CRITICAL REVIEW IN PHARMACEUTICAL SCIENCES

eISSN 2319-1082

Review Article

# MAPPING OF GLOBAL REGULATORY REQUIREMENTS FOR TRADITIONAL MEDICINE/ COMPLEMENTARY AND ALTERNATIVE MEDICINE(TM/CAM)

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**ABSTRACT**
Certain forms of traditional, complementary and alternative medicines play an increasingly important role in health care and health sector reform globally, hence the safety and efficacy, as well as the quality control, of traditional medicine and complementary and alternative medicines have become important concerns for both health authorities and the public. Therapies and theories of TM/CAM differ from country to country and region to region. There is a lack of common standards and understanding and appropriate methods for evaluating traditional medicine to ensure the safety, efficacy and quality control of TM/CAM. Therefore sharing national experience and information is crucial. Countries face major challenges in the development and implementation of the regulation of traditional, complementary/alternative medicines. These challenges are related to regulatory status, assessment of safety and efficacy, quality control, safety monitoring and lack of knowledge about TM/CAM within national drug regulatory authorities. Traditional Medicine(TM) and complementary & alternative medicines (CAM) are attracting more & more attention within the context of health care provisions & health sector reforms. Use of Traditional medicine remains widespread in developing countries, while use of CAM is increasing rapidly in developed countries.
**Key word: Global requirements, traditional medicine, complementary and alternative medicine**

## INTRODUCTION

Certain forms of traditional, complementary and alternative medicines play an increasingly important role in health care and health sector reform globally, hence the safety and efficacy, as well as the quality control, of traditional medicine and complementary and alternative medicines have become important concerns for both health authorities and the public. Therapies and theories of TM/CAM differ from country to country and region to region. There is a lack of common standards and understanding and appropriate methods for evaluating traditional medicine to ensure the safety, efficacy and quality control of TM/CAM. Therefore sharing national experience and information is crucial. Countries face major challenges in the development and implementation of the regulation of traditional, complementary/alternative medicines. These challenges are related to regulatory status, assessment of safety and efficacy, quality control, safety monitoring and lack of knowledge about TM/CAM within national drug regulatory authorities. Traditional Medicine(TM) and complementary & alternative medicines (CAM) are attracting more & more attention within the context of health care provisions & health sector reforms. Use of Traditional medicine remains widespread in developing countries, while use of CAM is increasing rapidly in

developed countries.Countries in Africa ,Asia, and Latin America Chiefly use traditional medicine(TM) to help meet some of their primary health care needs.Even industrialized countries are turning towards TM for health care purposes.TM,thus has not only maintained its popularity in all regions of the developing world,its use is rapidly spreading in industrialized countries which is exemplified from following facts.

