

**CIVIL AND CRIMINAL LIABILITIES OF TRADITIONAL AND
COMPLEMENTARY MEDICINE PRACTITIONERS UNDER THE
MALAYSIAN TRADITIONAL AND COMPLEMENTARY MEDICINE ACT
2016**

*RESPONSABILIDADES CÍVEIS E CRIMINAIS DE PRATICANTES DE MEDICINA
TRADICIONAL E COMPLEMENTAR DE ACORDO COM A LEI DE MEDICINA
TRADICIONAL E COMPLEMENTAR DA MALÁSIA DE 2016*

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Abstract

Freedom embodies the fundamental human aspiration to exercise autonomy and make decisions concerning one's own life. Apart from this context, Malaysia's evolving regulatory framework for Traditional and Complementary Medicine (T&CM) continues to shape the duties, liabilities, and professional standards of practitioners under the T&CM Act 2016. This study examines the evolving regulatory landscape governing T&CM practice in Malaysia, with particular focus on the legal duties and liabilities arising under the Traditional and Complementary Medicine Act 2016. This paper adopts a qualitative methodology. While global scholarship on the legal implications of T&CM regulation is expanding, detailed analyses specific to the Malaysian context remain limited. Addressing this gap, the research provides a systematic exploration of practitioners' statutory obligations, the mandatory registration regime implemented on 1

Resumo

A liberdade incorpora a aspiração humana fundamental de exercer autonomia e tomar decisões sobre a própria vida. Além desse contexto, o quadro regulatório em evolução da Malásia para a Medicina Tradicional e Complementar (MTC) continua a moldar os deveres, responsabilidades e padrões profissionais dos praticantes, conforme a Lei de MTC de 2016. Este estudo examina o cenário regulatório em evolução que rege a prática da MTC na Malásia, com foco particular nos deveres e responsabilidades legais decorrentes da Lei de Medicina Tradicional e Complementar de 2016. Este artigo adota uma metodologia qualitativa. Embora a produção acadêmica global sobre as implicações legais da regulamentação da MTC esteja se expandindo, análises detalhadas específicas para o contexto malaio ainda são limitadas. Para suprir essa lacuna, a pesquisa oferece uma exploração sistemática das obrigações estatutárias dos



March 2021, and the qualification requirements introduced to enhance professional standards. It assesses the extent to which these measures enhance patient safety and service quality, while also addressing concerns raised by scholars regarding the adequacy of the existing legal framework in addressing contemporary regulatory challenges. The study also considers Malaysia's broader efforts to institutionalise T&CM within its national healthcare system, as well as the parallel regulatory emphasis on ensuring the safety of herbal and related products. Thus, this research contributes nuanced insights into the legal architecture of T&CM in Malaysia and offers perspectives that may inform future policy refinement and comparative regulatory developments.

Keywords: Traditional and Complementary Medicine (T&CM), Practitioner Liability, Regulatory Framework, Mandatory Registration, Patient Safety.

praticantes, do regime de registro obrigatório implementado em 1º de março de 2021 e dos requisitos de qualificação introduzidos para aprimorar os padrões profissionais. Avalia-se em que medida essas medidas aprimoram a segurança do paciente e a qualidade do serviço, ao mesmo tempo que se abordam as preocupações levantadas por acadêmicos quanto à adequação do quadro legal existente para lidar com os desafios regulatórios contemporâneos. O estudo também considera os esforços mais amplos da Malásia para institucionalizar a Medicina Tradicional e Complementar (MTC) em seu sistema nacional de saúde, bem como a ênfase regulatória paralela na garantia da segurança de produtos fitoterápicos e afins. Assim, esta pesquisa contribui com insights detalhados sobre a estrutura legal da MTC na Malásia e oferece perspectivas que podem orientar o aprimoramento de políticas futuras e o desenvolvimento de regulamentações comparativas.

Palavras-chave: Medicina Tradicional e Complementar (MTC). Responsabilidade do profissional. Marco regulatório. Registro obrigatório. Segurança do paciente.

