

# REGULATION ON HERBAL PRODUCT USED AS MEDICINE AROUND THE WORLD: A REVIEW

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**Abstract:-** Globally, regulation over herbal products implemented under different classifications, some of which are: Complimentary medicines, Natural health products, Prescription medicines, over the counter medicines, Supplements, Traditional herbal medicines, etc.

Around the world maximum countries have already developed or developing their plan of work in regulation of herbal market. Herbs are the thing which varies drastically from region to region. However it was believed herbal medicines are completely safe but as per WHO all herbs are not at safe, providing their citizen the best product is the responsibility of every government. Vigilance over herbal product is highly required in current scenario.

The regulatory requirements of these vary considerably. While prescription medicines are strictly regulated, the extent of control on supplements is relatively low. A review of the regulatory status of the herbal medicines across the globe is given in the present article.

## INTRODUCTION:

However in present day modern medicine is very much developed in the vast majority of the world, but still world is looking for alternative natural pathways where herbs are playing a key role for public interest. Through the contribution of many researchers on goodness of many herbs are identified. Ayurveda has already mentioned usage of many herbs for their therapeutic usage. Depending on Ayurveda large no of company developing many product for therapeutic and supplementary use. Earlier it was believed that herbal products has no side effect but now it is known that herbs are not always safe. If we look into herbal products marketed in India we easily found the don't bears product leaflet, they don't have indications for use. However if we compare the same with allopathic medicines we will find a huge difference. To be available in the market a pharmaceutical company spends a large amount of money to establish its efficacy which passes through a different level of criteria like bioavailability, toxicity, safety, clinical data etc. But herbal products do not require such thing and results failure of maximum herbal product. If we just look into the regulation status on herbal product around the World we will come to know how strict is other countries in safety of human.

India is pioneer of herbal medicines the ancient literature of herbs is belongs to India. But the vigilance over herbal medicines in India is very poor. Countries around the world are marketed their herbal product in India. Because of globalization and online marketing very poor quality products are sold in India. Interaction of herbal products are not tested, clinical trial not performed, pharmacovigilance not effective. However AYUSH has introduced regulation to control production of herbal products but in India in the year of 1945. But it is still under development.

International Trade of Herbal Drugs is subject to compliance with the International treaties like Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). [18]

## GLOBAL REGULATORY STATUS:

### India[25,5]:

Phytomedicines or botanical medicines commonly known in the market as herbal medicines. Which is the usage of plants through different way for therapeutic or medicinal purpose. This emerging herbal market is regulated by AYUSH which is Ministry of Ayurveda, Yoga and naturopathy, Unani, Siddha and Homoeopathy under the Drug and Cosmetic Act (D and C) 1940 and Rules 1945 in India. Manufacturers are instructed to obey AYUSH guideline for marketing of herbal product. More precisely they should go accordingly Drug and cosmetic act, section C and D for formulation composition, licensing, labelling, manufacturing, packing, quality and export. In addition good manufacturing practice (GMP) has also been implemented through schedule "T" in 2016.

Herbal drugs are regulated under the Drug and Cosmetic Act (D and C) 1940 and Rules 1945 in India, where regulatory provisions for Ayurveda, Unani, Siddha medicine are clearly laid down in Chapter IV-A. There are 18 different section are present from section 33C to 33 O.

Its intention to ensure that the studies are scientifically and ethically sound and that the clinical properties of the ASU medicine under investigation are properly documented. The guidelines seek to establish two cardinal principles: protection of the rights of human

subjects and authenticity of ASU medicine clinical trial data generated.

#### **Uganda [25]:**

In Uganda under the National Drug Authority Statute and Policy of 1993 herbal medicines are regulated. The law applied for conventional pharmaceuticals are same applied on herbal medicines. No specific regulatory status given to herbal medicines. Consideration of safety assessment is subject to report of misuse. In 2002 registration of herbal medicines are introduced however no medicine has been registered yet. No regulation over sealing of herbal medicines are recommended and nor post marketing survey are planned.

