



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



CONSULTATION PAPER

REGULATION OF HOMOEOPATHIC AND RELATED MEDICINES IN A JOINT AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AGENCY

CALL FOR COMMENT

December 2004

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INTRODUCTION

This paper invites comment from stakeholders on the regulatory arrangements for homoeopathic and related medicines in the joint Australia New Zealand therapeutic products agency (the joint Agency).

The Australian and New Zealand Governments have agreed to harmonise the regulatory arrangements for therapeutic goods between both countries. Under the joint Agency, products represented to be for therapeutic use are to be regulated as therapeutic products. This includes homoeopathic and related medicines and products containing homoeopathic preparations.

This current consultation process offers stakeholders the opportunity to identify matters that will need to be considered in the development of a risk-based approach to the regulation of these products. This consultation paper outlines the current regulatory system for homoeopathic medicines (see [Appendix 1](#)) and poses a number of questions in relation to issues that have been identified with this system.

The TGA and Medsafe encourage stakeholders to give consideration to the issues raised in this paper, as responses will be used to inform the development of a risk-based regulatory framework for homoeopathic and related medicines. Stakeholders are also invited to provide any other comment that will assist in the development of appropriate regulatory arrangements for these medicines. The resulting regulatory system must meet the needs of consumers, industry, health professionals and regulators, while contributing to the protection and enhancement of public health and safety in Australia and New Zealand.

The issue of the definition of a homoeopathic medicine is being considered separately as part of the Consultation Paper: *Proposed Regulatory Definitions for Complementary Medicines and Homoeopathic Medicines in a Joint Australia New Zealand Therapeutic Products Agency*. Stakeholders are invited to take the opportunity to comment on the proposed definition for 'homoeopathic medicine' via this alternate consultation route in order to retain context as a complementary medicine. However, for ease of reference, the rationale and the wording of the proposed definition are included in [Appendix 2](#).

HOW TO COMMENT ON THIS CONSULTATION PAPER

Submissions may be sent by post and/or email and, where possible, should be structured to address the specific questions posed in the consultation paper. In addition, stakeholders are encouraged to provide other comments that will assist in the development of appropriate regulatory arrangements for homoeopathic and related medicines.

Submissions should, where possible, contain relevant evidence, and/or examples, to support the views expressed.

The Australian Self-Medication Industry (ASMI), the Complementary Healthcare Council of Australia (CHC) and the New Zealand Self-Medication Industry (NZSMI) and have agreed to distribute the Consultation Paper: *Regulation of Homoeopathic and Related Medicines in a Joint Australia New Zealand Therapeutic Products Agency* and coordinate responses on behalf of their members in Australia and New Zealand. Members of ASMI, CHC and NZSMI are therefore invited to provide written comment to their respective organisations.

Other stakeholders are invited to provide written comment on the Consultation Paper: *Regulation of Homoeopathic and Related Medicines in a Joint Australia New Zealand Therapeutic Products Agency* directly to the postal and/or email address below.

Content of submissions

It would be helpful if your submission included:

- € your name and full contact details including: address, telephone number and, if applicable, facsimile and email address
- € the particular question being addressed (eg. Other Issues, Question 6.1)
- € information and data concerning the impact of proposed changes on affected parties
- € in the case of organisations; the level at which the submission was authorised.

In addition, submissions might:

- € include any other relevant information eg. scientific and technical, economic, international obligations, business and consumer information
- € identify and discuss any perceived omissions or alternative approaches, in addition to those already included in the consultation paper.

Confidentiality of submissions

If you wish any information contained in a submission to be treated as confidential, please clearly identify the information and outline the reasons why it is confidential.

Address for submissions

Electronic submissions should be emailed to

comp.medicines@jtaproject.com

Hard copy submissions should be addressed to

The Project Officer
Regulation Review Project
c/- Joint Agency Establishment Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT AUSTRALIA

Questions relating to submissions

Any questions relating to submissions should be directed to the Project Officer, by email at
comp.medicines@jtaproject.com

Deadline for submissions

The deadline for receipt of submissions is **close of business, Friday 11 March 2005.**

ISSUES TO BE CONSIDERED

In considering an appropriate level of regulation for homoeopathic and related medicines, it is essential that matters of definition, quality, safety and efficacy be considered.

The questions outlined below are not intended to be limiting, but rather a guide to the matters to be considered in the development of regulatory policy for such medicines. Please indicate the source of information/facts you provide in response to these questions, and other points you raise, for future reference, and for further research by the project team if necessary.

Note that it is not necessary to respond all questions. However, please be aware of the issues raised in these questions when considering your response to managing the safety, quality and efficacy of homoeopathic and related medicines.

Background information detailing the current regulation of homoeopathic medicines in Australia and New Zealand is included in [Appendix 1](#).

