Received: 3/12/2025 | Accepted: 4/12/2025 | Published: 30/1/2026

CONTEMPORARY RESEARCH IN NATURAL PRODUCTS

Review

Herbal medicines in Malaysia: Current status of research and development and regulatory aspects

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Edited by Intan Safinar Ismail, PhD

Keywords:

Herbal medicine
Ethnopharmacology
Quality
Efficacy
Safety
Regulation

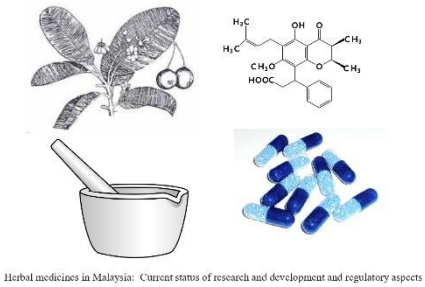
Abbreviations:
TMM
MOH
R & D & C

ABSTRACT

Herbal medicine research and development in Malaysia has grown rapidly in recent years due to the increasing recognition of the potential benefits of natural medicines in treating various human diseases. The objective of this article is to provide a comprehensive overview of the current status of research and development in herbal medicine in Malaysia, highlighting recent scientific advancements, efficacy studies, and innovative technologies employed in this field. Furthermore, the article aims to examine the regulatory landscape governing herbal products locally, discussing the challenges and frameworks established by health authorities to ensure their safety, efficacy, and quality. By synthesizing these aspects, the article seeks to inform practitioners, researchers, and policymakers about the potential and limitations of herbal medicine within contemporary healthcare. The development of herbs for medicinal purposes involves rigorous scientific evaluation to ensure their safety, efficacy and quality. Strict quality control measures, standardized extract preparation methods, and comprehensive preclinical and clinical evaluation are essential to ensure the consistency, potency and safety of herbal products. This multidisciplinary approach allows for a more systematic and evidence-based evaluation of herbal ingredients, leading to the identification of new drug candidates and therapeutic interventions. Monographs and pharmacopoeias serve as important references for the standardization and regulation of herbal products, helping to establish consistent quality control measures. Regulation of herbal medicine is essential to ensure consumer safety and maintain the integrity of the industry. However, challenges remain, such as the proliferation of counterfeit products and unethical advertising practices, which require stronger enforcement and monitoring mechanisms. Collaboration between traditional medicine practitioners, researchers, government agencies and industry players is essential to advance herbal research and integrate traditional knowledge with modern scientific approaches. In conclusion, the direction and status of herbal medicine research and development are poised for further advancement, driven by increasing recognition of the therapeutic potential of natural medicines. With continued collaboration and regulatory efforts, the field of herbal medicine promises to provide safe, effective and high-quality treatment options for a variety of health conditions.

MALAYSIAN NATURAL PRODUCTS SOCIETY

GRAPHICAL ABSTRACT



1. INTRODUCTION

Our ancestors were indeed wise in the science of ethnobotany and ethnopharmacology. Through 'crude clinical trials' and experience in the use of natural materials, they have left us with the basic knowledge in nutrition, diet, medicine, pharmacy and other scientific fields. They have screened hundreds of thousands of plants as sources of food and medicine for generations, leaving us with hundreds of plants that can be eaten and used as medicine (Sharma et al., 2021). They have tips that are tasty as food, bitter as medicine. Historical records state that they observed how animals like monkeys choose food. Which is eaten as food, which is avoided as medicine. Bitter is said to be a sign that it can be used as medicine. They searched and tried, some may have been injured, and some may have died of poisoning because they tried. In fact, they are also researchers of natural compounds like us but they did not have computers, equipment facilities and technology like we have. The responsibility of modern scientists is to translate and transform this knowledge of ethnobotany and ethnopharmacology into new knowledge so that the legacy of using natural ingredients continues to be used as safe, quality and effective food, beverages and medicines (Balakriskna et al., 2024).

Traditional medicine has played a significant role in the development of herbal medicine in Malaysia by providing a foundation of knowledge and practices that have been passed down from generation to generation. The use of plants and natural ingredients in traditional medicine has led to the discovery of many medicinal properties and active compounds that are now being studied and used in modern herbal medicine. By studying traditional medical practices from Malay culture, researchers and scientists have been able to identify new sources of potential medicinal plants and compounds, as well as learn about the uses and effective traditional preparation methods for treating various diseases. Furthermore, traditional medicine has also contributed to the development of complementary and alternative medicine practices, which integrate traditional and herbal medicine with modern medical approaches. This has led to a more holistic approach to healthcare that combines the best practices of traditional and modern medicine (Jantan, 2006).

Overall, the role of traditional medicine in the development of herbal medicine emphasizes the importance of preserving and studying traditional knowledge to continue to discover new ways to harness the healing properties of plants and natural substances for human health benefits (Waldram, 2000). Ethnopharmacology

plays a vital role in the development of herbal medicine by studying the traditional knowledge and practices of different cultures regarding the use of medicinal plants. This field of study helps researchers identify potential new therapeutic compounds from natural sources and understand the mechanisms of action behind traditional treatments. By combining traditional wisdom with modern scientific methods, ethnopharmacology contributes to the discovery and development of new herbal medicines that are safe, effective, and culturally relevant (Suntar, 2020).

2 TRADITIONAL MALAY MEDICINE IS BASED ON A HOLISTIC APPROACH

Traditional Malay Medicine (TMM) is based on a holistic approach that integrates various aspects of health and well-being, including physical, mental and spiritual components. It emphasizes the interconnectedness of the body, mind and spirit, aiming for overall balance and harmony. TMM is heavily influenced by religious practices, especially Islam, with some influence from Hinduism. TMM is rooted in the belief of maintaining a harmonious balance between the four elements (fire, earth, air and water), for good health. TMM practices are based on empirical knowledge, namely ethnopharmacology. It is drawn from centuries of accumulated knowledge, often documented in texts such as the Kitab Tibb, which outlines various healing practices and their applications. TMM practitioners are known as bomoh, who carry out treatments based on knowledge inherited or through apprenticeship (Jamal, 2006).

