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Review

Current regulations for herbal products

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Abstract

Officinal plants and their products have great social and economic consequences, and today they are used in four principal sectors: food, cosmetics, health and medicine. The medicinal use of the herbaI drugs, Phytotherapy, is differently controlled in different countries, but with only marginal differences because phytotherapeutic products must possess quality, safety and efficacy. The use of herbs as health foods, as well as food supplements, complicates the formulation of regulations by countries throughout the world. The increasing supply of herbal products to international markets makes it necessary for international organizations, such as the World Health Organization (WHO) to develop standards relative to their commercialization throughout the world. The classification of drugs varies from country to country, with active foods, dietary supplements and traditional medicines being included in certain categories. The stability of those products is also unknown and complex to the critical problem in the analysis of herbal products that this is a complex ingredient combination, as well as the elements responsible for the treatment effects. In order to identify the changes to the newly introduced regulations or regulations, detailed literary searches and online searches for herbal medicinal products regulations have been made in South-east Asia and European countries.

Keywords: Harmonization, herbal medicine, herbal products

INTRODUCTION

Herbal medicine (also herbalism) is the study of pharmacognosy and the use of medicinal plants, which are a basis of traditional medicine.[1] There is limited scientific evidence for the safety and efficacy of plants used in 21st century herbalism, which generally does not provide standards for purity or dosage.[1,2] The scope of herbal medicine commonly includes fungal and bee products, as well as minerals, shells and certain animal parts. Herbal medicine is also called phytomedicine or phytotherapy.[3]

Paraherbalism describes alternative and pseudoscientific practices of using unrefined plant or animal extracts as unproven medicines or health-promoting agents.[1,2,3,4] Paraherbalism relies on the belief that preserving various substances from a given source with less processing is safer or more effective than manufactured products, a concept for which there is no evidence.[4]

Herbal medicines are the natural plants and their parts which are being used for medicinal purpose. This is one of the oldest types of medicine in human history. Herbal medicine is still widely practiced all over

the world. This practice also is known as Herbalism[5] . Herbalism is one of the forms of Alternative Medicine. A number of old books available about the plants and their medicinal use called Herbals. The ancient Chinese, Indians, Egyptians, Babylonians, and Native Americans were all herbalists a Chinese herbal that is probably a compilation of an even older oral tradition the ancient Greeks and Romans were also renowned herbalists. Surgeons traveling with the Roman army spread their herbal expertise throughout the Roman Empire, in Spain, Germany, France, and England. Dioscorides (c. 40-c. 90) and Galen (131-200 A.D.), both Greek surgeons in the Roman army, compiled herbals that remained the definitive materia medica texts for 1500 years.[6]

The 16th and 17th centuries were the golden eras of Herbal Medicine. The more and more plants incorporated during 18th and 19th centuries in Americas. In the 19th century, analysis of chemical came in practice. Researchers and scientists began to extract and analyze active ingredients from plants.

Classification of herbal medicines

(Based on their origin, evolution and the forms of current usage)

Category 1: Indigenous herbal medicines

- Historically used in a local community or region and is very well known through long usage by the local population in terms of its composition, treatment, and dosage. Detailed information on this category of TM, which also includes folk medicines, may or may not be available.

Category 2: Herbal medicines in systems

- Medicines in this category have been used for a long time and are documented with their special theories and concepts, and accepted by the countries. Ayurveda, Unani, and Siddha.

Category 3: Modified herbal medicines

- These are herbal medicines as described above in categories 1 and 2, except that they have been modified in some way–either shape or form including dose, dosage form, mode of administration, herbal medicinal ingredients, methods of preparation and medical indications. They have to meet the national regulatory requirements of safety and efficacy of herbal medicines.

Category 4: Imported products with a herbal medicine base

- This category covers all imported herbal medicines including raw materials and products. Imported herbal medicines must be registered and marketed in the countries of origin. The safety and efficacy data have to be submitted to the national authority of the importing country and need to meet the requirements of safety and efficacy of regulation of herbal medicines in the recipient country.