1. DEFINITIONS

Note: The issue of the definition of a homoeopathic medicine is being considered separately as part of the Consultation Paper: *Proposed Regulatory Definitions for Complementary Medicines and Homoeopathic Medicines in a Joint Australia New Zealand Therapeutic Products Agency*.

However, for context and ease of reference, the rationale and the wording of the proposed definition for homoeopathic medicine are included in [Appendix 2](#).

- 1.1 How should remedies similar to homoeopathic medicines, but not consistent with the homoeopathic paradigm, be defined? (These medicines will be referred to as 'related medicines' in this paper)

The definition(s) should ensure that the identified medicines are clearly differentiated from those that are consistent with the homoeopathic paradigm. Related medicines might include, for example, flower essences, gem essences, and other vibrational remedies. Please suggest appropriate definitions where applicable.

Issues for consideration

The definition of a homoeopathic medicine should ensure that it is clearly differentiated from those medicines inconsistent with the homoeopathic paradigm.

Consideration needs to be given to definitions for other remedies or medicines with similar, but not consistent, paradigms. As with homoeopathic medicines, these types of remedies, such as flower essences, gem essences, and other 'vibrational' remedies, are likely to be of low risk to the consumer. However it is essential that they be defined properly so that they may be managed where appropriate.

2. QUALITY

- 2.1 For regulatory purposes, what standards of quality should apply to homoeopathic and related medicines?

Consider the need for appropriate pharmacopoeial standards (if so, which ones), the need for manufacturers to be licensed and comply with the requirements of Good Manufacturing Practice (GMP) and any other standards, principles or guidelines that you believe should apply to these medicines.

Issues for consideration

Under the current Australian legislation, any homoeopathic preparation that is more dilute than a one thousand fold dilution of a mother tincture, and which is not required to be sterile, is exempt from the requirement to be manufactured under an Australia New Zealand recognised code of Good Manufacturing Practice (GMP).

This exemption means that there is effectively little regulatory control of homoeopathic preparations (or purported homoeopathic preparations) once a preparation has been potentised further than a 4X dilution of the stock (mother tincture etc). Considering that appropriate and accountable dilution and succussion is imperative to ensure the preparation of an authentic homoeopathic remedy, the lack of regulatory controls for these processes does not appear appropriate. Also, exemption from the requirements of GMP does not provide assurance that there are controls in place to ensure that hazardous homoeopathic starting materials are sufficiently attenuated to allow for safe use.

3. SAFETY

- 3.1 What factors affect the safety of homoeopathic and related medicines?

How should these factors be controlled to assure the safety of these medicines?

Issues for consideration

Consideration needs to be given to the factors that affect the safety of homoeopathic and related medicines, and how these factors should be controlled to assure the safety of these medicines.

The TGA considers homoeopathic medicines to be low risk, and this is currently reflected in the level of regulation applied to homoeopathic medicines in Australia. However, because most homoeopathic medicines are exempt from the requirement to be produced by a licensed manufacturer under a recognised code of GMP, assurance of quality (and associated safety) through compliance with recognised standards, cannot be assured (for example, manufacturing standards to control misidentification of starting materials, contamination and variability of ingredient potentisation) – see Quality above.

Further, as most homoeopathic medicines are not required to be included on the Australian Register of Therapeutic Goods (ARTG), they are not subject to the same level of post-market scrutiny that applies to other low risk medicines.

In general, risks associated with homoeopathic medicines may be direct and/or indirect.

Direct risks refer to direct toxic effects of the ingredients, or adverse effects associated with the use of the medicine. The latter may be associated with active ingredients, excipients, such as preservatives, or interaction with other medicines.

Examples of indirect risks in homoeopathy include delaying the use of more appropriate or effective treatment for a condition, either because of inappropriate prescribing or self-medication.

It is partly because of these and other potential risks, albeit small, that it may be appropriate to require that homoeopathic medicines be included on a database of therapeutic products prior to supply, and that they not be exempt from the requirement to be manufactured by holders of an appropriate licence.

4. EFFICACY

Issues relating to the levels and types of evidence to support indications and claims for homoeopathic and related medicines will be considered as part of the review of the *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims*.

4.1 What factors affect the efficacy of homoeopathic and/or related medicines?

How should these factors be controlled for regulatory purposes? Consider issues such as combination medicines, directions for use, etc.

Issues for consideration

Factors that affect the efficacy of homoeopathic and related medicines need to be considered. Some traditional homoeopathic theories dictate that homoeopathic medicines should be taken as single ingredient preparations. However there are many combination products on the market - combinations of homoeopathic preparations, as well as homoeopathic preparations combined with non-homoeopathic ingredients. The issue of whether or not combination products have a legitimate role in the homoeopathic paradigm needs to be resolved.

