Asian Journal of Pharmaceutical Technology & Innovation
ISSN: 2347-8810

Review Article

A Comparative Study of Marketing Conditions and Labelling Requirements for Homeopathic Drug in US, Europe and India

Pathan Asmatbanu Mehmood Khan[1], Dilip G. Maheshwari[2]*

Received on: 29-03-2016
Accepted on: 31-03-2016
Published on: 15-04-2016

Corresponding Author:

***Dr. Dilip G. Maheshwari,**
Head of Department of Quality Assurance and Pharm Regulatory Affairs,
L. J. Institute of Pharmacy,
Ahmedabad.
India.

e-mail: dgmaheshwari@gmail.com

ABSTRACT

India is the country which exporting the homeopathic drug product to the foreign countries like USA, Germany and United Kingdom. 90-95% of homeopathic products are exported to Germany from India. Since 1992-93, Indian Homeopathic product is increasing for USA. India also exports to the developing countries like Russia Ukraine and Sri lanka. For Sri lanka export is increasing since 1992-93. The OTC homeopathic drug products in US the established annual sales are around $ 75 million and exploring up to 15-20% annually. The Federal, Food, Drug and Cosmetic Act standardize as official drugs and its standard in Homeopathic Pharmacopoeia of United State (HPUS) and its supplements. According to article 1of Directive 92/73/EC of homeopathic medicinal product means any medicinal product formulated products or substances or composition known as homeopathic stocks according to homeopathic manufacturing process stated in European pharmacopoeia or in absence pharmacopoeia available and currently used in official member states. Central Council for Research in Homeopathy (CCRH) was built up as an independent association in 1978, under the Dept. of AYUSH, Ministry of Health and Family Welfare, and Govt. of India. The National Institute of Homeopathy (NIH) in Kolkata as a self-governing association under the Ministry of Health and Family Welfare, Government of India.

Key-words: Homeopathic drug, AYUSH, Central Council ofHomeopathy, HPUS

Cite this article as:
Pathan Asmatbanu MehmoodKhan, Dilip G. Maheshwari, A Comparative Study of Marketing Conditions and Labelling Requirements for Homeopathic Drug, Asian Journal of Pharmaceutical Technology & Innovation, 04 (17); 2016, 71-82 .
www.asianpharmtech.com

1Department of Quality Assurance and Pharm Regulatory Affairs, L. J. Institute of Pharmacy, Ahmedabad.
2 Head of Department of Quality Assurance and Pharm Regulatory Affairs, L. J. Institute of Pharmacy, Ahmedabad.

INTRODUCTION:
Definition of Homeopathy

Homeopathy is an alternative and complementary medical science based on theory of "Similar cures similar" found by Dr. Samuel Hahnemann, a German physician. It is the science of treating disease that employs very low quantity of drug substance that may be in higher quantity shows symptoms of other diseases in normal healthy person.

HOMEOPATHIC DRUG REGULATION IN US

Definition:

Homeopathic drug: The drug which is listed and monographed in Homeopathic Pharmacopoeia of United States (HPUS), and to its addendum or supplements. The potency of homeopathic drugs is specified in dilution pattern like 1X, 2X, etc. Homeopathic drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are nit homeopathic drug products.

Marketing Conditions of Homeopathic Drug in US under Compliance Policy Guidance (CPG) 400.400:

The Federal, Food, Drug and Cosmetic Act standardize as official drugs and its standard in Homeopathic Pharmacopoeia of United State (HPUS) and its supplements.