AIM AND OBJECTIVE

- Herbal medicine aims to return the body to a state of natural balance so that it can heal itself. Different herbs act on different systems of the body.
- The aim of herbal treatment is usually to produce persisting improvements in well-being.
- The major use of herbal medicines is for health promotion and therapy for chronic, as opposed to life-threatening, conditions. However, usage of traditional remedies increases when conventional medicine is ineffective in the treatment of disease, such as in advanced cancer and in the face of new infectious diseases.
- Support Member States, in the context of the WHO International Drug Monitoring Programme, to strengthen national pharmacovigilance capacity in order to carry out effective safety monitoring of herbal medicines
- Provide technical guidance on the principles of good pharmacovigilance and the inclusion of herbal medicines in existing national drug safety monitoring systems; and where these systems are not in place, to facilitate the establishment of an inclusive national drug safety monitoring system
- Provide standard definitions of terms relating to pharmacovigilance, and safety monitoring of herbal medicines
- Promote and strengthen internationally coordinated information exchange on pharmacovigilance, and safety monitoring of herbal medicines among Member States
- Promote the safe and proper use of herbal medicines. The regulation of herbal medicines and their place in national health-care systems differs from country to country, and these guidelines will therefore need to be adapted to meet the needs of the local situation.

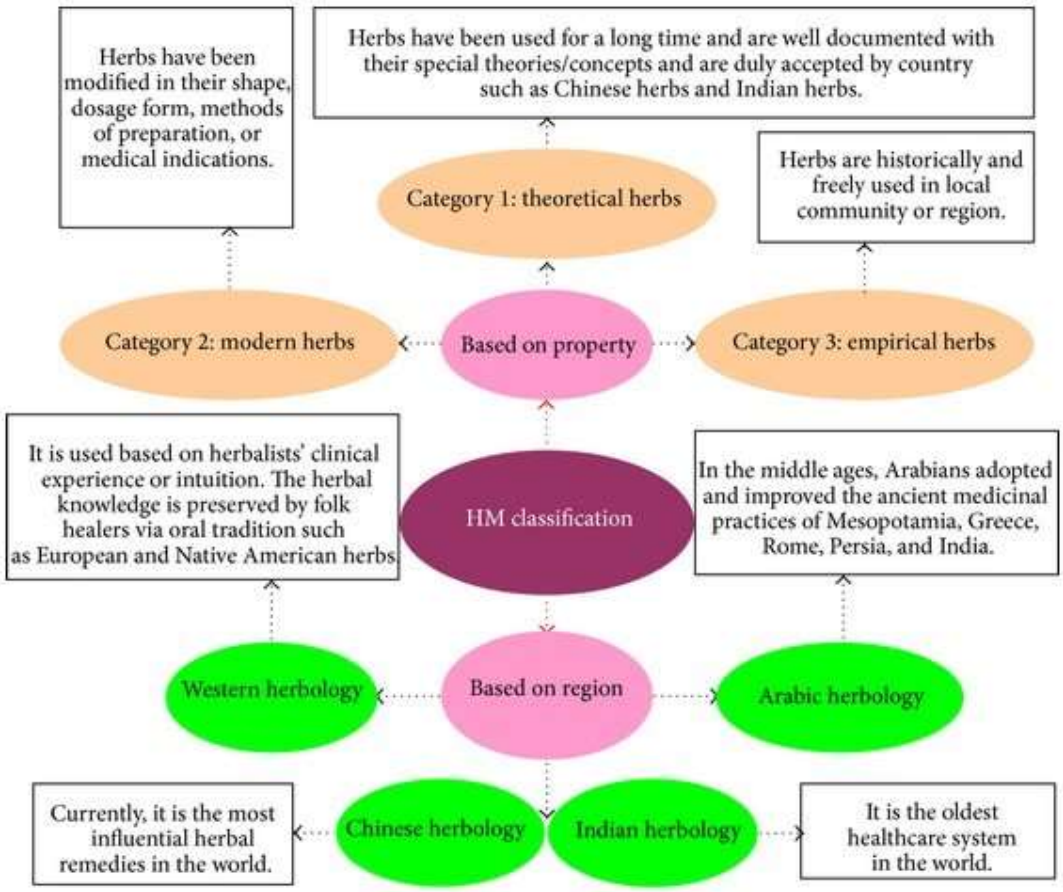


Fig 1: Herbal Medicine Classification

The role of herbal medicines in traditional healing

The pharmacological treatment of disease began long ago with the use of herbs (Schulz et al., 2001). 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.

