Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj. Kami : (5) dlm. BPFK/PPP/01/03 Jilid 1
Tarikh : 14 DEC 2010

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984 (PINDAAN 2006)
ARAHAN PENGARAH KANAN PERKHIDMATAN FARMASI BILANGAN 9 TAHUN 2010:
GARISPANDUAN PENDAFTARAN PRODUK HOMEOPATI

Adalah saya merujuk kepada Arahan Bilangan 9 tahun 2010 oleh Pengarah Kanan Perkhidmatan Farmasi.

2. Dimaklumkan bahawa Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia dalam Arahan Bilangan 9 Tahun 2010 telah mengarahkan pelaksanaan Garispanduan Pendaftaran Produk Homeopati seperti pada surat arahan Bil. (5) BPFK/PPP/01/03 Jilid 1 (Lampiran 1).

3. Pihak pemegang pendaftaran adalah diarahkan untuk mematuhi keperluan tersebut.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(SELVARAJA SEERANGAM)
Pengarah Regulatori Farmasi
Biro Pengawalan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

s.k. Pengarah Bahagian Amalan dan Perkembangan Farmasi, BPF
Pengarah Penguatkuasa Farmasi, BPF
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BPFK/PPP/01/03(5)Jilid 1

ARAHAN DI BAWAH PERATURAN 29 PERATURAN – PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

BILANGAN _9_ TAHUN 2010

GARISPANDUAN PENDAFTARAN PRODUK HOMEOPATI

TUJUAN

1.1 Arahan ini bertujuan memaklumkan pelaksanaan garispanduan pendaftaran produk homeopati di Malaysia.

1.2 Peraturan 29 Peraturan – Peraturan Kawalan Dadah dan Kosmetik 1984 (Pindaan 2006) memberi kuasa kepada Pengarah Perkhidmatan Farmasi untuk mengeluarkan arahan ini.

LATAR BELAKANG

2.1 Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuaratnya kali ke **233** pada 28 Oktober 2010 telah memutuskan untuk menerima pakai Dokumen Garispanduan Pendaftaran Produk Homeopati di Malaysia. (Sila rujuk Lampiran 1)

2.2 Garis panduan yang komprehensif ini adalah hasil dari usahasama Majlis Perubatan Homeopati Malaysia (MPHM) dan Bahagian Perubatan Tradisional dan Komplementeri, Kesihatan Malaysia yang menepati keperluan antarabangsa dari segi kualiti, efikasi dan keselamatan produk. Ia merupakan garispanduan tambahan bagi pendaftaran produk homeopati. Keperluan – keperluan lain pendaftaran turut dinyatakan di dalam *Drug Registration Guidance Document (DRGD)*, Malaysia.

PELAKSANAAN

3. Oleh itu arahan – arahan berikut dikeluarkan :-

3.1 Arahan ini berkuatkuasa **mulai dari tarikh pekeliling ini** dan merangkumi semua permohonan pendaftaran produk baru dan produk yang sedang dalam proses penilaian.

TARIKH KUAT KUASA

4. Tarikh kuat kuasa arahan ini ialah mulai 14 DEC 2010

"BERKHIDMAT UNTUK NEGARA"

(DATO' EISAH A. RAHMAN)
Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia.

s.k:

Pengarah Amalan Perkembangan Farmasi
Pengarah Penguatkuasa Farmasi
Pengarah Regulatori Farmasi

LAMPIRAN 1

GENERAL GUIDELINES

FOR THE REGISTRATION OF HOMEOPATHIC PRODUCTS

National Pharmaceutical Control Bureau,
Ministry Of Health Malaysia.
October 2010

Acknowledgements

The National Pharmaceutical Control Bureau acknowledges its indebtedness to the Malaysian Homeopathic Medical Council and the Traditional & Complementary Medicine Division, Ministry of Health who provided comments and advice during the preparation of these guidelines.

Contents

1. ABOUT THIS GUIDELINE

This document serves as an additional reference on the requirements for the registration of homeopathic products. Other aspects of registration requirements are covered in the Drug Registration Guidance Document. Applicants for product registration are also requested to refer to the latest edition on the Guidelines of Good Manufacturing Practices (GMP) for Traditional Medicines.

