



Consultation Paper:

Proposed regulatory definitions for complementary medicines and homoeopathic medicines in a joint Australia New Zealand therapeutic products agency

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Regulatory Definitions

- Regulatory definitions are critical for clearly determining the requirements and processes applicable to particular products or ingredients.
- Medicines in the joint Agency will be classified as either Class I or Class II medicines. This will determine the level of regulatory control and how product licenses are obtained.
- Complementary medicines may be Class I or Class II (most will be classified as Class I – low risk).
- A product or ingredient determined NOT to be a complementary medicine may still be regulated as a Class I medicine.



Current Regulatory Definition

Section 52F *Therapeutic Goods Act 1989*

complementary medicines means therapeutic goods consisting wholly or principally of one or more **designated active ingredients**, which has a clearly established identity and:

- (a) a traditional use; or
- (b) any other use prescribed in the regulations.

traditional use means use of a designated active ingredient:

- (a) that is well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over an extended period of time; and
- (b) that accords with well-established procedures of preparation, application and dosage.



Regulatory Definition: Designated Active Ingredients (Schedule 14 Therapeutic Goods Regulations 1990)

- an amino acid; charcoal; choline salts; essential oil
- plant or herbal material (or a synthetically produced substitute)
- a homoeopathic preparation
- a microorganism, whole or extracted, except a vaccine
- a mineral including a mineral salt and a naturally occurring mineral
- a mucopolysaccharide, a sugar, polysaccharide or carbohydrate
- non-human animal material (or a synthetically produced substitute)
- a lipid, including an essential fatty acid or phospholipid
- a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
- a vitamin or provitamin



Considerations in developing a regulatory definition

- allow for traditional methods of manufacture of complementary medicines, but also to permit the use of more modern methods in their manufacture provided other conditions are met;
- allow for innovation by the complementary medicines industry in Australia and New Zealand;
- ensure that substances which fall within the definition, but which need control over their access were adequately catered for;



Considerations in developing a regulatory definition - contd.

- ensure that new chemical entities, which are not 'related' to complementary medicines are not permitted by the definition;
- is enduring to allow, with time, complementary medicines may become conventional, orthodox medicines;
- a definition for regulatory purposes should not diminish or limit the way 'complementary medicines' are understood in the wider community;
- in cases where the definition is inappropriate there are discretionary powers available to the regulator to ensure public safety and/or an appropriate means of evaluation.



Proposed 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.

Explanatory Notes and a Glossary are included in the Consultation Paper

Note: This is NOT a definition of a Class 1 (low risk) medicine



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	<p>A substance or mixture of substances obtained by extraction, distillation, purification or a traditional preparation of a material described in Item 1.</p> <p><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.</p>



Item 2 Purification

Purification (separation processes). In relation to Item 2, 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.



Item 2 *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 tradition preparation must have a documented methodology established over at least three generations (for example, frying in honey).



Table 1. Complementary medicine substances contd

Item	Substance
Item 3	A vitamin or provitamin , including salts and other compounds of the following types: vitamin A, B1, B2, B3, B5, B6, B12, C, D, E, K and 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



Item 3 A vitamin or provitamin

- Vitamins (and provitamins).*** 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.
- evidence of essentiality in humans by inclusion in national nutrient reference values.



Table 1. Complementary medicine substances

Item	Substance
Item 3	A vitamin or provitamin, including salts and other compounds of the following types: vitamin A, B1, B2, B3, B5, B6, B12, C, D, E, K and 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



Item 4 An amino acid listed in Table 3

Table 3 Acceptable amino acids

Alanine, Arginine, Asparagine, Aspartic acid, Cysteine, Glutamine, Glutamic acid, Glycine, Histidine, Isoleucine, Leucine, Lysine, Methionine, Phenylalanine, Proline, Serine, Threonine, Tryptophan, Tyrosine, and Valine.

Note: the list of 20 acceptable amino acids includes the α -amino acids that make up most proteins.



