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HERBAL MEDICINES: OVERVIEW ON REGULATIONS IN INDIA AND SOUTH AFRICA

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ABSTRACT

Herbal medicines, also known as Phytomedicines or Botanical medicines, 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 medicine in Indian, Chinese, Egyptian, Greek, Roman and Syrian texts dates back to about 5000 years. 80% of the world population relies on herbal medicines as their primary healthcare system. 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). Regulatory provisions for Ayurveda, Unani, Siddha medicine are laid down in Drugs and Cosmetics Act 1940 and Rules 1945. On the other hand In South Africa these medicines known as complementary medicines. These regulated according to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) for manufacturing, distributing, marketing of the CAM. There was no regulatory body present for controlling these medicines. Medicines Control Council with various committees control these medicines in South Africa. There is in South African Common Technical Document (Za CTD) or South African Electronic Common Technical Document (Za eCTD) present for registration of these medicines.

KEYWORD: Herbal medicines, AYUSH,CAM,ZaCTD,GMP.

INTRODUCTION

Herbal medicine is the oldest and still the most generally used system of medicine in the world at present.[1] It is medicine made completely from plants parts (leaves, roots, stem, flowers, and seeds). Herbal medicine, also entitled as botanical medicine or phytomedicines. The World Health Organization (**WHO**) evaluates that 80 percent of the world population, currently using herbal medicine for some aspect of primary health care.[2]

As per WHO there are three kinds of herbal medicines: crude plant materials, processed plant materials and medicinal herbal products.[3] The earliest recorded evidence of herbal medicine use in Indian, Chinese, Egyptian, Greek, Roman and Syrian texts dates back to about 5000 years. The classical Indian texts on herbal medicines include Rigveda, Atherveda, Charak Samhita and Sushruta Samhita. Herbal medicines are used by practitioners of traditional system of medicines across the world due to their well-established and widely acknowledged use. The well accepted and accumulated experience of many practitioners and patients over an extended period of time make herbal medicines more popular. Furthermore, the use of herbal medicine is generally and currently regarded as safe.

Classification of Herbal Medicines

Herbal medicines can be classified into four categories as per WHO, based on their origin, evolution and the forms of current usage. While these are not always mutually exclusive, these categories have sufficient distinguishing features for a constructive examination of the ways in which safety, efficacy and quality can be determined and improved.

Category 1: Indigenous herbal medicines

This category of herbal medicines is 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 traditional medicines (TM), which also includes folk medicines, may or may not be available. It can be used freely by the local community or in the local region. However, if the medicines in this category enter the market or go beyond the local community or region in the country, they have to meet the requirements of safety and efficacy laid down in the national regulations for herbal medicines.

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. For example, Ayurveda, Unani and Siddha would fall into this category of TM.

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.[4]

Indian Regulations

In India, herbal medicines are regulated under the Drug and Cosmetic Act (D and C) 1940 and Rules 1945, where regulatory provisions for Ayurveda, Unani, Siddha medicine are clearly laid down. Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy **(AYUSH)** is the regulatory authority and mandate that any manufacture or marketing of herbal drugs have to be done after obtaining manufacturing license, as applicable. The main focus of this department is on development of Education and Research in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy systems. Laws and regulations on herbal medicines are partly the same as those for conventional pharmaceuticals. The D&C Act extends the control over licensing, formulation composition, manufacture, labelling, packing, quality, and export. **Schedule "T"** of the act lays down the good manufacturing practice (GMP) requirements to be followed for the manufacture of herbal medicines.[5] The official pharmacopoeias and formularies are available for the quality standards of the medicines. First schedule of the D&C Act has listed authorized texts, which have to be followed for licensing any herbal product under the two categories:

Ayurvedic, Siddha or Unani drugs

Patent or proprietary medicines [5]

Ministry of AYUSH

The Ministry of AYUSH was formed on 9th November 2014 to ensure the optimal development and propagation of AYUSH systems of health care. Earlier it was known as the Department of Indian System of Medicine and Homeopathy (ISM&H) which was created in March 1995 and renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in November 2003, with focused attention for development of Education and Research in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy. In India, manufacturing, marketing, promotion of ASU drugs is controlled by Ayush.[6]

Drug and cosmetic Act 1940

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** Table 1**.** These all sections provide all information related to ASU drugs regulations for manufacture, sale, registration, GMP certificate, licensing, and penalties

Table 1: List of ASU drug regulation different section[5]