HPUS monograph approval criteria for eligibility:

1. HPCUS has states that drug is safe and effective.
2. Pharmacy and preferred section of HPUS.
3. The given documentation complies an approved format as set forth in specific sections of HPUS. Two important facts are safe/effective (1, 2, 3) and homeopathic principle of similar (4, 5, 6 or 7).
4. The therapeutic utilization of drug is novel and non-official homeopathic drug is framed by homeopathic drug proving and clinical verification allowable to HPCUS. Between the periods of clinical verification the drug will be accepted for provisional review and should be available on monitored basis. Refer to the guideline of homeopathic drug proving and guideline for clinical verification further information.
5. The therapeutic activity of drug is established through published documentation the drug the drug was in previously to 1962. This documentation must include symptom picture including subjective and any available objective syndrome.
6. The therapeutic usefulness of drug is established by at least two adequately controlled double blind clinical studies using drug as the single intervention, the study is to be accompanied by adequate statistical analysis and adequate description of symptom picture acceptable to HPCUS which contains subjective symptom and where appropriates the objective symptomatology.
7. The therapeutic use of drug obtained by:
   (a) Data gathered from clinical experience encompassing the symptom picture pre and post treatment including subjective and any objective symptoms,
   (b) Data documented in medical literature subject to further verification.

Monograph Review Committee (MRC):

MRC makes recommendation to board of directors on monographs after examining formulae, molecular weight, description, range and habitat for botanicals or zoological preparation, toxicology classification and suggested attenuation level for OTC/RX/external use for drugs under considerations and a initial review of references.

Pharmacopoeia Review Committee (PRC):

PRC make recommendation to board of directors on monograph after completing an in depth review of references, ensuring adequacy of symptom or proving according to convention guidelines and full compliance with criteria HPCUS procedure manual for eligibility of HPUS.