TMM encompasses holistic practices that integrate the following:

a) Use of natural medicine: Medicinal ingredients from natural sources, especially herbal medicines.
b) Involvement of spiritual healing: Involves prayer, meditation, rituals, incantations, and invocations of supernatural entities to restore health, especially for illnesses believed to be caused by spiritual disturbances. The use of amulets (wafaq), and the recitation of verses from the Quran are often practiced to enhance the effectiveness of treatment.
c) Practicing the concept of vital force or spirit: Health is seen as a reflection of this life force.
d) Healthy eating practices: This includes dietary restrictions and taboos on certain foods, which are believed to influence health outcomes. It emphasizes the importance of maintaining a balanced diet and lifestyle to prevent disease and promote overall well-being.
e) Massage therapy: Believed to promote healing by improving blood circulation, reducing muscle tension, and removing toxins from the body. Massage has been used to address physical discomfort, promote relaxation, and restore balance in the body's energy flow.

Overall, TMM emphasizes a personalized approach to healthcare, focusing on addressing the specific needs of the individual and restoring balance to promote overall well-being. The scientific value of traditional Malay medicine lies in the knowledge and experience passed down through generations, as well as the ongoing study and validation of its efficacy through modern scientific methods. Studies have shown that certain herbs and medicines used in TMM contain bioactive compounds that have medicinal properties, such as anti-inflammatory, anti-microbial and antioxidant effects. Overall, TMM offers a unique perspective on health and healing, combining traditional knowledge with contemporary scientific understanding to provide a holistic approach to well-being (Ikram & Abd Ghani, 2015).

TMM, like many forms of traditional medicine, can have both positive and negative effects (Siti et al., 2009). Some of the potential adverse effects of TMM include:

a) Toxicity: Some herbal medicines may contain toxic substances that can lead to harmful effects on the body if used incorrectly or in excessive doses.

b) Allergic reactions: People may be allergic to certain herbs or other ingredients used in TMM, leading to allergic reactions such as skin rashes, itching, or difficulty breathing.
c) Drug interactions: Some herbal medicines in TMM may interact with prescription medications, leading to side effects or reducing the effectiveness of the medication.
d) Mislabeling or contamination: There is a risk of mislabeling or contamination in herbal products, which can lead to unwanted side effects or health risks.
e) Lack of scientific evidence: Some medicines in TMM lack scientific evidence to support their effectiveness or safety, making it difficult to assess the potential risks and benefits.

It is important to consult with a healthcare professional such as a doctor and pharmacist before using traditional Malay medicine to minimize the risk of adverse effects and ensure safe use.

3 THE SCIENTIFIC VALUE OF HERBAL MEDICINES IN TRADITIONAL MEDICINE

Traditional medicine such as Traditional Malay Medicine, Traditional Chinese Medicine and Ayurveda has been practiced for a long time and are based on a combination of ethnopharmacology and testimonials of their effectiveness. These practices may not always adhere to the same standards of scientific evidence as modern medicine. The public should understand that herbal medicines used in traditional medical practices, although widely used and often considered natural and safe, vary greatly in terms of efficacy, safety and quality. (Moreira et al., 2014). Herbal medicines have varying levels of effectiveness depending on the herb and the individual using them. Some herbs have been scientifically proven through experimental and clinical studies to be effective in treating certain health conditions, while others may have limited or no evidence to support their effectiveness. It is important for the public to exercise caution and seek advice from a healthcare professional before using herbal medicines to ensure they are using a product that has been proven safe and effective (Siti et al., 2009)

Taking herbal products as medicine can be likened to driving a car to a destination. You need to use a good vehicle (quality medicine), drive safely (safe medicine) and get to your destination (effective medicine). Quality medicine is medicine that is effective and safe. Medicine cannot be considered of high quality if it lacks safety, even it proves effective. Just because a product is labelled as 'natural' does not mean it is automatically safe. Herbal medicines can interact with prescription drugs and cause dangerous side effects if not used correctly. People should be aware of the potential risks associated with herbal medicines, especially if they have pre-existing health conditions or are taking other medications.

As a researcher, it is useful to be aware of the beliefs, approaches and practices of various types of traditional medicine as it will help him/her conduct research based on science and evidence to validate traditional claims. He/she also needs to know how to distinguish between traditional claims and therapeutic claims of natural products as stipulated under the Drug Registration Guidance Document (DRGD) of the Ministry of Health, Malaysia (MOH, 2025). Scientific research on herbal medicines in traditional medicine involves studies aimed at identifying and understanding the active components, as well as their mechanisms of action, including their safety and therapeutic effects in human clinical studies (Jantan, 2006). It is important to note that although traditional medicines may not always have the same level of scientific evidence as modern pharmaceuticals, they can still play a valuable role in healthcare, especially in areas where they are widely practiced and have been refined over a long period of time. The integration of traditional and modern medical practices, along with further research and validation, can help improve the overall effectiveness and safety of traditional healthcare treatments (Calahan et al., 2016; Ghosh, & Mukherjee, 2019).

4 Development of herbal medicines to treat human diseases

Developing herbal medicines to treat human diseases involves various stages from experimental studies in the laboratory to clinical trials on humans in clinics or hospitals. The development of herbal medicines for therapeutic use usually requires a large financial investment and a long period of time mainly due to the rigorous scientific research and testing process involved. Developing herbal medicines involves identifying active compounds in natural plant sources, conducting preclinical studies to assess safety and efficacy, followed by clinical trials to determine efficacy in humans. These steps require considerable resources, time and expertise to ensure the safety, quality and efficacy of herbal medicines before they can be approved for therapeutic use (Firenzuoli & Gori 2007; Tilburt & Kaptchuk, 2008).

The development timeline and cost of creating an herbal medicine for therapeutic use can vary significantly depending on a variety of factors such as the complexity of the herbal medicine, the need for clinical trials, the regulatory process, and the cost of research and development. On average, it can take several years, typically between 5 and 15 years, and the cost can range from millions to hundreds of millions of dollars. This process involves research, preclinical studies, clinical trials, regulatory approval, and scale-up manufacturing to bring an herbal medicine from concept to market (DiMasi, 2002, Ahmed et al., 2023).

