikram (2015) compiled and divided their findings into two outputs: the healthcare system framework and the doctor-patient consultation framework in traditional Malay medicine. This study emphasised the need to form proper regulations for the TCM industry in Malaysia to address training issues of its practitioners, licensed providers, and standard conduct procedures. Regarding the qualification of TCM practitioners, Kim (2017) agrees that the government, under the influence of China's administration of TCM, has progressed well in introducing TCM-related courses at the tertiary level. Another report by Park (2022) mentioned that homoeopathy services may co-exist with modern medicine in combatting rising health issues within society. The preceding literature has yet to delve into the rights to health concerning TCM in Malaysia. The main focus of the previous study was the consumer's perception, the history of TCM, and the general discussion on laws and regulations.

## 3.0 Methodology

This research is designed based on the doctrinal study comprising the primary and secondary data and investigation on the legal framework governing the Traditional and Complementary Medicine in Malaysia and the State of the People's Republic of China, essential in providing consolidated analytical findings for the reformation proposal. The primary data consists of the main legislation for TCM, namely the Traditional and Complementary Medicine Act 2016 and its regulation and Control of Drugs Legislation, as listed in Table 1 below. The secondary data comprises the data from journals and online database materials. The online semi-structured interview is conducted with respondents who were selected using purposive sampling. The respondents were the Traditional and Complementary Medicine department officers of the Ministry of Health. Data acquired through literature reviews, doctrinal studies, and semi-structured interviews were analysed using thematic and content analysis. The analysis and discussion were guided by four main themes: the legislation governing TCM, the administration of TCM, the influence of culture in TCM, and the regulation of TCM practitioners in both countries.

## 4.0 Findings

The study discovered that in China, among the aims of the TCM regulation is to inherit and promote traditional Chinese medicine and protect and promote the development of traditional Chinese medicine. In contrast, Malaysia's TCM regulations aim to regulate the safety and efficacy aspects and the practitioners of TCM. Preserving traditional knowledge becomes secondary. The integrated system between TCM practice and service with modern medical practice is more precise in China than in Malaysia. The various cultures that form an essential part of Malaysia's identity have produced many methods of TCM practice. Regulating TCM practices and services in Malaysia is more challenging than in China. This can be seen in Malaysia's diverse interpretation of TCM compared to China. The findings of this study are summarised in the following table according to the selected themes:

Table 1: Comparative Analysis between Malaysia and China

	Malaysia	China	Sources of data
Legislation	<ul style="list-style-type: none"> <li>• Sales of Drugs Act 1952</li> <li>• Poison Act 1952</li> <li>• Dangerous Drugs Act 1952</li> </ul>	<ul style="list-style-type: none"> <li>• Regulation on the Administration of Medical Institutions (Amendment) 2016</li> </ul>	Most respondents agreed that in China, the aim of the TCM regulation is to preserve the

	<ul style="list-style-type: none"> <li>Control of Drugs and Cosmetic Regulations 1984(CDCR)</li> <li>Traditional and Complementary Medicine Act 2016</li> <li>Regulations supporting TCM Act 2016 (Traditional and Complementary Medicine Regulation 2021)</li> <li>Practise guidelines and Good Practice Guidelines in each TCM clinical practice 2007.</li> </ul>	<ul style="list-style-type: none"> <li>Detailed Rule for the Implementation of the Regulation on the Administration of Medical Institutions (Amendment) 2017</li> </ul>	<p>inheritance of TCM. This is in line with the findings from various literature reviews.</p> <p>The data collected from the respondents and literature showed that, in contrast, Malaysia's legislation on TCM focuses on regulating the safety and efficacy aspects as well as the practitioners of TCM.</p>
<b>Administration</b>	<ul style="list-style-type: none"> <li>Ministry of Health</li> <li>TCM Division</li> <li>TCM Council</li> <li>Drugs Control Authority</li> <li>National Pharmaceutical Regulatory Control (NPRA)</li> </ul>	<ul style="list-style-type: none"> <li>The State Council of The People's Republic of China established NATCM.</li> <li>National Health Commission (NHC)-administer NATCM.</li> <li>The National Medical Products Administration (NMPA)</li> <li>National Administration of Traditional Chinese Medicine (NATCM)- to manage and regulate TCM in the country. NATCM has its autonomy in regulating TCM.</li> </ul>	<p>Data from the interview and literature that were analysed using content analysis on the administration of TCM reveal that the integrated system between TCM practice and service with modern medical practice is more precise in China than in Malaysia.</p>
<b>Impact of culture on TCM</b>	<ul style="list-style-type: none"> <li>Multi-racial with different TCM methods. This leads to the complexity and diversity of TCM practice in Malaysia.</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>	<p>The various cultures that form an essential part of Malaysia's identity have produced many methods of TCM practice. Regulating TCM practices and services in Malaysia is more challenging than in China.</p>
<b>Regulating practitioners</b>	<ul style="list-style-type: none"> <li>Traditional and complementary medicine is based on different ethnicities' beliefs and cultures.</li> <li>Have a branch for foreign complementary medicine.</li> </ul>	<ul style="list-style-type: none"> <li>Traditional medicine originated in China and is characterised by holism and treatment based on pattern identification/syndrome differentiation.</li> </ul>	<p>The data collected can be summarised to say that regulating TCM might be more challenging in Malaysia due to the multiple modalities of TCM, its practitioners and TCM products.</p>