Sections	Title
33C.	Ayurvedic, Siddha and Unani Drugs Technical Advisory Board.
33D.	The Ayurvedic, Siddha and Unani Drugs Consultative Committee.
33E.	Misbranded drugs.
33EE.	Adulterated drugs.
33EEA.	Spurious drugs.
33EEB.	Regulation of manufacture for sale of Ayurvedic, Siddha and Unani drugs.
33EEC.	Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drugs.
33EED.	Power of Central Government to prohibit manufacture, etc., of Ayurvedic, Siddha or Unani drugs in public interest.
33F.	Government Analysts.
33G.	Inspectors.
33H.	Application of provisions of sections 22, 23, 24 and 25.
33-I.	Penalty for manufacture, sale, etc., of Ayurvedic, Siddha or Unani drugs in contravention of this Chapter.
33J.	Penalty for subsequent offences.
33K.	Confiscation.
33L.	Application of provisions to Government departments.
33M.	Cognizance of offences.
33N.	Power of Central Government to make rules.
33O.	Power to amend First Schedule.

Schedule T -Good Manufacturing Practices for Ayurvedic, Siddha and Unani medicines

In India for getting approval to manufacture or sale of ASU drugs, manufacturer have to take GMP certificate. According to D and C act rule 157, for getting a certificate of 'Good Manufacturing Practices 'of ASU drugs, the applicant has to file application on a plain paper with full information on existing infrastructure of the manufacturing unit including instruments available, equipment's and technical staff name with qualification. After full verification by licensing authority as per Schedule 'T' requirements licensing authority will issue the certificate within a period of 3 months in Form 26-E-I.[5]

New Guidelines for Herbal Medicines

Ayush providing time to time new revised regulations for ASU drugs. Before there is no such guidelines for conducting clinical trials, but in March 2013 Ayush publish new **GCP guidelines** for clinical trials on ASU drugs.[7]

Good Clinical Practice is a set of guidelines which incorporates the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects. The fundamental tenet of GCP is that in research on man, the interest of science and society should never take precedence over considerations related to the well-being of the study subject. 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.

These guidelines are formulated based on CDSCO Document on GCP Guidelines (2001) for Clinical Trials on Pharmaceutical Products.[7] They should be followed for carrying out all ASU medicine research in India at all stages of drug development, whether prior or subsequent to product registration in India. These GCP guidelines have to be followed during a clinical trial, if this not follow than clinical trial will be suspended by regulatory authorities. GCP guidelines also provide the compensation related guidelines for participants if any unwanted result or death of participants occur during clinical trial.

From 2017 onwards, its also mandatory that there must be expiry and manufacturing date present on product label.[6]

Regulation in South Africa

In South Africa herbal medicines known as "Complementary Medicine" (CAM). These medicines regulated according to the Medicines and Related Substances Act, 1965 (Act 101 of 1965). There is 40 sections present in this ACT, related to registration procedure, labelling, prohibition, penalty, establishment and power of Medicines Control Council.[8] According to this act "complementary medicine" means any substance or mixture of substances that- (a) originates from plants, minerals or animals; (b) is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and (c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982).

Earlier there was no such regulations for manufacturing, distributing, marketing of the CAM. There was no regulatory body present for controlling these medicines. Now South Africa has developed a medicines regulatory authority with internationally recognised standing that is known as Medicines Control Council (MCC) Fig.1.[9]

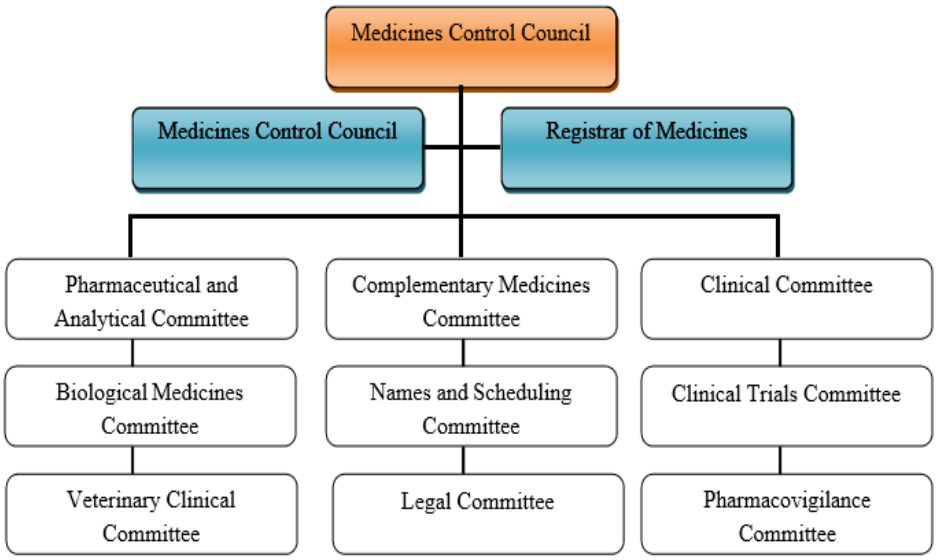

Fig. 1: Flow chart of Medicines Control Council with other regulating committees[10]

