Legal regulations of complementary and alternative medicines in different countries

Ajazuddin, Shailendra Saraf

University Institute of Pharmacy, Pt. Ravi Shankar Shukla University, Raipur, Chhattisgarh, India

Submitted: 25-03-2011 Published: 23-08-2012

ABSTRACT

Traditional medicines that formed the basis of health care throughout the world since the earliest days of mankind are still widely used and have considerable importance in international trade. Recognition of their clinical, pharmaceutical, and economic value is still growing, although this varies widely between countries and therefore regulation of exploitation and exportation is essential, together with international cooperation and coordination for their conservation so as to ensure their availability for the future. World Health Organization and European Union issued the guidelines defined the basic criteria for the evaluation of quality, safety, and efficacy of herbal medicines with the goal of assisting national regulatory authorities, scientific organizations, and manufacturers in assessing documentation, submissions, and dossiers in respect of such products. Legislative controls in respect of medicinal plants have not evolved around a structured control model. There are different ways in which countries define medicinal plants or herbs or products derived from them. The present review highlights the status of different countries adopted various approaches to licensing, dispensing, manufacturing, and trading to ensure their safety, quality, and efficacy.

Key words: Efficacy, legislation, quality, safety, traditional medicines

INTRODUCTION

During the past decade, complementary and alternative medicines have become a topic of global importance. Current estimates suggest that in many developing countries, a large proportion of the population relies heavily on traditional practitioners and medicinal plants to meet primary healthcare needs. Although modern medicine may be available in these countries, herbal medicines (phytomedicines) have often maintained popularity for historical and cultural reasons. Concurrently, many people in developed countries have begun to turn to alternative or complementary therapies, including medicinal herbs. World Health Organization (WHO) estimated that the world market for herbal medicines and herbal products is worth US$ 62 billion and would hit US$ 5 trillion by 2050. The market is growing at 7% per annum (*The Times of India*, 7-4-2000).

A common feature of most systems of traditional medicine (TM)/complementary and alternative medicine (CAM) is that they take a holistic approach to promote health, prevent disease, and help the individual treat disturbances by regulating his/her physical, emotional, and mental aspects and living environment. According to its characteristics and concepts, TM/CAM can be used not only for curing disease and relieving symptoms but also for the regulation, improvement, and promotion of the function of the human body. Few plant species that provide medicinal herbs have been scientifically evaluated for their possible medical application. Safety and efficacy data are available for even fewer plants, their extracts and active ingredients, and the preparations containing them. Furthermore, in most countries the herbal medicines' market is poorly regulated, and herbal products are often neither registered nor controlled. Assurance of the safety, quality, and efficacy of medicinal plants and herbal products has now become a key issue in industrialized and in developing countries. Both the general consumer and healthcare professionals need up-to-date, authoritative information on the safety and efficacy of medicinal plants. With the widespread use of TM as well as CAM and the rapid expansion of international herbal medicine markets, the development of national policies and regulations on TM/CAM has become an important concern for both health authorities and the public. Providers of TM/CAM,

Address for correspondence:
Mr. Ajazuddin,
University Institute of Pharmacy, Pt. RSU, Raipur, Chhattisgarh, India.E-mail: write2ajaz@gmail.com

Access this article online

Quick Response Code:

Website: www.phcogrev.com

DOI: 10.4103/0973-7847.99950

other healthcare professionals, and TM/CAM consumers alike are calling for regulations that can ensure the safety of TM/CAM therapies and products, promote recognition of these systems and modalities, and further define their role in modern healthcare systems. National policies and regulations on TM/CAM could ensure the safety, quality, and efficacy of these therapies and products and function as important steps toward integrative healthcare systems. However, relatively few countries have developed policies and regulations on TM/CAM so far. Only 25 of WHO's 191 countries have a national policy on TM/CAM and only 64 countries regulate herbal medicines.[1]

To assist countries in the development of TM/CAM policies and regulations of herbal medicines, WHO has published a series of technical guidelines and reviewed regulations on herbal medicines in the document "Regulatory Situation of Herbal Medicines: a Worldwide Review."[2] The purpose of the document is to share national experience in formulating policies on traditional medicinal products, introduce measures for their registration and regulation, and facilitate information exchange on these subjects among Member States.

