



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



CONSULTATION PAPER

PROPOSED REGULATORY DEFINITIONS FOR COMPLEMENTARY MEDICINES AND HOMOEOPATHIC MEDICINES IN JOINT AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AGENCY

CALL FOR COMMENT

December 2004

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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 inclusion/exclusion of specific substances in the definitions posed in this consultation paper. In addition, stakeholders are encouraged to provide other comments that will assist in the development of appropriate regulatory arrangements for the evaluation of complementary medicines in the joint Agency.

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) have agreed to distribute the consultation paper 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 directly to the postal and/or email address below.

Contents 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 aspect of the definition(s) being addressed
- € 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 2606
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.**

INTRODUCTION

Legislation for the new joint Australia New Zealand therapeutic products agency (the joint Agency) will include regulatory definitions for prescription, OTC and complementary and homeopathic medicines. Clear and unambiguous definitions are critical in determining the regulatory requirements and processes applicable to a particular medicinal product or ingredient.

Draft definitions for complementary and homoeopathic medicines are being made available for stakeholder comment in order to assist the joint Agency in finalising its position on these definitions.

All medicines will be regulated by the joint Agency using a risk-based approach. This means that the level of control applied is consistent with the risk associated with the product. Medicines will be classified as either Class I or Class II medicines. The class will determine the level of regulatory control applied and the manner in which product licenses are obtained.

Class I medicines must:

- € contain only ingredients from a published list of permitted ingredients;
- € not contain scheduled medicines;
- € not be required to be sterile; and
- € not be intended to be used in the prevention or treatment of a serious disease.

Product license applications for Class I medicines will not be evaluated by the joint Agency prior to a product license being issued.

Class II medicines are higher risk medicines for which a product license can only be granted following evaluation by the joint Agency for safety, quality and efficacy of the medicine. However, within this class there is a continuum of risk and the product licensing process and data requirements applying to a Class II complementary medicine will be commensurate with the risks associated with the medicine.

It is expected that most of the complementary medicines currently being supplied in New Zealand, and all of the products currently Listed in Australia, will fall into the low-risk (Class I) category.

The draft definition of a complementary medicine has been developed to more clearly define the boundary for those medicines to be regulated as complementary medicines in the joint Agency. The proposed definition includes more objective criteria for determining the eligibility of a medicinal product or ingredient to be regulated as a complementary medicine. It allows for innovation, otherwise precluded by the criterion of traditional use, as required by the current Australian definition. (Please note that even if a medicinal product or ingredient is determined NOT to be a complementary medicine, it may still be eligible for regulation as a Class I medicine).

The draft definition for a homoeopathic medicine has been developed to more adequately define these medicines for regulatory purposes and to ensure that *bone fide* homoeopathic medicines are clearly differentiated from those medicines inconsistent with the homoeopathic paradigm.

[Explanatory Notes and a Glossary](#) have been developed to provide additional guidance on the scope of the definition and an explanation of the terms used.

DEFINITIONS

Complementary medicine means:

- (a) a medicine that:
 - (i) contains as active ingredients only substances set out in [Table 1](#); and
 - (ii) is not included in [Table 2](#); or
- (b) a homoeopathic medicine or a medicine based on a related paradigm, which is not included in [Table 2](#).

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.

TABLE 1 – Complementary medicine substances

Item	Substance
Item 1	A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
Item 2	A substance or mixture of substances obtained by extraction, distillation, purification or a traditional preparation of a material described in Item 1. <i>Traditional preparation.</i> A preparation obtained from a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material for therapeutic application in humans using a method that is based on health theories, beliefs or experiences indigenous to different cultures.
Item 3	A vitamin or provitamin, including salts and other compounds of the following types: vitamin A vitamin B1 vitamin B2 vitamin B3 vitamin B5 vitamin B6 vitamin B12 vitamin C vitamin D vitamin E vitamin K biotin folic acid
Item 4	An amino acid listed in Table 3
Item 5	A synthetic equivalent of a substance described in any of items 2 to 4
Item 6	A mineral
Item 7	A microorganism, whole or extracted, except a vaccine

TABLE 2 – Substances ineligible for regulation as complementary medicines

Item	Substance
Item 1	A single chemical entity obtained from a material described in Item 1 of Table 1 where there is no history of human use <u>or</u> the intrinsic risk fulfils the criteria of a substance that should only be available on prescription, require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence, or for which the manufacture, possession, sale or use should be prohibited to avoid abuse or misuse ¹ .
Item 2	A specified therapeutic product.
Item 3	A medicine declared by the Managing Director not to be a complementary medicine

¹ These criteria are consistent with those that currently apply for inclusion of a substance in Schedule 4, 8 or 9 of the *Standard for the Uniform Scheduling of Drugs and Poisons*. These criteria are being reviewed as part of establishing a joint Australia New Zealand regulatory scheme for therapeutic goods.