#### **Argentina [25,1]:**

Herbal regulation in Argentina was introduced in 1998 in Resolution 144/98. Regulations are similar as conventional pharmaceuticals, but separate. In Argentina, herbal medicines are regulated as prescription medicines, over the counter medicines and dietary supplements. The relevant regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs and special GMP rules. Requirements of safety assessment include traditional use without demonstrated harmful effects, reference to documented scientific research on similar products, toxicological studies when traditional use cannot be demonstrated and submission of a full toxicological and pharmacological dossier. Registration procedure for herbal medicines are in place, however registered medicines number is not currently available. Post marketing surveillance system in Argentina includes a national system to monitor adverse effects of all medicines, including herbal medicines, which was established in 1993. [25]

The Herboristerias are authorized for sale as plant drugs but not as mixtures. Mixtures of plant drugs are controlled. In 1993, a Ministry of Health regulation determined the obligatory registration of medicinal herbs. However, there is lack of control of raw materials, lack of control over the wild plant, lack of scientific criteria for the collection of plants, and lack of control over methods of drying, conservation or grinding. [1]

#### **Brazil [25]:**

In , Brazil, there is currently no national policy on herbal medicine, but the Ministry of Health is extending the Natural Medicine and Complementary Practices national Policy, which included phytotherapy, acupuncture, homeopathy and anthroposophic medicine. A standardization proposal for the use of medicinal plants and phytotherapeutic medicines in the Sistema Único de Salud (Unified Health System – SUS) is being drafted. Laws and regulations and a national programme are in preparation. Regulation of herbal medicine has existed in Brazil since 1967, and the fourth version of the

regulations, RDC 48/2004, was put in place in 2004. It is somehow similar to the legislation on conventional pharmaceuticals. The regulatory requirements for manufacturing include adherence to the information contained in pharmacopoeias and monographs, and the same rules of good manufacturing practice as for conventional pharmaceuticals, as well as special rules. Requirements of safety assessment include the same requirements as for conventional pharmaceuticals and special requirements of traditional use without demonstrated harmful effects; again, there is no existing control mechanism, but reference is made to documented scientific research on similar products. The implementation of these requirements is ensured through annual inspections. There are more than 1000 herbal medicines registered in Brazil; none is included on the national essential drug list; however, a list of phytotherapeutic medicines is currently being prepared for inclusion. There is a post marketing surveillance system that includes adverse effect monitoring, established in 2001.

#### **Canada [25, 1, 11, 14]:**

In 1986, the Canadian Health Protection Branch (HPB) constituted a special committee (3pharmacists, 2 herbalists, 1 nutritionist and 1 physician) and classified herbal drugs as “Folk Medicine”. The regulation is based on traditional uses, as long as the claim is validated by scientific studies. In 1990, the HPB listed 64 herbs that were considered to be unsafe. In 1992, the HPB submitted a regulatory proposal to the Canadian Parliament and listed another 64 herbs that were considered to be adulterants. The Canadian regulatory system is consistent with WHO guidelines for the assessment of herbal medicines.

As per Natural Health Products regulation product licence holder has to monitor all adverse reactions related to their product and they must have to report serious adverse reaction to health Canada.

The awareness of pharmacovigilance has been created in consumer to report any unwanted effect to report their health care provider.

Clinical trial on human subjects has also been advised to discover or verify the product's effects, to identify any adverse events that are related to its use, to study its absorption, distribution, metabolism and excretion, to test its safety or efficacy. [14]

#### **United States of America [25, 1]:**

Since 1994, herbal medicines have been regulated under the “Dietary supplement health and education Act of 1994”. On the basis of this law, herbal medicines are not evaluated by the Food and Drug Administration and, most important, these products are not intended to diagnose, treat, cure, or prevent diseases. The US government has established the “Office of Alternative Medicine” at the National Institutes of Health (NIH) with

the following aims: 1) To explore the potential role of dietary supplements in the improvement of health; 2) To promote the scientific study of supplements for maintaining health and preventing chronic diseases; 3) To compile a database of scientific research related to supplements 4) To coordinate NIH funding for dietary supplements related to the treatment of chronic disease.