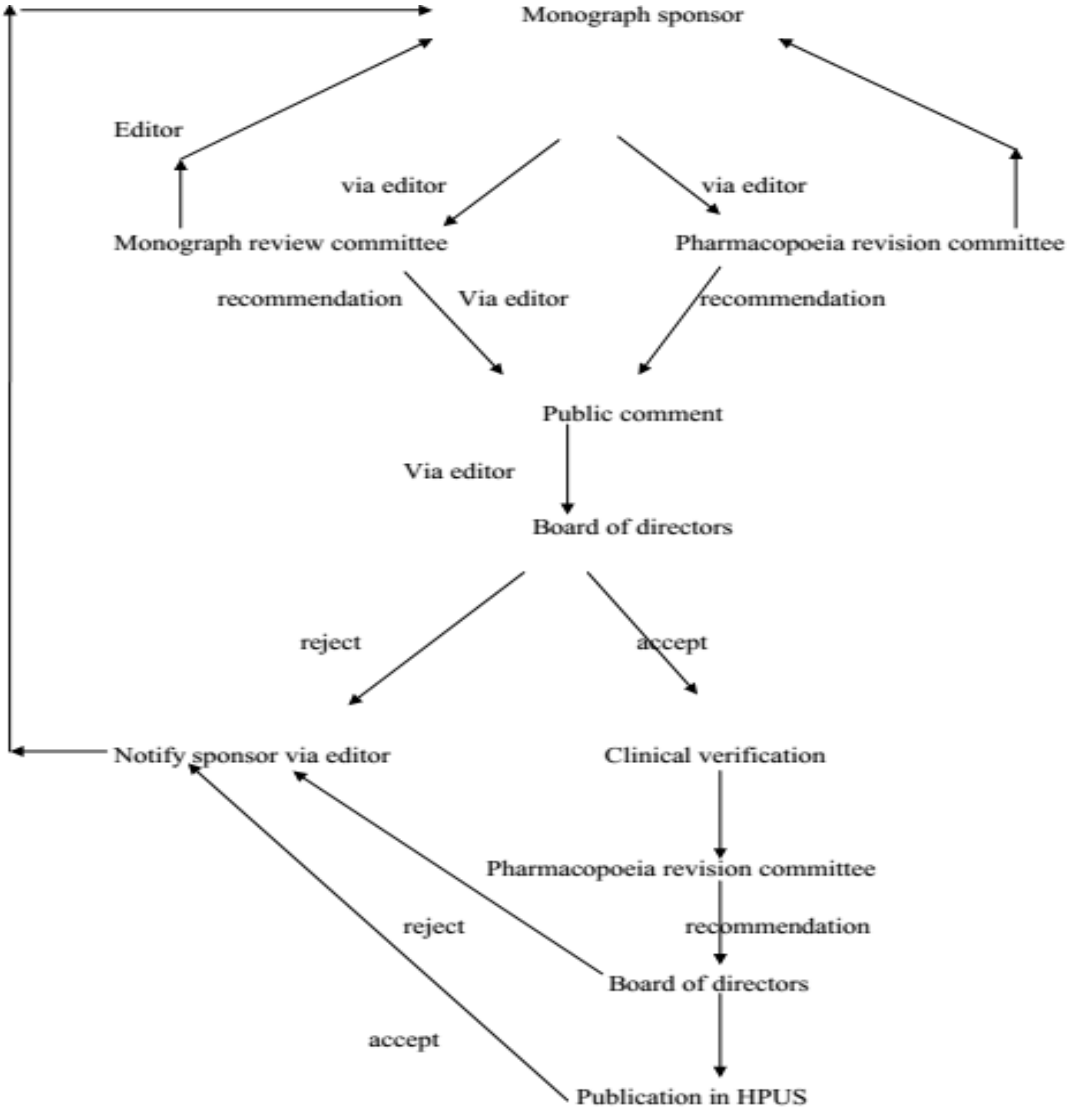


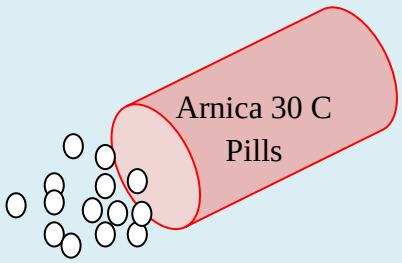
Figure –1: Monograph Review and Approval Process

Labelling of Homeopathic Drug as per US CPG 400.400:

General labelling guidelines:

1. Name and place of business: Drug label contains name and place of business of manufacturer, packer or distributor in sec. 502(b) of the act and 21 CFR 201.1.
2. Direction of use: Label of drug product contains direction for use in sec. 21 CFR 201.5. It is applicable only up to prescription drugs.
3. Statement of ingredients: Label must contain statement of quantity amount of ingredients in products from sec. 21 CFR 201.10 e.g. homeopathic potencies like 1X, 2X. For those drugs not specified by HPUS, documents are required to support are included in HPUS addendum or its supplements.
4. Established name: According to 21 CFR 210.10 from HPUS products bear Latin names. All labelling should be in English names as current labelling requirements. It is permissible for industry to include in the labelling both English and Latin names.
5. Container size: products which packaged in small container to adjust the label complies the required information under 21 CFR 201.10(1) for OTC drugs and in 21 CFR 201.100 (b) (7) for prescription drugs. Each product also contains statement of identity, potency, name and place of manufacturers, packers or distributor.
6. Language: It should be in English under 201.15 (c)(1), for industry, foreign language also implies.

Label of Homeopathic dosage (Pills) form as per US Guidelines:

Arnica 30 C Pillules A Homeopathic medicinal product Net Quantity: 80 Pillules	
Drug Facts **Active Ingredients:** Arnica montana 30 C HPUS Inactive ingredients: Lactose, Sucrose	
Directions Press base twice to release two pillules into cap. Unscrew cap. Tip pillules directly from cap into mouth without touching them. Pillules should be either chewed or placed under the tongue until dissolved and taken between meals.	
Uses Temporarily relieves muscle pain and stiffness due to minor injuries, overexertion and falls Reduces pain, swelling and discoloration from bruises	
Warnings Ask a doctor before use in children under 2 years of age. Stop use and ask a doctor if condition persists for more than 3 days or worsens. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.	
1234567890 XYZ homeocare limited.	

HOMEOPATHIC DRUG REGULATION IN EUROPRE

Definition:

Homeopathic medicinalproducts: medicinal products are any medicinal product made from drug called homeopathic medicinal products according to homeopathic procedure stated in European pharmacopoeia or in absence thereof, currently used pharmacopoeia in official member states. A number of principles applied to homeopathic medicinal products.

Marketing Condition of Homeopathic Drugs in Europe:

Homeopathic medicinal products are regulated by Directive 2001/83/EC which gives special provision applies to homeopathic medicinal product.