In present review, we have compiled name of various regulatory authorities made for herbal medicines in different countries with their major responsibilities and year of establishment which will definitely help the new researchers working in the field of quality control and standardization of TM/CAM.

The role of herbal medicines in traditional healing

The pharmacological treatment of disease began long ago with the use of herbs.[3] Methods of folk healing throughout the world commonly used herbs as part of their tradition. Some of these traditions are briefly described below, providing some examples of the array of important healing practices around the world that used herbs for this purpose.[4]

Traditional Chinese medicine

Traditional Chinese medicine has been used by Chinese people from ancient times. Although animal and mineral materials have been used, the primary source of remedies is botanical. Of the more than 12,000 items used by traditional healers, about 500 are in common use.[4] Botanical products are used only after some kind of processing, which may include, for example, stir-frying or soaking in vinegar or wine. In clinical practice, traditional diagnosis may be followed by the prescription of a complex and often individualized remedy. Traditional Chinese medicine is still in common use in China. More than half the population regularly uses traditional remedies, with the highest prevalence of use in rural areas. About 5000 traditional remedies are available in China; they account for approximately one-fifth of the entire Chinese pharmaceutical market.[4]

Japanese TM

Many herbal remedies found their way from China into the Japanese systems of traditional healing. Herbs native to Japan were classified in the first pharmacopoeia of Japanese TM in the ninth century.[5]

Indian TM

Ayurveda is a medical system primarily practised in India that has been known for nearly 5000 years. It includes diet and herbal remedies, while emphasizing the body, mind, and spirit in disease prevention and treatment.[6]

WHO GUIDELINES FOR HERBAL MEDICINES

These guidelines recognized the importance of herbal medicines to the health of many people throughout the world, stating: "A few herbal medicines have withstood scientific testing, but others are used simply for traditional reasons to protect, restore, or improve health." Most herbal medicines

Table 1: Different WHO guidelines with their major resolutions and year of establishment

WHO guidelines	Major resolutions taken	Year	Ref
Quality control methods for medicinal plant materials	Emphasized the need to ensure the quality of medicinal plant products by using modern control techniques and include suitable standards and limits for contaminants are included.	1998	[7]
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems	Provide technical guidance on the principles of good pharmacovigilance and the inclusion of herbal medicines in existing national drug safety monitoring systems.	2004	[8]
Guidelines for the Regulation of Herbal Medicines in the South-East Asia Region	This guideline aims to facilitate the registration and regulation of herbal medicines by establishing the foundation for a harmonized regulatory standard to meet the common demands of the region.	2003	[9]
General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine	Harmonize the use of certain accepted and important terms in TM, summarize key issues for developing methodologies for research and evaluation of TM, improve the quality and value of research in TM, and provide appropriate evaluation methods to facilitate the regulation and registration of TMs.	2000	[10]
National policy on TM and regulation of herbal medicines Report of a WHO global survey	Main objectives of this report are framing policy for safety, efficacy, and quality of herbal medicines and its promoting rational use.	2005	[11,12]
WHO guidelines on good agricultural and collection practices for medicinal plants	Quality assurance of medicinal plant materials used as the source for herbal medicines, and encourage and support the sustainable cultivation and collection of medicinal plants of good quality.	2003	[13]