Within the homoeopathic paradigm, it is sometimes believed that when and how a homoeopathic medicine is taken can affect its therapeutic action (eg. concomitant ingestion of strong tasting foods/drinks, or use of toothpaste). Guidance is sought as to how much these factors impact on the ultimate efficacy of homoeopathic medicines.

5. NAMING, QUANTIFICATION AND LABELLING

5.1 How should ingredients in homoeopathic and related medicines be quantified?

5.2 How should homoeopathic and related medicines be labelled to ensure they are differentiated from other medicines?

5.3 How should ingredients in these medicines be expressed on the label?

Consider how the needs of consumers for meaningful information about homoeopathic medicines can best be met.

- 5.4 Is it appropriate for indications for homoeopathic medicines to be included on the label?
If so, how should indications be expressed on labels?
- 5.5 Should consumers be given written guidance on labels as to how and when homoeopathic remedies should be taken?
Consider factors that may affect efficacy, such as brushing teeth, drinking coffee, etc.

Issues for consideration

There are currently no names approved specifically for homoeopathic ingredients. An agreed system for naming and expressing the content of homoeopathic preparations is required. The system should take into account appropriate identification and differentiation of the homoeopathic preparation, common terminology for homoeopathic medicines, and perhaps reference to the homoeopathic authority to which the preparation complies.

In the present Australian regulatory system, sponsors are encouraged to use the equivalent Australian Approved Name for the substance from which the preparation is derived wherever possible, to provide consumers with consistent terminology for chemical, herbal or biological names. However, there is the potential for the label to be misleading where the name could imply that the preparation contains a prescription ingredient, rather than the homoeopathic form of that ingredient.

Consideration also needs to be given to agreed terminology for expressing potency.

The *British Pharmacopoeia* (BP) and Therapeutic Goods Orders (TGO's) are currently the official standards for regulatory purposes in Australia. In the current BP general monograph for 'Homoeopathic Preparations', 'potentisation' is defined as follows:

Dilutions and triturations are obtained from stocks by a process of potentisation in accordance with a homoeopathic manufacturing procedure: this means successive dilutions and succussions, or successive appropriate triturations, or a combination of the 2 processes.

The potentisation steps are usually one of the following:

1 part of the stock plus 9 parts of the vehicle¹; they may be designated as "D", "DH" or "X" (decimal),

1 part of the stock plus 99 parts of the vehicle; they may be designated as "C" or "CH" (centesimal).

The number of potentisation steps defines the degree of dilution; for example, "D3", "3 DH" or "3X" means 3 decimal potentisation steps, and "C3", "3 CH" or "3C" means 3 centesimal potentisation steps.

"LM-" (or "Q-") potencies are manufactured according to a specific procedure.

Thus the process of potentisation is generally clear. However some pharmacopoeia may express the same dilution of a homoeopathic preparation as different potencies, depending upon whether they are derived from chemical, herbal or biological substances. For example, a 1000 fold dilution of a herbal mother tincture is considered to be a 4X potency according to the *Homoeopathic Pharmacopoeia of the United States* (HPUS), but it is a 3X potency according to the *Pharmacopée Française* (French Pharmacopoeia).

For regulatory purposes, consistent potency expression is desirable to assist in determining safety of more toxic potentised substances.

¹ Vehicles are excipients used for the preparation of certain stocks or for the potentisation process. They may include for example: purified water, alcohol of a suitable concentration, glycerol and lactose.

Confusion over the way homoeopathic medicines are expressed and quantified needs to be resolved. While guidance for expression of homoeopathic potency and quantification is given in Therapeutic Goods Order 69 - *General requirements for labels for medicines* (TGO 69), some sponsors have chosen not to use the recommended format.

For example, in the supplementary notes for TGO 69, sponsors are advised that similarly to other medicines, the expression of content of the active ingredient on the label should provide information on the final concentration of the active ingredient in the preparation. If the homoeopathic product contains more than one active ingredient, the relative quantities should be stated, for example:

Each 1mL contains:
ingredient A 5X 300 microgram/L
ingredient B 4X 500 microgram/L
etc.

or

Contains equal parts of
ingredient A 5X
ingredient B 4X etc .

However some sponsors have chosen to express the ingredient as:

Each 1mL contains:
300mcg ingredient A 5X
500mcg ingredient B 4X etc.

As many consumers appear to be unaware of what a 'homoeopathic medicine' is, and what the designation of potency (eg 5X) means, consumer confusion and misunderstanding have resulted. Complaints to the TGA have indicated that some label statements have been taken to mean that the product contains 300mcg of the nominated substance rather than 300mcg *of the homoeopathic form* of the nominated substance, and that the potency designation has been interpreted as an expression of strength.

Homoeopathic medicines should be clearly differentiated from other medicines on the label of the product to ensure that consumers are aware of the different nature of these medicines.