1 INTRODUCTION

A comprehensive review of existing literature reveals a nascent but growing body of scholarship analysing the legal ramifications for T&CM practitioners in various jurisdictions, though specific, detailed analyses about the Malaysian context remain limited. This research endeavors to bridge that gap by meticulously dissecting the duties and potential liabilities imposed by the Act, thereby offering crucial insights for both practitioners and patients within Malaysia's T&CM sector

Over time, Malaysia has developed a strong regulatory framework for Traditional and Complementary Medicine (T&CM), with the Traditional and Complementary Medicine Act 2016 playing a pivotal role in formalising T&CM practices. A key advancement under this Act is the compulsory registration of T&CM practitioners in recognised fields, which was implemented on March 1, 2021. This mandate, along with the requirement for practitioners to possess recognized qualifications, highlights a dedicated effort to improve safety and quality in the sector, with penalties for

noncompliance emphasizing the importance of these regulations (Park *et al.*, 2022). Although these regulations reflect a mature approach to T&CM, some experts argue that the current legal framework may need further updates to effectively tackle modern challenges and ensure the highest quality and safety for both practitioners and the public (Aziz *et al.*, 2024). This ongoing refinement is part of Malaysia's broader strategy to institutionalize and integrate T&CM into the national healthcare system, a gradual process that provides valuable insights for other nations (Park *et al.*, 2022). Additionally, regulatory efforts also focus on the safe use of T&CM products, such as finished herbal products, underscoring the continuous commitment to protecting public health (Roziman *et al.*, 2024).

2 CUPPING THERAPY: RE-EVALUATING EFFICACY AND THERAPEUTIC APPLICATIONS

Traditionally examined from multiple perspectives, cupping therapy is now receiving growing acknowledgment through modern academic studies, which provide clearer insights into its effectiveness. Recent evidence-mapping studies and systematic reviews strongly endorse cupping therapy, especially for pain management. It is recognized as a promising non-drug intervention for various chronic pain conditions, such as chronic pain, knee osteoarthritis, low back pain, neck pain, and herpes zoster, supported by moderate to low-quality evidence (Wang *et al.*, 2023). Notably, a thorough 2024 systematic review and meta-analysis verified that cupping therapy significantly alleviates pain and disability in individuals with low back pain, showing lasting effects that surpass some traditional treatments (Zhang *et al.*, 2024). Beyond addressing pain, the therapeutic range of cupping therapy is broadening; it has demonstrated potential as a safe and effective complementary method for metabolic syndrome, aiding in the reduction of waist circumference, body weight, BMI, and LDL cholesterol in certain patient groups (Wu *et al.*, 2023). Researchers are continuing to explore the specific mechanisms and essential components that contribute to its wide-ranging therapeutic advantages (Tao *et al.*, 2020).

3 THE GLOBAL PUSH FOR INTEGRATED HEALTHCARE MODELS

Freedom reflects the essential human pursuit of autonomy and the ability to make personal life choices. The global effort to merge traditional and modern medicine is a complex undertaking, encountering ongoing challenges such as the necessity for more scientific validation, standardization, and overcoming professional resistance (Thamizhoviya, 2025). Despite these hurdles, there is an increasing agreement on the significance of evidence-based methods, comprehensive regulatory reforms, and coordinated policy strategies to enable successful integration (Thamizhoviya, 2025). Organizations like the World Health Organization are actively promoting traditional, complementary, and integrative healthcare. Their initiatives include encouraging research, setting regulations for practices, practitioners, and products, and advocating for the inclusion of T&CM in national health systems to enhance universal health coverage (Schoen-Angerer *et al.*, 2023). These international efforts highlight a broader trend towards healthcare systems that utilize the strengths of both traditional and modern medical practices to improve global health outcomes. This strategic integration is particularly noticeable in countries such as China, India, and Brazil, which have made significant strides in combining traditional practices with modern healthcare, offering valuable models for global adoption (Thamizhoviya, 2025). The World Health Organization further reinforced this commitment by deciding to develop a new Global Strategy for Traditional Medicine 2025-2034, recognizing the proven benefits of Traditional, Complementary, and Integrative Medicine in managing various health conditions, including the COVID-19 pandemic (Patwardhan *et al.*, 2023). This strategic plan aims to further integrate traditional and complementary medicine into global health systems, promoting universal well-being, affordability, access, and equity (Patwardhan *et al.*, 2023). This strategy also seeks to tackle ongoing challenges such as limited scientific validation and a lack of standardization, which continue to impede the full integration of T&CM practices worldwide (Thamizhoviya, 2025).

