

REGULATORY CONTROL OF HERBAL AND TRADITIONAL MEDICINES IN MALAYSIA: ISSUES AND CONCERNS

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ABSTRACT

Many herbs are believed to be beneficial in curing diseases, in addition to improving general health and well-being. With the booming of many herbal and traditional medicines into local markets, it is feared that the harmful side effects might prevail over their potential benefits as there is a lack of or even no scientific basis for the belief. The popularity of these medicines in the modern age is proliferated by the rapid growth of the internet usage worldwide vis-à-vis aggressive online marketing by the manufacturers, producers, retailers and sellers. These categories of medicines generally fall under the purview of various regulations such as the Control of Drugs and Cosmetics Regulations 1984, Sale of Drug Act 1952, Poison Act 1952, and the Advertisement and Sale Act 1956. Despite these regulations, production and sale of traditional medicines might pose some issues in relation to their safety to the consumers as they contain some new active ingredient of plant extracts which are chemicals that have the potential of causing adverse implication to health, similar to those purified medications. Generally, registration requirements for food supplements are not as stringent as those made applicable for pharmaceutical products and hence, many herbal and traditional medicines are registered under the former rather than the latter categories. Setting on this background, this paper seeks to examine the current legal framework regulating herbal and traditional medicines in Malaysia, with a special emphasis on the issues and challenges revolving around them. This paper uses qualitative research method, that is a content analysis of the existing literature from journals, articles, periodicals and various websites. Doctrinal analysis is applied to examine the relevant laws in selected jurisdictions, such as the United Kingdom, European Union, Australia and Japan, with the aim of emulating the most suitable, best practice from these countries. This paper concludes with some suggestions such as imposing the requirement of clinical evidence and adopting a systematic post-marketing surveillance to overcome the problems and weaknesses of the current legal mechanism in regulating products of herbal and traditional medicines.

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1. INTRODUCTION

Herbal and traditional medicines which form part of complementary medicine have become the popular choice both in developed and developing countries. The popularity of these medicines in the modern age is proliferated by the booming and rapid growth of the internet usage worldwide vis-à-vis aggressive online marketing by the manufacturers, producers, retailers and sellers. Historically, the usage and consumption of herbal and traditional medicines could be traced back to the practice of ancient civilization and thus an integral part of the daily life, with the aim of improving well-being and health (Sooi & Keng, 2013). In term of global statistics, annually, such medicines were reported to reach USD60bil (approximately RM192bil) and the figure is projected to grow at a steady rate. This figure is estimated to grow up to 20 times over the next few decades. The estimated figure as released by the World Bank was US\$5tril, or RM16tril in 30 years, that is by the year 2050. Such a steady increase in use and consumption has prompted concerns about the safety and efficacy of traditional and herbal medicine (Colwell, 2016).

As a country with very rich biodiversity resources, the herbal products industry has been identified as one of important industry to drive Malaysia's emerging bio-economy. In fact, herbal medicine industry in Malaysia if properly researched and work on, would be able to generate a lucrative income as the potential of the existing species of plants are enormous. It was estimated that ten percent of the total 20,000 species of plants if properly researched and developed, could be produced as a useful alternative medicine (Shah, 2017). To achieve the mission, the Government has made a serious effort to spur the growth of the herbal industry by placing it under Entry Point Project 1 (EPP1) of Agriculture, which is one of 12 National Key Economic Areas (Heng, 2015).

For millions of people in developing countries, traditional and herbal medicinal products remain as a very popular choice as they are perceived as the most accessible and affordable treatment option (Colwell, 2016). Other than local consumers' traditional strong belief on herbal and traditional medicines, some of the reasons which are associated with the escalating popularity of these products are; population from the middle and high income group are becoming more health conscious and thus they have resorted to these complementary medicines to maintain a healthy lifestyle. This scenario is supported by an aggressive marketing via various social media, including those traditional products and supplements which are promoted as 'natural' or herbal based. Other than the above two groups of population, complementary medicines such as traditional and herbal products have also become the preferred choice for lower income group for some reasons such as affordability, cultural and surrounding influences (Milton, 2008).

