APPENDIX 7A

HOMEOPATHIC PRODUCTS

The following guidance notes are published as First Edition in October 2010 and the latest revision is in October 2012.

This guidance notes serve 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 on Good Manufacturing Practice for Traditional Medicines and Health Supplements.

2nd Revision

Acknowledgements

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

Glossary for Homeopathic Products:

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).

Diluent: Substance used for the preparation of a stock/ starting material or the potentisation 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 potentised as described below (see the definition of potentisation). 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 Potentisation below). Dilution occurs at all stages of production of the homeopathic medicines whether by addition of solid excipient in trituration or the addition of diluent in the liquid phase and succussion.

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 potentisation) 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.

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.

Mother tincture (also called tincture): The initial homeopathic preparation made from source material that can be further potentised (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.

Potentisation (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, potentisation represents the process by which the activity of a homeopathic medicine is developed.)

Table I: 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.

Outline:

1. Introduction
2. Exemptions
3. Preparations not considered by the Authority for registration
4. Ingredients
5. Quality
6. Good Manufacturing Practice
7. Labelling
8. Indications for use

Attachments:

- Attachment 1: List of Exempted Single Homeopathic Potentised Dilutions
- Attachment 2: Negative List
- Attachment 3: List of Acceptable References
- Attachment 4: List of Endangered Animal Species/ Protected Wildlife

1. INTRODUCTION

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

Under Regulation 2, CDCR 1984, "**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. This would include preparations that are to be chewed, sucked, swallowed whole and applied topically.

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) Protection of Wildlife Act, 1972

2. EXEMPTION

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

i) single homeopathic potentised dilution;

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

iii) All Mother Tinctures;

iv) Unmedicated sugar globules and tablets.

3. PREPARATION NOT CONSIDERED BY THE AUTHORITY FOR REGISTRATION

The Authority will only register homeopathic products used for oral administration, nasal or mouth sprays and external application only. The following dosage forms will not be considered for registration.

- Sterile preparations such as eye-drops and injectables;
- Suppositories and vaginal tablets;
- Transdermal patch;
- Sublingual preparations;
- Preparation in combination with non-homeopathic active ingredient, such as vitamins, minerals and herbs.
- Preparations containing substance listed in the Poison List (except **Attachment 1**).

4. 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 same level of evidence as for traditional products.

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

4.1 POSITIVE LIST

Homeopathic medicinal ingredients are allowed as multi ingredient in homeopathic products and the active ingredient must be documented in a monograph as a homeopathic medicinal ingredient as stated in the current edition of Homeopathic Pharmacopoeias recognized by the Authority listed in **Attachment 3**.

Homeopathic products are allowed to be registered when the homeopathic medicinal ingredients used in their products are more than 2C or 4X.

4.2 NEGATIVE LIST

Homeopathic products containing single or multiple ingredients in **Attachment 2** and **Attachment 4** will not be registered by the Authority.

4.3 LIMIT OF HOMEOPATHIC INGREDIENTS IN MULTI INGREDIENT HOMEOPATHIC PRODUCTS

Homeopathic Products are allowed to contain a maximum of 12 potentised single homeopathic dilutions.

5. QUALITY

A certificate of analysis (CoA) for raw material potentised dilution and finished product must be provided as proof on the dilution used.

6. GOOD MANUFACTURING PRACTICE

The requirements for Good Manufacturing Practice of the premises as outlined in the Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements apply to all homeopathic products.

7. LABELLING

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

On the label of this homeopathic product:

a) The word 'homeopathic product', 'homeopathic medicine', 'homeopathic preparation', 'homeopathic remedy' (either one) - must appear on the innermost label of the container.
b) The scientific name or common name of the active ingredient.
c) Potency and type of scale use.
d) Declare the percentage of alcohol contained in the product.

8. 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 potentised dilution in the form of raw material and finished homeopathic product. No indications are also allowed for mother tinctures.

ATTACHMENTS

Attachment 1:

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

No.	Ingredient
1.	Aconite
2.	Amyl nitrite
3.	Antimony
4.	Apomorphine
5.	Arsenic
6.	Barium
7.	Belladonna
8.	Bismuth
9.	Boric Acid
10.	Caffeine
11.	Cantharidin
12.	Colchinine
13.	Coniine
14.	Creosote
15.	Curare
16.	Digitalis
17.	Ephedra
18.	Ergot
19.	Gelsemium
20.	Hydrogen Cyanide
21.	Hyoscine
22.	Iodine
23.	Jaborandi
24.	Lead Acetate
25.	Lobelia Inflata
26.	Mercury

No.	Ingredient
27.	Morphine
28.	Nicotine
29.	Nux Vomica
30.	Phosphorus
31.	Physostigmine
32.	Picric Acid
33.	Piper Methysticum (Kava-kava)
34.	Quebracho
35.	Quinine
36.	Radium
37.	Rauwolfia
38.	Sabadilla
39.	Santonin
40.	Sparteine
41.	Stavesacre
42.	Strophanthus
43.	Thallium
44.	Veratrum
45.	Vinca
46.	Yohimba

Attachment 2:

Negative List

NO.	SUBSTANCES
1.	**Mother tincture of Narcotics**
	Homeopathic Products
	Cannabis
	Cocainum
	Cocainum muriaticum
	Coca leaves
	Narceinum
	Opium
2.	**Mother tincture of Radiopharmaceuticals**
	Uranium
	X-ray
3.	**Mother tincture of Animal materials: Nosodes, toxins and blood products**
4.	**Mother tincture of human or human organ**
5.	**Mother tincture of Bacteria**
6.	**Mother tincture of Viruses**

Attachment 3:

Homeopathic Pharmacopoeia from the Following Countries Will Be Accepted as References

NO.	COUNTRIES
1.	Germany (GHP)
2.	Britain
3.	France (Phf)
4.	USA (HPUS)
5.	Pakistan
6.	India (HPI)
7.	European Pharmacopoeia

Attachment 4:

List of Endangered Animal Species/ Protected Wildlife

As listed in the Protection of Wildlife Act, 1972

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

REFERENCES

a) List of Ingredients Prohibited and Restricted in Pregnancy

1. Benchmarks for training in traditional Chinese medicine (WHO)
2. American Pregnancy Association
3. Natural Standards
4. Health Canada
5. TCM Discovery (Contraindication of Chinese Medicinal Herbs)
6. Motherlove Herbal Company (Herbs to avoid while Pregnant)
7. Green Earth Herbs (Herbs Contraindicated in Pregnancy)
8. Home. Caregroup.Org (Herbs during Pregnancy and Lactation)

b) Homeopathic Products:

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