#### **Egypt [25,22,9]:**

Herbal medicine regulation in Egypt began in 1955, and is achieved through the same laws as are used for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over the counter medicines, self medication and dietary supplements. Regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs, the same rules of GMP as for conventional pharmaceuticals and special GMP rules. Regulatory requirements for safety assessment are limited to reference to documented scientific research on similar products. Control mechanisms exist for both manufacturing and safety assessment requirements. There are 600 registered herbal medicines. No herbal medicines are included on the national essential drug list. There is a post marketing surveillance system and a national system to monitor adverse events for herbal medicines.

#### **Iran[25,24]:**

The Islamic Republic of Iran established its national policy on TM/CAM in 1996, and in that year laws and regulations were developed. Regulation of herbal medicines was revised in 1996. Herbal medicines are regulated as prescription and over the counter medicines and as dietary supplements. Special GMP rules apply to the manufacture of herbal medicines; the implementation of these requirements is ensured by GMP inspection and national laboratory testing. Safety assessment requirements are traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Implementation of these requirements is ensured by the adverse drug reaction centre. The registration system has registered 170 herbal medicines. No herbal medicines are included on an essential drug list. A post marketing surveillance system that includes adverse effect monitoring exists.

#### **Pakistan[25,6]:**

In the Islamic Republic of Pakistan, Laws and regulations were developed in 1965 and amended in 1970 and 2002. The Drugs Control and Traditional Medicines Division of the National Institute of Health serves as the national institute on traditional medicine and was established in 1991. The Drugs Act of 1962 controls the regulation of herbal medicines as regards advertising and prevention of misuse. Herbal medicines are regulated as over the counter medicines and dietary supplements. The Tibb e

Unani, Ayurvedic, Homoeopathic, Herbal and Any Other Non Allopathic Medicine Act has been prepared to regulate the manufacture, sale, storage, import and export of medicines from these systems. The Act has been approved by the Federal Cabinet and Prime Minister of Pakistan; however, there are currently no regulatory requirements for either manufacture or safety assessment of herbal medicines. There is no registration system. Herbal medicines are not included on an essential drug list. A post marketing surveillance system is being developed.

#### **Saudi Arabia[25,12]:**

In Saudi Arabia Herbal products are categorised as traditional product those are continuously traditionally used for 50 years. It specified the preparation has to be same as used for traditionally.

According to supportive data traditional medicinal product can be categorised as 1) Pharmacopoeial evidence for traditional products, 2) Nonpharmacopoeial evidence for traditional products.

For the 1<sup>st</sup> category, the medicinal ingredients, quantity, recommended dose, route of administration, duration of use, dosage form, directions of use, risk information should be same as the Pharmacopoeia and the method of preparation must be traditional.

For the 2<sup>nd</sup> one, any two independent references must be provided to supplement the evidence supporting the safety and efficacy of the product, from clinical studies, pharmacopoeias, and textbooks references, peer-reviewed published articles, data from nonclinical studies on pharmacokinetics, pharmacodynamics, toxicity information, reproductive effects, and the potential genotoxicity or carcinogenicity of an ingredient or information based on previous marketing experience of a finished product. (1)

Herbal medicine regulation in Saudi Arabia was established in 1996 with the issue of a separate law specifically for herbal medicines. The regulatory categories for herbal medicines include over the counter medicines, self medication, dietary supplements, health foods and functional foods. Regulatory requirements for manufacturing include some of the same GMP rules as for conventional pharmaceuticals, as well as special GMP rules. (WHO)