Herbal medicine research and development involves a variety of scientific approaches to ensure the quality, safety, and efficacy of herbal products (Parveen et al., 2015). Here is an overview of the process:

a). Discovery and identification: The first step involves identifying and selecting plants or plant extracts that have potential medicinal properties. This often involves the use of ethnopharmacology (traditional uses) and screening various botanical sources to identify bioactive compounds that may have therapeutic effects.

b). Preclinical studies: Once potential herbal candidates have been identified, preclinical studies are conducted on standardized extract preparations to assess their safety, efficacy and mechanism of action. This may involve in vitro studies using cell cultures or *in vivo* studies using animal models to determine the pharmacological, pharmacokinetic and pharmacodynamic effects of the herbal extract.

c). Formulation development: At this stage, researchers work to develop suitable formulations for the herbal extract. This may involve optimizing the extraction process, standardizing the active ingredients and determining the most effective delivery method.

d). Safety and toxicity testing: Before moving on to clinical trials, extensive safety and toxicity testing is conducted to ensure that the herbal preparation is safe for human use. This includes assessing its potential side effects, interactions with other drugs, and long-term effects. Preclinical studies provide important preliminary data on factors such as possible side effects, dosage, mechanism of action, and overall safety profile. Without comprehensive preclinical studies, it is unethical and potentially dangerous to go straight to clinical trials in humans because the risks and benefits of the herbal extract are unknown. Therefore, preclinical studies serve as the necessary foundation to ensure the safety and efficacy of the herbal extract before it can be considered for human clinical trials.

e). Phase I-III clinical trials: Clinical trials are conducted in three phases to evaluate the safety and efficacy of herbal medicines in humans. Phase I trials focus on safety and dosage, phase II trials evaluate efficacy and side effects in a larger group of patients, and phase III trials involve large-scale studies to confirm the effectiveness of the drug and monitor for any rare side effects.

f). Regulatory approval: After successfully completing clinical trials, herbal medicines undergo regulatory review by health authorities to gain approval for commercialization. This involves submitting a comprehensive document of data from preclinical and clinical studies to demonstrate the safety and efficacy of the medicine.

g). Post-market surveillance: Once a herbal medicine is approved and available on the market, post-market surveillance continues to monitor its safety and efficacy in real-world conditions. This helps to identify any rare or long-term side effects that may not be seen during clinical trials.

By following these stages, herbal medicines undergo rigorous testing and validation to ensure their safety and efficacy for treating various diseases (Koonrungsesomboon et al., 2024). The regulation of herbal extracts as therapeutic agents is governed by the principles of evidence-based medicine. Clinical and preclinical studies play a crucial role in establishing the safety and efficacy of herbal extracts for treating specific diseases. Without adequate studies to demonstrate the effects of the extract, its mechanism of action, and potential side effects, it cannot be marketed as a therapeutic agent. This is to ensure that consumers are not misled or put at risk by unproven treatments (Choi, 2008; Pelkonen et al., 2014). The widespread marketing of herbal products for human diseases without adequate preclinical and clinical data in the local market is a matter of great concern. Without appropriate and adequate research and testing, it is difficult to determine the safety, efficacy, and potential interactions of these products with existing drugs or conditions. The lack of data also hinders the ability of healthcare professionals to make informed decisions when recommending treatment options to patients. It is essential that herbal products undergo rigorous scientific evaluation to ensure their safety and efficacy before being marketed for therapeutic use (Govindaraghavan and Sucher, 2015).

5 THE ROLE OF MONOGRAPHS AND PHARMACOPOEIAS IN THE DEVELOPMENT OF THE HERBAL INDUSTRY

Herbal monographs and herbal pharmacopoeias are important references in the development of the herbal industry. These documents provide detailed information on the identification, quality, purity and characteristics of herbal products. They serve as guidelines for manufacturers, researchers, regulators and healthcare providers to ensure the standardization and safety of herbal products. By setting uniform criteria and specifications for herbal products, herbal monographs and pharmacopoeias help promote the reliability, efficacy and quality of herbal medicines. Therefore, having this resource is essential for the progress and growth of the herbal industry. The development of herbal monographs and herbal pharmacopoeias for a country is usually overseen by the national pharmacopoeia authority or regulatory agency responsible for ensuring the safety, quality and efficacy of herbal medicines. These authorities are often affiliated with the country's Ministry of Health or equivalent department. In some cases, international organizations such as the World Health Organization (WHO) may also provide guidance and support in developing herbal monographs and pharmacopoeias (Roth et al., 2018).

An herbal monograph is a detailed document that provides comprehensive information about a particular herb or plant, including botanical description, traditional uses, chemical composition, therapeutic properties, and safety information. It serves as a standard reference guide for herbalists, manufacturers, and regulatory agencies to ensure consistency and quality in the production and use of herbal products. On the other hand, an herbal pharmacopoeia is a summary or collection of standards and specifications for the quality and safety of herbal medicines, including information on identification, purity, potency, and testing methods. It serves as an essential reference for herbal manufacturers, healthcare practitioners, and regulatory agencies to ensure the efficacy, safety, and quality of herbal medicines. Both herbal monographs and herbal pharmacopoeias play an important role in the herbal industry by promoting standardization, quality control, and safety of herbal products. They help establish guidelines and standards for the cultivation, harvesting, processing, and labeling of herbs, ensuring that consumers have access to reliable and effective herbal medicines. In addition, these documents assist in the regulation and oversight of herbal products, leading to increased trust and credibility in the herbal industry (Alamgir, 2017).

In Malaysia, to date, 69 herbal monographs have been published as the Malaysian Herbal Monograph (MHM). It is a non-obligatory reference document that provides detailed information on Malaysian medicinal plants used in the herbal industry. The MHM Committee is currently working on establishing the Malaysian Herbal Pharmacopoeia (MHP), with the aim of improving the quality control of herbal ingredients. The MHP is a legally binding document that will standardise quality control for herbal products, focusing on aspects such as identification, purity and potency. It will be the legal document required for the registration of herbal products in Malaysia (Tan et al., 2020).

6 QUALITY, EFFICACY AND SAFETY OF HERBAL PRODUCTS IN THE MALAYSIAN MARKET

Research and development in herbal medicine faces several key issues related to quality, efficacy and safety. Quality control of herbal products is a major concern due to variations in cultivation conditions, harvesting methods and processing techniques, which can affect the potency and composition of herbs. Standardization of herbal preparations is essential to ensure consistent quality and efficacy. The efficacy of herbal medicine is a complex issue because many herbal products contain a variety of compounds that can interact with each other, with drugs or with other substances in the body. Research is needed to understand the mechanisms of action of herbal medicines and to establish evidence-based guidelines for their use. Safety is another critical issue in herbal medicine, as some herbs can have toxic effects or interact with prescription drugs. Research is needed to identify potential adverse effects of herbal products and to establish safe dosage and usage guidelines (Wang et al., 2023).