Some supporting statistics in relation to the above scenario can be seen from a survey which was carried out in 2005 by the Malaysian Health Ministry. The survey found that 69.4% respondents were users and consumers traditional or complementary medicines in their whole life and hence it reflects the lifestyle of Malaysians generally. In terms of the number of registered products under

the category of traditional medicines, the Malaysian Health Ministry's Drug Control Authority disclosed that up to December 2007, the cumulative figure comprised of 18,200 which is 46.5%, while prescription medicines accounted for 30.2% and 23.3% was from over-the-counter medicines. The substantial portion of registered traditional medicines is parallel to the concept of 'supply and demand', thus explaining the booming of such products in local market (Colwell, 2016). World Health Organization (WHO) estimated that the traditional and complementary medicines industry in Malaysia could generate the total sales of RM1000 million annually (WHO, 2001). Undoubtedly, traditional and complementary medicines contribute to a substantial portion of the Malaysian health sector, affecting the public at large.

2. TERMINOLOGIES

The terms traditional, complementary and herbal medicine are succinctly defined by the World Health Organization (WHO). These three terms are closely related and it is not surprising that they may be used interchangeably. According to WHO, as provided on its website, traditional medicine generally refers to, "the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness" (WHO, 2018). The broad concept of traditional medicines seems to encompass diverse aspect of cultural varieties across the globe.

The terms "complementary medicine" or "alternative medicine" in turn denotes "a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system". This definition emphasizes on the practices which exist concurrently with modern health care system but remain as a distinct regime.

The most significant terminology is herbal medicine which is defined "to include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations". This is in fact the focus of this paper, *ie* legal issues and challenges revolving around these products, which have now flooded the local markets and become a very popular choice among consumers.

3. LAWS GOVERNING TRADITIONAL AND HERBAL MEDICINES IN MALAYSIA

Traditional medicines, herbal products, and supplements in Malaysia come under the purview of a number of legislations such as the Control of Drug and Cosmetic Regulations 1984, Poison Act 1952, Sale of Drug Act 1952, Advertisement and Sale Act 1956 and Protection of Wild Life Act 1972. It is to be noted that these legislations are applicable for all kinds of sale and marketing of the medicines, inclusive of online and offline sale. The Sale of Drugs Act 1952 for instance, governs the sale of drugs generally. In relation to the advertisement of traditional and herbal medicines, it must conform to the Medicines (Advertisement and Sale) Act 1956. For registration related matters, the Control of Drugs and Cosmetics Regulations 1984 serves as an important legal mechanism. Since the Government has been taking numerous initiatives to assist in developing traditional medicines, the National Health Policy on traditional and complementary medicine was launched in 2000 with the aim to ensure safety and complementary medicine practices as well as

products.

As far as traditional and herbal medicines are concerned, they are required to adhere to the safety requirements of the Malaysian Health Ministry's Drug Control Authority (DCA). The criteria of requirements focus on ensuring specific limits for heavy metals and microbial contamination, ensuring non-existence of steroids and other adulterants, prohibition of herbs with adverse effect and maintaining compliance with Good Manufacturing Practice (GMP). Nevertheless, it is worth noting that it is usually a common practice by the local manufacturers and producers of these products to register them as supplements. This is due to the fact that generally, registration requirements for food supplements are not as stringent as those made applicable for pharmaceutical products and hence, many herbal and traditional medicines are registered under the former rather than the latter categories. Consequently, there is no need to comply with the above-mentioned safety requirement as imposed by DCA.

The National Pharmaceutical Control Bureau (NPCB) as the secretariat of DCA is given the responsibility in respect of safety and quality of traditional products. In other words, DCA is the main body which is accorded with high responsibility for product registration. In addition, all producers of traditional medicine are obliged to comply to adhere to good manufacturing practices. The important task undertaken by DCA is to perform lab testing with the primary aim to ensure that the heavy metals contained in traditional medicines are within the permissible limits. Besides, lab testing is crucial in determining whether the traditional products have been contaminated with pathogenic microorganisms or adulterated with scheduled poisons.