4 METHODOLOGY

This paper adopts a qualitative methodology. This research is a doctrinal research, which is synonymous with legal research. The research will be based on the Malaysian

Traditional and Complementary Medicine Act 2016. This paper will discuss a brief history of traditional and complementary medicine in Malaysia. Relevant international law and national T&CM laws are being analysed about the T&CM 2016. Relevant Malaysian acts and international law are cross-referred to explain the liabilities of practitioners in traditional and complementary medicine. Discussions on the implementation of the relevant provisions of the act regarding the duties of practitioners are highlighted in this research based on library research on several acts, articles and books. The study emphasises the aspect of primary data, including official documents, legislative texts, and policy guidelines (Mohd Zamre Mohd Zahir *et al.*, 2019a; Mohd Zamre Mohd Zahir *et al.*, 2019b). It involves the critical interpretation of legal texts, case law, and comparative statutory provisions, focusing on normative as opposed to empirical construction. Data collection is mandatory (Na'aim *et al.*, 2025). This is a useful study and review stage (Rahman *et al.*, 2023).

In past centuries, indigenous or traditional medicine served as the primary source of healthcare practiced by residents in Peninsular Malaysia, Sabah, and Sarawak (Ahmad, 2002; Haris *et al.*, 2023; Ramya *et al.*, 2024). The historical overview of traditional medicine in Malaysia, including Traditional Chinese Medicine, further elucidates this foundational role in the region (Liu *et al.*, 2019).

Regarding the legislative process for Traditional and Complementary Medicine in Malaysia, while your text mentions that on January 11, 2006, the Malaysian cabinet approved the Ministry of Health's proposal, academic literature available through my search capabilities does not specifically confirm this exact cabinet approval date. However, academic sources consistently highlight the subsequent legislative developments. The Traditional and Complementary Medicine Act was enacted in 2016 to regulate T&CM practice (Liu *et al.*, 2019). This Act was a significant step in formalizing T&CM in Malaysia, with its provisions leading to the development of several regulations under the T&CM Act 2016 (Aziz *et al.*, 2024; Park *et al.*, 2022). Over the past twenty years, the Malaysian government has actively pursued policies to institutionalize and incorporate T&CM into the national health care system, leading to the enforcement of regulatory measures for its practitioners and services (Park *et al.*, 2022).

5 DISCUSSION: COMPLEMENTARY MEDICINE PRACTITIONER UNDER THE MALAYSIAN TRADITIONAL AND COMPLEMENTARY MEDICINE ACT 2016

The Traditional and Complementary Medicine Act 2016 establishes a legal framework that imposes various duties on T&CM practitioners in Malaysia, outlining both criminal and civil liabilities (Liu *et al*, 2019). Practitioners facing criminal charges could incur imprisonment and/or fines, while civil liabilities often lead to patients pursuing claims based on contractual obligations and tortious actions. This regulatory oversight is critical for enhancing the quality and safety of T&CM services for both practitioners and the public (Aziz *et al*, 2024).

Criminal liabilities for practitioners include offenses such as failing to obtain or maintain a valid license and practicing beyond their recognized scope. For instance, since March 1, 2021, all individuals practicing in recognized T&CM areas in Malaysia are required to register and hold recognised qualifications under Article 21 of the Act. Failure to comply can lead to fines and/or imprisonment (Park *et al*, 2022). The T&CMA represents a significant legislative step in formalizing and regulating T&CM practice in Malaysia (Liu *et al*, 2019).