Overall, the key research and development issues in herbal medicine include improving quality control measures, conducting rigorous efficacy studies and ensuring the safety of herbal products for consumers. Collaborative efforts between researchers, regulatory agencies and industry partners are essential to address these challenges and advance the field of herbal medicine. The scientific value of most local herbal products is still not at a satisfactory level in terms of quality, efficacy and safety because they are not provided with sufficient information regarding ingredients, uses, dosage, pharmacology, contraindications and expected side effects. Among the reasons why the quality, efficacy and safety of herbal products are not considered satisfactory is the lack of scientific research and rigorous data to support their use as health supplements or therapeutic agents to manage and treat diseases (Calixto, 2000). Without thorough research, data on proper dosage, potential side effects, interactions with other medications, and mechanisms of action may be lacking. This can lead to uncertainty about the efficacy and safety of herbal products, making it difficult for healthcare professionals to confidently recommend them as therapeutic interventions. Conducting more research and clinical trials on herbal products can provide valuable insight into their potential benefits and limitations, helping to improve their quality, effectiveness, and safety as a supplement or treatment of choice (Williamson et al., 2015)

Marketing of half-baked or incomplete herbal products with therapeutic claims by local companies in collaboration with researchers from research institutions and universities is increasingly prevalent. It is uncertain whether there is sufficient enforcement by the authorities to ensure that this unethical practice does not mislead consumers and potentially harm their health. The products being marketed may not have been registered in the Quest 3+ system of the National Pharmaceutical Regulatory Agency (NPRA), MOH or registered for low claims (general claims) but are marketed as modern claims or therapeutic claims. This false advertising violates the Medicines (Advertisement and Sale) Act 1956 (MOH, 1956). This act prohibits advertising related to medical matters and regulates the sale of substances recommended as medicines. Scientific evidence, especially on human studies, is important in determining the safety and efficacy of any product, especially those that claim to have therapeutic benefits. There are three guidelines related to claims for natural compound products, namely the Guideline on Registration of Natural Products 1992, Guideline on Natural Products with Therapeutic Claim, 2020 and Guideline on Natural Products with Modern Claim, 2024, which must be complied with by products

registered with the Ministry of Health (MOH, 1992, 2020, 2024). Without proper scientific validation, there is a risk of adverse effects on individuals using these products without receiving the intended benefits or, worse yet, experiencing adverse effects.

Therefore, it is important for researchers to ensure that they have conducted rigorous scientific studies before making any therapeutic claims and collaborating with industry to market their products. Unfortunately, most industry players make exaggerated claims for commercial gain, and focus on maximizing sales margins and profits, sometimes at the expense of scientific credibility. Unethical behavior by researchers and companies in the production of half-baked herbal products undermines the integrity and credibility of scientific research. More worrying, the recognition and awards given to such individuals and entities only serve to keep misleading information and potentially dangerous products on the market. It is important for authorities to uphold strict ethical standards and practices in scientific research and commercial production to protect public health and ensure product quality, safety, and efficacy. Researchers and industry players need to be ethical by fostering a balance between scientific rigor and commercial success for the development of high-quality herbal products that are not only profitable but also contribute positively to the well-being of consumers.

7 REGULATION OF HERBAL MEDICINES

In Malaysia, guidelines for natural products for therapeutic claims are usually administered by the NPRA under the Ministry of Health. These guidelines aim to ensure the safety, quality and efficacy of natural health products marketed in the country (MOH, 1992; 2020; 2024, 2025). Natural health products that wish to make therapeutic claims in Malaysia must undergo a comprehensive assessment process by the NPRA. This assessment includes a review of the scientific evidence supporting the proposed claims, an assessment of the quality and safety of the product and compliance with regulatory requirements.

Regulatory matters play a vital role in the research and development of herbal medicines. Regulations ensure that herbal medicines are developed, tested and marketed safely and effectively (Sharma, 2015; Chatfield et al., 2018). Here are some of the important roles regulatory matters play in this process:

a). Quality control: Regulations set quality standards for herbal products, including requirements for purity, potency, and composition. This helps ensure that consumers receive safe and effective products.

b). Safety evaluation: Regulatory agencies require extensive safety testing of herbal medicines to identify potential risks and side effects. This helps protect the health and well-being of consumers.

c). Efficacy evaluation: Regulations also require herbal medicines to demonstrate effectiveness through rigorous research and clinical trials. This ensures that the product is effective for its intended use.

d). Labeling requirements: Regulations specify the information that must be included on a product label, such as ingredients, dosage instructions, and potential side effects. This helps consumers make informed decisions about the use of herbal medicines.

e). Market authorization: Before an herbal product can be marketed and sold, it must obtain regulatory approval. This involves submitting detailed documentation about the product's safety, quality, and effectiveness.

In summary, regulatory matters play a vital role in ensuring high-quality, safe and effective herbal medicines for consumers. By setting standards and guidelines, regulations help instill trust in herbal products and protect public health (Rousseaux & Schachter, 2003). The Medicines (Advertisement and Sale) Act 1956 in Malaysia regulates the advertising and sale of traditional medicinal products (MOH, 1956). This act is important to ensure the safety, quality and efficacy of traditional medicines available in the country. It sets out guidelines for the

proper advertising of traditional medicinal products, ensuring that the information provided is accurate and does not mislead consumers. Under this act, traditional medicinal products must meet certain standards and requirements to be legally marketed and sold in Malaysia. These standards include proper labelling, ingredient specifications and compliance with safety regulations. The act also requires traditional medicinal products to be registered with the relevant authorities before being sold to ensure their quality and safety.

By regulating the advertising and sale of traditional medicinal products, the Medicines (Advertisement and Sale) Act 1956 helps protect consumers from potential harm and misinformation. It also helps promote the use of safe and effective traditional medicines in Malaysia, contributing to the overall well-being of the population.

8 CATEGORIES OF TRADITIONAL MEDICINES BASED ON EFFICACY CLAIMS

Traditional medicines need to be registered in the QUEST 3+ system at the Ministry of Health through the NPRA to obtain approval to be marketed as natural products with various efficacy claims. Traditional medicines must adhere to ethical standards, ensure safety for consumers, and provide transparent information about their claims and evidence of efficacy as claimed. Compliance with applicable regulations and guidelines is essential to establish credibility and trust among consumers and healthcare professionals in the efficacy and safety of traditional medicines.