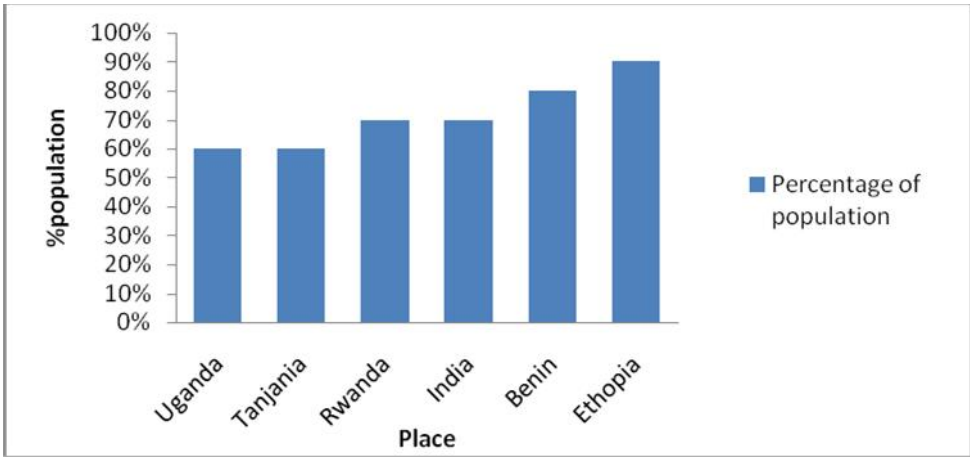



**Figure No.1.Use *of TM is extensive is some developing countries***

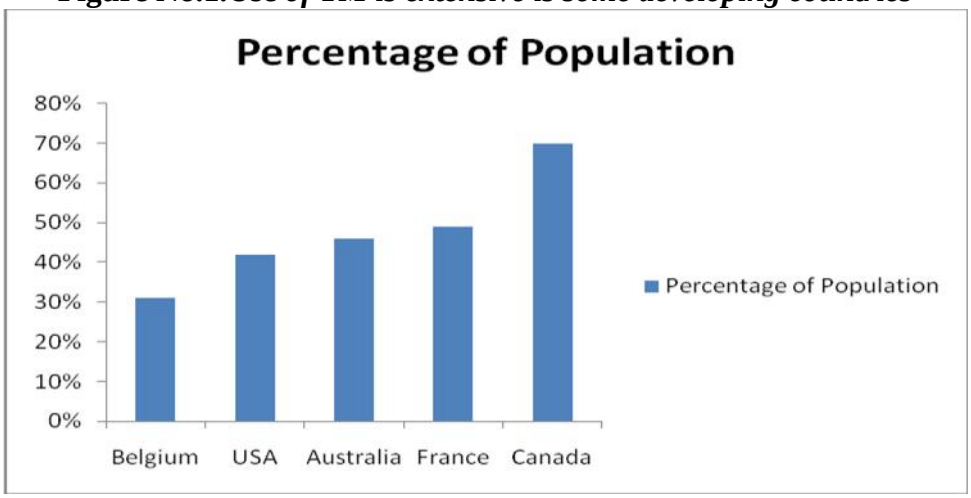



**Figure No.2.Percentage of population which has used CAM at least once in selected developed countries**

The popularity of these medicines can be attributed to many factors such as lower cost, higher accessibility in comparison to modern system of medicine. Further people have perception that traditional system of medicine /complementary and alternative system of medicine having long term usage(age tested) and therefore a safer with less side effects in comparison with the modern system of medicine.[1,2]

**TM/CAM in India** [3,4]

In India Traditional Medicine (TM)/Complementary and alternative medicine (CAM) are regulated under Drug and Cosmetic Act 1940 and Rules 1945. For the regulation of TM/CAM AYUSH department is responsible and it covers six main Indian therapies, which are ayurveda, Yoga, Unani for or in the diagnosis, Sidha, Homeopathy and Naturopathy.

**TM/CAM in Europe[**5]

Herbal medicinal products fall within the scope of the European Directive 2001/83/CE that foresees that marketing of each medicinal product requires and authorisation to be granted on the basis of results of tests and experimentation concerning quality,safety,and efficacy.

eISSN 2319-1082

**TM/CAM in Malaysia** [7]
The registration and licensing of TM/CAM is legislated through the control of Drugs and Cosmetics Regulations 1984.Regulation for traditional medicines,including herbal medicines and dietary supplements formed part of the Control of Drugs and Cosmetics Regulations in 1984.

**TM/CAM in Australia** [6]
In Australia, Medicinal products containing herbs ,vitamins,mineralsand nutritional supplements, homeopathic medicines and certain aromatherapy products are referred as complementary medicines. These are regulated as medicines under the therapeutic Goods Act 1989.Complementary medicines comprise traditional medicines including traditional Chinese medicines, Ayurvedic medicines, and Australian indigenous medicines.

**TM/CAM in Canada** [8]
The Natural Health Products Directorate (NHPD),a part of the Health Products and Food Branch of Health Canada, is the regulating authority for natural health products for sale in Canada.Products considered to be natural health products are regulated as over the counter self medications under the Natural Health Products Regulations which came into effect in January 2004.These regulations cover all aspects of manufacturing and sale of natural products including the required license, importing,clinical and laboratory studies,lebeling and claims.

**TM/CAM in USA** [9]
Complementary and alternative medicine, as defined by NCCAM, is a group of diverse medical and health care systems, practices and products that are not presently considered to be part of conventional medicine.The list of what is considered to be CAM changes continually,as those therapies that are proven to be safe and effective become adopted into conventional health care and as new approaches to health care emerge.

**COUNTRIES PERSPECTIVE**

**INDIAN PERSPECTIVE**

In India, Traditional Medicine (TM/COMPLEMENTARY & ALTERNATIVE MEDICINE) are regulated under Drug and Cosmetic Act 1940 and rules 1945.For the regulation of TM/CAM AYUSH department is responsible and it covers six main Indian therapies, which are ayurveda, Yoga, Unani for or in the diagnosis, Sidha, Homeopathy and Naturopathy.Ayurveda, Unani, Sidha, Yoga and Naturopathy come under TM category and Homeopathy comes under CAM category.”Ayurvedic, Sidhaor Unani drug” includes all medicines intented for internal or external use, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Sidha, and Unani system of Medicine.[10]

**REGULATORY CLASSIFICATION:**

**TRADITIONAL MEDICINE(TM)**

- AYURVEDIC MEDICINE
- SIDHA MEDICINE
- UNANI MEDICINE

**COMPLEMENTARY & ALTERNATIVE MEDICINE (CAM)**

- Homeopathic Medicine

Other herbal medicines are regulated under modern system of medicine

eISSN 2319-1082

## REGULATORY REQUIREMENT FOR REGISRATION OF TM/CAM

In India the TM/CAM can be registered under following categories:

**Classical Ayurvedic,Sidhha & Unani Product**:

Classical Ayuredic medicines are those medicines which contain ingredients which are listed in respective Authoritative books and also the formulation is listed in these authoritative books.