## 5.0 Discussions

### 5.1 The TCM legislation.

Traditional and Complementary Medicine (T&CM) Act (Act 775) was enforced on 10 Mac 2016 and August 1 2016. Following the Act's enforcement, internal restructuring represented the current administrative structure. (TCM Division,2021; Abdullah,2019) Currently, the registration of TCM products must be accompanied by additional documentation, such as administrative data and product information, to support product quality, safety, and efficacy via non-clinical and clinical documents. These features will strongly influence the progress and future development of T&CM in Malaysia. The Malaysian Traditional and Complementary Medicine Act 2016 aims to establish the Traditional and Complementary Medicine Council to regulate traditional and complementary medicine services in Malaysia and provide for connected matters. In Malaysia, the federal legislative body, the parliament, owns the jurisdiction to formulate and pass medicinal product laws (Federal Constitution, Schedule 9). The law that monitors the safety and efficacy of medicinal or pharmaceutical products will be governed by the Ministry of Health, which establishes the Drug Control Authority and National Pharmaceutical Regulatory Agency (NPRA). Although there is a specific division for the TCM administrative unit under the Ministry of Health, the safety and efficacy issues of TCM products are still under the jurisdiction of NPRA. NPRA controls and monitors the safety and efficacy aspect using the main legal provisions in the Sales of Drugs Act 1952, Poison Act 1952, and Control of Drugs and Cosmetic Regulations 1984. The introduction of the Traditional and Complementary Medicine Act 2016 is limited to governing the practices and facilities of TCM in Malaysia.

The Chinese laws governing traditional Chinese medicine were enacted to regulate the activities of TCM and the safety of TCM products. It was also built to inherit and promote traditional Chinese medicine, protect and promote the development of traditional Chinese medicine, and protect the health of the people (Article 1, China TCM Law, 2016). TCM practice in China is well integrated with the national healthcare system. This can be seen when the law provides that any plan for the construction of new healthcare facilities should also incorporate TCM services in the construction planning (Article 11, China TCM Law, 2016). This is to show the significance of the TCM healthcare delivery system in China, which receives tremendous support from the government in promoting and regulating TCM in the country. For construction planning, which involves TCM services, the law provides that NATCM should be referred to and consulted to understand the criteria and requirements needed for the development. This includes the development of general hospitals,

maternal and child health institutions and qualified specialised hospitals, and community health service centres which shall have TCM departments (Article 12, China TCM Law, 2016).