The following are the categories of traditional medicines based on efficacy claims:

a. General claim or Low claim: Traditional medicines that make general claims or traditional claims for traditional use only require basic evidence of traditional use based on ethnopharmacology or historical anecdotes to support their effectiveness. These claims are usually related to general health care or the relief of mild symptoms based on traditional use. They cannot be claimed to be used to maintain and treat serious diseases. The requirements for general claims are relatively light and do not require rigorous scientific verification or study. Only evidence based on traditional or ethnopharmacological use is required as documented in monographs, pharmacopoeias and reference documents recognized by the authorities. The MAL registration number for products in this category ends with the letter "T", for example MAL12345678T (MOH, 1992).

b. Modern claim or Medium claim:

Traditional medicines that make a moderate claim must have higher scientific evidence compared to general claims. The modern claim rules are based on the 'Guideline on Natural Product with Modern Claim, 2024'. These claims are based on evidence from experimental (cell and animal) and clinical scientific studies to improve health, reduce the risk of disease or help treat symptoms of a disease that can resolve on its own within a certain time. Scientific studies or clinical trials that support the effectiveness of the medicine may be required to confirm this claim. However, the level of evidence required is still moderate compared to a high claim. To date, there is only one (1) product registered in this category, which is Nova Hepar-P capsule (quantified ekstrak dukung anak, *Phyllanthus nuriri*) for the indication 'to support liver health'. The MAL for this product ends with the letter 'M', for example, MAL12345678M (MOH, 2024).

c. High claim:

A traditional medicine that makes a high claim means that it can be used for a therapeutic indication, that is, it can treat a specific disease. The high claim rules are based on the 'Guideline on Natural Product with Therapeutic Claim, 2020'. To support a high claim, extensive scientific evidence in the form of well-designed clinical trials (randomised double blind clinical trials, RCTs), meta-analyses or systematic reviews is required. The medicine must demonstrate safety, efficacy and quality to a high standard. High claims often involve obtaining regulatory approval and meeting strict criteria set by health authorities or regulatory bodies. To date, there is only one (1)

product registered in this category, which is Fespixon cream [standardised extracts of *Centella asiatica* (pengaga) and *Plectranthus amboinicus* (Mexican mint)] for the topical treatment of diabetic ulcers. The MAL registration number for products in this category ends with the letter 'B', for example MAL12345678B (MOH, 2020).

Be wary of the modern and high claims of many traditional medicines in the market, especially those advertised through social media such as Facebook, TikTok and Instagram. They may not be registered with the Ministry of Health or registered for general claims but are advertised and marketed as products with modern and therapeutic claims. Be a smart consumer so as not to be deceived and avoid the risk of harmful effects of such products. In addition, natural health products are expected to comply with Good Manufacturing Practice (GMP) guidelines to ensure consistent quality and safety standards during the manufacturing process. Proper labeling and packaging requirements must also be adhered to, providing accurate information for consumers and healthcare professionals. It is important for manufacturers of natural health products to conduct clinical trials and studies to support any therapeutic claims. The evidence must be scientifically sound and verified by regulatory authorities before the claim can be approved for marketing.

Compliance with these guidelines and regulations is essential to protect public health and ensure that natural health products in Malaysia are safe, effective and of high quality. False claims of herbal products without adequate scientific studies can be harmful. Promoting herbal products for therapeutic claims without adequate scientific data and relying solely on anecdotes and testimonials can be considered unethical in the fields of science and healthcare. This practice can lead to misinformation, misrepresentation of product efficacy, and potential harm to consumers. Herbal products often lack comprehensive research studies that scientifically prove their efficacy and safety for specific therapeutic claims. Without proper scientific data, it is difficult to assess the true benefits and potential risks associated with these products. Relying on anecdotes and testimonials from individuals, rather than peer-reviewed scientific studies, can result in biased or misleading information being presented to the public. (Indrayanto, 2024).

Furthermore, making unsubstantiated health claims about herbal products can give consumers a false sense of security and prevent them from seeking proper medical care when needed. This can delay or prevent individuals from receiving appropriate healthcare interventions, which can have serious consequences for their health and well-being. In the scientific community, promoting herbal products without adequate scientific evidence can undermine the principles of evidence-based practice and sound research methodology. It is important to conduct rigorous scientific studies to assess the safety and efficacy of herbal products before making therapeutic claims and promoting them to the public.

When practitioners, researchers, and industry players promote herbal products for therapeutic claims without sufficient scientific data and instead rely on anecdotes and testimonials, they are engaging in pseudoscience. Pseudoscience refers to practices or beliefs that are presented as scientific but lack the rigorous methodology and empirical evidence required for credibility. These practices can be motivated by personal interests, such as gaining popularity or commercial gain, rather than prioritizing the well-being and safety of consumers. It is important that claims about the efficacy and safety of herbal products be supported by solid scientific evidence obtained through rigorous research methodologies, such as clinical trials. Relying solely on anecdotes and testimonials can lead to misinformation, potential harm to consumers, and a lack of transparency in the healthcare industry. Consumers should exercise caution and critical thinking when evaluating products and health claims, seeking information from reliable sources, and consulting with healthcare professionals for guidance based on scientific evidence.

9 THE PROLIFERATION OF FAKE HERBAL PRODUCTS IN THE MALAYSIAN MARKET

The increasing popularity of fake herbal products, health supplements, and cosmetics with half-baked or incomplete research, and unethical claims [violating the Medicines (Advertisement and Sale) Act 1956] (MOH, 1956) in the market can be attributed to several factors:

a). Consumer demand: There is a growing interest among consumers in natural and alternative health remedies. This demand has led to an increase in the number of products claiming to provide various health benefits, even without solid scientific evidence to support these claims.

b). Limited regulation: The regulatory landscape for herbal products, health supplements and cosmetics is often less stringent than that for pharmaceuticals. This lack of strict monitoring can lead to companies making exaggerated or misleading claims about their products without facing immediate consequences. The very low penalty of RM 3000 for unethical traditional medicine claims under the Medicines (Advertisement and Sale) Act 1956 is not suitable as a deterrent. Penalties serve as a form of deterrence to deter unethical practices and protect consumers. With advances in science and growing awareness of the importance of evidence-based medicine, stricter penalties are needed to uphold ethical standards and ensure public safety in the fields of traditional medicine, including health supplements, and cosmetics.