In addition, specific tests such as "disintegration and uniformity of weight tests" are also conducted out on some specific forms of traditional medicines, namely tablets and capsules (Ministry of Health Malaysia, 2018). Thus, it is part of NPCB's obligation to carry out a proper analysis in ensuring the content of heavy metals not exceeding the approved limit as stated in Table 1. To accomplish this objective, lab testing is inevitable, comprising of both stages of registration (pre and post). Public safety issues are always the paramount concern and the Government via NPCB is serious in ensuring the safe consumption of traditional products.

Table 1: Limit of heavy metals in traditional products

Heavy metals	Toxic effects
Arsenic	NMT 5.0 mg/L or 5.0 mg/kg [5.0 ppm]
Mercury	NMT 0.5 mg/L or 0.5 mg/kg [0.5 ppm]
Lead	NMT 10.0 mg/L or 10.0 mg/kg [10.0 ppm]
Cadmium	NMT 0.3 mg/L or 0.3 mg/kg [0.3 ppm]

Source: Ministry of Health, Malaysia, 2018

The traditional products which have passed all the test and properly registered are given the registration number (MAL number) with hologram. Obviously, if the consumers opt to purchase unregistered products with all the claims that might be misleading or simply due to fancy marketing, they are exposed to adverse risks and can be fatal.

It is to be noted that there is another important mechanism to ensure consistent adherence to safety

and quality of the registered products which is undertaken DCA. It is obliged to carry out as part post-market surveillance via sample testing of registered products. For example, it was reported in 2007 that six product batches were recalled within 72 hours. The total number of registered products taken as sampling in that testing exercise was 2,538. It is worth noting that quality defects were identified as the main reason for the recall, which also involved a recall within 30 days for 138 product batches. In terms of categories of medicines being recalled, 12.8% was prescription medicines, 9.8% was over-the-counter medicines while the largest percentage came from traditional medicines which accounted for 77.4% (Milton, 2008). At this juncture, it is to be noted that the recall rate for traditional medicines is observed to be disproportionate in comparison to the percentage of total registered products (46.5%).

Currently, there is an absence of specific guidelines that are compatible for alternative medicine. The term 'alternative medicine' is meant to consist of formulas that are produced by using herbal and natural ingredients. The Malaysian Ministry of Health is fully aware of this situation and hence it is working towards establishing a new set of guidelines to cover aspects of clinical trials specifically catered for alternative medicine (Shah, 2017). Such an initiative is crucial to encourage and thus spur more regulatory approved products. Obviously, the Government is taking into account the existing regulation of medicine which is argued to be unsuitable for the herbal and traditional medicine. The proposed new guideline is aimed to expedite the normal process taken for clinical trials of herbal and traditional medicine. The present regular process usually consumes longer time, which may extend to a few years. The new guideline is significant as it would facilitate and provide a much feasible avenue for herbal and traditional medicine producers and industry players to obtain speedier and easier approval for their products.

4. EFFICACY AND SAFETY ISSUES

Traditional and herbal medicines are commonly perceived as being safe and much more effective in curing diseases or even as daily supplements because herbs are "natural" substances and hence are free from any hazardous chemicals (Manukyan, 2016). After all, the practice of using medicinal herbs and remedies as part of cure or treatment has been going on for many years, from one generation to another (Sooi & Keng, 2013). Such a perception and trust in traditional medicines persists, despite various reports highlighted in mass media about some popular supplements exposed for misleading and deceptive claims (Talib, 2006). It is also observed that many consumers easily trusted and hence became victims to those irresponsible sellers who do aggressive marketing to market their products solely based on testimonies or even unsupported scientific evidence (Mydin, 2015). Indeed, intense and reliable research is inevitable to ascertain whether existing traditional and herbal products in the market are really safe and efficient as inappropriate use of these products have led to dangerous impacts.

Generally, the evidence of the efficacy of traditional and herbal medicines are limited and this eventually gives rise to the issue of safety and adverse impact of the use and consumption of those products. Those testimonies and therapeutic claims relied on by consumers remain unsubstantiated. It is undeniable that there exists some scientific evidence gathered from randomized, scanty clinical trials of a small number of herbal medicines. For example, some herbal medicines are found to show similar effects like morphine, have been used for to relieve aches and pain. This explains the fact that approximately 25% modern medicines at present originate and are produced from selected

plants that were inherently used in traditional methods of treatment and hence reflects the significance of herbal medicines for proven cure and treatment (Milton, 2008).

