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Innovation development and standardization of Novel Herbal Formulation

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Overview on “Regulations of herbal medicine”

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Abstract

Herbal medicines are an important component for alternative medicine. Now a day's herbal medicine is becoming ever more popular in world. Herbal medicines are widely used for treatment of human diseases in various systems of medicines like Ayurvedic, Homeopathic, Sidha, Unani and other regional systems of medicines. Herbal drug products vary from country to country, including functional foods, dietary supplements and traditional medicines. A detailed literature survey for regulations of herbal drug products in Europe and India was performed to identify recently introduced changes in regulations as well as newly introduced regulations compliance with the regulatory bodies. Various committees for Herbal Medicinal Products (HMPC), Committee of European Medicines Agency (EMA) is developing guidelines for quality, nonclinical studies, clinical efficacy and safety. Drugs and Cosmetics Rules have been amended recently to control the quality, safety and efficacy of herbal drug products in India.

Keywords: Herbal medicines, Regulation, Quality control

Introduction

An herbal medicine is also known as Phytomedicines. It involves the use of plant parts (leaves, roots, stem, flowers, and seeds) for medicinal / therapeutic purpose. It is the oldest and still the most generally used system of medicine in the world at present. The earliest recorded evidence of use of these medicines in Indian, Chinese, Egyptian, Roman and Syrian texts dates back to about 5000 years. 80% of the world population relies on herbal medicines as their primary healthcare system [1].

As per World Health Organization (WHO) herbal medicines are of three types: Raw plant materials, processed plant materials and Medicinal herbal products. In India, herbal medicines are regulated by the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH).

According to definitions of herbal medicinal product, herbal drug substances and herbal preparations are as follows:

- Herbal medicinal product: It is defined as any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.
- Herbal substances: These are mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh.
- Herbal preparations: These are the preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

Regulatory Status of Herbal Medicines

The options were the following: prescription medicines, over-the-counter medicines, self medication only, herbal medicines as a separate regulatory category, dietary supplements, health foods, functional foods and other status. These definitions are presented below.

1. Prescription medicines: Any medicines /drugs that can only be purchased with a

prescription (i.e. a physician's order)^[2]. Over-the-counter medicines: Any medicines / drugs that can be purchased without a prescription from a physician^[2].

2. Self-medication only: medicines / drugs permitted for self-medication purposes only.
3. Dietary supplements: a dietary supplement is a substance which contains, for instance, a vitamin, a mineral, a herb or other botanical or an amino acid. A dietary supplement may be used to increase the total daily intake of a concentrate, metabolite, constituent, extract or combination of this ingredients^[3].
4. Health food: health foods are products that are presented with specific health claims and therefore regulated differently from other foods^[4].
5. Functional foods: functional foods may be products which are offered with specific health claims and therefore regulated differently from other foods^[4].
6. Other: products classified differently from the above mentioned categories.

Indian Regulations and guidelines

The national policy on Traditional medicine was introduced in 1940. National laws and regulations were also introduced in 1940, and updated in 1964, 1970 and 1982. The national programme was issued in 1964. The national office, the Department of Medicine and Homeopathy, was established in 1995 as part of the Ministry of Health and Family Welfare. There are a number of expert committees for different forms of Traditional medicine the earliest was established in 1962. There are also a number of national research institutes; the first was the Central Council of Indian Medicine, established in 1970. National regulation of herbal medicine started in 1940 with the publication of the Drugs and Cosmetics Act; the laws and regulations on herbal medicines are partly the same as those for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over the counter medicines and dietary supplements. Herbal medicines may be sold with medical, health and nutrient content claims.

India has two national pharmacopoeias one is the Ayurvedic pharmacopoeia of India and another is the Unani pharmacopoeia of India. Regarding national monographs, several sources are used, including a national database on medical plants used in ayurvedic medicine and monographs contained in the national pharmacopoeias.

• Quality control for herbal medicinal products

All herbal-based medicinal products should fulfilled the requirements for safety, efficacy and quality, as per the Categories of Herbal Medicines. All imported herbal medicinal products should to meet the requirements for safety, efficacy and quality control regulations.

Licensing authority

Licensing for importers, wholesalers, manufacturers and assemblers of herbal medicinal products should be issued by the national drug regulatory authority. Dealers of imported herbal medicinal products must to apply for one or more of the licences depending on the type of business involved, such as licence of importers, wholesalers, manufacturers and assemblers.

Import license

The responsibility of applying for an import licence shall rest with local companies which are approved by the licensing authority to import herbal medicinal products and sell them in

the importing countries. The following information related to the importing company is required for the application of an import licence:

- Particulars of the company;
- Particulars of the person making the application on behalf of the company;
- Certificate of company/business registration;
- Layout plan of the store.

• Guidelines related to quality control

The main purpose of quality control is to ensure quality of the products to meet specifications and standards. Information on appropriate standards can be found in official pharmacopoeias, monographs, handbooks, etc.

In choosing analytical methods, the availability, robustness and validity of the methods must be considered, such as microscopic identification, thin layer chromatography (TLC), titration of active substance. if possible, a full validation of more sophisticated methods, such as high-performance liquid chromatography (HPLC), gas chromatography (GC), and gas chromatography-mass spectrometry (GC-MS)^[5].

As per Drugs and Cosmetics Act 1940 amended in 1964, "Ayurvedic, Siddha or Unani drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment or prevention of disease / disorder in human beings or animals, and manufactured exclusively in accordance with the formulae which described in the authoritative books like Ayurvedic, Siddha and Unani (Tibb) systems of medicine, specified in the First Schedule^[6].

European regulations and guidelines

The main features of Directive 2001/EC are traditional herbal medicine definition, simplified registration procedure, provisions for community herbal monographs and community list of herbal substances and preparations and establishment of the Committee for Herbal Medicinal Products (HMPC). European Directive 2004/24/EC on traditional herbal medicinal products has brought forward specifically in recognition of the position that for many herbal medicines it was difficult for companies to meet the full requirements for a marketing authorization, particularly in relation to efficacy, as are required under Directive 2001/83/EC. The Directive 2004/24/EC has established a HMPC which is part of the EMA, the European Agency responsible for the evaluation of medicinal products and to carry out tasks concerning the simplified registration and authorization of herbal medicinal products. CHMP establish Community herbal monographs and list herbal substances and preparations.

Conclusion

The use of herbal drug products vary significantly from one country to another so it is very difficult for the free circulation of such products. European regulations are most comprehensive among most of the global regulations for herbal medicinal products. FDA guidelines on Phytomedicines drug products established New Drug Application (NDA) route parallel closely the route followed for a synthetic new chemical entity.

Indian regulations are still at preliminary stage when compared to regulations of Europe and US. Harmonization of regulations, like that in European Countries could overcome the barrier for efficient trade as well as uniform standards for herbal medicinal products.

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