TABLE 3 – Acceptable Amino Acids

1	Alanine
2	Arginine
3	Asparagine
4	Aspartic acid
5	Cysteine
6	Glutamine
7	Glutamic acid
8	Glycine
9	Histidine
10	Isoleucine
11	Leucine
12	Lysine
13	Methionine
14	Phenylalanine
15	Proline
16	Serine
17	Threonine
18	Tryptophan
19	Tyrosine
20	Valine

EXPLANATORY NOTES & GLOSSARY

Alga. A member of one of the protist biological kingdoms, consisting of unicellular, colonial or relatively simple multicellular eukaryotes that have a cell wall containing cellulose or silica, that usually produce their own food by photosynthesis using various chlorophylls and accessory pigments (some may also be heterotrophic under appropriate conditions), that are mostly aquatic and that lack multicellular dependent embryos.

Amino acid. Class of organic molecules that contains amino and carboxyl groups. Alpha amino acids form the main constituents of proteins that are found in a plant, plant material, an alga, a fungus, a bacterium or a non-human animal material. The ζ -amino acids for the purposes of this definition are included in [Table 3](#).

Animal. A member of the biological kingdom Animalia, consisting of complex multicellular eukaryotes whose cells have a membrane but no wall, that have muscle and nervous tissue in most members, that are heterotrophs that mostly ingest food into a specialized cavity where it is digested, and that reproduce sexually by means of motile sperm and larger, nonmotile eggs (in some animals, there is also asexual reproduction).

Appropriate proving or symptom picture. One that meets the principles as set out in the document *Recommended Guidelines for Good Proving*¹, published by the European Council for Classical Homeopathy (ECCH).

Bacterium. A member of one of the biological kingdoms of the domains Bacteria or Archaea, consisting usually of unicellular (sometimes aggregated, colonial or simple multicellular) prokaryotes whose cells lack nuclei or other internal compartmentalization. Most species have a cell wall external to the plasma membrane, composed primarily of peptidoglycan (except in *Archaea*). Bacteria have diverse means of nutrition; the group consists mostly of chemoheterotrophs, but there are also chemoautotrophs, photoautotrophs and photoheterotrophs. They reproduce by binary fission.

Enzyme. A protein that acts as a catalyst to promote biochemical reactions. Enzymes may be derived from a plant or a plant material, an alga, a bacterium, a fungus, or a non-human animal material.

Extraction. The process of treating a plant or a plant material, an alga, fungus, or non-human animal material with solvents to separate constituents from the original material.

Fungus. A member of the biological kingdom Fungi, consisting mostly of complex multicellular eukaryotes with a cell wall, usually composed primarily of chitin. Fungi are heterotrophs that absorb nutrients from their surroundings after decomposing organic material. They reproduce by unicellular spores produced sexually and/or asexually.

Homoeopathic medicines. In developing the draft definition, consideration was given to the following:

- € the definition must 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;
- € the definition should encompass the central tenet of homoeopathy, namely 'let like cure like' (it may be that inclusion in a 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; and

- € the definition should be broad enough to encompass products from a number of established variations on the original Hahnmanian philosophy (for example, multiple ingredient products).

The broader issue of the regulation of homoeopathic medicines, and medicines based on related paradigms, will be reviewed separately. Further detail regarding reasons for the proposed amendments to the current definition of 'homoeopathic preparation' will be outlined in this review.

Medicine. In the joint regulatory system, a medicine is defined as any substance or combination of substances presented as having properties for treating or preventing a disease ailment, defect or injury in human beings, or any substance or combination of substances which may be used in human beings with a view to making a medical diagnosis or to restoring, correcting, maintaining or modifying physiological functions.