As a matter of fact, there are few ways in which herbal products may produce toxicity. This varies from the toxic ingredient exist in some herbs, unintentional substitution of the herb with a toxic species, environmental contamination of the herbs to toxicity when taken in combination with modern medicines (Hussin, 2001). This in turn explains why herbal remedies are found to have toxic “natural” substances. For instance, the rhizome of *Smilax luzonensis* (*akar banar*), which is usually consumed as an aphrodisiac, to be quite popular among consumers and it is being locally sold in supplements with mercury as part of its ingredients (Mydin, 2015). Similarly, a study has disclosed that herbal medicines can cause kidney failure and liver damage in some consumers This is due to the fact that those herbal medicines or supplements contain toxic chemicals or heavy metals, or in some instances, produce harmful reaction when consumed with other drugs (Davey, 2017).

In this regard, it is observed that there is still a lack of quality control to regulate herbal products, in comparison the strict codes which must be complied with by all players in the pharmaceutical industry in particular producers and manufacturers. The inherent and persistent risk of microbial contamination continues to exist. This can be seen from the fact that from time to time, NPRA has been receiving reports of cases involving adverse reactions to alternative medicines which include “contamination or substitution with herbs known to be toxic (such as *Magnolia*, *Aristolochia*, *Chapparal*), contamination with heavy metals as well as the illegal inclusion of a drug (for example, *corticosteroids*, *analgesics*, *hypoglycemic* agents)” (NPRA, 2000).

In terms of manufacturing process, problems also ensued in relation to the quality of manufacturing. Whenever the process involves the usage of some plants or herbal substance, the exact amount or level of chemical and active ingredients is made dependent on the specific selected variety of plants, the ways they are grown and harvested, their processing and manufacturing as well as storage methods (Milton, 2008). This is because the concentrations of compounds in these products may vary on the basis of the said factors and may give untoward impacts on the ultimate users.

According to the latest report by the Health Ministry of Malaysia, it has taken action based on the reports and complaints about traditional medicine products. The Ministry has used its power to seize unregistered and counterfeit traditional medicines which amounted to 5,487 products in the year 2018 alone. The total value of the seized products was estimated at RM13.1mil. In addition, the ministry's Medicine Advertisement Board has also taken a stern action involving 64 cases in relation to traditional products with unreasonable, baseless and unsubstantiated claims (Chu, 2018).

5. INTERNATIONAL REGULATION: SOME SELECTED JURISDICTIONS

Proliferation of the use and consumption has given rise to an awareness of the potential health and safety risks associated with traditional herbal medicine. This in turn prompts regulatory efforts worldwide (Colwell, 2016). Though different countries have different ways and legal mechanism in regulating this issue, most of them have enacted relevant laws treating traditional and herbal medicines as prescription drugs and subjecting them to good manufacturing practices. It is worth noting that WHO has made a serious effort in harmonizing and standardizing the regulation of herbal medicines globally. To achieve this objective WHO has published some guidelines for

herbal medicine safety and efficacy assurance. They include, Quality Control Methods for Medicinal Plant Materials (1998), WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants (2003), and WHO Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues (2007).

For the purpose of benchmarking and emulating best practices from developed countries, this paper will now examine the regulations and legal framework as currently being practised in the European Union (EU) and the United Kingdom (UK), Australia and Japan.

5.1. *European Union and United Kingdom*

The use of traditional and herbal medicines is widespread in many parts of the world and this includes European countries. There have been some reports of potentially life-threatening and fatal adverse impacts (Pickup & Hodges, 2002). The escalating concerns over the safety and quality issues have paved the ways to strengthen the regulatory mechanism governing such products. As such, relevant regulations pertaining to traditional and herbal medicines need to be reviewed for the sake of market harmonization of various national herbal regulatory regimes. The registration of Traditional Herbal Medicinal Products is now regulated by Directive 2001/83/EC as amended by Directive 2004/24/E (Official Journal of the European Union, 2004). The Directive mandates a simplified registration procedure for herbal substances, herbal preparations, traditional herbal products and their combinations intended for oral, external and/or inhalation preparations, in so far as they meet some conditions.