c). Profit motive: The health industry is a lucrative market, and some companies may prioritize profit over scientific rigor and ethical standards. This can result in the introduction of products that have not been thoroughly tested for quality, efficacy, and safety.

d). Information proliferation: With the rise of social media and online marketing, it has become easier for companies to promote their products directly to consumers without proper scrutiny. Misinformation and exaggerated claims can spread quickly, leading to a proliferation of products with questionable research support.

e). Lack of education: Many consumers may not have the scientific knowledge or skills to evaluate the validity of claims made by herbal products, health supplements, and cosmetics. This lack of understanding can make them more vulnerable to misleading marketing tactics.

f). Unethical research practices: Researchers engaging in collaboration with industry players to market products with incomplete or unethical research can lead to serious consequences. This may include putting consumers at risk due to a lack of adequate safety testing, misleading the public with false claims about the quality and efficacy of the product, and ultimately damaging the reputations of both researchers and the companies involved. It is important for researchers to maintain high standards of transparency, integrity, and scientific rigor in their collaboration with industry partners to ensure that any products brought to market are safe, effective, and supported by sound research. By upholding these principles, researchers can foster trust with consumers, promote the advancement of scientific knowledge, and contribute to the development of products that truly benefit public health and well-being (De Regt et al., 2020).

To address this issue, it is important for all four parties (consumers, regulators, industry, and researchers) to remain vigilant and demand transparency, quality control, and evidence-based research from the companies that sell these products. Education in critical thinking skills and an understanding of scientific research can also empower individuals to make informed decisions about their health and well-being.

10 OVERCLAIMED HERBAL PRODUCTS

Unethical practices by some pharmaceutical and herbal companies, health professionals (medical doctors, pharmacists, dietitians and nutritionists), researchers, influencers, motivational speakers including religious teachers, and celebrities in over-promoting herbal products, health supplements, nutrition, and health services are becoming increasingly common, especially on social media. There are a growing number of TikTok doctors

who are giving health advice while promoting health products unethically. Promoting health products without scientific support can have serious consequences for the health and well-being of consumers. When these products are marketed with exaggerated or false claims, it can mislead people into believing that they are effective or safe when there is little or no scientific evidence to support these claims (Marmat et al., 2020).

In Malaysia, the Medicines (Advertisement and Sale) Act 1956 and the Guidelines on the use of natural products and health supplements provide regulations to ensure that products are marketed responsibly and ethically (MOH, 1956, 1992, 2020, 2024, 2025). Over-hyped products in the market may promise unrealistic benefits such as instant weight loss, cures for chronic diseases or miraculous healing properties without sufficient evidence to support these claims. This type of misleading advertising has the potential to cause individuals to forgo proven medical treatments, waste money on ineffective products, and even suffer adverse health effects from the use of unregulated or unproven substances. It is important for consumers to be aware of the importance of critically evaluating health claims and seeking advice from a qualified health care professional before incorporating any new product or service into their health regimen.

Pharmaceutical and herbal companies need to be held accountable for regulatory standards and promote evidence-based practices, to help protect consumers from falling victim to misleading marketing tactics and uphold the integrity of the healthcare industry. Consumers should be aware that exaggerated health product claims by companies and individuals can lead to a phenomenon known as the placebo effect. This effect occurs when a person believes that a product will have a certain health benefit, even though the product itself may not have those qualities. Essentially, the power of suggestion can influence a person's perception of a product's effectiveness, leading to a placebo response.

To combat this, it is important for consumers to be better informed about the scientific evidence supporting the health claims made by companies and individuals. By staying informed and critically evaluating the information provided, consumers can make more informed and accurate decisions about the health products they choose to use. It is important to seek out reputable sources, such as research studies and expert opinions, to verify the validity of health claims before making a purchase. By doing so, consumers can protect themselves from falling victim to unethical marketing practices and make more informed choices for their health and well-being.

The unethical practice of herbal companies advertising and selling their products in violation of the Medicines (Advertisement & Sale) Act 1956 in Malaysia can have serious implications for consumer health (MOH, 1956). Under this Act, there is a ban on advertising medicines, devices, or remedies for the prevention or treatment of 20 serious diseases as follows: kidney disease or defect, heart disease or defect, diabetes, epilepsy or convulsions, paralysis, tuberculosis, asthma, leprosy, cancer, deafness, drug addiction, hernia, eye disease, hypertension, mental disorders, infertility, frigidity, sexual dysfunction or impotence, venereal disease, nervous weakness, or other complaints or infirmities, arising from or related to sexual intercourse.

The advertising and sale of unethical herbal products and herbal supplements with overclaimed claims online on various social media platforms, especially Facebook, TikTok, and Instagram, has become a major problem that is difficult to address. The promotion and marketing of these products violate the Medicines (Advertisement and Sales) Act 1956 and guidelines such as the Guideline on Natural Products with Therapeutic Claims 2020, MOH. (MOH, 1956, 2020). The efficacy and safety of the products as promoted are not supported or proven by complete and accurate research data, and some have not even been scientifically studied.

The regulatory landscape for herbal products, health supplements and cosmetics is often less stringent than for pharmaceuticals. This lack of strict oversight can lead to companies making exaggerated, false or misleading claims about their products without facing immediate consequences (Ho et al., 2022). The relatively low penalty

of RM 3000 for unethical advertising and sales of medicines including traditional medicine under the Medicines (Advertisement and Sales) Act 1956 is not appropriate as a deterrent. Penalties serve as a form of deterrence to deter unethical practices and protect consumers. With advances in science and growing awareness of the importance of evidence-based medicine, stricter penalties are needed to uphold ethical standards and ensure public safety in the field of herbal medicine, including health supplements, and cosmetics.

By violating this law, herbal companies can provide products that have not been thoroughly evaluated for their effectiveness or potential side effects. This can mislead consumers and prevent them from making informed choices about their health and well-being. Additionally, herbal products that have not been properly tested may interact with conventional medications or have unknown side effects that could be harmful to an individual's health. Without proper oversight, consumers are exposed to the risks posed by unregulated and potentially dangerous herbal products.