**Proprietary Ayurvedic,Sidhha & Unani Product:**

Proprietary ASU medicines are those medicines which contain ingredient which are listed in respective Authoritative books but their composition, manufacturing process and formulation complies with in house specification& has in house composition and manufacturing process.

**Modern drug (other than in Schedule C, C1&X)**:

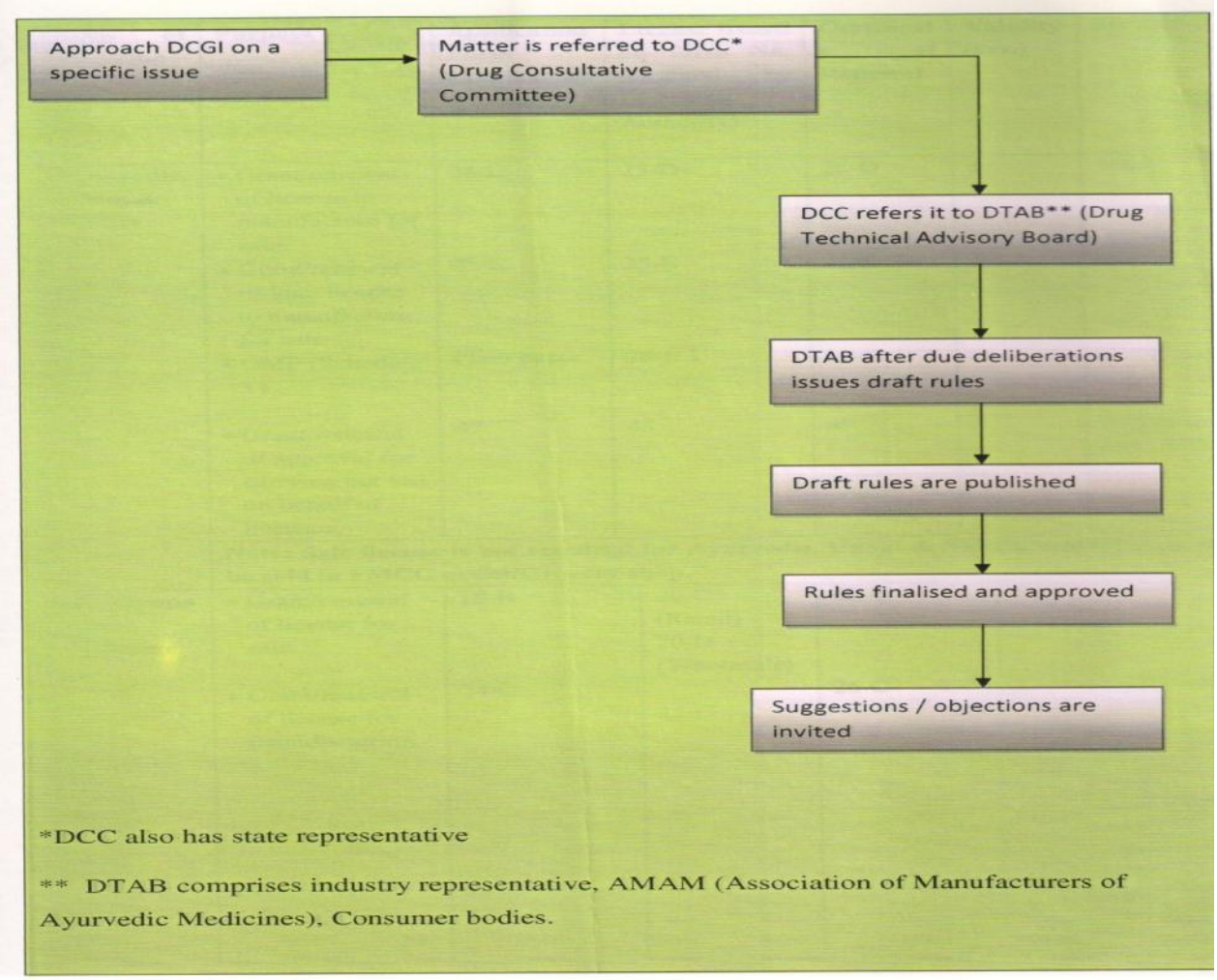
Herbs which are not listed in the 54 Authoritative books and regulated under Modern drugs and manufacturing license is granted in Form -25.

**Homoeopathic Medicine**:

When a drug product qualify then definition of Homeopathic medicine as given in Rule 2dd of Drugs and Cosmetic Act 1940.

**New Homeopathic Medicine**

The drug which qualify the definition of New Homeopathic medicine as given in Rule 30AA of Drugs & Cosmetic Act and Rules 1945.To import a New Homeoathic medicine,the importer have to submit the requirements mentioned in schedule D1 & D11.