5.1 Criminal Liabilities of Traditional and Complementary Medicine Practitioners Under the Malaysian Traditional and Complementary Medicine Act 2016

5.1.1 Duty not to practice beyond skills

The T&CMA imposes criminal liabilities on practitioners who exceed their defined scope of practice. Section 21 of the T&CMA mandates that practitioners must operate exclusively within recognized areas. Practicing without formal registration in a recognized practice area can lead to significant penalties, including fines and/or imprisonment (Park *et al*, 2022). This underscores the legal imperative for practitioners to possess a valid and current practicing certificate issued by the Traditional and Complementary Medicine Council, which is obtained through an application supported by evidence of qualifications and experience.

5.1.2 Duty to refer to medical or dental practitioner

Section 30 of the T&CMA imposes a duty on T&CM practitioners to refer patients to medical or dental practitioners in the event of an acute medical emergency or if the ailment falls outside the registered practitioner's skill, expertise, or competency. Such referrals must be directed to qualified medical or dental professionals. Practitioners are also obligated to explain this referral requirement to the patient or their guardian, ensuring an informed decision can be made. This provision aims to ensure patients receive comprehensive care and to mitigate the risks associated with negligence.

5.1.3 Duty to report an epidemic

The Malaysian T&CMA, under Section 31, also mandates that practitioners report any epidemic or localised outbreak of diseases or other illnesses. This duty aligns with Section 10 of the Prevention and Control of Infectious Diseases Act 1988, which requires any person in charge to immediately notify the nearest district health office, government health facility, police station, or village head upon discovering an infectious disease. This is a crucial measure for preventing further community transmission.

5.1.4 Duty not to make excessive claims

Traditional and Complementary Medicine practitioners are prohibited from making spurious claims in advertisements, as stipulated by Section 33 of the T&CMA. This section also prohibits false or misleading representations intended to induce, influence, or cause a patient to enter into a contract for services. Penalties for a first offense can include a fine not exceeding RM30,000 or imprisonment not exceeding 2 years, or both, with increased penalties for subsequent offenses (Section 31(a) & (b) T&CMA). The broader issue of deceptive marketing in healthcare, particularly concerning herbal and traditional medicines, is a recognized concern in Malaysia and other regions, with studies highlighting the need for robust legal frameworks to protect consumers from misleading online advertisements (Aziz *et al*, 2018; Ismail *et al*, 2018). These studies underscore the importance of stringent advertisement guidelines to maintain public trust and safety, preventing the propagation of false hope or misleading

information. Intentional misrepresentation, which can lead to fraud by inducing reliance on faulty information for the perpetrator's benefit and to the victim's detriment, must be avoided in T&CM practice (Aziz *et al.*, 2018).

5.2 Informed Consent In Complementary And Alternative Medicine

Informed consent is a critical ethical and legal requirement in healthcare, including within the realm of Complementary and Alternative Medicine (Caspi *et al.*, 2009; Cohen, 2000). This process involves the practitioner disclosing all material information relevant to a patient's decision to undergo or reject a specific medical procedure, ensuring the patient's comprehension (Cohen, 2000). While the specifics of obtaining informed consent can vary across different CAM modalities and among practitioners, it remains fundamental to upholding patient autonomy and preventing non-consensual interventions (Caspi *et al.*, 2009). The complexities of negotiating consent are particularly evident when practitioners utilize multiple therapeutic approaches (Porcino *et al.*, 2014).

5.2.1 Civil duties of traditional and complementary medicine practitioners under the malaysian traditional and complementary Medicine Act 2016

Civil duties imposed on practitioners by the Traditional and Complementary Medicine Act 2016 aim to protect patients and uphold professional standards. Unlike criminal liabilities, civil cases typically involve patients seeking recourse based on contractual obligations and tortious liabilities, with punitive measures often taking the form of damages rather than imprisonment (Liu *et al.*, 2019).

5.2.2 Duty to maintain confidentiality

The duty to maintain confidentiality is a fundamental aspect of healthcare practice, crucial for fostering trust within the doctor-patient relationship (Kassim & Ramli, 2016). Section 40 of the T&CMA reinforces this obligation. In Malaysia, the Personal Data Protection Act 2010 extends its applicability to health data in commercial contexts (Cieh, 2012; Manap & Salleh, 2020), ensuring a degree of privacy for patient information,

particularly within the private sector (Sarabdeen & Ishak, 2024). The PDPA mandates responsibilities for those handling patient medical information, granting patients rights to access, update, and modify their health data, which healthcare providers can primarily use for therapeutic purposes (Mamra *et al*, 2017).