2. INTRODUCTION

Regulation 7(1)(a) of the Control of Drugs and Cosmetics Regulations 1984 requires all products to be registered with the DCA prior to being manufactured, sold, supplied, imported or possessed for sale, unless the product is exempted under the specific provisions of the regulations

"Homeopathic medicine" means any pharmaceutical dosage form used in the homeopathic therapeutic in which diseases are treated by the use of minute amounts of such substances which are capable of producing in healthy persons symptoms similar to those of the disease being treated. (*Control of Drugs and Cosmetics Regulations 1984)*

Applicants are reminded that it is their responsibility to ensure that their products comply with these regulations and also other related legislations namely:

(i) Sale of Drugs Act 1952

(ii) Dangerous Drugs Act 1952

(iii) Poisons Act 1952

(iv) Medicines (Advertisement & Sale) Act 1956

(v) Wildlife Protection Act 1972

3. EXEMPTION

All homeopathic products are registrable under the *Control of Drugs and Cosmetics Regulations 1984*. Exemption to this are:

i) single homeopathic dilution

ii) Extemporaneous preparation for an individual patient by a registered/ licensed homeopathic practitioner

iii) All Mother Tinctures which are not listed in Appendix 1 and Appendix 2

4. PREPARATION NOT CONSIDERED BY DCA FOR REGISTRATION

The DCA will only register homeopathic products used for oral administration or external application only. The following dosage forms will not be considered for registration.

i) Sterile preparations such as eye-drops and injectables,

ii) Suppositories and vaginal tablets.

iii) Transdermal patch.

iv) Sublingual preparations.

v) Preparation in combination with non-homeopathic active ingredient such as vitamins, minerals and herbs.

vi) Preparations containing substance listed in the Poison List.

5. INGREDIENTS

Homeopathic products are prepared from natural or synthetic sources that are referenced in pharmacopoeia monographs or other recognized documents. Not considering imponderable, the source materials for homeopathic medicines may consist of the following:

- plant material such as: roots, stems, leaves, flowers, bark, pollen, lichen, moss, ferns and algae;
- microorganisms such as: fungi, and plant parasites;
- animal materials such as: whole animals, animal organs, tissues, secretions;
- Minerals and chemicals.

For each medicinal ingredient, a copy of the monograph from the pharmacopoeia to which the applicant attests must be provided. Also for homeopathic medicines with a specific claim, it must be supported by the some level of evidence as for traditional products.

Products containing a combination of homeopathic and non-homeopathic medicinal ingredient will not be evaluated as homeopathic product.

5.1. **Positive List**

5.1.1 Homeopathic medicinal ingredients are allowed in single or multi ingredient in homeopathic products and documented in a monograph as a homeopathic medicinal ingredient as stated in the current edition of Homeopathic Pharmacopoeias recognized by the DCA listed in Appendix 3.

5.1.2 Homeopathic products of the above category, containing homeopathic medicinal ingredients as in Appendix 1 are allowed to be registered when the homeopathic medicinal ingredients used in their products are more than 2C or 4X.

5.2. **Negative list**

Homeopathic products containing single or multiple ingredients in Appendix 2 and 4 will not be registered by DCA.

5.3 **Limit of Homeopathic Ingredients in Multi Ingredient Homeopathic Products**

Homeopathic Products are allowed to contain maximum 4 (four) Mother Tinctures not being listed in Appendix 1 and 2 products.

6. QUALITY

A certificate of analysis (CoA) must be provided as proof on the dilution used.

7. GOOD MANUFACTURING PRACTICE

The requirements for Good Manufacturing Practice of the premises as outlined in the Guidelines on Good Manufacturing Practice (GMP) for Traditional Medicines apply to all homeopathic products.

8. LABELLING

The labeling of homeopathic products is the same as for traditional products in DRGD with the following additional requirements:

On the label of this homeopathic product:

i) The word 'homeopathic product', 'homeopathic medicine', 'homeopathic preparation', 'homeopathic remedy' (either one) – must

appear on the innermost label of the container.

ii) The scientific name or common name of the active ingredient.
iii) Potency and type of scale use.
iv) Declare the percentage of alcohol contained in the product.

9. INDICATIONS FOR USE

Indications allowed for homeopathic product is the same as those allowed for traditional products in the DRGD.

Recommended use or indications for specific claims must be supported by evidence for the multi ingredient homeopathic products.

