REVIEW ARTICLE

Regulation of traditional and complementary medicinal products in Malaysia

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In Malaysia, mainly there are three complimentary systems of medicine practiced they are the traditional Malay, Chinese and Indian systems. The traditional herbal medicines and their preparations have been widely used in Malaysia for thousands of years. The pervasive use of complementary medicines raises several concerns. Many of these arise because most complementary medicines are not licensed as medicines, and therefore evidence of quality, efficacy and safety is not required before marketing. In this paper, I would like to present an overview of the characteristics of regulation, quality and registration of traditional and complementary medicinal (TCM) products in Malaysia.

Key words: Herbal medicines, legislation, Malaysia, quality TCM products, regulation

INTRODUCTION

Herbal medicine is still the mainstay of about 75-80% of the world population, mainly in the developing countries, for primary health care because of better cultural acceptability, better compatibility with the human body and lesser side effects. However, in the last few years there have been seen a major increase in their use in the developed world. It is now recognized that about half the population of industrialized countries regularly use complementary medicine. Higher education, higher income, and poor health are predictors of its use.[1]

The World Health Organization (WHO) has recently defined traditional medicine (including herbal drugs) as comprising therapeutic practices that have been in existence, often for hundreds of years, before the development and spread of modern medicine and are still in use today.[2] The history of medicine includes many ludicrous therapies. Nevertheless, ancient wisdom has been the basis of modern medicine and will remain as one important source of future medicine and therapeutics. The future of natural products will be more holistic, personalized and will involve wise use of ancient and modern therapeutic skills in a complementary manner so that maximum benefits can be accrued to the patients and the community. The term complementary medicine describes a range of pharmaceutical-type preparations, including herbal medicines, homoeopathic remedies, essential oils and dietary supplements, which mainly sit outside conventional medicine. The use of complementary medicines is a popular healthcare approach in Malaysia, and there are signs that the use of such products is continuing to increase. Patients and the public use complementary medicines for health maintenance, treatment and prevention of minor ailments, serious and chronic illnesses.[3]

Present Status of Complementary Medicines in Malaysia
Present healthcare system in Malaysia based on western medical sciences for decades traditional medicine has undoubtedly played a remarkable role in primary healthcare (WHO) through traditional medicine programme that has encouraged Malaysia to formulate national policies on traditional medicine. The main objectives of traditional medicine programme is to facilitate the integration of traditional medicine into national health care systems, to promote the rational use of traditional medicine through the development of technical guidelines and standards and to disseminate information on various forms of traditional medicine.

The diversity in traditional medical systems in Malaysia reflects the diverse population of Malay, Chinese, Indian and indigenous heritage. In addition to allopathic medicine, the major systems of medicine practiced in Malaysia include ayurveda, siddha, unani, traditional Chinese medicine and traditional systems of medicine, such as that provided by traditional medicine practitioners, spiritualists, bonesetters, traditional birth attendants and others who use home remedies. Medical options also include homeopathy, naturopathy, reflexology, aromatherapy and chiropractic.[4] From 2000 to 2005, annual sales for traditional medicines increased from US$ 385 million (RM 1 billion) to US$

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1.29 billion (RM 4.5 billion). The prevalence and factors associated with its use are largely unknown, although the use is believed to be widespread. Patients and the public have been known to self-prescribed herbal medicines for health maintenance.[5]

Malaysia Traditional and Complementary Medicine Policy

Malaysia has established its own National Policy on Traditional and Complementary Medicine (TCM) in 1999 outlines its vision, mission, objectives and strategies, with emphasis on practice, education and training, raw materials and products, and research. TCM policy goals are to develop regulatory and legal reforms to ensure good practice and to extend primary healthcare coverage, while ensuring the authenticity, safety and efficacy of these medicines. Ministry of health recognizes traditional medicine as an integral part of national healthcare systems, cooperation between modern and traditional medicine practitioners, promotion of rational use of products, introduction of quality assurance systems, consistent supply of raw materials and enhancement of research and reinforcement of regulatory actions.

TCM and Primary Healthcare

Ministry of health (MOH) has taken a positive and proactive approach towards the development of the domestic traditional medicine sector; herbal remedies have emerged as a preferred common choice among self-care therapies towards integrating traditional and complementary medicine into the allopathic healthcare system.

Regulatory Situation

In Malaysia, the National Pharmaceutical Control Bureau (NPCB) shall ensure the quality and safety of pharmaceutical products through the implementation of the relevant legislation by a competent workforce working together in strategic alliance towards improving the health of the people. In Malaysia, registration of herbal medicines is compulsory. It has mandated registration of traditional medicines since 1992, but largely for safety and quality and only partially for efficacy. The Drug Control Authority (DCA) is responsible for product registration, including quality and safety. Every manufacturer of traditional medicine is required to comply with good manufacturing practices, and importers are required to comply with good storage practices. All homeopathic medicines have to be registered with the NPCB.[6]

Legislation

Regulatory controls over the pharmaceutical sector in Malaysia were introduced in the 1950s, starting with the promulgation of three ordinances: the Sales of Food and Drugs Ordinance of 1952, the Poisons Ordinance of 1952 and the Dangerous Drugs Ordinance of 1952. These were followed by the Medicines (Advertisement and Sale) Ordinance of 1956. Combined, the laws provided a legal framework to regulate the general handling of pharmaceuticals, including poisons and narcotics, in respect of importation, manufacture, compounding, storage, distribution and transportation. They also covered advertising, sales, record keeping and use of pharmaceuticals.