**Regulatory Process: Figure no.3**

eISSN 2319-1082

**Licensing Requirements for Manufacture,sale and Distribution 1**
**Table no-1**

| Class of Medicine | Purpose | Application Form | License issued on Form No.(Granted by Licensing Authority) | Certificate of Renewal | Validity(yrs) | Fee(Rs) |
|---|---|---|---|---|---|---|
| Ayurvedic,Unani & Siddha | Grant/renewal of license to manufacture for sale | 24-D | 25-D | 26-D | 3 | 101000 |
| | Grant/renewal of loan license to manufacture for sale. GMP(schedule T) | 25-E | 25-E | 26-E | 3 | 600 |
| | Grant/renewal of approval for carrying out test on behalf of licensee | Plain Paper | 26-E-1 | - | - | - |
| | | 47 | 48 | 49 | 3 | Inspection Fee-6000 |
| | Note:Sale license is not required for Ayurvedic,unani & Siddha medicine,so can be sold in FMCG outlet/Grocery shop. | | | | | |
| Homeopathic Medicine | Grant/renewal of license for sale | 19-B | 20C(Retail) 20D(Whole sale) | 20-E | 5 | 250 |
| | Grant/renewal of license for manufacturing | 24-C | 25-C | 26-C | 5 | 200+100(Inspection fee) 50(Inspection for renewal of license |

**Sale and Distribution:**
For sale and distribution of Ayurvedic,Siddha and Unani medicines sale-license is not required so can be sold in grocery shop/FMCG outlets.In case of Homoepathic medicine,sale license is required and medicines are sold in specific pharmacy outlets.In most of the cases doctors prescribe and give homeopathic medicine to their patient.

**Advertising 10**
Advertising of TM/CAM is similar to that of conventional pharmaceuticals and is regulated under the Schedule-J of Drugs and Cosmetics Rule 1945 and the Drug and Magic Remedies Act 1954 of Drugs and Cosmetics Act 1940

**European Perspective**

Herbal medicinal products fall within the scope of the European Directive 2001/83/EC thatb foresees that marketing of each medicinal product requires an authorisation to be granted on the basis of results of tests and experimentations concerning quality,safety and efficacy.

**Regulatory Classification[** 24]

Table no-2

| Category | Subcategory | Legal basis | Main characteristics |
|---|---|---|---|
| HMP with MA | Full dossier new MA,(DCP,MRP,CP) | §8(3) directive 2001/83/EC | Full CTD including safety /efficacy data |
| Biliographic application (well established use), (MRP,DCP) | | §10a directive 2001/83/EC WEU defined by Annex 1 of 2001/83/EC amended by 2003/63/EC | No individual but bibliographic safety/efficacy data (mixed applications possible) |
| HMP with simplified registration | Registration as Traditional herbal medicinal product(THMP) | §16a directive 2001/83/ECamended by 2004/24/EC | Full quality part,safety replaced by expert statement,efficacy replaced by traditional use (30/15 years) |
| Homeopathic MP Anthoposophic MP (treated legally as Homeopathic according directive 92/73/EEC) | | § 14-15 directive 2001/83/EC | Simplified registration,no individual safety/efficacy data |
| HP outside medicine legislation | Food supplements Cosmetic Products consumer goods | E.g.178/2002/EC for demarcation foodstuffs-MP,2002/46/EC for food supplements:Cosmetic Directive 76/768/EEC+93/35/EEC | Mainly notification only |

**GMP Requirements:**

The compliance with GMP(including Directive 2003/94/EC) will be required.GMP will also apply to herb active ingredients used as active substances.There will be a requirement to hold a manufactures Licence and/or WholesaleDealers Licence as Appropriate.

eISSN 2319-1082

**Labelling Requirements:**

In addition to the provisions laid down in articles 54-65 of Directive 2001/83/EC,any labelling and user package leaflet shall contain a statement to the effect that:

- The product is a traditional herbal medicinal product for use in specified indications exclusively based upon longstanding use
- The user should consult a doctor or a qualified health care practitioner if the symptoms persist during the use of the medicinal product or should adverse effects not mentioned in the package leaflet occur.

**Australian Perspective**

In Australia, medicinal products containing herbs, vitamins, minerals, and nutritional supplements, homeopathic medicines and certain aromatherapy products are referred to as complementary medicines. These are regulated as medicines under the Therapeutics Goods Act1989.Complementary medicines comprise traditional medicines, including traditional Chinese medicines, Ayurvedic medicines and Australian indigenous medicines.