## 5.2 Administration of TCM

In 1982, the People's Republic of China's Constitution promoted allopathic and traditional Chinese medicine. The development can be evidenced by the integration of traditional medicine into the national healthcare system and the integrated training of health practitioners in both healthcare systems. China has placed a comprehensive qualification system not only for the practitioner but for the traditional medical assistant. To protect the integrity of conventional medicine and safeguard patients' interests, China state administration has introduced annual testing of classic Health professionals. In China, the highest authority in the administration of law is the State Council of The People's Republic of China (Article 3, China Constitution). The State Council has the power to develop laws, make rules, and set the direction of a policy for the country. Specifically, for TCM, the State Council is the premier body in the development of the policies and sets the direction for TCM, provides the standard for TCM services as well as TCM education and the requirement for the national examination system (State Council Notice No.79,1986). The implementation of the Drug Marketing Authorization Holder (MAH) System by the new version of the Drug Administration Law of the People's Republic of China (DAL hereinafter) in August 2019 is another significant step forward in regulating Chinese medicine. Meanwhile, the certificates of Good Manufacturing Practice (GMP) and Good Supply Practice (GSP) have been revoked, and the MAH now has the overall responsibility for ensuring the safety and quality of the drug. (Hu, 2021). In China, the need for clinical safety data may be exempted from "classic Chinese medicine formulas" which have been used in clinical practice for hundreds or thousands of years (Liang et. al, 2021). The National Medical Products Administration (NMPA) supervises the safety of drugs (including traditional Chinese medicines (TCMs)), regulate the registration of drugs, medical devices, and cosmetics, and undertakes standards management. China practices a dual regulation system to regulate the health care facilities in the country where the regulation on the Administration of Medical Institutions (Amendment) 2016 and the Detailed Rule for the Implementation of the Regulation on the Administration of Medical Institutions (Amendment) 2017 cover for both TCM and modern medical facilities. The regulatory flexibility is fixed as directed by the headquarters and will be enforced by the National Administration of Traditional Chinese Medicine (NATCM) department established in the respective health department at the provincial level until the county level. They are responsible to oversees TCM facilities in their respective administrative areas. NATCM is an agency established directly under the State Council and is administered by the National Health Commission (NHC). The main task of NATCM is to manage and regulate TCM in the country, pursuant to the directive by the State Council. Even though NATCM administratively is under NHC, NATCM has its own autonomy in regulating TCM despite having to report to NHC in matters of TCM and modern medicine. The Healthy China 2030 plan is a national plan that includes TCM. The launch of this plan will facilitate the country to set direction and have proper guidance and planning for the next fifteen years to improve and empower the Health of Chinese people. The plan sets out a series of tasks and measures to implement a program for developing traditional Chinese medicine. On top of that, the State Council also launched the Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2016–2030), which acknowledges the development of traditional Chinese medicine as a national strategy. As for Malaysia, although the government has acknowledged TCM to form part of the National Healthcare system there still needs to be more integration with the national healthcare system. The administration of TCM in Malaysia is parked under the Ministry of Health, where there is a specific division on TCM under which the TCM council was created. To date, the following issues on TCM in Malaysia remain unresolved:

### *i) There needs to be specific measures in ensuring effective implementation of the TCM practice.*

Although therapies involving these agents have shown promising potential, with the efficacy of a good number of herbal products clearly established, many of them still need to be tested, and their use is either poorly monitored or not even monitored at all. The consequence of this needs to be improved knowledge of their mode of action, potential adverse reactions, contraindications, and interactions with pharmaceuticals. Currently, the law that monitors the efficacy of the medicinal product is the Sales of Drugs Act 1952, Poison Act 1952, and CDCR 1984.

### *ii) Lack of trained personnel*

There were comments stating that the patients were not well informed regarding the proper use of these medicines, resulting in incorrect usage, overdoses, counterfeit herbal medicines, and unintentional injuries. (Zakaria,2021) This is a breach of the rule of informed consent. By expanding trainees' knowledge, and appreciation of diverse healthcare benefits and medical practices, improving TCM physician-to-patient communication, enhancing self-care, and the increasing sense of competence and job satisfaction, educating conventional healthcare providers about TCM may directly or indirectly improve trainee professionalism. (Kim, 2017). Malaysia has regulated TCM practice on a nationwide basis since 2016. The registration of TCM practitioners has cleared the ground for TCM to be integrated into Malaysia's mainstream health care system. (Kim, 2017). According to the statistical data obtained from the Division of TCM, Ministry of Health, Malaysia, in 2011, a total of 4910 local TCM practitioners had registered with e-PENGAMAL system since 2008.