Breach of confidentiality in clinical practice, whether due to negligence or indiscretion, fundamentally jeopardizes the inherent duty of care owed to the patient (Kassim & Ramli, 2016). Ethical reflections on this duty highlight its importance in maintaining patient trust and protecting sensitive personal information (Tegegne *et al*, 2022). As noted by prominent ethicists such as Albert R. Jonsen, confidentiality is deeply ingrained in medical ethics, emphasizing the physician's role in safeguarding patient information (Varkey, 2020). Breaches can occur through various means, including informal conversations or inappropriate access to electronic data (Bourke & Wessely, 2008). While your text mentions the case of *Lew Cher Phow @ Lew Cha Paw & 11 Ors v. Pua Yong Yong & Anor*, it was held that invasion or violation of privacy is not a recognised tort and provides no cause of action in Malaysia.¹ In Malaysia Personal Data Protection Act 2010 (PDPA 2010) is applicable to commercial matters. (Olivia Tan Swee Leng, Rossanne Gale Vergara, Shereen Khan 2021)². The Federal Court in the case of *Sivarasa Rasiah v Badan Peguam Malaysia* [2010] 2 MLJ 333. observed that Article 5(1) of the Federal Constitution, which guarantees that ‘no person shall be deprived of his life or personal liberty, save in accordance with law’, encompasses the right to privacy. In the case *Lee Ewe Poh v Dr Lim Teik Man & Anor* [2011] 4 CLJ 397 the court recognised invasion of privacy as a tort. The defendant is liable for violation of the plaintiff's privacy by photographing her private parts during a medical procedure without her consent. (Olivia Tan Swee Leng, Rossanne Gale Vergara, Shereen Khan 2021)³. However, in the case of *Lew Cher Phow @ Lew Cha Paw & 11 Ors v. Pua Yong Yong & Anor* [2009] 1 LNS 1256 Johor Bahru High Court Civil Suit No. MT 4-22-510-2007, it was held that invasion or violation of privacy is not a recognised tort and provides no cause of action in Malaysia.

¹ Shapiro R. Breaking the code: is a promise always a promise? In: Kushner TK, Thomasma DC, editors. *Ward Ethics: Dilemmas for Medical Students and Doctors in Training*. Cambridge: Cambridge University Press; 2001. p. 50–2

² Olivia Tan Swee Leng, Rossanne Gale Vergara, Shereen Khan *Digital Tracing and Malaysia's Personal Data Protection Act 2010* (2021) 1 *Asian Journal of Law and Policy* 47–62

³ *ibid*

5.2.3 *Duty to obtain informed consent*

Section 40 of the T&CMA also underscores the duty to obtain informed consent. This principle requires practitioners to disclose relevant information, ensuring patients understand and agree to their treatment plans (Jameson & AlTarawneh, 2022; Ng, 2024). In Complementary and Alternative Medicine, obtaining informed consent can be particularly complex due to the diversity of modalities, the varied backgrounds of practitioners, and the use of specialised terminology that patients may find difficult to comprehend (Caspi *et al.*, 2009; Nalubega *et al.*, 2024). This environment, despite T&CM's patient-friendly image, can inadvertently limit patient autonomy and potentially affect treatment adherence and outcomes (Caspi *et al.*, 2009). There is often variability and a lack of standardized practices for informed consent among CAM therapies (Nalubega *et al.*, 2024).

From a conventional medical viewpoint, prerequisites for valid consent typically include a direct interaction between the practitioner and the patient (or guardian/next of kin), clear explanation of the procedure's nature and objective, discussion of alternative treatments, and disclosure of potential risks and complications (Ng, 2024; Thirumoorthy, 2023). These principles are vital across all healthcare settings to ensure that the patient's decision is truly informed and voluntary (Ng, 2024). Malaysian courts have increasingly recognised patient autonomy in medical treatment through legal means, particularly in cases relating to consent, advice, and information disclosure (Lee *et al.*, 2022; Ngah *et al.*, 2019). While your text mentions a "Schneider" case where a patient was found 50% negligent due to consent given for nonsurgical breast cancer treatment, academic sources specifically analyzing this particular case were not found within the available academic search results. However, academic literature extensively discusses medical negligence, causation in medical litigation, and the implications of informed consent, especially concerning a practitioner's failure to warn of inherent risks (Barton-Hanson & Barton-Hanson, 2015; Sarela *et al.*, 2025; W *et al.*, 2017).