Herbal companies can engage in a number of malpractices when advertising and marketing their products, including:

a) False advertising: Making exaggerated or unsubstantiated claims about the health benefits of their products without scientific evidence to support these claims. Overclaiming herbal products refers to situations where manufacturers or sellers of herbal products make exaggerated or unsubstantiated claims about the effectiveness or safety of their products. These claims are contrary to guidelines set by regulatory bodies for natural products.

   [The modern claim rules are based on the 'Guideline on Natural Product with Modern Claim, 2024'. These claims are based on evidence from experimental (cell and animal) and clinical (human trials) scientific studies to improve health, reduce the risk of disease or help treat symptoms of a disease that can resolve on its own within a certain time. Scientific studies or clinical trials supporting the effectiveness of the medicine may be required to verify these claims. Herbal medicines that make high claims mean that they can be used for a therapeutic indication, i.e. can treat a specific disease. The high claim rules are based on the 'Guideline on Natural Product with Therapeutic Claim, 2020' (MOH, 2020). To support high claims, extensive scientific evidence in the form of well-designed clinical trials (randomised double blind clinical trials, RCTs), meta-analyses or systematic reviews is required. The medicine must demonstrate safety, efficacy and quality to a high standard. High claims often involve obtaining regulatory approval and meeting strict criteria set by health authorities or regulatory bodies].

b) Profit motive: The health industry is a lucrative market, and some companies may prioritize profit over scientific rigor and ethical standards. This can result in the introduction of products that have not been thoroughly tested for quality, efficacy, and safety.

c) Misleading labeling: Using misleading labels or packaging that misrepresents the product's ingredients, quality, or effectiveness.

d) Contamination: Selling products that are contaminated with toxins, heavy metals, or other harmful substances.

e) Lack of quality control: Failing to ensure the quality and authenticity of their products through proper testing and quality control measures.

f) Lack of regulatory compliance: Ignoring regulatory requirements and guidelines set by health authorities for herbal products, such as overclaiming, proper labeling, dosage instructions, and safety warnings.

It is important for consumers to be aware of this potential for abuse and to research and choose herbal products from reputable companies that prioritize safety, quality, and transparency in their marketing practices.

11 RESEARCHERS WORKING WITH HERBAL COMPANIES NEED TO BE ETHICAL IN PROMOTING HERBAL PRODUCTS

Unethical researchers who promote herbal products to the industry based on incomplete, half-baked, or biased research findings are engaging in pseudoscience. Pseudoscience is characterized by the presentation of claims that appear scientific but lack empirical evidence or are based on flawed methodology. In this case, promoting herbal products without solid scientific evidence can mislead consumers and potentially harm their health. It is important for researchers and industry professionals to adhere to strict scientific standards and ethical practices to ensure the safety and efficacy of products marketed to the public. In herbal research, thorough preclinical and clinical studies are essential for the registration of products intended to manage or treat human diseases because of the rigorous scientific process involved in evaluating the safety and efficacy of these products (Miller, et al., 2004).

Preclinical studies are conducted in laboratory settings using cell cultures and animal models to evaluate the biological effects of herbal compounds. These studies help researchers understand the mechanisms of action, potential toxicity, and pharmacokinetics of herbal products. Clinical studies involve human participants and are conducted in several phases to evaluate the safety and efficacy of herbal products. These studies provide valuable data on therapeutic effects, optimal dosage, possible side effects, and interactions with other drugs.

Overall, a combination of preclinical and clinical studies is essential in establishing the scientific validity and safety profile of herbal products intended for the management or treatment of human diseases, ensuring that they meet regulatory requirements for registration and approval. When researchers promote herbal products that have not been fully developed or tested for efficacy and safety, it can be a worrying issue in the herbal research field. These products may not meet the standards required for registration and could potentially pose risks to consumers if used to manage or treat human diseases. Researchers who are unaware of these requirements or who promote half-baked products may inadvertently mislead consumers and undermine the credibility of herbal medicine as a whole. Collaboration between researchers, industry partners and regulatory bodies is essential to ensure that herbal products are developed and marketed responsibly, with the ultimate goal of providing safe and effective treatments for human diseases.

Researchers who collaborate with herbal companies in marketing their products may engage in a number of unethical or fraudulent activities, including:

a) Lack of understanding of the direction of herbal research: Researchers may lack knowledge or be confused about the requirements of studies that need to be conducted for the purpose of product registration in various categories of claims, especially for the management and treatment of human diseases.

b) Biased results: Researchers may manipulate the design or results of studies to favor the herbal product marketed by the company, leading to biased or misrepresented findings.

c) Conflicts of interest: Collaborating researchers may have financial incentives or relationships with herbal companies, compromising the independence and objectivity of their research.

d) Lack of transparency: Researchers may fail to disclose their collaboration with herbal companies or the extent of their involvement, resulting in a lack of transparency in the presentation of research findings.

e) Exaggeration of benefits: Researchers collaborating with herbal companies may exaggerate the efficacy or benefits of products to promote sales, which can potentially mislead consumers and healthcare professionals.

f) Underreporting of risks: Researchers may downplay or downplay any potential risks or side effects associated with marketed herbal products, which can lead to safety concerns for consumers.

g) Pursuit of popularity and promotion: Researchers may pursue popularity and promotion when research institutions or universities emphasize and insist on the commercialization of research results as a key performance indicator (KPI) and criterion for promotion. This misrepresentation or unethical behavior undermines the integrity of researchers and scientific research, and can have negative implications for public health and consumer trust in the herbal industry.

The sale of illicit drugs, controlled medicines including fake and unregistered herbal products and health supplements is rampant online and is difficult to curb. NPRA faces challenges in monitoring the marketing and distribution of these illicit products online because the companies involved are quick to change their website addresses (Ismail, et al., 2018). They also use influencers consisting of famous celebrities, as well as unethical health professionals and researchers to promote their products. The advertising and sale of unethical herbal products and herbal supplements with overclaimed claims online on various social media platforms, especially Facebook, TikTok and Instagram, has become a major problem that is difficult to address. The promotion and marketing of these products violate the Medicines (Advertisement and Sale) Act 1956 and guidelines such as the Guideline on Natural Products with Therapeutic Claims 2020, MOH (MOH, 1956, 2020). The effectiveness and safety of the products as promoted are not supported or proven by complete and accurate research data, and some have not been scientifically studied at all.