#### **Sudan[3,25] :**

Laws and regulations are currently at the development stage. Sudan first issued regulations on herbal medicines in 1996 and renewed them in 1998 and 2002. These regulations are separate from those for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, self medication and dietary supplements. The regulatory requirements for manufacturing include adherence to information in the British herbal pharmacopoeia and the WHO

monographs, as well as the GMP rules for conventional pharmaceuticals and special GMP rules for herbal medicines. The implementation of these requirements involves evaluation of quality control data submitted by the manufacturer, GMP inspection and documentation of the raw material supply. Requirements for safety assessment include traditional use without demonstrated harmful effects and biosafety studies. To ensure adherence to these requirements, the biosafety study protocols are strictly followed. There are eight herbal medicines currently registered. Sudan is planning to create an independent list of essential Sudanese medicinal plants. A post marketing surveillance system is currently being developed.

#### **Germany [25, 10]:**

In Germany, The national laws and regulations on herbal medicines in Germany were issued in 1976, and have been updated, for instance by several amendments to the Medicines Act. Herbal medicines are regulated as prescription medicines, over the counter medicines and as medicines for self care purposes, which are sold outside pharmacies. Regulatory requirements for the manufacture of herbal medicines include adherence to the information in pharmacopoeias and, in the absence of pharmacopoeias, monographs, other monographs, the GMP rules for conventional pharmaceuticals and special GMP rules, the German Medicines Act, and Eudralex (the European Union rules relating to medicinal products). Compliance with these requirements is ensured through inspection and marketing authorization. Safety regulatory requirements include those required for conventional pharmaceuticals. Implementation of these requirements is ensured through pharmacovigilance and literature reviews. There are approximately 3500 herbal medicines registered in Germany. The post marketing surveillance system, established in 1978, includes monitoring for adverse effects of herbal medicines.

#### **Ireland [25,7]:**

The regulation of herbal medicines was introduced in 1998 with the passage of the Medicinal Products (Licensing and Sale) Regulations, which regulate conventional and herbal medicines. Herbal medicines are regulated as prescription medicines, over the counter medicines, dietary supplements and medicines for self medication purposes. Regulatory requirements for the manufacture of herbal medicines include adherence to the information contained in pharmacopoeias and monographs, the GMP rules for conventional pharmaceuticals and special GMP rules. Implementation of these requirements is ensured through the licensing of manufacturers and authorization of herbal products. Regarding safety, the same regulatory requirements that apply to conventional pharmaceuticals also apply to herbal medicines; compliance is likewise ensured by the same means. There is no registration system, nor are herbal medicines included on a national essential drug list. The same post

marketing surveillance system used for conventional medicines is used to monitor herbal medicines.

#### **Russia [25,4]:**

In the Russian Federation, the national policy was issued in 1991 and national laws and regulations in 1993. The regulatory status used for herbal medicines is prescription medicines, over the counter medicines or dietary supplements. Herbal medicines are legally sold with medical, nutrient content, and structure/function claims in the Russian Federation. Manufacturing regulatory requirements include adherence to information in pharmacopoeias and monographs and the same GMP rules as those required for conventional pharmaceuticals. The implementation of manufacturing requirements is ensured through licensing of the manufacturing process, compliance with established regulations and certification of products. The requirements for the assessment of safety of herbal medicines are same as for conventional pharmaceuticals, with additional requirements, namely radioactivity control. There are approximately 260 herbal medicines registered in the Russian Federation and they are almost all included in the essential drug list, which is issued annually. There is a post marketing surveillance system and a national system to monitor adverse effects of herbal medicines.

#### **Spain[25,19]:**

The Spanish Medicinal Products Act No. 25 of 1990 regulates both herbal medicines and conventional pharmaceuticals. Herbal products are regulated as prescription and over the counter medicines, self medication and health foods. Regulatory requirements for the manufacture of herbal medicines include adherence to information in pharmacopoeias and monographs, the same GMP rules as for conventional pharmaceuticals and special GMP rules.