The requirements of TGO 69 have raised issues with regard to homoeopathic remedies as therapeutic goods, as all therapeutic goods in Australia currently require the inclusion of an indication on the label. Specific unqualified indications are generally not in accordance with the philosophy of homoeopathy, as a particular remedy is usually only appropriate for a specific 'symptom picture' rather than for a particular condition. For example, a 'headache' might indicate any one of a number of remedies, dependent upon factors such as whether the headache is better or worse for pressure or touch, hot or cold, morning or evening etc. It may not be appropriate for a particular homoeopathic remedy to claim to 'assist in the management of headaches', as this would require the user to be familiar with the type of headache that a particular remedy might be used for. However, the lack of indications on the label of homoeopathic medicines may in itself cause confusion and misuse of the product. This matter needs resolution.

6. OTHER ISSUES

- 6.1 How should excipient ingredients be expressed and quantified for homoeopathic and related medicines?
- 6.2 How should adverse event reporting for homoeopathic and related medicines be managed?
Consider issues such as reporting of apparent homoeopathic ‘aggravations’, etc.
- 6.2 Are there any other matters you believe should be considered when formulating policy for the supply of homoeopathic and related medicines?
Please provide details.

Issues for consideration

The need to facilitate adverse reaction reporting to homoeopathic medicines worldwide.

Although rare, there have been documented cases of studies attributing adverse effects to high potency (highly diluted) homoeopathic remedies.

Consumers of homoeopathic medicines might consider a homoeopathic ‘aggravation’ to be an adverse event. This is despite the fact that many practitioners, as part of homoeopathic healing philosophy, advise that aggravation is a positive sign of the correct route of recovery. Sensitive patients are often said to be more prone to severe aggravation, which on rare occasions can result in hospitalisation (for example aggravation of asthma). Despite the doubts of some as to whether the phenomenon does occur, the fact that there are many who believe it does could significantly increase the risk of delaying appropriate treatment

Individuals who self medicate will rarely be aware as to whether they are likely to experience aggravation of symptoms. They are also less likely to recognise them as such, let alone be aware of the correct course of action if they do experience aggravation. Should this phenomenon be conveyed to consumers? If so, what is the most appropriate way for doing this?

APPENDIX 1

CURRENT REGULATION OF HOMOEOPATHIC MEDICINES

BACKGROUND

The Regulatory Framework for Medicines in Australia

The Therapeutic Goods Administration (TGA) is responsible for administering the provisions of the *Therapeutic Goods Act 1989* (the Act). The overall objective of the Act is to ensure the quality, safety, efficacy and timely availability of therapeutic goods, including medicines, supplied in or exported from Australia. The Act is supported by the *Therapeutic Goods Regulations 1990* (the Regulations) and various Therapeutic Goods Orders (TGOs) and Determinations.

The TGA maintains the Australian Register of Therapeutic Goods (ARTG), a database that includes details of all therapeutic goods that are imported into, supplied in, or exported from Australia. It is a legal requirement that, unless specifically exempt or excluded, all therapeutic goods be included on the ARTG prior to their supply. Therapeutic goods cannot be included on the ARTG unless an application is lodged by a sponsor (the person or company responsible for applying to the TGA to have their goods included on the ARTG, who must be a resident of Australia or carrying on business in Australia). Based on risk, Australia has a two-tiered approach to regulation of medicines. Risk is determined by factors such as the ingredients in a medicine, the dosage form, indications and claims, the significance of side effects and the effects of prolonged or inappropriate use of the medicine.

Registered medicines

Medicines that are assessed to be of higher risk are individually evaluated for safety, quality and efficacy before they can be released onto the market.

If, following evaluation, a higher risk medicine is approved by the TGA for use, it is included on the ARTG as a Registered medicine. Registered medicines include both prescription medicines and non-prescription medicines.

Listed medicines

A different process is applied to low risk medicines, which includes most complementary medicines. Low risk medicines are included on the ARTG as Listed medicines. These medicines are not required to be evaluated for safety, quality and efficacy before they are released onto the market, but are checked to ensure they comply with certain legislative requirements. For example, that:

- 4 the medicine only contains substances previously approved by the TGA as suitable for use in low risk medicines;
- 4 each step in the manufacture of the medicine has been carried out by a licensed manufacturer and to an acceptable standard; and
- 4 the presentation is acceptable.

In addition, the sponsor² must certify to the TGA that they hold information or evidence to support any claim made in relation to the Listed medicine.

The Australian Code of Good Manufacturing Practice

Australian manufacturers of medicinal products are required to comply with the *Australian Code of Good Manufacturing Practice for Medicinal Products* (16 August 2003). The code is based entirely on the international standard, *Guide to Good Manufacturing Practices for Medicinal Products*, published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S). The Australian code was implemented on 21 August 2003 and applies to all medicines manufactured in Australia, including complementary medicines.