Table 2: Legal status of different countries for herbal drug regulation

Country	Legal status/policy	Major responsibilities	Year of establishment	Ref
Australia	Therapeutic Goods Act (Commonwealth of Australia, 2001a)	The overall objective of the Act is to ensure the quality, safety, and efficacy of therapeutic goods, including medicines and medical devices available to the Australian public.	1989	[16,17]
Argentina	Health Ministry of the Provincia de Buenos Aires	Regulation for registration and commercialization of medicinal plants.	1993	[18]
Austria	Herbal medicine regulation Law No.541	Marketing authorizations. Issuing of license.	1989	[19, 20]
Belgium	Ministry of Health	Under the law, proof of quality, safety, and efficacy became an essential precondition for the registration of drugs.	1995	[21-23]
Canada	Natural Health Products Regulations	Ensure that the herbal medicinal plant product is safe under the recommended conditions of use without a prescription, effective for the proposed claims, and of high quality.	2004	[24-27]
Chile	Unidad de Medicina Tradicional	Incorporating TM with proven efficacy into health programs and of contributing to the establishment of their practice.	1992	[28]
China	The Drug Administration Law ofthe People's Republic of China	Encourages the development of both modern and traditional drugs, protects the resources of wild herbal drugs, and promotes domestic cultivation of herbal drugs.	1984	[18]
Colombia	Ministry of Health	Issuing of license. Documentation on the manufacturing process, quality control, and, if necessary, toxicity studies.	1990	[29]
Denmark	Danish Ministry of Health Order No. 790	Proof of quality, safety, and efficacy must be given; a bibliographic application with respect to therapeutic use is accepted if it contains descriptions in the relevant scientific literature of Europe or North America.	1992	[30, 31]
Egypt	National Applied Research Centre for Medicinal Plants and National Organization for Drug Control and Research	Medical, health, and nutrient content claims made by law. Rules of GMP are implemented for herbal medicines.	1995	[18]
Estonia	Medicinal Products Act	To maintain the documents concerning chemical, pharmaceutical, biological, pharmacological-toxicological, and clinical information of the herbal drugs.	1996	[32]
Fiji	Pharmacy and Poisons Act of Fiji	Permits importation of TMs for use by ethnic communities	1994	[33,34]
Finland	Administrative regulation 9/93 (Marketing Authorization, 1993)	Quality and manufacture of herbal remedies	1993	[35]
France	French Medicines Agency	Marketing authorizations		[36]
Germany	Medicines Act of 24 August 1976	Herbal finished drugs have to comply with the same criteria for quality, safety, and efficacy as all other finished drugs	1976	[37-39]
Greece	Ministry of Health	Issuing of license, documentation on the manufacturing process, and toxicity studies.	1994	[40]
Hungary	Law on Public Health, Chapter IV, Section 104	Herbal drugs regulated as over the counter medicines for self-medication purposes and by law, medical claims, and health claims may be made.	1996	[41]
India	Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of. 1945	Regulate the import, manufacture, distribution, and sale of drugs and cosmetics.	1945	[42]
Indonesia	Directorate of Traditional Drug Control	Production, distribution and labeling of traditional drugs, and licensing of traditional drugs and imported traditional drugs.	1975	[18]
Ireland	Guidelines for Application for Product Authorization of Herbal Products" issued by National Drugs Advisory Board	Licensing of manufacturers and authorization of herbal products	1985	[43,44]
Italy	Italian Health Authority	Grant licensed and ensure the quality, safety, and efficacy.	1981	[45]
Japan	Ministry of Health and Welfare	Improve quality control of Kampo drugs	1972	[46]
Korea	The Ministry of Public Health and Social Affairs	Regulate and rule on the herbal medicines and their preparations.	1969	[47-50]
Malaysia	National Pharmaceutical Control Bureau, Ministry of Health	Manufacturing, import, supply, or sailing of the TMs.		[18]
Mali	Traditional Medicine Department under the Ministry of Health	Postmarketing surveillance and adverse effect monitoring of herbal medicines.	1968	[18]

Table 2 Contd.