No indication will be allowed for single homeopathic product. No indications are also allowed for mother tinctures.

Appendix 1

List of "Single Homeopathic Dilution (2C or 4X or 1:10000)" exempted from the Poisons List.

No.	Ingredient
1	Aconite
2	Belladonna
3	Physostigmine
4	Colchinine
5	Coniine
6	Curare
7	Ephedra
8	Ergot
9	Gelsemium
10	Hyoscine
11	Jaborandi
12	Lobelia Inflata
13	Nicotine
14	Nux Vomica
15	Piper Methysticum (Kava-kava)
16	Quebracho
17	Rauwolfia
18	Sabadilla
19	Stavesacre
20	Veratrum
21	Vinca
22	Yohimba
23	Amyl nitrite
24	Antimony
25	Apomorphine
26	Arsenic
27	Barium
28	Bismuth
29	Boric Acid
30	Caffeine
31	Cantharidin
32	Creosote
33	Digitalis
34	Hydrogen Cyanide
35	Iodine
36	Lead Acetate

37	Mercury
38	Morphine
39	Phosphorus
40	Picric Acid
41	Quinine
42	Radium
43	Santonin
44	Thallium
45	Sparteine
46	Strophanthus

Appendix 2

NEGATIVE LIST

1.1. Mother tincture of Narcotics

Homeopathic Products
Cannabis
Cocainum
Cocainum muriaticum
Coca leaves
Narceinum
Opium

1.2 Mother tincture of Radiopharmaceuticals
Uranium
X-ray

1.3 Mother tincture of Animal materials: Nosodes, toxins and blood products
1.4 Mother tincture of human or human organ
1.5 Mother tincture of Bacteria
1.6 Mother tincture of Viruses

Appendix 3

HOMEOPATHIC PHARMACOPOEIA FROM THE FOLLOWING COUNTRIES WILL BE ACCEPTED AS REFERENCES

1. Germany (GHP)
2. Britain
3. France (Phf)
4. USA (HPUS)
5. Pakistan
6. India (HPI)
7. European Pharmacopoeia

Appendix 4

List of endangered animal species/ protected wildlife as listed in the Wildlife Protection Act.

[These lists are not exhaustive and will be amended from time to time as and when the need arises]

GLOSSARY

Active substance: Active substances are considered to be source materials processed by one or a sequence of homeopathic manufacturing procedures listed in pharmacopoeias in official use and other officially recognized documents (e.g. mother tinctures, dilutions or triturations).

Diluents: Substance used for the preparation of a stock/starting material or the potentization process and which may also represent the substance of the dosage form. Liquid diluents usually consist of purified water, aqueous solution, glycerol or ethanol of a suitable concentration or for which there is an appropriate monograph. The commonest solid diluent is usually lactose monohydrate.

Dilution: Dilution has two meanings in homeopathy:
- For a product, a dilution is a liquid homeopathic preparation which is potentized as described below (see the definition of potentization). Individual dilutions are also called potencies;
- As a procedure, dilution means the de-concentration process of a liquid or a solid preparation. One part of each stage in the preparation of a homeopathic medicine from its stock or previous dilution (potency) by adding one part of a previous solid or liquid phase to a predetermined weight or volume of the diluent (see Potentization below). Dilution occurs at all stages of production of the homeopathic medicines whether by addition of solid excipients in triturating or the addition of diluent in the liquid phase and succession.

Dosage form: a dosage form in homeopathy complies with any relevant specifications for that dosage form for which an appropriate characterization exists in a pharmacopoeia in official use, or in other officially recognized documents. The most commonly encountered homeopathic dosage form, *the globule (pillule or pellet)*, is a solid spherule which consists of lactose, sucrose or any other suitable vehicle. Usually, preformed globules are impregnated with a dilution or directly by a mother tincture. The homeopathic dosage form *tablet* is a solid preparation which complies with any relevant characterization in the pharmacopoeia in official use (or in other officially recognized documents) for tablets. Homeopathic medicines in tablet form are either prepared by impregnation of preformed tablets or by compression of triturations with the vehicle. The most commonly used *liquid homeopathic medicines* are either alcoholic solutions or oral liquids.

Excipient: Substance needed for manufacturing a dosage form (used after potentization) such as wheat starch and magnesium stearate for tablets. It may also represent the substance of the dosage form.