5.2.4 *Duty to ensure safety of medications*

Section 40 (a), (b), and (c) of the T&CMA 2016 specifically mandates that traditional and complementary medications must be free from illegal or undisclosed

compounds, safe for human consumption or application, and fit for their intended purpose. This duty applies unless the patient did not rely on the practitioner's skill or judgment, or such reliance was unreasonable. Some natural products, despite beliefs of inherent safety, have been found to contain toxic compounds or banned ingredients, highlighting the need for thorough safety evaluations and adequate regulatory systems (Pauzi *et al.*, 2021).

The classification and regulation of medicinal plants can be challenging, as a single plant may be categorized differently (e.g., food, functional food, dietary supplement, or herbal medicine) across various national legislations, leading to potential confusion for both regulators and consumers (Rostam J, *et al.*, 2015). Malaysia has established a regulatory system for T&CM products, initiating registration in 1992 and licensing manufacturers and exporters since 1999 (Liu *et al.*, 2019). The National Pharmaceutical Regulatory Agency plays a crucial role in overseeing these products, with continuous efforts to analyze and improve approval processes (Roziman *et al.*, 2024; Sani *et al.*, 2025). By 2016, all T&CM products supplied in Malaysia were required to bear a registration number, and manufacturers were mandated to follow Good Manufacturing Practice (All TCM products supplied in Malaysia must bear a registration number. The active ingredient content and quantity, manufacturer and importer information shall be in the label and a hologram sticker must be on the packaging to differentiate the original and counterfeit products that might cause harm to consumers. Five years later, the government forced all traditional medicine firms to follow Good Manufacturing Practice. In, 2016; the Bureau became the National Pharmaceutical Regulatory Agency. In, 2004; the Traditional and Complementary Medicine Division was renamed. In, 2018).

Herbal medicines are also subject to provisions under other relevant Malaysian legislation, including the Poisons Act 1952 (Act, 1956), the Dangerous Drugs Act 1952 (Dangerous Drugs Act, 1952), the Wildlife Conservation Act 2010 (Wildlife Conservation Act, 2010), and the Patents Act 1983 (Patents Act, 1983). Furthermore, international intellectual property rules, such as those within the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights framework, also influence the regulation of traditional medicinal items, addressing issues like biopiracy and the protection of traditional health knowledge (Friedrich K. Juenger, 1994; Gollin, 2002; Javed *et al.*, 2020; Priya & Kurian, 2018; Rostam J *et al.*, 2015). Proper administration and labeling of medications are compulsory, requiring details such as the

T&CM premise or practitioner's name and address, generic name of the medicine, patient's name, date of supply, and clear instructions for use (Ministry of Health Malaysia, 2021).

5.2.5 *Duty to ensure safety of treatment*

Sections 40 (d), (e), (f), and (g) of the T&CMA 2016 establish implied terms regarding the safety and quality of T&CM treatment. These provisions stipulate that registered practitioners must be qualified, experienced, and adequately trained; that T&CM services should be delivered with reasonable skill and judgment; that services will be reasonably fit for their particular purpose; and that patients may reasonably rely on the practitioner's expertise, unless circumstances indicate otherwise.

The qualification and sufficient training of practitioners are paramount to ensuring patient safety and treatment efficacy (Kim, 2021; Park *et al.*, 2022). Malaysian registration requirements for T&CM practitioners often include specific experience levels or recognized academic qualifications in their respective fields, with foreign practitioners also required to register with the T&CM division of the Ministry of Health (Farooqui, 2013; Kim, 2017; Park *et al.*, 2022).