Africa

Up to 80% of the population in Africa uses traditional medicine as primary health care.[7]

Americas

Native Americans used about 2,500 of the approximately 20,000 plant species that are native to North America.[8] In Andean healing practices, the use of Entheogens, in particular the San Pedro cactus (Echinopsis pachanoi) is still a vital component, and has been around for millennia.[9]

China

Some researchers trained in both Western and traditional Chinese medicine have attempted to deconstruct ancient medical texts in the light of modern science. In 1972, Tu Youyou, a pharmaceutical chemist, extracted the anti-malarial drug artemisinin from sweet wormwood, a traditional Chinese treatment for intermittent fevers.[10] 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 (Li, 2000). 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.

Japan

Japanese traditional medicine Many herbal remedies found their way from China into the Japanese systems of traditional healing. Herbs native to Japan were classified in the first pharmacopeia of Japanese traditional medicine in the ninth century.

India

A platter of herbal medicines at Goa, India

In India, Ayurvedic medicine has quite complex formulas with 30 or more ingredients, including a sizable number of ingredients that have undergone "alchemical processing", chosen to balance dosha.[11] In Ladakh, Lahul-Spiti and Tibet, the Tibetan Medical System is prevalent, also called the 'Amichi Medical System'. Over 337 species of medicinal plants have been documented by C.P. Kala. Those are used by Amchis, the practitioners of this medical system.[12,13] The Indian book, Vedas, mentions treatment of diseases with plants.[14]Ayurveda is a medical system primarily practiced 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.

Indonesia

Different types of Indonesian jamu herbal medicines held in bottles

In Indonesia, especially among the Javanese, the jamu traditional herbal medicine may have originated in the Mataram Kingdom era, some 1300 years ago.[15] The bas-reliefs on Borobudur depict the image of people grinding herbs with stone mortar and pestle, a drink seller, an herbalist, and masseuse treating people.[16] The Madhawapura inscription from Majapahit period mentioned a specific profession of herbs mixer and combiner (herbalist), called Acaraki.[16] The book from Mataram dated from circa 1700 contains 3,000 entries of jamu herbal recipes, while Javanese classical literature Serat Centhini (1814) describes some jamu herbal concoction recipes. Though possibly influenced by Indian Ayurveda systems, the Indonesia archipelago holds numerous indigenous plants not found in India, including plants similar to those in Australia beyond the Wallace Line.[17] Jamu practices may vary from region to region, and are often not recorded, especially in remote areas of the country.[18] Although primarily herbal, some Jamu materials are acquired from animals, such as honey, royal jelly, milk and Ayam Kampung eggs.

Traditional Herbal Medicines and Human Health

Herbal medicines which 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. Medicinal plants are important for pharmacological research and drug development, not only when plant constituents are used directly as therapeutic agents, but also as starting materials for the synthesis of drugs or as models for pharmacologically active compounds. Regulation of exploitation and exportation is therefore essential, together with international cooperation and coordination for their conservation so as to ensure their availability for the future.

The United Nations Convention on Biological Diversity states that the conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential. 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. Despite the use of herbal medicines over many centuries, only a relatively small number of plant species has been studied for possible medical applications. Safety and efficacy data are available for an even smaller number of plants, their extracts and active ingredients and preparations containing them.