Table 2: Legal status of different countries for herbal drug regulation

Country	Legal status/policy	Major responsibilities	Year of establishment	Ref
Mongolia	Traditional Medicine Department under Mongolian National Medical University	Production, development, and investigation of TMs.	1989	[51]
Nepal	Department of Drug Administration under the Ministry of Health	Price approval, safety, efficacy, and quality of products. Authorization for import, export, and distribution of the product, and the mode of distribution and promotion.	1996	[52]
New Zealand	Medicines Act of 1981	Control of active ingredients and excipients, method of manufacture, control tests of the finished product, labeling, stability, etc.	1981	[18]
Nicaragua	The national pharmaceuticals law-292	Safety assessment	1998	[53]
Oman	Ministry of Health	Grant of license for manufacturing and import permission	1995	[54]
Pakistan	The Drugs Act of 1962	Controls the regulation of herbal medicines as regards advertising and prevention of misuse	1962	[18]
Portugal	Portugal Drug Act	Regulation of herbal medicines in the same laws as those covering conventional pharmaceuticals.	1995	[55]
Qatar	Ministry of Public Health	By law, medical, health, nutrient content, and structure/function claims may be made about herbal medicines.	1990	[56]
Saudi Arabia	Ministry of Health, KSA	Medical, health, nutrient content, and structure/function claims may be made	1996	[18]
Singapore	Traditional Chinese Medicine Practitioners Act	Marketing authorization and licensing of manufacturers.	2000	[57,58]
South Africa	Medicines Control Council (MCC)/ Dietary Supplement Health and Education Act of	Safety assessment requirements include traditional use without demonstrated harmful effects, reference to documented scientific research on similar products, and clinical data.	1994	[2]
Spain	The Spanish Medicinal Products Act No. 25	Objective of the Act is to ensure the quality, safety, and efficacy of therapeutic goods, including herbal medicines.	1990	[59, 60]
Switzerland	The Swiss Agency for Therapeutic Products (Swissmedic) under Federal Department of Home Affairs	Marketing authorization. And implementation of GMP rules.	2002	[61]
Thailand	The Drug Act B.E. 2510	Premarketing control, licensing and registration process, and postmarketing control by quality control analysis.	1967	[18]
United Kingdom	Medicines and Healthcare products Regulatory Agency (MHRA) and Medicines Act 1968	Postmarketing surveillance Licensed medicinal products require evidence of quality, safety, and efficacy and are regulated by the Medicines Control Agency.	1968	[62-66]
United States	Food Drug and Cosmetics Act Dietary Supplement Health and Education Act	Ensuring that a dietary supplement is safe before it is marketed, and the United States Food and Drug Administration is responsible for taking action against any unsafe dietary supplement product after it reaches the market.	2000 1994	[67-70]

still need to be studied scientifically, although the experience obtained from their traditional use over the years should not be ignored. As there is not enough evidence produced by common scientific approaches to answer questions of safety and efficacy about most of the herbal medicines now in use, the rational use and further development of herbal medicines will be supported by further appropriate scientific studies of these products, and thus the development of criteria for such studies. In this regard, WHO has issued guidelines for the assessment of herbal medicines. These guidelines defined the basic criteria for the evaluation of quality, safety, and efficacy of herbal medicines with the goal of assisting national regulatory authorities, scientific organizations, and manufacturers in assessing documentation, submissions, and dossiers in respect of such products.

The below mentioned WHO guidelines [Table 1] stressed the need for assessment of efficacy including the determination of pharmacological and clinical effects of the active ingredients, cultivation and collection of the medicinal plants, and labeling which includes a quantitative list of active ingredient, dosage, and contraindications.

THE EUROPEAN UNION

The European Pharmacopoeia was created in 1964; its efforts have resulted in the creation of 83 monographs on herbal drugs that are used either in their natural state after desiccation or concentration or for the isolation of natural active ingredients. The Association of the European Self-Medication Industry has carried out a study for the European Commission on herbal medicinal products in the European Union (EU). The