Homeopathic medicinal are marketed by two procedures are as follows:

1. Simplified registration procedure
2. Marketing authorization procedure

1. Simplified Registration Procedure:

Formulation of oral or external use which does not requires therapeutic indication on label and formulation available in 1:10000 dilution of mother tincture are stated in article 14 of Directive 2001/83/EC. Proof of therapeutic efficacy does not require.

Quality safety of source materials, standard homeopathic medicinal product is framed by regulation and guidelines of GMP Directive 2003/94/EC.

Criteria of homeopathic medicinal products according to article 14 of Directive 2001/83/EC for simplified registration process:

1. They are administered orally
2. Therapeutic indication does not appear on label of medicinal product
3. Sufficient degree of dilution for safety of homeopathic medicinal product does not contain greater than 1 part per 10000 of mother tincture.

Article 14 states proof of therapeutic efficacy shall not require for homeopathic medicinal products.

Time for assessment:

Directive 2001/83/EC article 17(1) member state should take proper steps to ensure the procedure of granting an authorization to place a medicinal product on market is completed within 210 days of submission of a valid application.

Validity of license:

According to article 24, authorization shall be valid for 5 years and shall be renewable for five year periods, on application by holder at least 3 months before the expiry date and after consideration in particular by details of data on Pharmacovigilance and other information relevant to monitoring of medicinal product.

Refusal of registration:

Article 26 marketing authorization shall be refused if, after verification of particulars and documents listed in article 8 and 10(1) proves that:

1. Medicinal product is harmful in normal condition of use
2. That its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant
3. That its qualitative and quantitative composition is not as declared

Suspension or cancellation of registration:

According to article 116 an authorization shall be suspended or revoked where particulars supporting the application as provided are incorrect or have not been amend in accordance with article 23.

Documents are required for Special Simplified Registration Process attached in with application specified in article 15:

1. Scientific name or other name given in pharmacopoeia of homeopathic stock, with a statement of various route of administration, pharmaceutical forms and degrees of dilution to be registered.
2. Dossier states homeopathic stock is/are obtained and controlled which justifies homeopathic nature.
3. Manufacturing and control file for each pharmaceutical form and a description of dilution and potentization.
4. Manufacturing authorization of medicinal product concerned.
5. Copies of any registration or authorization obtained for same medicinal product in other member states.

6. One or more specifications or mock-ups of outer packaging and immediate packaging of medicinal products to be registered.
7. Data concerning the stability of medicinal product.

Special, simplified registration procedure requires module 1 to 4, it does not require data of clinical trials.

2. Marketing Authorization Procedure for Homeopathic Medicinal Product:

Article 16 of Directive 2001/83/EC states that homeopathic medicinal product excluding to in article 14(1) shall be employed marketing authorization procedure.

All other homeopathic medicinal product that the meet the requirements for eligibility of simplified registration procedure, are less attenuated that 1:10000 and not useful for oral or external use and which are marketed for a particular indication as self care product covered in article 16 of Directive 2001/83/EC are subject to marketing authorization application.

A concerned member state required to produce toxicological and pharmacological test and clinical trials of homeopathic medicinal products according to principles and characteristics of homeopathy.

Marketing authorization procedure:

- According article 8 to obtain an authorization to place a medicinal product on marketing application shall be made to competent authority.
- A marketing authorization granted to applicant of community.
- Application shall contains following documents:
  (a) Name or address of applicant or manufacturer
  (b) Name of medicinal product
  (c) Qualitative and quantitative particulars of medicinal product in usual terms without empirical formulae, mention International proprietary name
  (d) Description of manufacturing method
  (e) Therapeutic indication, contraindication and adverse reaction
  (f) Pharmaceutical form and route of administration
  (g) Safety precaution of storage administration, disposal of waste product
  (h) Description of control methods used by manufacturer
  (i) Results of: Physicochemical, biological or microbiological tests, Toxicological and pharmacological test, Clinical trials
  (j) Summary of product characteristics, package leaflet
  (k) Documents showing that manufacturer authorization is in his own country to produce medicinal products
  (l) Copies of any authorization obtained another member state