Regulation and Registration of Herbal Medicines

The legal situation regarding 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. Developing countries, however, often have a great number of traditionally used herbal medicines and much folk-knowledge about them, but have hardly any legislative criteria to establish these traditionally used herbal medicines as part of the drug legislation. For the classification of herbal or traditional medicinal products, factors applied in regulatory systems include: description in a pharmacopoeia monograph, prescription status, claim of a therapeutic effect, scheduled or regulated ingredients or substances, or periods of use. Some countries

draw a distinction between "officially approved" products and "officially recognized" products, by which the latter products can be marketed without scientific assessment by the authority.

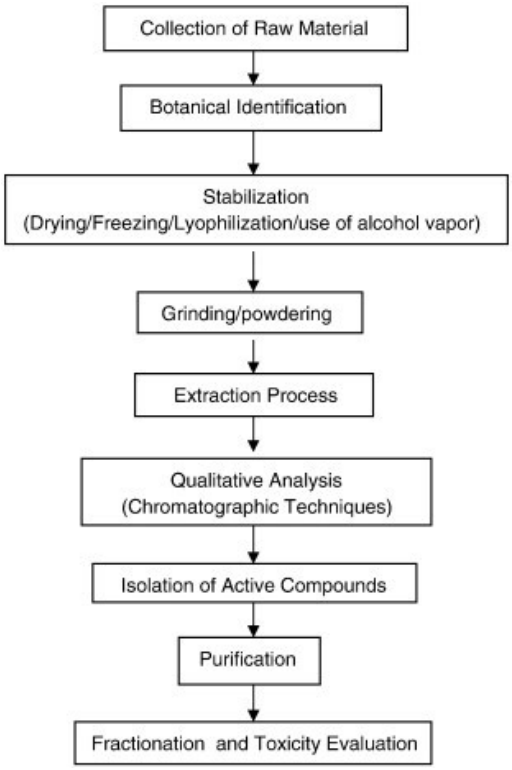


Fig 2: Herbal Drugs Standards and Regulation

Categories of Herbal Medicines

The various legislative approaches for herbal medicines fall into one or other of the following categories:

Same regulatory requirements for all products; same regulatory requirements for all products, with certain types of evidence not required for herbal/traditional medicines; exemption from all regulatory requirements for herbal/ traditional medicines; exemption from all regulatory requirements for herbal/ traditional medicines concerning registration or marketing authorization; herbal/ traditional medicines subject to all regulatory requirements; and herbal/ traditional medicines subject to regulatory requirements concerning registration or marketing authorization.

Where herbal medicines and related products are neither registered nor controlled by regulatory bodies, a special licensing system is needed which would enable health authorities to screen the constituents, demand proof of quality before marketing, ensure correct and safe use, and also to oblige55 license holders to report suspected adverse reactions within a post-marketing surveillance system.

WHO Policy and Activities

Countries have their own set of laws and regulations for herbal medicines and traditional medicines. WHO recommends that each country or area should adopt a regulatory system to manage the appropriate use of herbal medicine. Adopting a regulatory mechanism has always helped in ensuring that herbal medicines have acceptable quality, safety and efficacy. The WHO Guidelines for the assessment of herbal medicines may be consulted when assessment processes for herbal medicines are being prepared.

The WHO guidelines on good agricultural and collection practices for medicinal plants are intended for national regulatory bodies and offer advice on cultivation and collection methods, site selection, climate and soil considerations and the correct identification of seeds and plants.

These guidelines also offer guidance on post-harvest operations such as labeling and legal components including national and regional laws on quality standards, patent status and benefits sharing. It is not a binding guideline for any country, but it is a model or a sort of checklist which they can use to make their own national regulations. Protocols on safety, efficacy, standardization and documentation of herbal medicines have also been published by International Union of Pure and Applied Chemistry (IUPAC) subcommittee on bio-molecular chemistry.