The next wave of major legislative activities and capacity building relating to drug regulation came in the late 1970s and 1980s. New legislation was introduced in 1984 in response to increased concerns about the infiltration of products into the market and the inaccuracy of information provided by the pharmaceutical industry. This legislation was promulgated under the Control of Drugs and Cosmetics Regulations 1984. This Act provided for the establishment of the DCA, which started registering pharmaceutical products in January 1985. However, the initial implementation of this law was limited only to the states of Peninsular Malaysia (West Malaysia). In 1990, the law was extended to cover the states of Sabah, Sarawak and the Federal Territory of Labuan (in East Malaysia). The Poisons Ordinance, revised to become the Poisons Act 1952, was again revised in 1989 to include the Poisons Regulations (Psychotropic Substances Act 1989). Similarly, the Sales of Food and Drugs Ordinance was revised in 1959 to become the Sales of Drugs Act 1952 and re-revised in 1989. In Malaysia, several laws were enacted in the early 1950s, which laid the groundwork for drug regulation in the country.

Malaysia has the DCA, whose members are appointed by the Minister of Health. The NPCB, within the Pharmaceutical Services Division, is the secretariat to the DCA. Advisory boards are 'semi-independent' structures whose chairperson is either the Director-General of Health or the Director of the Pharmaceutical Services Division. These advisory boards report to the Minister of Health. Coordination between the federal and state regulatory authorities has been created by establishing a Deputy Director of Health in each state, who reports directly to the Pharmaceutical Services at the federal level. The Pharmaceutical Services are responsible not only for drug regulation, but also for procuring and distributing drugs and managing hospital pharmacies.

Expansion of Scope of Registration

New drug laws were introduced in Malaysia in the mid 1980s, which revised registration procedures and greatly expanded the scope of registration. Under the new laws, traditional medicines, veterinary medicines, cosmetics and pharmaceutical raw materials must all now be registered. The new laws were phased in gradually, so that the pharmaceutical industry could prepare for the new legal

requirements and regulators could prepare themselves for their additional responsibilities. Implementation of the new laws, which started in 1985, was carried out in four phases. The initial two phases of registration, covering scheduled and non-scheduled drugs, have been successfully completed. The third phase of registration, which started in 1992, covers registration of traditional medicines. The final phase, Phase 4, covering registration of cosmetics started in 2001. Regulatory control will be extended later to cover medical devices, veterinary medicines and pharmaceutical raw materials.

Control of Clinical Trials

Clinical trials are regulated by the National committee for clinical research (NCCR) Established in 1997 to coordinate and encourage clinical trials. Drug Control Authority (DCA) under Ministry of Health Malaysia ensures implementation of trial related guidelines and legislation.

Regulation of Traditional Medicines

Regulations for traditional medicines, including herbal medicines and dietary supplements, formed part of the Control of Drugs and Cosmetics Regulation in 1984. The DCA was established in 1985 to ensure quality, safety and efficacy of pharmaceutical products prior to marketing. Traditional manufacturers are required to adhere to the GMP requirements for traditional products, a major part of which has been adapted from the GMP guidelines for pharmaceuticals.

Adverse drug reaction monitoring of traditional medicines, market sampling and investigation of product complaints have since been included in the programme. Traditional medicines are allowed to be sold, as over the counter medicines without any restrictions, limited health claims may be made. Malaysia does not have any national pharmacopoeia. International pharmacopoeias such as the Chinese pharmacopoeia and the Indian Pharmacopoeia are used as references, but are not considered legally binding. The post-marketing surveillance programme was introduced for pharmaceuticals in 1987 and was extended to cover traditional medicines in 1997.

National Policy on TCM

Malaysia has a national policy on TCM, which was launched in the year 2001. The registering and licensing of TCM is legislated through the Control of Drugs and Cosmetics Regulations established in 1984. As of December 2003, the DCA has registered approximately 12,000 traditional medicines, including herbal products. However, none of these products are included on the national essential drug list.