Herbal remedies in the UK have historically been exempted from licensing. According to the Human Medicines Regulation (2012), a product comes under the classification of herbal medicines “if the active ingredients are herbal substances and or herbal preparations only. Herbal preparation is further defined to cover situations when herbal substances are put through specific processes, which include extraction, distillation, expression, fractionation, purification, concentration and fermentation. The herbal substance being processed can be reduced or powdered, a tincture, an extract, an essential oil, an expressed juice as well as a processed exudate (rich protein oozed out of its source)”. It is to be noted that not all herbal products would be classified as medicines, as some fall within the categories of food supplements or cosmetics.

At present, an application for a traditional herbal registration (THR) in the UK must be accompanied with an “evidence that the herbal medicinal product has been traditionally used to treat the stated condition for a minimum of 30 years, 15 years of which must have been in the European Union (EU)”. This requirement is provided under Directive 2004/24/EC of the European Parliament and of the Council. The implementation of the Directive is done via the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, and came into full force on 30 April 2011. Undoubtedly, it has played an important role in establishing a new mechanism to facilitate regulatory approval specifically catered for herbal medicines in the UK and across the EU. The Traditional Herbal Medicines Registration Scheme is administered by the Medicines and Healthcare Products Regulatory Agency (MHRA). To obtain a THR, those interested manufacturers, producers or suppliers “must demonstrate a history of traditional use for at least 30 years (of which generally 15 years must have been in the EU), evidence of safety, adherence to appropriate manufacturing standards and provision of appropriate product information to users”. The list of herbal medicines which are afforded with THR as issued by MHRA is provided via

"Guidance Herbal medicines granted a traditional herbal registration" and is updated regularly. The list is very comprehensive, embracing details such as traditional herbal registration (THR) number, grant date, registration holder, product name, active ingredient as well as product indications for traditional use.

A THR may still be granted in cases of absence of clinical evidence to prove the efficacy of herbal medicines provided they meet the EU's standards of quality and safety, as well as "bibliographic or expert evidence demonstrates 30 years of traditional use for the required indication, of which at least 15 years must normally have been within the EU". Since the year 2006 when the first THR was granted in the UK, the number has shown a steady increase and by the end of 2012, almost 200 THR has been granted. A product which is granted with THR will be accompanied with a Public Assessment Report (UKPAR), and it is available at the MHRA's official website *ie* at "<http://www.mhra.gov.uk>". Among the details which are accessible include, "substantial information including the Summary of Product Characteristics and images of the label and in-pack leaflet, and can be found by entering the product name in the search box". The products in the market can easily be recognized via a THR number and a unique 'THR' logo printed on the product packaging (BHMA, 2018).

It is worth noting that all herbal medicines marketed in the UK since April 2011 need to have either a THR or a MA. This is an effective mechanism in ensuring that those medicines comply with all the standard and the EU's strict requirements which are imposed on all medicine in the market (BHMA, 2018). In short, the Directive applies to manufactured herbal medicinal products sold over the counter, prohibiting the continued sale of unlicensed products. Thus, it has now become the practice and the norm in the UK in ensuring a high standard of quality is met, safety level is regularly and closely monitored, as well as details of the products are made available to the consumers via in-pack leaflets. Ultimately, this assures safety and efficacy of traditional and herbal medicines consumed by consumers.

5.2. *Australia*

In Australia, the common term which is being used at present is 'complementary medicines.' It basically refers to "medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homeopathic and certain aromatherapy preparations." This type of complementary medicines comes under the purview of the Therapeutic Goods Act 1989. Legal definition of the term is provided under the Therapeutic Goods Regulations 1990. It includes "therapeutic good consisting principally of one or more designated active ingredients" as specifically spelt out in Schedule 14 of the Regulations.