The principles to assure quality of medicinal products are defined mainly in two Directives of volume 1: Directive 2001/83/EC (which was amended by Directive 2004/24/EC) and Directive 2003/63/EC. These concepts are essential for setting quality standards for HMP, as they are by definition complex in nature and so quality requirements set for purified compounds are not suitable for herbal products.

Compliance with requirements is ensured through the national pharmacovigilance system. In Spain, there are 2 277 registered herbal medicines; however, none is included in an essential drug list. The same post marketing surveillance system used for conventional pharmaceuticals, including adverse effect monitoring, is used for herbal medicines; it was established in 1985.

#### **Sweden[25]:**

Regulation of herbal medicine was first introduced in 1978. In 1993, a new act was put into force in Sweden. As part of this regulation, the product group "natural



remedy" was defined. It includes herbal medicinal products and medicinal products where the active constituent is a bacterial culture, mineral, salt or salt solution. Furthermore, under the act, the Medical Products Agency should assess the chemical pharmaceutical, safety and efficacy documentation and decide to approve or reject the product. The requirements for the chemical pharmaceutical documentation are partly the same as for conventional medicinal products, with due consideration of the special characteristics of herbal material. Concerning safety and efficacy, applications including bibliographical documentation are more common with natural remedies than conventional medicinal products. With the new directive on traditional herbal medicine products, 2004/24/EC, the legislation in Sweden and the rest of the European Union will be revised during 2005. Regulatory requirements for the manufacture of herbal medicines involve adherence to information in the European pharmacopoeia, where applicable, and to the same GMP rules as those used for conventional pharmaceuticals. Implementation of these requirements is ensured through inspection of the manufacturing site by the competent medical authority. Safety requirements pertain to the active constituent or the finished product, and include special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research. Implementation of these requirements is ensured as part of the pharmacovigilance system for conventional medicines. In this regard, the number of defined daily dosages of the product sold is taken into account. There are 103 approved natural remedies in Sweden; none is included on a national essential drug list. The post marketing surveillance system, which includes adverse effect monitoring, was first applied to natural remedies in 1980.

#### **Australia [25,1]:**

The Australian Parliament established the working party on Natural and Nutritional Supplements to review the quality, safety, efficacy and labelling of herbal and related products (Therapeutic Good Act, 1990). The act provides: "that traditional claims for herbal remedies be allowed, providing general advertising requirements are complied with and providing such claims are justified by literature references".

Regulatory requirements for herbal medicines include adherence to information in pharmacopoeias and monographs and the same GMP rules as those used for conventional pharmaceuticals. Implementation of these requirements is ensured through GMP licensing for finished goods manufacturers. Safety requirements for herbal medicines include the same requirements as for conventional pharmaceuticals, as well as special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Compliance with these requirements is ensured through "compositional guidelines". There are 1 500 herbal medicines registered

in Australia; none is included on the national essential drug list. The post marketing surveillance system has included adverse effect monitoring since 1970.

#### **China[25,8,10,22]:**

In the People's Republic of China, The national regulations on herbal medicine were issued in 1963 in the same laws as for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over the counter medicines, self medication, dietary supplements, health foods and functional foods and as a separate regulatory category. Regulatory requirements for herbal medicines include adherence to information contained in pharmacopoeias and monographs, the same GMP rules that apply to conventional pharmaceuticals and special GMP rules. No detailed information is available on the control mechanisms used for these requirements. Safety assessment requirements for herbal medicines include the requirements applying to conventional pharmaceuticals as well as special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. There are more than 9 000 registered herbal medicines; by the end of 2002, 1 242 herbal medicines had been included on the national essential drug list. The national post marketing surveillance system has included adverse effect monitoring since 1984.