**Registration of Complementary Medicine[11]**

Complementary medicine in Australia can be registered under following categories depending upon the rules applied:

a) As Registered medicine (AUST-R)

b) As Listed medicine

A) Registered Complementary medicine

- Registration is similar to modern medicine
- The licensing and audit of manufactures
- Pre-market assessment of the products
- Post market activities

B) Listed complementary Medicine

- Listed medicines may be supplied following application to the TGA by the sponsor
- Self certification by sponsor
- Validation by TGA that certain Key requirements of the legislations are being met.

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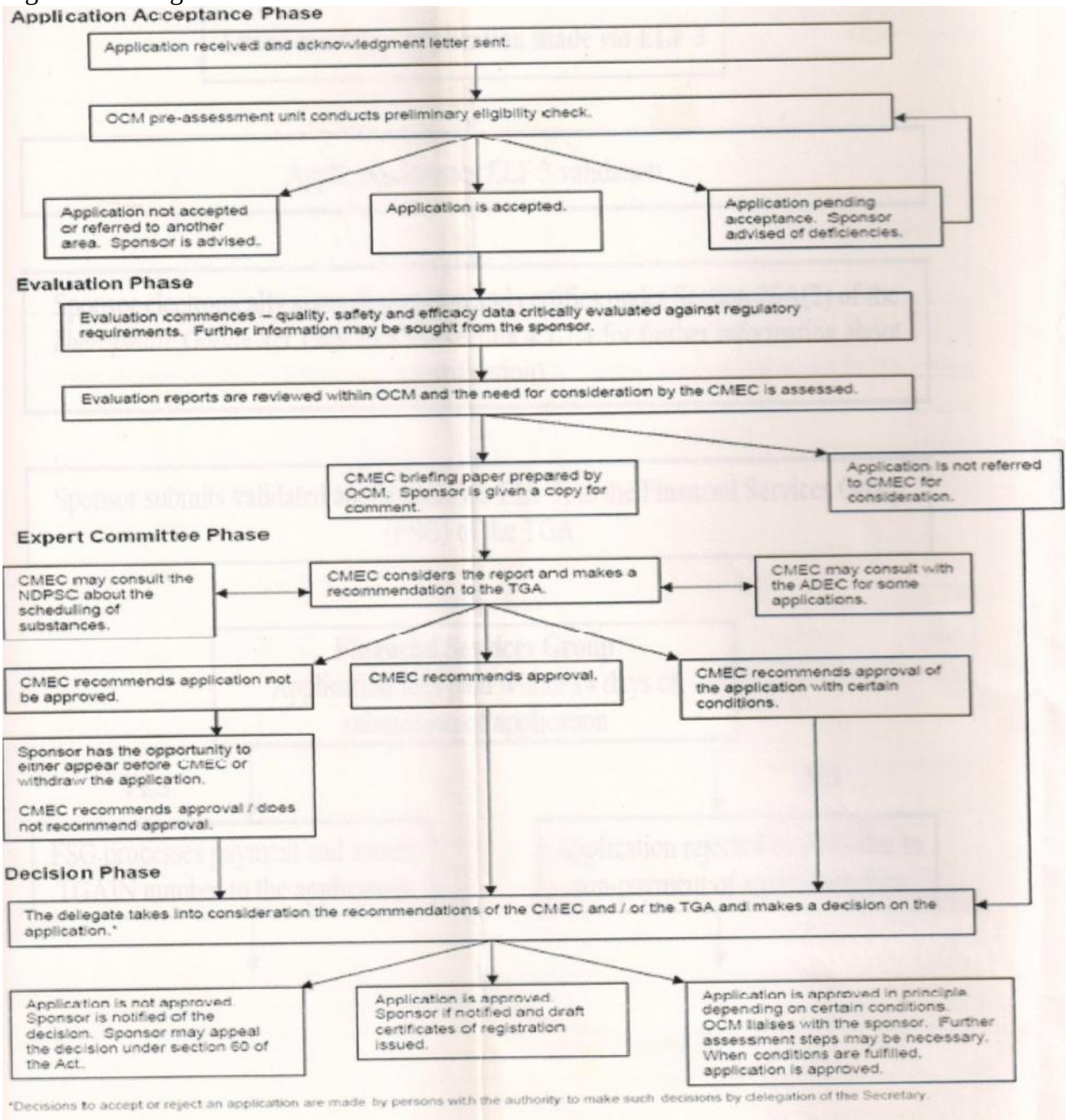
**Registration Process**