According to article 11 Summary of product characteristics contains following information:

1. Name of medicinal products
2. Qualitative and quantitative composition terms of active substance and constituent of excipient
3. Pharmaceutical form
4. Pharmacological properties
5. Name or corporate name and permanent address of marketing authorization holder
6. Pharmacological particular
   (a) Major incompatibilities
   (b) Shelf life after reconstitution of medicinal product
   (c) Special precaution
   (d) Nature and content of immediate packaging
   (e) Special precaution for disposal of unused medicinal product or waste derived from medicinal product.
7. Clinical particulars
   (a) Therapeutic indication

(b) Contraindication
(c) Adverse reaction
(d) Special precaution
(e) Use during pregnancy and lactation
(f) Interaction with other medication and forms of interaction
(g) Posology and method of administration of adults
(h) Overdose
(i) Special warnings
(j) Effect on ability to drive

According to article 23, after an authorization issued, holder must shows the method of manufacture and control takes account of scientific and technical progress.

Time for assessment:
Procedure for granting an authorization to place a medicinal product on market is completed within 210 days.

Validity of authorization:
According to article 24 authorizations is valid for 5 years and renewed within 5 years at least before expiry date.

Table-1: Difference between simplified registration and marketing authorization procedure:

Parameters	Simplified registration	Marketing authorization
Dosage form	Oral or external	All products are applicable
Potency of homeopathic dilution	10000 dilution	All dilutions are applicable
Documentation required	Modules 1 to 4 Pharmacological-toxicological required	Modules 1 to 4 Pharmacological-toxicological required
Clinical documentation	Not applicable	Applicable Module 5 CTD

Dossier Requirements For Homeopathic Drug As Per Europe:

For Special Simplified Registration procedure of Homeopathic medication, dossier necessities contains Module-1 to Module-4, it doesn't require verification of adequacy (Module-5) so clinical documentation is not required.

For Marketing Authorization of homeopathic medication all dossier prerequisite is essential from Module-1 to Module-5.

Labelling guidelines of homeopathic drug in Europe:

1. Name and address of registration holder or manufacture
2. Route and method of administration
3. Expiry date(month, year)
4. Pharmaceutical form
5. Content of sales present
6. Special storage condition
7. Special warning
8. Manufacturing batch number
9. Registration number
10. Homeopathic medicinal product without approved therapeutic use
11. A warning advising user to consult doctor if symptom persist

Label of Homeopathic dosage (Pills) as per Europe Guidelines:

Thuja 30 C Pillules A Homeopathic medicinal product **Net Quantity: 94 Pillules**
Drug Facts **Active Ingredients: Thuja occidentalis** **Inactive ingredients: Lactose, Sucrose**
Directions At onset of symptoms turn upside down and twist clear cap until 3 to 5 pellets fall. Allow pellets to dissolve in mouth. Repeat 3 times a day until relieved or as directed by a physician.
Method of Administration: Oral
Uses Stimulating immune function, Bronchitis, Pneumonia, Skin infections, Nerve pain, Strep throat, Abortions, Arthritis.
Warnings Pregnancy and breast-feeding: It's likely unsafe to take thuja by mouth if you are pregnant. Thuja might cause a miscarriage. It is also likely unsafe to take thuja by mouth if you are breast-feeding because of possible toxicity. Stay on the safe side and avoid use.
Storage: 28-37° C, Well closed container
XYZ homeocare limited. / **Mfg Date: February 2016** **Expiry date: February 2017**

HOMEOPATHIC DRUG REGULATION IN INDIA

Definition

Homeopathic medicines: Homeopathic medicines include any drug which is stated in homeopathic proving, therapeutic efficacy of which has been obtained by long clinical experience are stated in authoritative homeopathic literature of India and abroad and which is formed according to method of homeopathic pharmacy and include combination of ingredients of such homeopathic medicine but does not include a medicine which is administered by parenteral route.