Quality Control of Traditional and Complementary Medicines

Quality control monitoring ensures the safety, efficacy and quality of herbal medicines and their preparations. Therefore, quality control consists of a regular check of the quality of TCM products and is performed according to the specifications of the product which details the requirements for identity, purity and content of characterizing compounds. The National Pharmaceutical Control Laboratory was set up in 1978 for the purposes of regulatory control. Starting from the year 2000, the Drug Analysis Division (DAD) of the NPCB has implemented a procedure for test results to be confirmed by an external independent laboratory. This procedure is intended for market surveillance samples that have failed tests conducted by the laboratories in the DAD. The manufacturers or the registration holder are given the choice as to whether they would like to have their test results confirmed by an independent laboratory. If they agree, NPCB will then make the necessary arrangements with the relevant independent laboratory. All costs including those for handling, delivery and tests are to be borne by the manufacturer/registration holder. The independent laboratory may either be a laboratory attached to an official regulatory agency or a laboratory which is ISO 17025 certified. Up to this date, the DAD has identified SIRIM QAS Sdn. Bhd. and Therapeutic Goods Administration (TGA) Laboratories, Australia, as independent laboratories. SIRIM QAS Sdn. Bhd, being an ISO 17025 certified laboratory, has been assigned by NPCB to conduct the limit test for heavy metals like arsenic, lead and mercury and the microbial limit test for traditional products. On the other hand, TGA Laboratories, a laboratory attached to the Australian Regulatory Agency located in Canberra, has been assigned to conduct confirmation tests on physico-chemical characteristics and dosage performance for pharmaceutical products. The test results from the independent laboratory are deemed to be conclusive.

REGISTRATION PROCEDURES FOR TCM

Registration Criteria

To ensure that products available in the market are safe, with good quality and effective for human use. The following are the important registration criteria for traditional and complementary medicines: limits for heavy metals, microbial contamination, absence of adulterants, approved claims and indications, prohibition of herbs with known adverse effects, prohibition of endangered animal species and compliance to good manufacturing practice (GMP) as well as good storage practice (GSP). Regarding quality it should comply with GMP, stability studies, limits for disintegration time and uniformity of weight. For efficacy it should be proved by clinical trials, bioavailability and bioequivalent studies.

For Local Products
Initial registration is valid for 5 years or such period specified in the registration certificate, unless sooner suspended or cancelled by the DCA for valid reasons. Renewal of product registration should be done not later than 6 months prior to expiry of product registration.

Applicant should be a locally incorporated company and be authorized in writing by the product owner to be the holder of the registration certificate and be responsible for all matters pertaining to the registration of the product.

A separate application is required for each product, for example products containing the same ingredients but made to different specification in terms of strengths, dosage form, description etc. Different manufacturer shall require separate applications for TCM registration.

For Imported Products
For all imported products, a Certificate of pharmaceutical products or a Certificate of Free sales should be obtained by producing a GMP certificate, and same criteria is also followed for a Repacking license.

Registration Number
A registration number ending with the alphabet A, T, X followed with C, R, S, (E) for example CAL 0709321 AC for prescription drugs, CAL 0709321 TCR for traditional and complimentary products are given.

Rejection and Appeals
Malaysian DCA can reject, cancel or suspend any registration with or without notice.

Appeal can be made to the ministry within 14 days from the date of notice; 90 days is given for submission of any requested data And 180 days for biotech products and new chemical entities .

Processing Fees
A processing fee of RM 500 is collected for traditional and complementary products and a additional fee of RM 700 is charged for laboratory testing services.

New Polices
Deletion of statement (diluluskan oleh kkm)
The DCA at its 199th meeting held on 4 December 2007 agreed that this phrase to be taken from product labels; the rationale behind this step is the use of the Meditag hologram which is a more effective means of verifying authenticity of a product rather than this statement. A grace period of 6 months is given to the companies to comply with the above directive.

Prohibition on the use of premixes in natural products
Premixes used in the manufacture of natural products were found to be adulterated in many instances. It is difficult to verify that premix ingredients in locally manufactured traditional formulation. Existing manufactures who are currently using premix in their formulation were given a period of 6 months from 1 June 2007 to find an alternative source like single blended herbs in replacement of premix ingredients. Approval to use premix has been given on a case-to-case basis, and this should be tested by an approved laboratory.

NEW POLICY IMPLEMENTATION

For single ingredients with known safety profile, the registration number will be issued as soon as the product is approved at NPCBs internal meeting and it is no longer necessary to wait for the DCA meeting. From June 2008, the regulatory agency is trying to reduce time frame for approval, to increase customer satisfaction and to conserve the resources.

DCA will reject applications if insufficient or inappropriate or incomplete data are provided in response to queries during evaluation dossiers. All the applicants will be given two reminders within a 6-month time frame to provide the necessary information required for evaluation for product dossier. Submission failures will result in the rejection of the application for registration.

Harmonization
ASEAN Traditional Medicine and Health Supplement (TMHS) Product Working Group (THMS–PWG) is formed in August 2004 to implement the TCM under Health care integration roadmap chaired by Indonesia and Co-chaired by Malaysia. TMHS–PWG report to ASEAN Consultative Committee forSstandard and Quality (ACCSQ). The member countries of ACCSQ TMHS–PWG are Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philipines, Singapore, Thailand and Vietnam to form ASEAN Alliance Health Supplement Associations (ASHSA).

The main objective of TMHS–PWG is to develop harmonization schemes of TMHS regulations of the ASEAN member countries to complement and facilitate the objective of AFTA, particularly the elimination of technical barriers to trade posed by regulations without compromising safety, quality and efficacy.[7-9]

CONCLUSION

Government of Malaysia encourages TCM and has the potential to be develop as a new industry and should be

explored. There is a need for new research to resolve safety and effectiveness issue of TCM products in Malaysia.

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