following summary is taken from this report.[14] The importance of herbal medicinal products varies from one country to another. These products are not a homogeneous group. In general, they are either fully licensed medicinal products with efficacy proven by clinical studies or by references to published scientific literature (in accordance with Article 4.8 a (ii) of Council Directive 65/65/EEC)[15] or are available as products with a more or less simplified proof of efficacy according to their national use. Many Member States have these two categories, but there are major discrepancies between the Member States in the classification of individual herbal drug preparations and products into one of these categories as well as in the requirements for obtaining a marketing authorization. According to Council Directive 65/65/EEC,[15] which has been implemented in national law in all Member States, medicinal products require prior marketing approval before gaining access to the market. In almost all Member States, herbal medicinal products are considered as medicinal products and are, in principle, subject to the general regulations for medicines as laid down in the various national medicine laws. In many cases, a specific definition of herbal medicinal products is available, which is in line with the EU Guideline "Quality of Herbal Medicinal Products." This includes plants, parts of plants, and their preparations, mostly presented with therapeutic or prophylactic claims. Different categories of medicinal products containing plant preparations exist or are in the process of being created. For instance, draft legislation in Spain includes the definitions "herbal medicinal products" and "phytotraditional products." The latter are not considered as "pharmaceutical specialties" and are therefore not classified as herbal medicinal products.

Legal status of different countries for herbal drug regulation

Legislative controls in respect of medicinal plants have not evolved around a structured control model. There are different ways in which countries define medicinal plants or herbs or products derived from them, and countries have adopted various approaches to licensing, dispensing, manufacturing, and trading to ensure their safety, quality, and efficacy, and due to these reasons herbal preparations varies from country to country. In some, phytomedicines are well established, whereas in others they are regarded as food and therapeutic claims are not allowed. This article follows a generalized template that includes regulatory authorities of various countries and their major responsibilities with year of establishment [Table 2].

CONCLUSION

The growth of the pharmaceutical industry and the unceasing development of new and more effective synthetic and biological medicinal products have not diminished the importance of medicinal plants in many societies. On the contrary, population growth in the developing world and increasing interest in the industrialized nations have greatly expanded the demand for medicinal plants themselves and the products derived from them. Regulations in countries for the assessment of the quality, safety, and efficacy of medicinal plants, and the work of WHO and EU in supporting the preparation of model guidelines in this field, have been helpful in strengthening recognition of their role in health care. It is hoped that assessment of these traditional remedies could become the basis for a future classification of herbal medicines, as well as for evaluative studies on their efficacy and safety, and their potential use in national healthcare systems in different parts of the world.

AKNOWLEDGEMENT

The authors acknowledge the University Grant Commission [F. No. 34-131/2008 (SR)], New Delhi, India, for financial support.

REFERENCES

1. World Health Organization. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines. Manila: 1993.
2. World Health Organization. Regulatory Situation of Herbal Medicines. A Worldwide Review (WHO/trm/98.1). Geneva, 1998.
3. Schulz V, Hänsel R, Tyler VE. *Rational Phytotherapy.* A Physician's Guide to Herbal Medicine. 4th ed. Berlin: Springer; 2001.
4. Li L. Opportunity and challenge of traditional Chinese medicine in face of the entrance to World Trade Organization. Chin Inform trad Chin Med 2000;7:7-8.
5. Saito H. Regulation of herbal medicines in Japan. Pharmacol Regul 2000;41:515-9.
6. Morgan K. Medicine of the Gods: Basic Principles of Ayurvedic Medicine, 2002. Available from: http://www.compulink.co.uk/mandrake/ayurveda.htm. [Last accessed on 2010 Jul 02].
7. World Health Organization. Regulatory Situation of Herbal Medicines. A Worldwide Review. Geneva: World Health Organization; 1998.
8. World Health Organization. Guidelines on safety monitoring of herbal medicines in pharmacovigilance systems 2004.
9. World Health Organization. Guidelines for the Regulation of Herbal Medicines in the South-East Asia Region. 2003.
10. World Health Organization. General guidelines for methodologies on research and evaluation of traditional medicine. Geneva: WHO; 2000.
11. World Health Organization. National policy on traditional medicine and regulation of herbal medicines Report of a WHO global survey 2005.
12. World Health Organization. Traditional Medicine Strategy. 2002–2005.
13. World Health Organization. Guidelines on good agricultural and collection practices (GACP) for medicinal plants. 2003.
14. AESGP (Association Européenne des Spécialités Pharmaceutiques Grand Public; The Association of the European Self-Medication Industry) 1998.
15. European Commission Council Directive 65/65/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relation to proprietary medicinal products. Off J 1965;22:369-73.
16. Briggs DR. The regulation of herbal medicines in Australia. Toxicology 2002;181-182:565-70.
17. Therapeutic Goods Administration Medicines Regulation and

the TGA. Woden, ACT, Australia; 1999.