Assessing whether an integrative care practice is appropriate involves critical questions: Is the treatment effective and safe? Is there sufficient scientific evidence supporting its efficacy and safety compared to established treatments? Are there known risks or side effects? Or has the treatment been proven ineffective or unsafe through rigorous analysis (Michael H. Cohen, 2007). These considerations guide responsible practice. Academic discourse also highlights that Complementary and Alternative Medicine may have its own standard of care, which differs from conventional medicine, and providers are not necessarily required to offer the same treatment as conventional doctors, provided due control is in place (Raposo, 2019). The *Shakoor v Situ (t/a Eternal Health Co) 1 W.L.R. 410* case highlights that while a patient's choice to opt for alternative practitioners is considered, it does not diminish the practitioner's obligation to provide care with reasonable skill and competence.

6 CONCLUSION

Informed consent remains a cornerstone of ethical medical practice, particularly in the integration of Traditional and Complementary Medicine within Malaysia's healthcare system, where evolving legal standards like those post-Montgomery emphasize patient autonomy and material risk disclosure over paternalistic Bolam tests (Jameson & AlTarawneh, 2022; Sarela *et al.*, 2025; W *et al.*, 2017). Despite robust regulatory advancements, such as the National Pharmaceutical Regulatory Agency's oversight since 2004 (the Bureau became the National Pharmaceutical Regulatory Agency in 2004), mandatory Good Manufacturing Practices (All TCM products supplied in Malaysia must bear a registration number. The active ingredient content and quantity, manufacturer and importer information shall be on the label and a hologram sticker must be on the packaging to differentiate the original and counterfeit products that might cause harm to consumers. Five years later, the government forced all traditional medicine firms to follow Good Manufacturing Practice. In, 2016), and the Traditional and Complementary Medicine Division's renaming in 2018 (the Traditional and Complementary Medicine Division was renamed. In, 2018)—significant gaps persist in standardizing consent for herbal and alternative therapies, as evidenced by inconsistent practitioner attitudes akin to those in Uganda (Nalubega *et al.*, 2024) and limited shared decision-making amid COVID-19 impacts (Lee *et al.*, 2022). Liability risks for failure to warn of inherent risks further underscore the need for causation reforms inspired by cases like *Chester v. Afshar* (Barton-Hanson & Barton-Hanson, 2015; Khoury, 2006), *Chester*, the claimant, had been coping with severe back pain for several years, which greatly restricted her mobility and affected her bladder control. A medical evaluation and tests identified an issue with her spinal cord, leading her doctor, the defendant, to recommend surgery as a solution. Importantly, this procedure involved a very small risk (approximately 1%) of exacerbating the condition, but the defendant did not inform the claimant of this potential risk. The House of Lords rejected the appeal with a narrow 3-2 decision, determining that the defendant had breached his professional duty in tort, thereby meeting the 'but for' test, and concluded that the claimant was entitled to a remedy. While intellectual property protections under the Patents Act 1983 (Patents Act, 1983) and Wildlife Conservation Act 2010 (Wildlife Conservation Act, 2010) must

balance traditional knowledge access with safety (Gollin, 2002; Javed *et al.*, 2020; Priya & Kurian, 2018).

To enhance the practice of Traditional and Complementary Medicine (T&C;M) in Malaysia, it is imperative to implement explicit informed consent protocols within practitioner licensing (Ng, 2024; Thirumoorthy, 2023), improve education on patient autonomy (Kim, 2017; Ngah *et al.*, 2019), and align with global standards (Kim, 2021; Park *et al.*, 2022; Rostam J, *et al.*, 2015). These initiatives, in conjunction with rigorous safety assessments (Pauzi *et al.*, 2021; Roziman *et al.*, 2024) and transparent regulatory practices (Sani *et al.*, 2025), will reduce the risk of malpractice (Cohen, 2000; Cohen & Eisenberg, 2002; Michael H. Cohen, 2007; Raposo, 2019), thereby promoting safer, patient-centered care that adheres to ethical standards within a diverse healthcare environment.

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Authors' Contribution

All authors contributed equally to the development of this article.

Data availability

All datasets relevant to this study's findings are fully available within the article.

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