Figure No.4 Registration Process flow chart

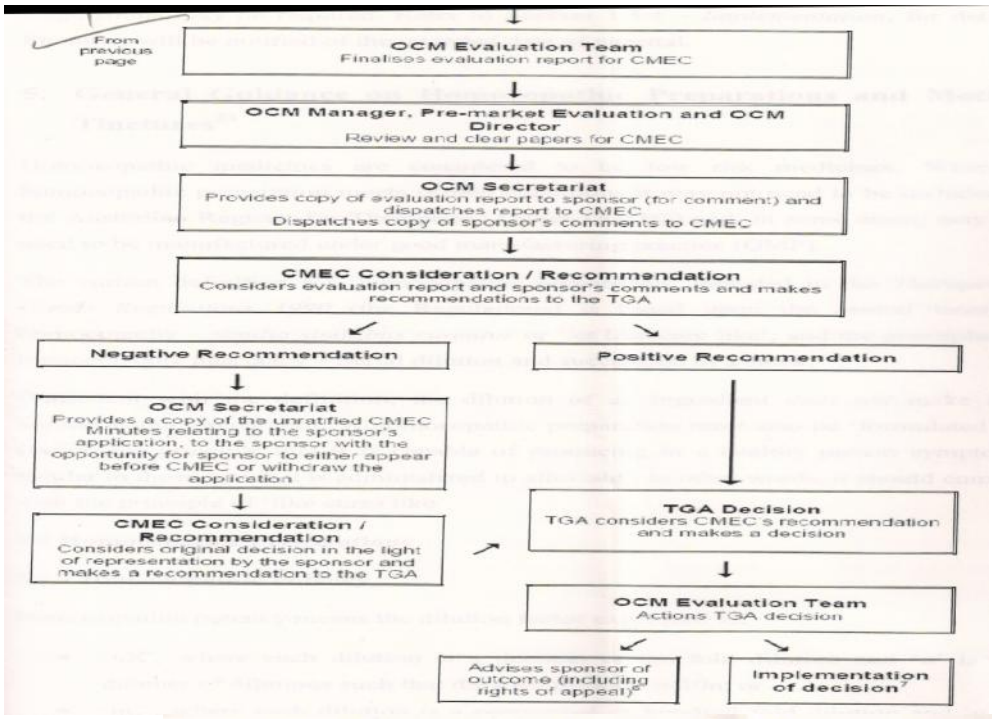


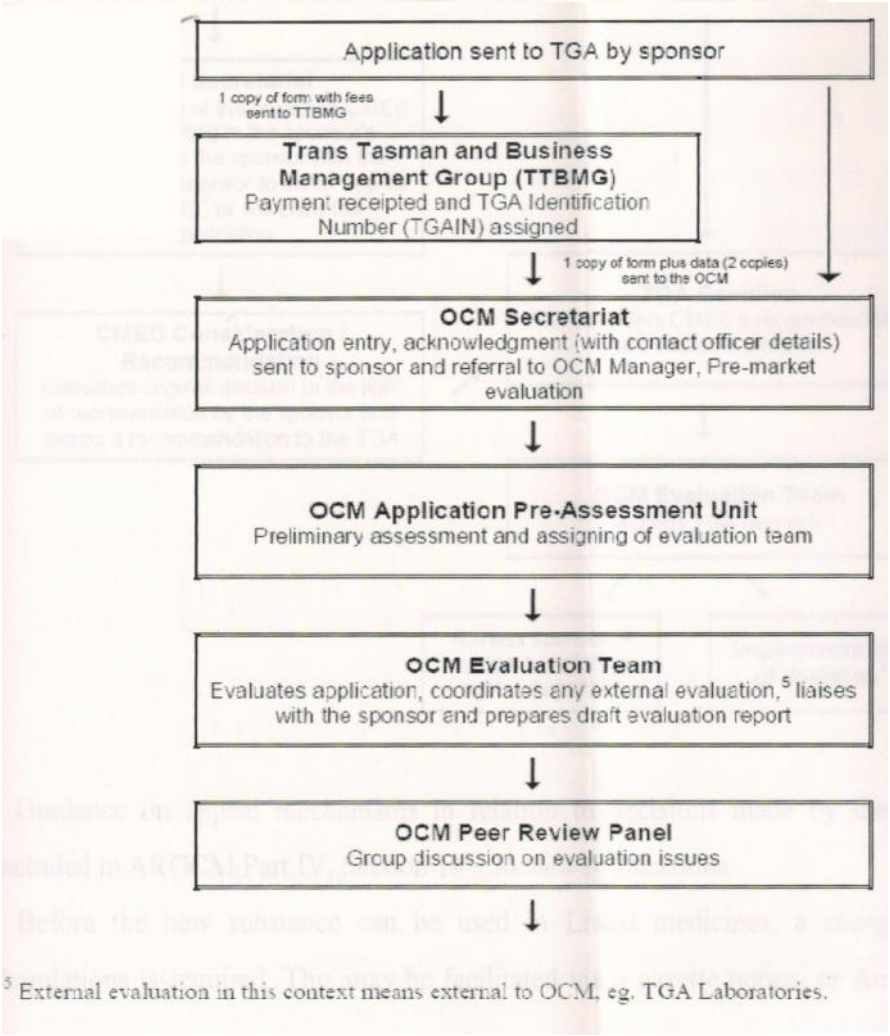

**Evaluation Process of Complementary medicine[ 12]**

**The** following flow chart illustrates the stages through which an application for the evaluation of a new substance progresses within the therapeutic Goods Administration(TGA).Applications for new substances evaluated through the office of Complementary Medicines(OCM/Complementary medicines Evaluation committee (CMEC)route have taken approximately 8 months from the receipt of the application to review by CMEC.