18. Xiaorui Z. Regulatory situation of herbal medicines: A worldwide review. Tradit Med Program 1998;1-45.
19. Regulation of the Minister of Health, Sports and Consumer Protection, the Regulation concerning facilitation of the admission of certain Medicinal products is changed. Federal Law Gazette Republic of Austria, 1992, 3912-5.
20. Regulation of the Minister for Health and Public Service and the Federal Minister for Economic Affairs of 21 November 1989 on the tax and labeling of certain drugs in the retail selling (Delimitation Regulation). Federal Law Gazette of the Republic Austria, 1989; 4049-78.
21. Sofia, Bulgaria; Information letter of the Ministry of Health, National Drug Institute. dated 1996 Feb 07.
22. Ministry of Public Health and Environment. Ministerial circular instructions to the constitution of the file registration of herbal medicines. monitor Belgian 1995 and 3103-9.
23. Ministry of Public Health and Environment. Circular Ministerial nE 367, 1989.
24. Jordan SA, Cunningham DG, Marles RJ. Assessment of herbal medicinal products: Challenges, and opportunities to increase 2 the knowledge base for safety assessment. Toxicol Appl Pharmacol 2010:243:198-216.
25. Johnson T. Chinese medicine now part of primary care scene in BC. CMAJ 2001;164:1195.
26. Sibbald B. New federal office will spend millions to regulate herbal remedies, vitamins. CMAJ 1999;160:1355-7.
27. Kozyrskyj A. Herbal products in Canada. How safe are they. Can Fam Physician. 1997;43:697-702.
28. Calixto JB. Efficacy, safety, quality control, marketing and regulatory guidelines for herbal medicines (phytotherapeutic agents). Braz J Med Biol Res 2000;33:179-89.
29. Ministry of Health of the Republic of Colombia resolution Number 1990.
30. Order on herbal medicines. Ministry of Health. No. 1992; 790.
31. NLN Regulatory Seminars in Quality Assessment of Natural Remedies. NLN Publication No. 40. Uppsala: Nordic Council on Medicines; 1996.
32. Procedure for registration of medicinal products and approval of variations to the terms of registered medicinal products.: Estonia; 1996.
33. Bailey M. Communication of the Ministry of Health, Suva, Fiji, with World Health Organization. 1996.
34. The NSW Therapeutic Medicines Information Centre. The uncertain world of "herbal" medication - A drug information viewpoint. Drug Bull 1993;19.
35. Commission Directive 91/507/EEC of 19 July 1991 modifying the Annex to Council Directive 75/318/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products. Official Journal of the European Communities nE L. 270/32 of 26 Sept 1991.
36. Castot A, Djezzar S, Deleau N, Guillot B, Efthymiou ML. Drug surveillance of herbal medicines. Thérapie 1997;52:97-103.
37. Kraft K. Herbal medicine products and drug law. Forsch Komplementärmed 1999;6:19-23.
38. Sandberg F, Corrigan D. Natural remedies. Their Origins and Uses, New York: Taylor and Francis; 2001.
39. Keller K. Legal requirements for the use of phytopharmaceutical drugs in the Federal Republic of Germany. J Ethnopharmacol 1991;32:225-9.
40. Minister of health, providence and social insurance regulation. Ankara. 1994.
41. Association of European Self-Medication Consumer (AESGP), editor. Economic and Legal Framework for Non-Prescription Medicines in Europe. Brussels: AESGP,1996. p. 105-9.
42. Drug and cosmetic act, Government of India.1942.
43. Morris JM. Communication of the Irish Medicines Board with World Health Organization; 1996.