Compliance with the code is ascertained by carrying out pre-licensing audits and, thereafter, regular on-site audits of manufacturers of medicinal products. The TGA has good manufacturing practice (GMP) inspection agreements with some other countries and organisations to obtain inspection reports, GMP certificates and other GMP-related information about overseas manufacturers exporting or wishing to export medicinal products to Australia.

Regulation of Homoeopathic Medicines in Australia

In Australia, homoeopathic medicines and products containing homoeopathic preparations are regulated under the Act.

The term 'homoeopathic preparation' is currently defined in Regulation 2 of the Regulations, as a preparation:

- a) formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate; and
- b) prepared according to the practices of homoeopathic pharmacy using the methods of:
 - i) serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or
 - ii) serial trituration in lactose.

Homoeopathic medicines are considered to be low risk medicines. Homoeopathic medicines are required to be Listed on the ARTG. However, where a homoeopathic preparation meets certain conditions it is exempt from this requirement. In some situations, the manufacture of homoeopathic medicines are exempt from the requirement to comply with the *Australian Code of Good Manufacturing Practice for Medicinal Products* or other standards of GMP.

The historical basis for these exemptions dates back to the development and implementation of the current Regulations, when it was considered that homoeopathic preparations did not present a significant health risk to the general public, and hence minimal regulation was appropriate.

² A sponsor of a therapeutic good is the person or company responsible for applying to the TGA to have their goods included on the ARTG. The sponsor must be a resident of Australia or carrying on business in Australia.

Schedule 4 of the Regulations, Items 4A and 5, describes those homoeopathic preparations which must be included on the ARTG:

Item 4A

homoeopathic preparations that:

- (a) consist of, or contain a dilution of, mother tincture that:
 - (i) is a 1,000-fold dilution, or a lesser dilution, of that mother tincture; and
 - (ii) is not required to be sterile; and
 - (iii) is not subject to a Schedule to the Poisons Standard otherwise than because of a component that is more than a 1,000-fold dilution of a mother tincture; and
- (b) do not consist of, or contain as a component, a preparation of a herb specified in Part 4 of this Schedule as a 1000-fold dilution, or a lesser dilution, of a mother tincture

Item 5

homoeopathic preparations (where each dilution is more dilute than a one thousand fold dilution of a mother tincture), each of which:

- (a) is not required to be sterile; and
- (b) according to the indications proposed by the sponsor of the preparation, is for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the *Therapeutic Goods Advertising Code*³

Homoeopathic preparations meeting the conditions set out under Schedule 5, Item 8 of the Regulations, are exempt from the requirement to be included on the ARTG:

Item 8

the following drugs unless the indications proposed by the sponsor are in the treatment of a condition referred to in clause 4 of the *Therapeutic Goods Advertising Code*:

- (a) homoeopathic preparations more dilute than a one thousand fold dilution of a mother tincture and which are not required to be sterile;

and which do not include an ingredient of:

- (i) human origin; or
- (ii) animal origin, if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer:
 - (A) adrenal;
 - (B) brain;
 - (C) cerebrospinal fluid;
 - (D) dura mater;
 - (E) eye;
 - (F) ileum;
 - (G) lymph nodes;
 - (H) pineal gland;
 - (I) pituitary;
 - (J) placenta;
 - (K) proximal colon;
 - (L) spinal cord;
 - (M) spleen;
 - (N) tonsil;

³ The *Therapeutic Goods Advertising Code*

In summary, a homoeopathic product is exempt from inclusion on the ARTG if:

- a) **all** the ingredients in the preparation are present a dilution **greater** than a 1000 fold serial dilution of the mother tincture; *and*
- b) the preparation is not required to be sterile; *and*
- c) it does not contain ingredients of human origin, or ingredients derived from the animals and parts specified in Schedule 5, Item 8 of the Regulations.

However, a homoeopathic product that would otherwise be exempt is required to be Listed on the ARTG if the therapeutic indications for that preparation are for the treatment of a prohibited or restricted representation, as defined in the Appendix 6 of the *Therapeutic Goods Advertising Code*. A homeopathic medicine required to be Listed because of reference to a prohibited or restricted representation, may only advertise those indications to practitioners who are members of those organisations and associations included in Schedule 1 of the *Regulations*. The label for these medicines must also include a statement that the indications have not been 'approved' by the TGA (see below).

The conditions exempting homoeopathic medicines to be manufactured under the requirements of the *Australian Code of GMP* are detailed in Schedule 7, Item 7 of the Regulations:

Item 7

homoeopathic preparations more dilute than a one thousand fold dilution of a mother tincture, and that are not required to be sterile

Labelling

Therapeutic Goods Order No. 69 *General requirements for labels for drug products* (TGO 69) is the standard which deals with the labelling of therapeutic goods. In general, all homoeopathic preparations must comply with this standard, even if exempt from the requirement to be included on the ARTG. Label requirements are detailed under Clause 3 of TGO 69. The particulars that must be included on a label, or labels of medicines, are outlined under subclause 3(2) of TGO 69. They include (for full list of requirements refer to subclause 3(2)), the name(s) of all active ingredients in the goods, and the quantity or proportion of all active ingredients in the goods.