The National Institute of Homeopathy (NIH) was set up on 10 December 1975 in Kolkata as a self-governing association under the Ministry of Health and Family Welfare, Government of India. The Institute has been putting forth Degree courses in Homeopathy since 1987 and Postgraduate courses subsequent to 1998-99. The NIH was partnered to the University of Calcutta up to 2003-04 and is associated toward the West Bengal University of Health Sciences from 2004-05 onwards The NIH likewise directs standard Orientation Training courses for Teachers and Physicians.

Central Council for Research in Homeopathy (CCRH) was built up as an independent association in 1978, under the Dept. of AYUSH, Ministry of Health and Family Welfare, and Govt. of India. Basically an examination body, CCRH has a multi-dimensional way to deal with exploration and its changed exploration exercises incorporate 'Study, gathering and development of restorative plants', 'Medication institutionalization', 'Medication demonstrating', 'Clinical confirmation' and 'Clinical examination'. Furthermore, CCRH additionally works together with other exploration bodies for examines and screens extramural looks into. To meet its target of result-situated exploration, CCRH seeks after different clinical studies on various conditions or illnesses. These assorted exercises have taken CCRH to the rudder of undertakings of homeopathic examination and the Council has started to get acknowledgment from all sides. CCRH endeavors to continue running with its endeavors of redesigning the art of Homeopathy, through a down to business and normal methodology and to take Homeopathy to more up to date statures.

MARKETING CONDITIONS OF HOMEOPATHIC DRUGS UNDER D AND C ACT 1940:

Sale of homeopathic drug:

A (1) The license authority appointed by state government purpose specified in this part.

(2) The license to sale stock or exhibit or distribute an application made in form 19-B by licensing authority with a fee of rupees two hundred fifty within six month of expiry of license additional two hundred fifty is required for renewal of license.

(3) If original license is defaced, damaged or loss a duplicate copy is issued with fee of rupees fifty only.

B State government approve and licensing authority approves in writing to give power to sign to any other person.

C Forms of license to sale drugs: Form 20-B or 20-D is required to sale or stock or offer or distributes homeopathic medicines.

D Sale at more than one place: A separate license is issued by separate application sold, stocked a drugs at more than one place.

E Duration of licence: An original license or renewed license is valid for:

i) License is granted or renewed for a period of 5 years.

ii Application for renewal of license before the expiry of license within six months with additional fee payment , the license is continued until the order passed.

EE certificate of renewal: The certificate of renewal of sale license in forms 20-C and 20-D shall be issued in form 20-E.

F Condition to be satisfied before a license form 20-C or form 20-D is granted:

1) To sale or stock or exhibit or offered for sale or distribute of homeopathic medicines only granted to any person if all the requirements of factory premises and plant meets the requirement under this act occurs in form 20-C or 20-D.

2) Any person who is aggrieved by order passed by license authority under subrule(1) may within thirty days from date of receipt of such an order appeal to the state government.

G Condition of License: License in form 20-C or 20-D shall be subject to conditions as follow:

1) Maintain clean condition of premises of homeopathic medicines that are stocked or sold.

2) Homeopathic medicines are sale under the supervision of a person.

3) The license holder allows an investigator to audit the premises and formulate a record under the provision of this act.

4) The license in form 20-D maintain records of purchase and sale of homeopathic medicines consisting of alcohol along with names and address of parties to when sold

5) The license in form 20-C maintains records and purchases and sale of homeopathic medicines consisting of alcohol. No records of sale in respect of homeopathic potentized preparation in 30 ml contain upto 60 ml capacity.

6) The license holder shall maintain an audit book in form 35.

GG Additional information to be furnished by an applicant for license or a licensee to the licensing authority:

The application for grant of license or any person granted a license under this part shall on demand furnished to the licensing authority before the grant of license or during the period of license in force as the case may be documentary evidence in respect of ownership or occupation or rental or other basis of premises specified in

application for license or in license granted, constitution of firm, or other relevant matter, which may be required for purpose of verifying the correctness of statements made by applicant or the license, applying for or after obtaining the license as the case may be.