In comparison to Malaysia, the EU and the UK, Australia has a slightly unique and different approach in regulating traditional and herbal medicine. It is essentially an approach which focuses on risk-based, supported with a two-tiered system. The system is comprehensive as it covers regulation of all types of medicines, inclusive of complementary medicines. The unique two-tiered system apparently consists of; first, lower risk medicines which appear on the list the Australian Register of Therapeutic Goods (ARTG); and second, higher risk medicines. The latter category is required to be registered on the list of the ARTG. It is to be noted that some complementary medicines are not required to be registered and hence are afforded with exemption from the ARTG. For example, exemption is given to "certain preparations of homeopathic medicines" (ARCGM,

2018).

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. TGA undertakes the obligation to carry out a range of evaluation, which includes monitoring activities. The main aim is to ensure therapeutic goods on the market meet the required standard. Monitoring task also involves the important role of post-market regulatory activities with the objective of continuing safety of the listed and registered products. Eventually, the task undertaken by the TGA will greatly ensure consumers are provided with therapeutic goods which are effective, safe and of high quality.

As part of monitoring processes, the TGA Manufacturing Quality Branch regularly inspects manufacturers to ensure compliance with GMP. This is due to the issues such as complementary medicines found to have some unexpected and undesirable effects. It is worth noting that the TGA has a strong and effective “pharmacovigilance” program. The program focuses on the assessment of adverse events that are reported to the TGA by various parties such as consumers, health professionals and the pharmaceutical industry. The reports also come from international medicines regulators as well as relevant experts which include the medical and scientific experts on TGA advisory committees. Concerted effort and full co-operation of all parts of society is the main factor in ensuring the success of the “pharmacovigilance” program (ARGCM, 2018).

With regards to matters relating to marketing and advertising of therapeutic goods including complementary medicines, there is a legal requirement that it has to be carried out law requires in such a way that facilitates promotion of the quality use of the product. Besides, it needs to socially responsible to consumers and does not eventually lead to misleading of deception to them (Weir, 2013). Thus, such an advertisement is made subject to the advertising requirements provided under the Therapeutic Goods Act. The Act adopts the Therapeutic Goods Advertising Code (TGAC) and other relevant Regulations, in particular the Australian Consumer Law under the Competition and Consumer Act 2010.

5.3. *Japan*

Japanese traditional medicine could be divided into two main categories, namely folk medicine and 'Kampo' medicine. The latter denotes Chinese medicine from ancient China, and uses a formula consisting of 5-10 different herbs. More than 95% of Kampo drugs used in Japan are taken as ethical drugs (WHO, 1998). Both western herbal medicines and ancient formulations of traditional Chinese and Kampo medicines coexist and complement each other to maintain wellness and health. Japanese traditional medicine plays an important role as it is regarded as an integrative part, used by Western physicians in addition to conventional medicines. In fact, more than 70% of Japanese physicians use Kampo medicine in daily practice together with high-tech medical treatments such as organ transplantation and robotic operations (Nishimura, 2009). One of the unique features of the Japanese healthcare system, as compared to Malaysian, almost 100% of the Japanese population is covered by the National Health Insurance (NHI). This means that Japan practises a system for compensating for adverse drug reactions, which is under the administration of Japan's Pharmaceuticals and Medical Devices Agency.

In terms of laws and regulations, traditional and herbal medicines in Japan are heavily regulated in a similar manner as conventional pharmaceutical drugs. Majority of herbal formulations are sold

as over-the-counter-medications with details provided in the leaflet. Some other herbal formulations are sold as prescribed drugs, according to the needs of individual patients. The effect of herbal medicines depends entirely on the sum of pharmacological actions of the effective ingredients contained in the raw herb. In relation to the evaluation of efficacy and safety, those raw herbs which have long been used as folk medicine are listed in the corresponding monograph. For example, in the evaluation of efficacy of a Chinese medicine, due consideration is given to the empirical facts or experience such as reference data, clinical test reports etc. Generally, specified data on safety, stability, comparison with other drugs, clinical test results *etc* are required to be submitted in relation to herbal medicines.

Despite the facts that it is part of Japanese herbal medicines, new Kampo drugs are regulated in the same way as Western drugs in Japan. Hence, the time-consuming and expensive chronic toxicity tests, special toxicity tests and other related tests are required, inclusive of data for three-phase clinical trials (WHO, 1998).