## 5.3 The Influence of Culture in the TCM

The development and establishment of healthcare facilities in China are generally subject to the regulation of the Administration of Medical Institutions (Amendment) 2016. This regulation was promulgated by Decree No. 149 of the State Council of the People's Republic of China on February 26 1994. This regulation has been amended in accordance with the Decision of the State Council on Amending Some Administrative Regulations on February 6 2016. Under this regulation, the NATCM, has developed basic standards for medical institutions, covering both TCM hospitals and clinics. These basic standards outlined the specific requirements and criteria for developing and establishing TCM facilities. The categories of medical institutions in accordance with the Detailed Rules related to TCM

facilities include (i) traditional Chinese medicine hospitals and integrated hospitals of traditional Chinese modern medicine; (ii) outpatient departments of traditional Chinese medicine and integrated out-patient departments of traditional Chinese and modern medicine; and (iii) traditional Chinese medicine clinics. The TCM in China is very much influenced by its local culture where the legislating and administration strategies are centralised in traditional Chinese medicine.

In Malaysia, as a multi-cultural country, TCM practices are divided into various categories. Culture has a significant role in shaping the country's TCM direction. The registration of TCM practitioners is regulated by the Registration Guidelines for local TCM practitioners and the Registration Guidelines for Foreign TCM practitioners. The Registration Guidelines for Local TCM practitioners are further segregated into guidelines for the registration of seven forms of TCM namely Traditional Malay Medicine, Traditional Chinese Medicine, Traditional Indian Medicine, Homeopathy, Osteopathy, Chiropractic, and Islamic Medicine (TCM Division, 2021). All of these regulations came into effect on March 1 2021 and contain the same procedure of registration except for the provision that describes the branches of TCM practices of each type of TCM in Malaysia. The objective of this law is similar to the registration of TCM practitioners in China, which helps ensure compliance with ethical requirements among TCM practitioners, monitors safety, and safeguards the rights of the patient.

In Malaysia, most of the TCM services are offered in the private sector. The service providers include private hospitals with established TCM sections, practitioner premises, or home-based practitioners. Private healthcare facilities are governed by the Private Healthcare Facilities and Services Act 1998 which generally regulates private healthcare facilities and services. This legislation was introduced to replace the Private Hospitals Act 1971 and to address many new emerging issues during this period due to the rapid development of corporate private hospitals from the mid-1980s, which was in line with the "Malaysia Incorporated" policy. There were reports of unethical practices in the management of some of these private healthcare facilities. There is no specific section in this statute that has developed basic standards for the medical institution that covers TCM hospitals and Clinics. The TCM Act 2016 (Act 775) establishes the TCM Council, which is responsible for regulating TCM services and matters linked to them. It's an attempt to stop people from abusing each other. To ensure the safety and quality of the services, unethical practitioners must be avoided. Being made available despite the fact that TCM procedures have begun to be implemented, in selected public hospitals and clinics in the national health care system. The private sector accounts for the majority of TCM practice in Malaysia.

#### 5.4 Regulating Practitioner of TCM

In China, TCM practitioner who wishes to practice need to register pursuant to the Law on Licensed Doctors of the People's Republic of China (LDPRC), which was promulgated on June 26 1998 and implemented on May 1 1999, known as Licensed Doctors of the People's Republic of China 1998. The function of this law is to regulate the licensed doctors and licensed assistant doctors as the number of professions is rising in the country. The aim of this law is to professionalise the registered medical personnel through empowering medical ethics and safe conduct, safeguarding their lawful rights and interests as well as protecting the public interest in access to a safe and quality health care system. (Section 1, LDPRC).

## 6.0 Conclusion and Recommendations

This study faces some limitations in the early stage of research activities to assess the enforcement activities reports from the TCM division due to some ethical approval. There is also a need for sources studying the inadequacy of the TCM 2016 legislation. The limitations have required the researchers to modify the research methodology. The preliminary findings disclose some pertinent loopholes in the Malaysian legal framework for the TCM industry. This may lead to slow progress and the non-sustainability of this industry. Thus, learning from the best practices and the strength of China's legal framework may assist to remedy these existing loopholes. A future study is proposed for an in-depth study on the enforcement activities to monitor the compliance of the TCM practitioner in Malaysia to the 2016 TCM law.

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