H Cancellation or suspension of license:

1) The licensing authority may after providing licensee an opportunity to give reason for such an order not be passed by an order in writing stating the cause, reject a license given in this part, if the license holder failed to comply with any of the condition of license or with any provisions of act or rules made there under:

a) Act was not investigated or connived by his or licensee is a firm comply by a partner of firm or a director of company.

b) that he or his agent or employee had not been guilty of any similar act or omission in twelve months before the date on which act or omission in or where his agent or employee of any act or omission, licence had , knowledge of that previous act.

c) If the act was continuing act he had not or could not reasonably have had knowledge of previous act.

d) that he had employed due diligence to ensure that condition of the license or provision of act.

2) A license holder whose license has been suspended or cancelled may within three months of order under subrule(1), prefer an appeal against that order to the state government which shall decide the same.

Labelling of homeopathic drug as per India:

A) The subsequent particulars should be available on innermost label of container of any homeopathic drug:

1. The designation "Homeopathic medicine"
2. Name of medicine or drug specified in Homeopathic Pharmacopoeia United State (HPUS) or German Homeopathic Pharmacopoeia or Homeopathic Pharmacopoeia of India.
3. Descriptive nature of drug.
4. Decimal or centesimal or millesimal potency of homeopathic medicine.
5. For combination product, potency of each ingredient is expressed.
6. Name and address of manufacturer when sold in original container of manufacturer.
7. Homeopathic medicine containing alcohol (ethanol), its percentage should be expressed in terms of potency from 30 ml to 60 ml.

B) Homeopathic mother tincture contains following labelling requirements:

1. Batch number, reference number, information about manufacturer, lot number can also be used.
2. Manufacturing licence number or Mfg lic. No, or "M.L"

C) Proprietary name is not required for single ingredient homeopathic medicine:

No homeopathic medicine consists of 12% alcohol (ethanol) should be packed and sold in packing bottles of greater than 30 ml and for hospital or dispensaries or bottles of not more than 100 ml.

Label of Homeopathic dosage (Pills) form as per India Guidelines:

<table>
<tr><td colspan="2">Digitalis purpurea 200 C Pills
Homoeopathic medicine
Palpation and related Dyspnea</td></tr>
<tr><td>Active Ingredients
Digitalis purpurea 200 C
Inactive ingredients
Lactose, Sucrose

Direction
Adult or child:
Take three pills daily. Leaving a gap of 30 minutes after any food or as advised by your physician</td><td>Uses
Palpation and related Dyspnea

Manufactured by:

1234567890
XYZ Homeocare ltd, India</td></tr>
</table>

Table-2: Comparison of Regulation of Homeopathic Drug in US, Europe and India:

PARAMETER	US	EUROPE	INDIA
Definition	Homeopathic drug: The drug which is listed and monographed in Homeopathic Pharmacopoeia of United States (HPUS), and to its addendum or supplements. The potency of homeopathic drugs is specified in dilution pattern like 1X, 2X, etc. Homeopathic drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are nit homeopathic drug products.	Homeopathic medicinalproducts: medicinal products are any medicinal product made from drug called homeopathic medicinal products according to homeopathic procedure stated in European pharmacopoeia or in absence thereof, currently used pharmacopoeia in official member states. A number of principles applied to homeopathic medicinal products.	Homeopathic medicines: Homeopathic medicines include any drug which is stated in homeopathic proving, therapeutic efficacy of which has been obtained by long clinical experience are stated in authoritative homeopathic literature of India and abroad and which is formed according to method of homeopathic pharmacy and include combination of ingredients of such homeopathic medicine but does not include a medicine which is administered by parenteral route.
Regulatory authority	HPCUS: Pharmacopoeia review committee, Monograph review committee	European Commission Directive 2001/83/EC	Drug and Cosmetic act Licensing authority
procedure for granting an monograph approval/authorization takes	90 days	210 days	NA
Duration of license	NA	valid for five years	period of five years
Monograph approval/ registration process	Monograph approval process	Registration Process	Registration Process
Monograph approval/ registration authority	HPCUS monograph review committee (MRC) pharmacopeia revision committee (PRC)	Directive 2001-83-EC European Commission	Drug and Cosmetic Act authority State Government of India Licensing Authority