All Kampo medicines which are manufactured by Japanese pharmaceutical companies fall under the purview of the Pharmaceutical Affairs Law and strictly controlled by Good Manufacturing Practice. This legal mechanism is important in ensuring the product quality and safety at its highest level (Nishimura, 2009). At this juncture, it to be noted that the Pharmaceutical Affairs Bureau has set certain standards for manufacture and quality control of Kampo Drug. The Bureau is obliged to ensure that quality of herbs used in each original formula meets precise standards.

Japanese Ministry of Health and Welfare is also responsible in matters related to post marketing surveillance. It has three major systems for the collection of domestic adverse reaction data; first, the Adverse Drug Reaction Monitoring System under which specific monitoring hospitals are designated to report cases of adverse reactions, second, the Pharmacy Monitoring System, and third, Adverse Reaction Reporting for Manufacturers.

6. A WAY FORWARD – ENHANCING CURRENT LEGAL MECHANISM

6.1. *A Comparative Analysis*

Based on the preceding discussion, it is pertinent to make some comparative analysis on the relevant legislation of EU, UK, Australia and Japan in comparison to Malaysia. It is observed that generally, Malaysia has already in place a workable system of registration in relation to traditional and herbal medicines. Nevertheless, there is a real need to address the issues and challenges which have been identified, such as adulteration of those products, illegal manufacturing, unregistered products as well as slick marketing campaigns involving unsubstantiated testimonials and misleading claims (Thevendran, 2015). With the increasing number of traditional and herbal medicines in market, consumers are posed with increasing risk of harm if their safety, quality and efficacy remained unchecked or unregulated.

In comparison to EU and UK which requires the clinical evidence, there is a gap in Malaysian law on that part and hence, adopting some parts of EU Directive 2004/24/E in particular the requirement of clinical evidence of efficacy or expert evidence would be an avenue to overcome the problem of unsubstantiated testimonials and misleading claims. Despite the fact that DCA does

carry out post-market surveillance, the system could be enhanced by having a strong “pharmacovigilance” program as being practiced in Australia. Such a program would facilitate the assessment of adverse impacts, but the success of the mechanism is dependent on pro-active efforts on the part of consumers, health professionals, the pharmaceutical industry (Marimuthu, 2012). At this point, a higher level of awareness need to be raised in accomplishing concerted effort and co-operation by all parts of society.

In addition, emulating a systematic post marketing surveillance like what is done by Japanese Ministry of Health and Welfare would also be a way to enhance the present system in Malaysia. The issue of adulteration of traditional and herbal medicines could be tackled by imposing some further requirements to the manufacturers and producers on top of existing safety requirements by DCA, before they proceed to submit their application for product registration. Additional yet critical requirements should include much more detailed and specified data on safety, stability, comparison with other drugs, clinical test results *etc* of the traditional and herbal medicines. It might be time-consuming and would implicate additional cost on the part of manufacturers but consumers’ safety remains as a primary concern. After all, the system has proved to be working well in Australia and other countries, hence there is no reason that it is not feasible in Malaysia.

7. CONCLUSION

Enhancing current legal framework and mechanism is inevitable by tightening up the safety requirements under DCA, as well as strict adherence to acceptable standards of safety and quality as spelt out under policy statements of National Health Policy on traditional and complementary medicine. Besides, creating and raising awareness of the health risk to everyone inclusive of manufacturers, producers, retailers, and ultimate consumers is vital, so that consumers are fully aware of the risk and adverse impacts of unsafe traditional and herbal medicines. This is because, other than improving legal mechanism, public education and awareness remains indispensable (Talib, 2006). The public must be properly informed and not to fall victim easily by aggressive marketing in particular unproven testimonies. A change in mentality is inevitable to minimize the gullibility of consumers and eventually ensure that they only choose safe, effective and clinically proven products and that if the standard falls short of these, the responsible manufacturers would not escape the liability.

The widespread of false, misleading claims and irresponsible aggressive marketing should also be curtailed and monitored by responsible authorities, with the help of the public. On this point, there is a real need to facilitate the development of responsible advertisement with relevant agencies. Once stakeholders learn to fully appreciate that safe traditional and herbal medicine is critical to sustaining human health, unwanted adverse impacts can be prevented with greater support and ease.

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