#### **Malaysia [25,8]:**

Malaysia has a national policy which was launched in the year 2001. The registration and licensing of herbal medicine is legislated through the Control of Drugs and Cosmetics Regulations 1984. Regulations for traditional medicines, including herbal medicines and dietary supplements formed part of the Control of Drugs and Cosmetics Regulation in 1984. Traditional medicines are allowed to be sold as over the counter medicines. 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. Compliance with these requirements is ensured through routine inspection, GMP certification and licensing of manufacturers. Safety requirements for herbal medicines include evidence of traditional use without demonstrated harmful effects, compliance with the limits set for heavy metals (mercury, arsenic, lead), testing for microbial and fungal contamination, other physicochemical tests and screening for adulterants. As of December 2003, the Drug Control Authority (DCA) has registered approximately 12 000 traditional medicines, including herbal products. However, none of these products are included on the national essential drug list. The post marketing surveillance programme was introduced for pharmaceuticals in 1987 and was extended to cover traditional medicines in 1997. Adverse drug reaction monitoring of traditional medicines, market sampling and investigation of product complaints have since been included in the programme.

**Korea[25,8]:**

The national policy was issued in 1993; in the same year, laws, regulations and a national programme were also issued. Herbal medicine regulations were first issued in 1986 and were amended in 1994. The regulations on herbal medicine are part of the Pharmaceutical Affairs Law that governs conventional pharmaceuticals. Herbal medicines are regulated as prescription and over the counter medicines. Regulatory requirements for manufacturing of herbal medicines in the Republic of Korea are limited to adherence to the information in pharmacopoeias and monographs; no control mechanisms exist for this requirement. Safety requirements are limited to traditional use without demonstrated harmful effects; again, there are no control mechanisms for this safety requirement. There are about 4 000 registered herbal medicines in the Republic of Korea; 515 herbal medicines are included on the national essential drug list issued in 1959. A post marketing surveillance system for herbal medicines is being planned.

**Singapore [25,2]:**

There are national regulations on herbal medicines in Singapore. A subgroup of herbal remedies is Chinese proprietary medicines (CPM), which are traditional Chinese herbal medicines in finished dosage forms (e.g. tablets, capsules). In 1998, Singapore issued regulations on Chinese proprietary medicines, which are similar to those regulating conventional pharmaceuticals. Herbal medicines are regulated as over the counter medicines. Regulatory requirements for Chinese proprietary medicines are the same GMP rules used for conventional pharmaceuticals. There are currently no registration requirements for herbal medicines and none are included on a national essential drug list; however, a listing system has been established for CPM products. The post marketing surveillance system for all herbal medicines has included adverse effect monitoring since 1993.

The product should be of acceptable standards of quality in terms of product stability, adequacy of shelf-life period, proper packaging and labeling; and are manufactured and/or assembled under proper conditions.

**CONCLUSION:**

Herbal medicines are gaining a huge demand day by day. Around the world countries are becoming concern about the usage of herbal medicines. It is now known control over herbal medicine is required as herbs are not always safe. Major regulatory bodies around the world are developing new strategies to control market. Regulatory bodies are concern about the public safety. Many countries have developed new research institute, some are revising national policy others have already developed. Above all it has been understood that

requirement of post marketing surveillance is highly important. In the myth over safety of herbal medicine, this domain is always is neglected from the purview of pharmacovigilance. However importances of such things are now accepted today. Countries like India are in the growing stage of such development. AYUSH the Indian controlling authority has implemented many rules and law but how far those laws and rules are complied is a matter of investigation. Herbal products which are marketed are not having product leaflet none of them are clinically tested and GMP complied. To overcome all these problems public concern and development of public knowledge is highly required. Government must have to be more vigilant on online marketing. It is found practitioner is very much orthodox in herbal practicing so development in this domain is very much required.