Where the ingredient is a homoeopathic preparation, the following interpretation applies:

Clause 2

name of an active ingredient means:

- b) where the ingredient is a homoeopathic preparation:
 - i) either the name of the active ingredient, or the substance from which the dilution was prepared, that is approved for inclusion in the Australian Approved Names List, together with a statement of the homoeopathic potency; or
 - ii) until such time as a name appears in the Australian Approved Names List⁴, a traditional homoeopathic name in full, or as traditionally abbreviated with a statement of the homoeopathic potency.

and

homoeopathic potency means the dilution factor expressed as:

- a) 'nX', where each dilution is a decimal or ten fold dilution and 'n' is the number of dilutions such that the total dilution is 10^n ; or
- b) 'nC', where each dilution is a centesimal or hundred fold dilution and 'n' is the number of dilutions such that the total dilution is 100^n .

⁴ Where the product is to be included on the ARTG, an Australian Approved Name (AAN) must **first be approved** to permit entry of data onto the ARTG.

Note: Where a potency designation such as 'LM' is to be used, the product sponsor should apply to the Compliance Branch of the TGA for an exemption from TGO 69 to permit them to express the correct potency on the label. This matter has been highlighted for updating in the next version of the labelling order.

Subclause (15)(a) of Clause 3 sets out specific labelling requirements that apply to the homoeopathic preparations.

Subclause (15)(a)

Where all the active ingredients in the goods are homoeopathic preparations then:

- (a) the label on the container and the label on the outside of the primary pack, if any, must include, in addition to the relevant requirements in subclauses 3(2) and 3(3), a statement indicating that the active ingredients in the goods are homoeopathic preparations, such as, 'homoeopathic product' or 'homoeopathic preparation': and
- (b) where the indications for use are of a kind permitted to be advertised only to persons described in subregulation 4(1) and subregulation 4(2) of the Regulations, the label on the container and the label on the outside of the primary pack, if any, must include a statement that the therapeutic indications have not been approved, such as 'Homoeopathic product without approved therapeutic indications'

Subclause (5) of Clause 4 of TGO 69 outlines the requirements for expression of quantity or proportion of active homoeopathic ingredients in medicines.

Subclause (5)

for a homoeopathic preparation, where all the active ingredients are homoeopathic preparations:

- (a) notwithstanding subclauses 4(1), 4(2) and 4(3), as the quantity of the ingredient in one millilitre or in one gram of the preparations; or
- (b) where each active ingredient is included in the preparation in the same proportion as every other active ingredient – expressed as 'Contains equal parts of' followed by the name or each homoeopathic ingredient. (see also Supplementary note below)

Supplementary Notes to TGO 69 are intended to explain various parts of the Order but are not part of the Order. Clause 11 of the Supplementary Note 11 states that:

There are currently no names approved specifically for homoeopathic ingredients. However, sponsors are encouraged to use the equivalent Australian Approve Name wherever possible to provide consumers with consistent terminology for chemical, herbal or biological names.

Similarly, to other medicines, the expression of content of the active ingredient on the label should provide information on the final concentration of the active ingredient in the preparation. If the homoeopathic product contains more than one active ingredient, the relative quantities should be stated, for example:

Each 1mL contains:
ingredient A 5X 300 microgram/L
ingredient B 4X 500 microgram/L
etc.

or

Contains equal parts of
ingredient A 5X
ingredient B 4X etc .

TGO 69 also exempts those goods, which comprise a dispensing pack supplied solely to a complementary healthcare practitioner, from the requirement to include a 'statement of purpose for which it is intended that the goods be used' (indications) on the label (subclause 3(2)m(i)). These products should include, on the label, the words '*For Practitioner Dispensing Only*'. Such goods should also include the statement '*Homoeopathic product without approved therapeutic indications*'.

Dispensed or extemporaneously compounded homoeopathic medicines

Medicines (other than medicines used for gene therapy) that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person by a complementary healthcare practitioner, such as a homoeopaths, are not regulated by the TGA. The exemption applies to medicines prepared for individual patients, either following consultations with that particular patient, or to fill a prescription for that particular patient. The exemption does not cover situations where the practitioner makes up medicines in advance, in anticipation of patients who may come onto the premises and ask for that medicine.