Labelling requirements country wise	US	Europe	India
Name and address of manufacturer	Yes	Yes	Yes
Statement of Ingredients	Yes	Yes	Yes
Established Name	Yes	Yes	Yes
Container Size	Yes	NA	NA
Declaration of Net Quantity of Contents	Yes	Yes	NA
Indications for Use	Yes	Yes	NA
Warning	Yes	Yes	NA
Expiry date, in clear terms (month, year)	NA	Yes	NA
Special storage precautions	NA	Yes	NA
Manufacturer's batch number	NA	Yes	Yes
Registration number	NA	Yes	Na

CONCLUSION

This research article provides idea regarding newdrug approval or registration regulation of homeopathic drug in US, Europe and India about requirements to be incorporated by the manufacturer to get registered. There are basic similarities in the regulation of labeling and packaging which directs the harmonization and collaboration homeopathic drugs regulatory requirements by the manufacturer. The study of homeopathic drug regulation in US, Europe and India provide us the good knowledge, understanding and unexplored the regulatory requirements of homeopathic drug.This can be helpful to implement new policies for the proper regulation of homeopathic drug. Comparison of regulation of homeopathic drug provides various regulatory requirements in different countries. This shows the benefits and loss of different techniques and the change to be need in homeopathic drug regulation can be known.Apart from these differences and from the comparative data sheet, it can be concluded that on the basis of approval and registration procedures, labeling and packaging regulation, the homeopathic drug regulation is well developed in Europe and India than in US.

ACKNOWLEDGEMENT

I am thankful to Dr. K. Pundarikakshudu, Director of L. J. Institute of Pharmacy, Ahmedabad, India; for providing the best facility in the institute for the preparation of this manuscript.

REFERENCES

1. Alan V Schmukler, "What is Homeopathy? Definition and Details. A brief introduction to homeopathy", November 2009.
2. Dictionary Homeopathy, "Full Definition of Homeopathy", Merriam-Webster, Incorporated, 2015.
3. Natural Relief, "What is homeopathy?", Hylands, 1903.
4. Borneman J and Field R, "Regulation of homeopathic drug products", *Am. J. Health-Syst. Pharm*, **2006,** 63, 86-91.
5. U. S. Food and Drug Administration, "CPG Sec. 400.400 Conditions under Which Homeopathic Drugs May be Marketed", March 2015.
6. An Overview of the Regulation of Homeopathic Drug Products in the United States "Homoeopathic Pharmacopoeia Convention of the United States (HPCUS) Procedure Manual", April 2010.
7. REVISED DRAFT HPUS Labeling Guidelines.
8. Directive 2001/83/EC of The European Parliament and of the Council", November 2001.
9. ECHAMP, "The implementation status of Article 16 of Directive 2001/83/EC", May 2008.
10. European Commission, "Presentation and content of the dossier-Part 1 Summary of the dossier Part 1A", VOLUME 2B, December 2005.
11. Homeopathic Medicinal Product Working Group, "Guidance on Module 3 of the Homeopathic Medicinal Products Dossier", 2005.
12. Commission Directive 2003/63/EC, June 2003.
13. Medicines Evaluation Board, "Assessments Report Smpc, Package Leaflets, and Labelling", 2010.
14. Mudaliar M, "Authorization of Homeopathic Medicinal Product in Europe: An Overview", *AJPTI***, 2013,** 1(2), 10-20.
15. Singh P, "Status of Homeopathic Medicines in Drugs and Cosmetic Act, 1940 and Rules**,** 1975"**,**HJ 200*9.*
16. "Drugs and Cosmetics Rules, 1945", November, 2004.
17. Tiwari L, Rai N, Sharma R, "Regulatory Standards on Homoeopathic Drugs: Indian Perspective", IJAPST,2013; 1(1), 1-20.
18. Central Council of Homoeopathy, A Statutory Body Under The Ministry of AYUSH, Govt. of India, 2013.
19. Central Council for Research in Homoeopathy (CCRH), (ISO 9001:2008 Certified), Ministry of AYUSH, Govt. of India, 2011.