Figure no5: Evalution process

eISSN 2319-1082




[5] External evaluation in this context means external to OCM, eg. TGA Laboratories.

**Malaysian Perspective**

National policy on TM/CAM, which was launched in the year 2001.The registration and licensing of TM/CAM, is legislated through the control of Drugs and Cosmetics Regulations 1984.Traditional medicines are allowed to be sold as over-the-counter medicines. Traditional and complementary Medicine practice together is other than practice of medicine or surgery,by registered medical practioners as defined in medical act 1971.[ 13 ]

1. **Regulatory Classification**:

Traditional/complementary medicine classified into

**Traditional Malay Medicine** [14]

Malay traditional medicine is a field of knowledge and practices which cover aspects of health and healing which was practiced from generation to generation.

**Traditional Chinese medicine[** 15]

Traditional Chinese medicine has a history of over 4000 years in China and in recent times, it has expanded rapidly in most countries. There has been a similar increase in the practice of other aspects of Traditional Chinese medicine, including herbal medicine, therapeutic massage, manipulation, dietary therapy and exercise therapy.

**Traditional Indian medicine** [6]

The Indian system of medicine, prevalent about 1500 years over south-east Asia, comprises of 3 major systems namely Ayurveda,Sidha and Unani.Traditional Indian Medicine developed in a 3 phases: prehistoric or pre-vedic,vedic,ayurvedic.Records of ancient Hindu medicine are found in the Artharva-veda,Ayurveda,Charaka Samhita and Sushruta samhita

**Homeopathy[** 17]

Homeopathy is derived from the Greek word “Homeos” meaning similar and “Pathos” meaning suffering. National centre of Complementary Alternative medicine defines the homeopathy as a system of medicine that is based on the Law of similar.

**Registration and quality control of TM products :[18]**

The Malaysian government imposed the control of Drugs and Cosmetics Regulation 1984 in the yearn1992,wherby all herbal products intended to be produced ,imported and sold for human consumption must be registered with the Malaysian Ministry of Health in order to ensure and control the quality ,safety and efficacy of the herbal products.Exceptionally,in some countries,herbal medicines may also contain,by tradition,natural organic or inorganic active ingredients which are not of plant orgin.Currently every registered traditional medicine product bears the registration number on its label or package,starting with PBKD or MAL and ending with T which denotes it is a traditional medicine product.

**Canadian Perspective**

**The** Natural Health Products Directorate ,a part of the Health Products and Food Branch of Health Canada,is the regulating authority for natural health products for sale in Canada.Products considered to be natural health products are regulated as the over the counter self medications under the Natural Health products Regulations(NHPR) which came

**Requirements for product Registration[ 19]**

1. **Product Licensing**

   All natural health products require a product license before they can be sold in Canada.Obtaining a license requires submitting detailed information on the product to Health Canada,include medicinal ingredients,source,potency,non-medicinal ingredients and recommented use.

2. **Site licensing** [20]

eISSN 2319-1082

A system of site licensing requires that all Canadian manufactures,packagers,labellers and importers of natural health products be licensced.Sites must have procedures in place respecting distribution records and product recalls and for the handling,storage and delivery of their products,and demonstrate that they meet good manufacturing practice requirements.

3. **Good manufacturing Pratices [21]**

Good manufacturing practices (GMPs) for natural health products must be employed to ensure product safety and quality.This requires that appropriate standards and practices regarding product manufacture,storage,handling and distribution of natural health products be met.

**4.Clinical Trials [22]**

A Clinical trial is an investigation of a natural health product that involves human subjects and is intented:

- To discover or verify the products clinical,pharmacological or pharmacodynamic effects
- To identify any adverse events that are related to its use;to study its absorption,distribution,metabolism and excretion
- To ascertain its safety or efficacy

**5.Labelling and Packaging[ 23]**

**S**tandard labelling requirements are established to ensure consumers can make informed choices.

**USA Perspective**

Complementary and alternative medicine, as defined by NCCAM, is a group of diverse medical and health care systems, practices and products that are not presently considered to be part of conventional medicine.