44. Guidelines for Application for Product Authorization of Herbal Products. Dublin: National Drugs Advisory Board; 1985.
45. Prodotti a base di piante medicinali. Circolare n. 1 (N. 800.7.AG.8/254). Direzione Generale del Servizio Farmaceutico Divisione VII; 1981.
46. Eguchi K, Hyodo I, Saeki H. Current status of cancer patients' perception of alternative medicine in Japan. A preliminary cross-sectional survey. Support Care Cancer 2000;8:28-32.
47. Choi DW, Kim JH, Cho SY, Kim DH, Chang SY. Regulation and quality control of herbal drugs in Korea. Toxicology 2002;181-182:581-6.
48. Bonati A. Guidelines for the chemical and biological assessment of herbals and herbal preparations UNIDO. 1989;1-18 .
49. Korean Pharmacopoeia. 7th ed. Seoul, Korea: Medicine Publishers; 1997.
50. Korean Herbal Pharmacopoeia. Korea: Ministry of Health and Welfare; 1987.
51. Ministry of Health Traditional Mongolian Medicine. Information sheet. Mongolia;1996.
52. Gewali MB. Personal communication 1995 Nov 16.
53. Sotomayor U. Traditional Medicine in Nicaragua and its Integration into the Local Health Systems. Lecture held at the Morris Arboretum Symposium. Philadelphia, 1993 Apr 19-21.
54. Ministry of Health of the Sultanate of Oman. Conditions to allow import of traditional drugs. Muscat; 1995.
55. The flour, Cachadinha M. Some considerations on the Portuguese legislation, Herbal Medicine. LEF in July 1994. 2
56. World Health Organization Guidelines for the Assessment of Herbal Medicines (WHO Technical Report Series No. 863). Geneva: WHO; 1996.
57. World Health Organization Western Pacific Regional Office (WPRO). 1996.
58. Pharmaceutical Department of the Ministry of Health of Singapore. Communication with WHO 1996 Mar 13.
59. Des Medicines Act, Madrid, Art 42.Ley25/1990.
60. Order of October 3, 1973 by establishing the record special preparations of vegetables species medicinal. Ministry of the Interior. BOE 247 of 15 nE October, Madrid, 1973.
61. Communications from the ICS. ICS monthly report of Bern, 1992;6:345.
62. Griffin JP. The evolution of human medicines control from a national to an international perspective. Adverse Drug React Toxicol Rev 1998;17:19-50.
63. Ministry of Agriculture, Fisheries and Food (MAFF) Herb Legislation. London: Herb Society; 1998.
64. Mills SY. The House of Lords report on complementary medicine: A summary. Complement Ther Med 2001;9:34-9.
65. Shaw D. Risks or remedies? Safety aspects of herbal remedies. J R Soc Med 1998;91:294-6.
66. De Smet PA. Should herbal medicine-like products be licensed as medicines. BMJ 1995;310:1023-4.
67. Chang J. Scientific evaluation of traditional Chinese medicine under DSHEA: A conundrum. Dietary Supplement Health and Education Act. J Altern Complement Med 1999;5:181-9.
68. Angell M, Kassirer JP. Alternative medicine-the risks of untested and unregular remedies. N Engl J Med 1998;339:839-41.

69. Goldman SA, Kennedy DL. FDA's Medical Products Reporting Program. A joint effort toward improved public health. Postgrad Med 1998;103:13-6.

70. Food and Drug Administration, Guidance for Industry: Botanical Drug Products, Washington DC, Center for Drug Evaluation and Research 2000. Available from: http://www.fda.gov/cder/guidance/index.htm [Last accessed on 2010 Jul 02].

How to cite this Article: A, Saraf S. Legal regulations of complementary and alternative medicines in different countries. Phcog Rev 2012;6:154-60.

Source of Support: University Grant Commission [F. No. 34-131/2008 (SR)], New Delhi, India,, **Conflict of Interest:** None declared