**REFERENCE:**

1. Adhami HR, Mesgarpour B, Farsam H. Herbal Medicine in Iran. *Herbal Gram*.2007.74:35-43.
2. Ali GKM, Omer AM. Pharmaceuticals in Sudan: Development in regulations, governance and implementation of national drug policies. *African Journal of Pharmacy and Pharmacology*. 2012.6(1) 1-12.
3. Australian regulatory guidelines for complementary medicines(ARGCM). Australian government department of health. *Therapeutics goods Administration*.2018.7.2:1-243.
4. Endangered Species of Wild Fauna and Flora. Available from: <http://www.cites.org/eng/disc/what.php>.
5. Geneva, Switzerland: 2014. [Last cited on 2014 Apr 29]. *Convention on International Trade in*
6. Haggag M. Herbal medicine in Egypt, *Iranian Journal of Pharmaceutical Research*. 2004.11(3) 2:5-6.
7. Kozyrskyj A. Herbal products in Canada How safe are they? *Canadian Family Physician*.1997.43.
8. Kumar A, Venkatesh MP, Kumar TMP. Regulations And Challenges Of Herbal Medicines In Russia. *International journal of ayurvedic & herbal medicine*.2016. 6(1):2149-2169.
9. Kumar V. Herbal Medicines: Overview on Regulations in India and South Africa. *World Journal of Pharmaceutical Research*.2017.6(8):690-698.
10. Liu FX, Salmon J W. Herbal Medicine Regulation in China, Germany, and the United States. *Integrative Medicine*.2010.9(5)
11. Memon AR, Randhawa MA, Arain AA, Alrawaili YSH, AlrawailiYSK, Alharthi NF, Alhassan NS, Alshammari

- SOM, Alanazi MSA. Herbal medicine use: knowledge and attitude in patients at tertiary care level in northern border region of kingdom of Saudi Arabia. *Journal of Sheikh Zayed Medical College*. 2017; 8(3): 1241-1244.
12. Min TJ. Regulatory requirements for registration of health supplements in Malaysia. National Pharmaceutical Regulatory Agency Ministry of Health Malaysia. 2017.
13. New Regulation of Herbal and Traditional Medicines in Brazil. General Office of Medicines Brazilian Health Regulatory Agency - ANVISA. 2017. [www.anvisa.gov.br](http://www.anvisa.gov.br)
14. O'Sullivan T, Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland. Health Services Development Unit. 2002.
15. Park HL, Lee HS, Shin BC, Liu JP, Shang Q, Yamashita H, Lim B. Traditional Medicine in China, Korea, and Japan: A Brief Introduction and Comparison. Hindawi Publishing Corporation. Evidence-Based Complementary and Alternative Medicine. 2012.429103.
16. Poveda R. Regulation of Herbal (Traditional) Medicinal Products in the European Union. Pharmaceutical Regulatory Affairs. 2015.4.2
17. Ramakrishna C, Reddy J P, Alagusundaram M. Current Regulations for Herbal Products. *International Journal of Advance Research, Ideas and Innovations in Technology*. 2017;3(3):1597-1604.
18. Regulatory guidance. Health Sciences Authority – Health Products Regulation Group. 2018. GUIDE-CHP-300-008.
19. Sahoo N, Manchikanti P. Herbal Drug Regulation and Commercialization: An Indian Industry Perspective. *The Journal of Alternative and Complementary Medicine*. 2013 19(12):957-963.
20. Shaikh BT, Hatcher J. Complementary and Alternative Medicine in Pakistan: Prospects and Limitations. Advance Access Publication. 2005. 2(2)139–142.
21. Sharma S. Current status of herbal product: Regulatory overview. *Journal of Pharmacy and Bioallied Sciences*. 2015. 7(4): 293–296.
22. Sushma G, Debnath S, C SK, Chandu AN. Quality and regulatory affairs of herbal drugs: A world-wide Review. *Indo American Journal of Pharmaceutical Research*. 2011;1(5):389-396.
23. The Egyptian Guidelines for Registration of Herbal Medicines. 2015.
24. National policy on traditional medicine and regulation of herbal medicines. Report of a WHO global survey. World Health Organization Geneva May 2005.
25. ZHANG X. Regulatory Situation of Herbal Medicines a World Wide Review. 1998. who/TRM/98.1:1-45
26. <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation.html>.