Regulation in New Zealand

The regulatory framework for medicines in New Zealand is based on the *Medicines Act 1981*. Many products that would fall within the definition of "complementary medicine" are currently sold as dietary supplements, which are regulated under the *Dietary Supplements Regulations 1985* under the *Food Act 1981*. The current legislation does not adequately regulate complementary medicines, and New Zealand has for some time recognised the need to develop new legislation to regulate complementary medicines.

The *Dietary Supplements Regulations 1985* impose some restrictions on what a dietary supplement can contain, and therapeutic claims are prohibited. Homoeopathic medicines making therapeutic claims are regulated under the *Medicines Act 1981*. However, the term 'homoeopathic' is not defined.

APPENDIX 2

DEFINITION OF A HOMOEOPATHIC MEDICINE – RATIONALE AND PROPOSED WORDING

The definition of a homoeopathic medicine is being considered separately as part of the Consultation Paper: *Proposed Regulatory Definitions for Complementary Medicines and Homoeopathic Medicines in a Joint Australia New Zealand Therapeutic Products Agency*. Stakeholders are invited to take the opportunity to comment on the proposed definition for a 'homoeopathic medicine' via this alternate consultation route in order to retain context as a complementary medicine. However, for ease of reference, the rationale and the wording of the proposed definition are included below.

The current Australian definition for a 'homoeopathic preparation' included in the *Therapeutic Goods Regulations 1990* (the Regulations) is based upon the central tenet of homoeopathy; '*similia similibus curentur*' or 'let like cure like', and the principles of homoeopathic pharmacy; serial dilution and succussion of a stock.⁵

Where an ingredient meets the definition of a 'homoeopathic preparation', and meets the conditions set out under Schedule 5, Item 8 of the Regulations, it may be exempt from the requirement to be included on the Australian Register of Therapeutic Goods (ARTG). This does not apply where the homoeopathic preparation is included in a product with other ingredients requiring inclusion on the ARTG.

Where products are exempt from the requirement to be included on the ARTG, they are effectively removed from regulation under the Therapeutic Goods Administration (TGA), as when they meet this exemption, they are generally also exempt from the requirement to be manufactured under Good Manufacturing Practice (GMP). Exempt homoeopathic goods must still comply with TGO 69 *General requirements for labels for drug products*, even when exempt from the requirement to be included on the ARTG.

However, unless homoeopathic medicines exempt from the requirement to be Listed on the ARTG are brought to the attention of the TGA, the products are not reviewed as part of the TGA's post-market program. This makes it difficult to identify those products making claims not consistent with the homoeopathic remedy they are included in, which in turn may result in them not meeting the current definition of a 'homoeopathic preparation'.

It has become evident that a number of substances currently not permitted in Listed medicines are being presented on the market as homoeopathic preparations. Whilst these goods may be *bona fide* homoeopathic remedies, it is also possible that they are being formulated with little or no regard to homoeopathic principles or practice. The current exemption provisions applying to homoeopathic remedies are ONLY intended to apply where ingredients meet the current definition of a 'homoeopathic preparation' as defined in the Regulations.

Simply diluting a substance does not make it a homoeopathic preparation. In accordance with the definition (and faithful representation of the paradigm), a homoeopathic preparation must be used in a way that complies with the principle of 'like cures like'.

⁵ Stocks are substances, products or preparations used as starting materials for the production of homoeopathic preparations. A stock is usually one of the following: for raw materials of botanical or zoological origin, a mother tincture or a glycerol macerate; for raw materials of chemical or mineral origin, the substance itself.

It must be ‘formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate’. However, in practical terms, it is not possible to apply the principle of ‘like cures like’ where there is no evidence of a proving or a symptom picture for the substance in the first place.

Therefore, it would appear that the current definition of a ‘homoeopathic preparation’ should be amended to make it clear that *bona fide* homoeopathic preparations **only** are considered to be homoeopathic medicines, and not those resulting from dilution of the substance only.

The *British Pharmacopoeia* (BP) and Therapeutic Goods Orders (TGO’s) are currently the official standards for regulatory purposes in Australia. Where a substance is covered by a monograph in the BP, this is the minimum standard that must be applied in its entirety; otherwise a justification is required⁶. The requirements of applicable general monographs of the BP must also be met, except where a justification for not doing so is authorised by the TGA. Examples of BP general monographs are ‘Homoeopathic Preparations’ and ‘Mother tinctures for Homoeopathic Preparations’. The TGA currently considers the suitability of other national or international pharmacopoeial monographs or standards on a case-by-case basis. Note that the most recent edition of any cited pharmacopoeial monograph or standard should be used, or a justification for not doing so provided.

The *British Pharmacopoeia* defines ‘homoeopathic preparations’ as follows:

Homoeopathic preparations are prepared from substances, products or preparations called stocks in accordance with a homoeopathic manufacturing procedure. A homoeopathic preparation is usually designated by the Latin name of the stock, followed by an indication of the degree of dilution.