Mineral. Includes salts or other compounds of elements that have an Australian / New Zealand Recommended Dietary Intake (RDI). If there is no Australian / New Zealand RDI for the element, it must be recognised as an essential dietary element by inclusion in the RDI (or equivalent) of another country.

No history of human use. In relation to [Table 2](#), Item 1, means there is no history of human use of a material included in Item 1 of Table 1 from which the chemical entity was obtained.

Non-human animal material. A body part or secretion obtained from an animal other than a human.

Plant. A member of the biological Kingdom Plantae, consisting of complex multicellular eukaryotes that have a cell wall composed primarily of cellulose.

Plant material. Includes material obtained from a plant such as exudates and pollens.

Purification (separation processes). In relation to [Table 1](#), Item 2, this process does not include techniques or processes that involve chemical transformation of the original material (other than those chemical changes occurring incidentally to extraction, distillation or traditional preparation). Examples of changes occurring incidentally during solvent extraction, steam distillation or traditional preparation include hydrolysis of esters, lactone ring opening and isomerisation.

Recognised homoeopathic pharmacopoeia:

- € the *Homoeopathic Pharmacopoeia of the United States*²;
- € the *Homöopathische Arzneimittel* (the German Homoeopathic Pharmacopoeia)³;
- € specific homoeopathic monographs in the *Pharmacopée français*⁴ and the *European Pharmacopoeia*⁵.

Single chemical entity

Includes substances that exist as a mixture of isomers.

Specified therapeutic product. This definition is still being developed. Under the joint Agency it is envisaged that this definition will make reference to products which are to be evaluated by the prescription medicines evaluation unit of the joint Agency and is expected to include:

- € a medical gas;
- € a vaccine;
- € an allergen, except an allergen for skin patch testing on unbroken skin;
- € a biotechnology medicine;
- € an immunoglobulin;
- € a radio contrast agent, except barium sulphate preparation for radiological use;
- € a radiopharmaceutical;
- € a dialysis solution, except a haemodialysis solution;
- € a special dosage form, such as a transdermal system or osmotic pump;
- € an injectable medicine dosage form;
- € a blood product, unless coated on a therapeutic device;
- € a therapeutic device that depends upon the release of a substance for some or all of its action;
- € products referred to the prescription medicines unit for evaluation; or
- € an excipient in these products (i.e. products evaluated by the prescription medicines unit).

Synthetic equivalent. A substance obtained by chemical synthesis that shares an identical chemical structure and biological properties to a substance described in Items 2 to 4 in [Table 1](#).

A semi-synthetic substance may also be acceptable as a complementary medicine provided it shares an identical chemical structure and biological properties with a natural counterpart. A semi-synthetic substance is produced by a process that chemically changes a related starting material that has been extracted or isolated from a plant or a plant material, an alga, a fungus or a non-human animal material.

Traditional preparation. A preparation obtained from a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material for therapeutic application in humans using a method that is based on health theories, beliefs or experiences indigenous to different cultures. A traditional preparation based on health theories, beliefs or experiences indigenous to different cultures must have a documented methodology established over at least three generations. This is the minimum time considered necessary to provide a repository of systematic observation establishing a traditional preparation method of these medicines.

Vitamins. Naturally occurring organic substances, including salts and other forms of the vitamin, required by the body to maintain health and which have an Australian / New Zealand Recommended Dietary Intake (RDI). If there is no Australian / New Zealand RDI for the vitamin, it must be recognised as an essential nutrient by inclusion in the RDI (or equivalent) of another country.

¹ *European Guidelines for Homeopathic Education.* UK; European Council for Classical Homeopathy, June 2000. 2nd edition.

² *Homeopathic Pharmacopoeia of the United States.* The Homeopathic Pharmacopoeia of the United States Revision Service. Homeopathic Pharmacopoeia Convention of the United States. 1988-.

³ *German Homeopathic Pharmacopoeia.* Stuttgart :Medpharm Scientific; London : Stationery Office, 2003.

⁴ *Pharmacopée française : rédigée par ordre du gouvernement / élaborée sous la direction scientifique de la Commission Nationale de Pharmacopée.* Saint-Denis : Agence du médicament, [2000] 10e éd. refondue.

⁵ *European Pharmacopoeia.* Strasbourg: Council of Europe, 2004. 5th edition.