Most of these products are not registered in the MOH Quest 3+ system as medicines (pharmaceuticals) or cosmetics. Some are also registered as low claim products but advertise as medium/modern claim or high claim products. It is important for consumers to carefully consider the level of evidence supporting traditional medicines and health supplements before using them, as products with higher claims are generally more reliable and trustworthy.

[The MOH Quest 3+ system is a comprehensive healthcare management system that helps coordinate and improve various healthcare processes in Malaysia. The system integrates clinical, administrative and financial functions to improve patient care, reduce errors and increase efficiency in healthcare delivery. It enables better coordination among healthcare providers, facilitates data sharing, and enables evidence-based decision-making for healthcare policy development and resource allocation].

The advertising and sale of these products without evidence can be harmful to consumers for several reasons. First, false claims about the effectiveness of these products can lead people to rely on them instead of seeking proper medical care. Delays in receiving proper care can be dangerous, especially in cases where serious health conditions are involved. In addition, the ingredients in these products may not be properly regulated, leading to potential health risks from harmful ingredients or incorrect dosages. Inaccurate information or exaggerated benefits can also mislead consumers into thinking that these products are actually safe when they may have side effects or interact negatively with other medications.

Ultimately, the unethical promotion and sale of herbal and supplement products online not only impact the health and safety of individuals but also undermines public trust in the healthcare industry as a whole. It is important for consumers to be vigilant and obtain reliable information from reputable sources before purchasing any health-related products online.

12 HERBAL INDUSTRY DEVELOPMENT REQUIRES CLOSE COLLABORATION

To help advance the herbal and natural product industries, there needs to be close communication and collaboration between the four parties (researchers, funders, regulators, and industry players) in R (research) & D (development) & C (commercialization). This collaboration allows for the sharing of resources, expertise, and knowledge, which can accelerate the research and development process.

Researchers provide the scientific expertise needed to discover and understand the potential benefits of natural products, while funders support research financially. Regulatory bodies ensure that products meet safety and efficacy standards, and industry players are responsible for bringing products to market. By working together, these stakeholders can unlock the full potential of natural products, leading to thriving and sustainable industry growth (Xego et al., 2021)

However, until now, each party has different goals and there has been no meeting point between them to work together strongly in helping to develop the herbal and natural compounds industry.

a) Researchers

They are focused on obtaining grants and conducting scientific studies to produce as many quality publications in indexed journals as possible to achieve KPIs and increase the H index value. Many promotions to the top are based on this achievement. Many researchers pay less attention to C. Commercialization of research results if any is a bonus. There are also researchers who focus more on C and do not study fundamental knowledge in more depth, and there are also those who are trapped in conducting half-baked research because of C demands from funders.

b) Funders

They distribute funds by giving priority to proposals that promise research results that have the potential to have a C value and determine the conditions for mandatory study results to also have a C value. Proposals from the fundamental, prototype, and development levels all need support or cooperation with the industry. It is as if they do not take into account or are not aware of the constraints and limitations in the study of producing research products (health herbs, supplements, and medicines) in a short time (2-5 years) especially for therapeutic use, treating human diseases. They may also not know, the results of experimental studies: in vitro, in vivo and pre-clinical are still preliminary and the data produced is not sufficient or still cannot produce C products in a short time. They may not know, clinical trials are difficult due to cost and time, and are almost impossible to achieve by researchers and industry without the involvement of large pharmaceutical companies. They may also not be aware of the registration and claims of herbal and natural product categories based on regulations issued by authorities, NPRA, MOH.

c) Regulatory authorities

Authorities such as NPRA are focused on providing regulations, registering and monitoring herbal products, health supplements and medicines for consumer safety using international standards such as WHO. They interact more with the industry like drug police and are less interested in understanding the herbal and natural compound research scenario conducted by researchers, the constraints and limitations faced in R & D in research

institutions, academia and industry. The regulatory authorities need to have a strategy to help the local industry to be able to produce products in the category of modern and therapeutic uses.

d) Industry players

They are more oriented towards commercial profits without emphasizing the importance of R & D. There is no seriousness for R & D, because it involves high costs and a long time and many expect government funding. They face communication problems with the NPRA regulatory body regarding product registration. The willingness, capacity, and ability of the local industry to produce quality, safe and effective products are still low. Most of the advertised products are marketed in violation of acts and regulations, especially products with modern claims and therapeutic claims. There needs to be a strategic alliance between these four parties to ensure R & D & C in herbal products and natural compounds bring the expected results.

13 CONCLUSION

Based on the current trends and advances in herbal research and development, it can be concluded that there is an increasing recognition and integration of traditional medicine and ethnopharmacology in scientific studies. Researchers are increasingly exploring traditional knowledge as a valuable resource for developing new herbal medicines to treat various human diseases. The scientific value of traditional medicine is recognized for its unique compounds and potential therapeutic benefits. This is driving the development of herbal medicine as an effective and safe treatment option for various health conditions (Wang & Ren, 2002). The use of monographs and pharmacopoeias in herbal research and development helps to standardize the quality and safety of herbal products in the market. This ensures that consumers have access to consistent and reliable herbal medicines. Regulatory agencies also play an important role in monitoring and regulating the herbal product market to ensure quality control, safety and efficacy of these products. This oversight helps to protect consumers from potential risks associated with poor quality or mislabeled herbal products.

Given the current herbal research and development landscape, it is clear that the unethical promotion of products to treat human diseases without adequate scientific data remains a significant concern. This practice not only endangers individual health but also undermines the credibility and potential benefits of herbal medicine. To address this issue and ensure the advancement of herbal research and development, collaboration between researchers, government agencies, and industry players is essential. By working together, researchers can conduct thorough scientific investigations to confirm the efficacy and safety of herbal products. Government agencies can establish regulations and guidelines to prevent the unethical promotion of unproven treatments, thereby protecting public health. Industry players, in turn, can contribute their resources and expertise to support the development of evidence-based herbal remedies.

Ultimately, through collaborative efforts, the direction of herbal research and development can be directed towards a more ethical and rigorous approach, leading to the responsible use of herbal products for the treatment of human diseases. It is important for all stakeholders in the herbal industry to unite in upholding scientific integrity and prioritizing individual well-being. Overall, the direction of herbal research and development is moving towards a more evidence-based approach that integrates traditional knowledge with modern scientific methods. This trend bodes well for the continued growth and acceptance of herbal medicine as a valuable component of healthcare systems worldwide.

Competing interest disclosure

The author declares no conflict of interest.

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