EU Regulations

Most individual herbal medicinal products are licensed nationally by member states, the process for licensing and information on herbal substances and, preparations is harmonized across the European Union. In United Kingdom, to get a product registered, companies have to submit a dossier to the Medicines and Healthcare products Regulatory Agency (MHRA) demonstrating that it meets the requirements of quality, safety and patient information as per the Traditional Herbal Registration Scheme (THRS). Minor claims are permitted on the basis of evidence of traditional usage. Irrespective of the regulatory pathway to access the market, the quality of the herbal medicinal product must always be demonstrated. Community herbal monographs prepared by the Committee on Herbal Medicinal Products (HMPC) at the Agency are relevant for the traditional use registration as well as the well-established use marketing authorization.

US Regulations

In United States, the term complementary/alternative medicines (CAM) are most commonly used for traditional medicine systems.

Complementary medicine refers to use of CAM together with conventional medicine, such as using acupuncture, in addition to usual care to help lessen pain. Most use of CAM by Americans is complementary "Alternative medicine" refers to use of CAM in place of conventional medicine. "Integrative medicine" (also called integrated medicine) refers to a practice that combines both conventional and CAM treatments for which there is evidence of safety and effectiveness. CAM practices are often grouped into broad categories, such as natural products, mind-body medicine, and manipulative and body - based practices. Although these categories are not formally defined, they are useful for discussing CAM practices.

Indian Regulations

Herbal drugs today constitute a major share of all the officially recognized systems of health in India viz. Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy excluding Allopathy. Central Council of Indian Medicine (CCIM) is a statutory body under Indian Medicine Central Council Act (IMCC Act), the Research Councils i.e. Indian Council of Medical Research and Council of Scientific and Industrial Research (ICMR and CSIR), the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) & Drugs and Cosmetics Act 1940(D C Act) regulates the manufacture, distribution and sale of herbal medicines in India. Herbal medicines, remedies and medicinal plants which are to be incorporated in our modern system (Allopathic system) must follow Drug Controller General of India (DCGI's) regulations. As per the amendment in the Drugs and Cosmetics Act in 1964, Ayurvedic, Siddha or Unani drugs includes all medicines which are intended for internal or external use for treating, diagnosing, mitigation, prevention or curing of any disease or disorder in human beings or animals. These herbal medicines are manufactured strictly in accordance with the formulations described in reference books of Ayurvedic, Siddha and Unani (Tibb) systems of medicine as specified in the First Schedule. It is submitted that the amendment is provided for a limited set of controls, like manufacturing under prescribed hygienic conditions that too under the super vision of a qualified person, use of genuine raw materials and prescribed labeling of all the ingredients used.

CONCLUSION

The FDA considers herbal supplements foods, not drugs. Therefore, they are not subject to the same testing, manufacturing, and labeling standards and regulations as drugs.

The World Health Organization (WHO), the specialized agency of the United Nations (UN) that is concerned with international public health, published Quality control methods for medicinal plant materials in 1998 to support WHO Member States in establishing quality standards and specifications for herbal materials, within the overall context of quality assurance and control of herbal medicines.

In the European Union (EU), herbal medicines are regulated under the Committee on Herbal Medicinal Products.

In the United States, herbal remedies are regulated dietary supplements by the Food and Drug Administration (FDA) under current good manufacturing practice (cGMP) policy for dietary supplements. Manufacturers of products falling into this category are not required to prove the safety or efficacy of their product so long as they do not make 'medical' claims or imply uses other than as a 'dietary supplement', though the FDA may withdraw a product from sale should it prove harmful.

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 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 health care systems in different parts of the world.

It is submitted that the legal status and the practice of use of herbal drugs/ medicines/ products vary significantly from one country to another thus making it difficult for its free circulation. European regulations i.e. Directives are the most comprehensive among most of the global regulations for herbal medicinal products. Food and Drug Administration (FDA) guidelines for United States on herbal/ botanical drug products are parallel and closely follow the route as that for a synthetic new chemical entity. Indian regulations are also developing vis-a-vis global regulations for herbal drug products. Indian regulations relating to herbal medicines/ drugs are still at nascent stage as compared to regulations of Europe and US. Harmonization of regulations, like that in European Countries, US and other developed countries could overcome the barrier for efficient trade as well as uniform standards for herbal drugs/ medicinal products.

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