It must be noted, however, that the monograph in the BP is a quality standard only. It only deals with the appropriate manufacture of homoeopathic preparations. Whilst ensuring the quality of homoeopathic ingredients is imperative, this monograph does not identify those ingredients that are recognised as valid homoeopathic ingredients.

A useful way to address this issue may be to include in the definition of a ‘homoeopathic preparation’ the requirement that the ingredient may only comprise an ingredient for which there is a monograph in a recognised homoeopathic pharmacopoeia. Recognised homoeopathic pharmacopoeia could include, for example, the *Homoeopathic Pharmacopoeia of the United States* (HPUS), the *German Homoeopathic Pharmacopoeia* (GHP), or relevant homoeopathic monographs in the *Pharmacopée Française* (Ph.F.), *European Pharmacopoeia* (EP), and the *British Pharmacopoeia* (BP).

However, it should be noted that the HPUS and the *British Herbal Pharmacopoeia* are not accepted in Europe (for homoeopathic monographs). Therefore, in recognising a pharmacopoeia, it will be necessary to ensure that any monograph meets the necessary standards of the joint Agency.

Further, in any proposed definition, it should be stipulated that the homoeopathic ingredient must be prepared in accordance with the procedures prescribed by, and offered for sale in a dosage form defined in, the relevant recognised pharmacopoeia.

The adoption of specific homoeopathic pharmacopoeias could be accomplished through the development of a Managing Director’s Order to deal with homoeopathic preparations. In addition, the joint Agency would need to formally adopt the new edition of each recognised pharmacopoeia as appropriate.

⁶ Sponsors attempting to justify non-compliance with prescribed standards (eg BP or TGOs) must apply to the TGA in writing, seeking an exemption. Exemption requests should explain why the standard(s) cannot be met and detail what alternative(s) are proposed and why.

The above approach could help ensure that only those homoeopathic ingredients that have been established as homoeopathic ingredients (and presumably included in the homoeopathic pharmacopoeia only after an appropriate symptom picture has been developed) will be considered as valid or legitimate homoeopathic preparations.

However, this approach does not take into account new valid homoeopathic substances that do not have a recognised monograph. For such substances, it might be suggested that a sponsor should make an application to the joint Agency for approval of the ingredient as a legitimate homoeopathic preparation. The application could include a compositional monograph, and evidence of a proving or symptom picture. Where the applicant wishes to include the ingredient in an exempt homoeopathic medicine, a certificate of exemption could be issued following satisfactory evaluation of the application. Any new definition of a 'homoeopathic preparation' would need to reflect any requirements for potential homoeopathic ingredients that do not have a monograph in a recognised homoeopathic pharmacopoeia.

The above approach would also address one other problem with the existing definition of a 'homoeopathic preparation'. The current definition, if considered to refer to a completed homoeopathic product - that is, a preparation 'formulated for use...' (see definition) - does not take into account mixed remedies (both multiple homoeopathic ingredients and combined herbal/homoeopathic preparations). If a homoeopathic preparation is defined as a single ingredient that may, or may not, be combined with other ingredients, this will remove any ambiguity.

In summary, in order to adequately define a 'homoeopathic preparation', for the purposes of effectively regulating homoeopathic remedies, a number of factors must be kept in mind, namely:

- € the definition should be worded to make it evident that only those ingredients which have a legitimate role as ingredients in homoeopathic remedies will be regarded as valid homoeopathic preparations (it should therefore follow that only legitimate homoeopathic preparations will be permitted in exempt homoeopathic medicines)
- € the definition should encompass the central tenet of homoeopathy, namely 'let like cure like' (it may be that inclusion in an recognised homoeopathic monograph would achieve this)
- € the definition must specify that only those ingredients prepared according to established practices of homoeopathic pharmacy will be considered valid
- € the definition should refer to appropriate dosage form(s) for the homoeopathic ingredient
- € the definition should be broad enough to encompass products from a number of established variations on the original Hahnamanian philosophy (for example multiple ingredient products and anthroposophical medicines)

Based upon the above criteria, a draft definition for 'homoeopathic medicine' might include:

Homoeopathic medicine is a preparation:

- (a) prepared in accordance with the procedures prescribed by a recognised homoeopathic pharmacopoeia, using the methods of:
 - (i) serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or
 - (ii) serial dilution and succussion of a glycerol macerate in glycerol, or glycerol and alcohol of a suitable concentration, or glycerol and a solution of sodium chloride of a suitable concentration; or
 - (iii) serial trituration in lactose; and

- (b) for which there is an appropriate monograph:
 - (i) included in a recognised homoeopathic pharmacopoeia; or
 - (ii) approved by the Managing Director following acceptance of an appropriate proving or symptom picture for the substance; and
- (c) presented in a dosage form defined in a recognised homoeopathic pharmacopoeia.