MCC applies standards laid down by the Medicines and Related Substances Act, (Act 101 of 1965) which governs the manufacture, distribution, sale, and marketing of medicines. The prescribing and dispensing of medicines is controlled through the determination of schedules for various medicines and substances.[9]

The MCC operates through external experts who are members of Council Committee structures. Most experts evaluate data sets submitted by the pharmaceutical industry for purposes of registration. Many of these evaluators are from various academic institutions, mainly medical and pharmacy schools.[10]

New Advancements in CAM Regulation

Registration guidelines

Earlier there is no need to register the CAM drugs. There was no regulations related to labelling, no stability data required. But according to new regulations implemented by MCC, there is need to register the CAM drugs and stability, toxicity data also required.

Registration of CAM drugs

MCC published the new format for registration of CAM drugs. Now the manufacturer has to submit the registration application in South African Common Technical Document (Za CTD) or South African Electronic Common Technical Document (Za eCTD). The Za CTD and Za eCTD both are organised into five modules. 1. region-specific information 2.Summary documents 3. Quality-related information 4. Nonclinical study reports 5. Clinical study reports Fig.2. Review process in case of CTD it will take more time for approval and lengthy process time consuming process.[11]

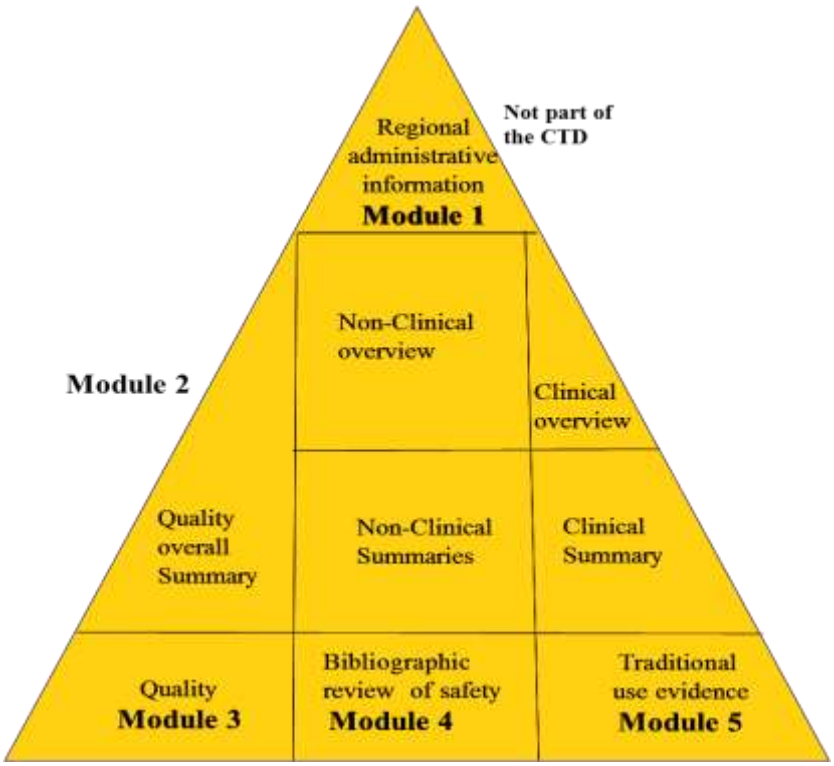

Fig. 2: Common Technical Document Modules

But in case of eCTD, it is easier for MCC Committees to review data, approve new drugs, and monitor drugs after they go on the market.[12] Using Za eCTD also simplifies the process for submitters, because it is the same format used by drug regulatory agencies in other countries.

New Labelling guidelines Developed

Previously there is no need to mention category of the drug and expiry date on labels of CAM drugs. But according to latest guidelines manufacturer has comply with these guidelines.

In terms of the provisions of Regulation 8 of the Medicines and Related Substances Act, 1965 all medicines falling in Category D must comply with the labelling requirements. This implies that label of each CAM drugs.

A. Shall be written in English and at least one other official language.
B. State on the product label.

- The category of medicine[8]
- The pharmacological classification of the medicine.
- The discipline of medicine.
- The words "This medicine has not been evaluated by the Medicines Control Council.
- This medicine is not intended to diagnose, treat, cure or prevent any disease.[8]

CONCLUSION

From this review we conclude that there is regulations present for herbal medicines in India and South Africa. But in case of South Africa they developed strict guidelines in less time in comparison to India. India develop guideline for conduct clinical trial on herbal medicines, but registration process is not regulated properly. But in South Africa there is Za CTD and Za eCTD both advanced regulation present for registration of complementary medicines.

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