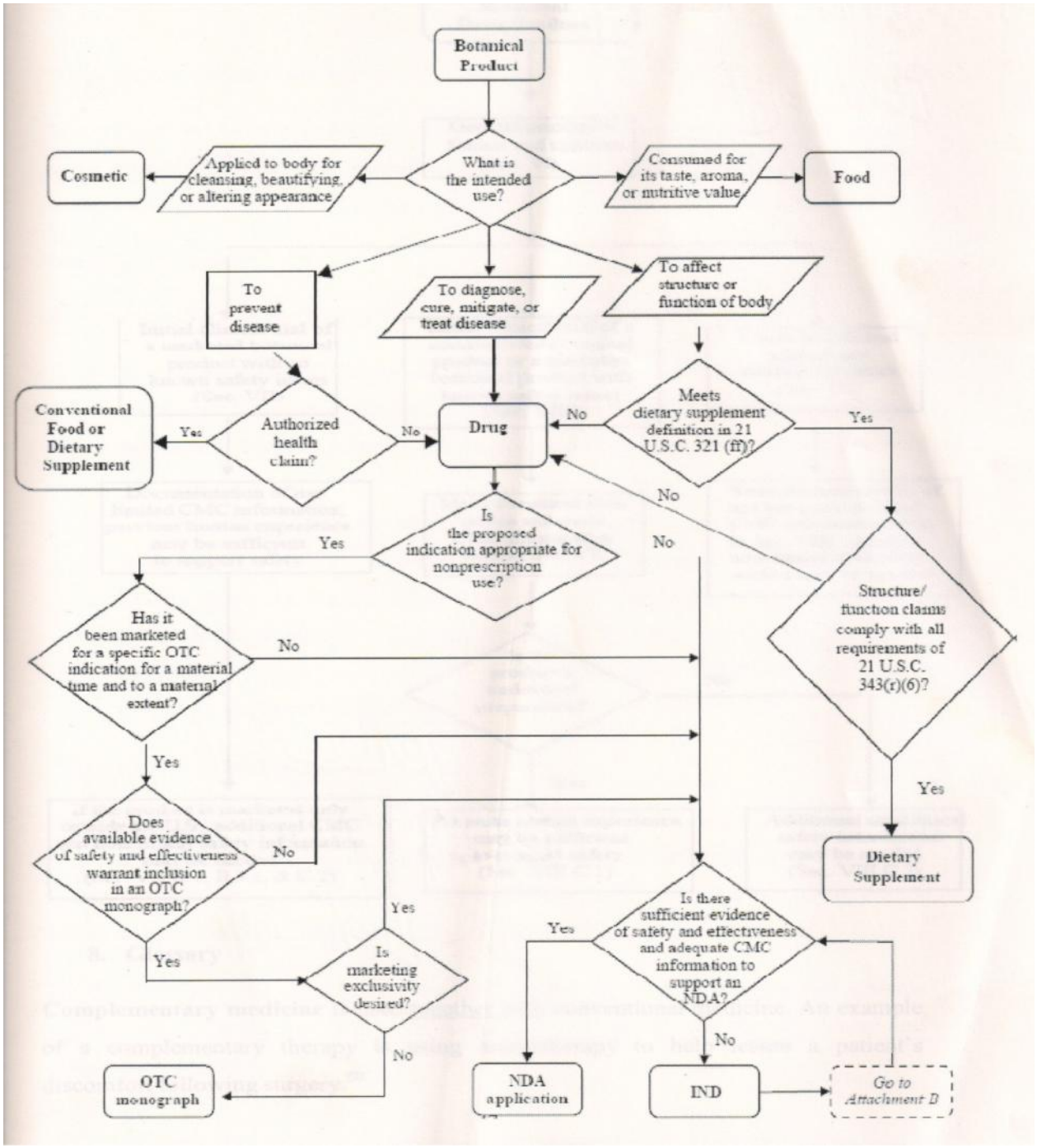
**Regulation of CAM under NCCAM[ 24]**

NCCAM classify the CAM medicine but the product can be register under the category(Drug and New-drug,Food,Food additive,Dietary Supplementary,cosmetic,Device ,or as Biological product) depending upon the intented use of product.Botanical products,depending on the circumstances,may be regulated as drugs,cosmetics,dietary supplements,or foods.All four types of products are subjected to the Act 51.Regulatory requirements for registration of CAM are same as for conventional/modern pharmaceuticals.

**Regulatory Approaches for marketing Botanical Drug products[ 25,26]**

**Figure 6:R**egulatory process

eISSN 2319-1082




## CONCLUSION

The usage of Traditional Medicines/Complementary and Alternative Medicines has grown globally. Almost half of the population of many industrialized countries regularly uses some form of the CAM or the other. Nature has the cure for all diseases including the serious disease such as cancer, AIDS, and therefore research on TM/CAM will help us to get solution for such diseases. With strong regulation coming in place, TM/CAM will find a respectable status in the healthcare system providing health solution which does not have cure in the modern system of medicine. This will also opens up opportunities for the pharma companies to enter into development of research and technology based TM/CAM giving the patients the confidence for safe and effective medicines.

eISSN 2319-1082

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