Homeopath: A qualified provider (practitioner) of homeopathic treatment.

Homeopathic medicines: Any medicine prepared in accordance with a homeopathic manufacturing procedure described by a pharmacopoeia in official use or other officially recognized documents. A homeopathic medicine may contain a number of homeopathic preparations.[1]

Homeopathy: Classical homeopathy is a system of medicine using preparations of substances whose effects, when administered to healthy subjects, correspond to the manifestations of the disorder in the individual patients (see also section 3.1.1).[1]

Mother tincture (also called tincture): The initial homeopathic preparation made from source material that can be further potentized (also called "liquid stock"), sometimes used as homeopathic medicines, is regarded as the most concentrated form of a finished homeopathic medicine. Mother tinctures are obtained classically by maceration or percolation (sometimes also by digestion, infusion, decoction or fermentation) techniques from source materials according to a procedure prescribed by a recognized homeopathic pharmacopoeia. Sometimes a mother tincture corresponds to the first decimal dilution, "1D" or "1X" (10-1), mostly when dry plant material is used as starting material.

Nosodes: Homeopathic medicines prepared from disease products from humans or animals; from pathogenic organisms or their metabolic products; or from decomposition products of animal organs.

Potency: The denominated degree of serial trituration or dilution and succession that is reached for each homeopathic medicine. The degrees of dilution or potencies are normally indicated by the letters D, DH or X for successive 1 to 10 (decimal) dilutions, the letters C, CH or K or CK for successive 1 to 100 (centesimal) dilutions while Q or LM denote successive 1 to 50 000 (Hahnemannian quinquagintamillesimal) dilutions. Dilution by 1 to 10 denotes 1 part processed with 9 parts of diluent (Hahnemannian decimal), dilution by 1 to 100, 1 part processed with 99 parts (Hahnemannian or Korsakovian centesimal), and so on. The number preceding the letters (e.g. D, C or LM) normally indicates the number of dilution steps employed (Table 1).

As a consequence of different views in various approaches in homeotherapy and because the notion of these terms may depend on the nature of the starting materials, the terms "high potency" and "low potency" cannot be defined unambiguously.

Potentization (also called dinamization): The combined process of serial dilution and succussion or trituration at each step in the manufacture of homeopathic medicines from stocks. (According to the tenet of homeopathy, potentization represents the process by which the activity of a homeopathic medicine is developed.)

Table 1. Potency table

Dilution ratio	*Common designation(s)*	*Examples*
1:10[a]	X	1X, 2X, 3X, etc.
1:10[a]	D	D1, D2, D3, etc.
1:10[a]	DH	DH1, DH2, DH3, etc.
1:100[b]	C	1C, 2C, 3C, etc. C1, C2, C3, etc.
1:100[b]	CH	1CH, 2CH, 3CH, etc. CH1, CH2, CH3, etc.
1:100[b]	CK	1CK, 2CK, 3CK, etc. CK1, CK2, CK3, etc.
1:100[b]	K	1K, 2K, 3K, etc. K1, K2, K3, etc.
1:50 000[a]	LM	1LM, 2LM, 3LM, etc.
1:50 000[a]	Q	Q1, Q2, Q3, etc.

[a]For 1:10 and 1:50 000 dilution ratios only the Hahnemannian method of manufacture (multi-flask method) is used.
[b]For 1:100 dilution ratios a C potency is assumed to use the Hahnemannian method of manufacture (multi-flask method) and can also be denoted as CH. When the Korsakovian method of manufacture (single-flask method) is used, the potency is designated as CK or K.

Sarcodes: Homeopathic medicines made from healthy animal tissues or secretions. In Greek, sarcode means fleshly.

Source material (raw material, starting material, mother substance): Source material is the original raw material used for the production of

Homeopathic medicines. This material is obtained from natural sources, e.g. of botanical, zoological, microbiological, mineral, chemical, animal and human origin, or synthetic procedures. Source materials may undergo preliminary treatment in order to be further processed.

Stock: Substances or preparations made from the source materials (e.g. by maceration, succussion or trituration) used as starting points for the production of homeopathic medicines. [1]

References

1. *Safety Issues in the Preparation of Homeopathic Medicines,* World Health Organization, 2009.