Table 1. Complementary medicine substances

Item	Substance
Item 3	A vitamin or provitamin, including salts and other compounds of the following types: vitamin A, B1, B2, B3, B5, B6, B12, C, D, E, K and 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



Item 5 A synthetic equivalent of a substance in Items 2 to 4

- A substance obtained by chemical synthesis that shares an identical chemical structure and biological properties to a substance described in Items 2 to 4.
- A semi-synthetic substance may also be acceptable provided it shares an identical chemical structure and biological properties with a natural counterpart.



Table 1. Complementary medicine substances

Item	Substance
Item 3	A vitamin or provitamin, including salts and other compounds of the following types: vitamin A, B1, B2, B3, B5, B6, B12, C, D, E, K and 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



Item 6 A mineral

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.

- evidence of essentiality in humans by inclusion in national nutrient reference values.
- eg. Ca, Cr, Cu, F, I, Fe, Mg, Mn, Mo, P, K, Se, Na, Zn



Table 2.

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.



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
Item 2	<i>A specified therapeutic product</i>
Item 3	A medicine declared by the Managing Director not to be a complementary medicine



Table 2 Eligibility for regulation as complementary medicines

SUBSTANCE	Yes/No	EXPLANATION
Salicin	Yes	Salicyl alcohol glucoside. A single chemical obtained from a material in Item 1 of Table 1 (an isolate or extract of <i>Salix sp.</i>)
Asprin	No	Acetylsalicylic acid. A single chemical entity. Not obtained from a material in Item 1 of Table 1. Is not an isolate or extract of <i>Salix sp.</i> Does not occur naturally.
Morphine	No	A single chemical entity obtained by purification of <i>Papava sp.</i> , and with a history of human use BUT the intrinsic risk fulfils the criteria consistent with those that currently apply for inclusion of a substance as a prescription medicine or controlled medicine (ie. in Schedule 4, 8 or 9 of the SUSDP in Australia).



Table 2 Eligibility for regulation as complementary medicines

SUBSTANCE	Yes/No	EXPLANATION
Digitoxin	No	A single chemical entity obtained by purification of <i>Digitalis purpurea.</i> , AND with a history of human use BUT the intrinsic risk fulfils the criteria consistent with those that currently apply for inclusion of a substance in a prescription medicine/controlled drug schedule.
<i>Digitalis purpurea</i> (Foxglove) extract	Yes	A mixture of substances obtained by extraction of material in Item 1 of Table 1 (<i>Digitalis purpurea.</i>). The intrinsic risk fulfils the criteria that currently apply for inclusion of a substance in a prescription medicine or controlled medicine (ie. in Schedule 4, 8 or 9 of the SUSDP in Aust) <u>BUT</u> the material is not a single chemical entity. Regulated as a Class 2 medicine.



Substances ineligible for regulation as complementary medicines

- Substances not meeting the definition of a complementary medicine may still be eligible for use in Class 1 medicines.
- Substances and products currently regulated in Australia as Listable ingredients and Listed medicines will continue to be regulated as Class I ingredients and products in the joint agency
 - irrespective as to whether they no longer meet the definition of a complementary medicine.



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
Item 2	<i>A specified therapeutic product</i>
Item 3	A medicine declared by the Managing Director not to be a complementary medicine



Table 2, Item 2 A 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. May 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; a radiopharmaceutical; a dialysis solution, except a haemodialysis solution; a special dosage form, such as a osmotic pump; an injectable medicine dosage form; a blood product; products referred to the prescription medicines unit for evaluation; or an excipient in these products
(ie. products evaluated by the prescription medicines unit)



Proposed 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
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Homoeopathic Medicines

The proposed definition 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.



Homoeopathic Medicine is a preparation:

- a) prepared in accordance with the procedures prescribed by a recognised homoeopathic pharmacopoeia, using:
- 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**



Homoeopathic Medicine is a preparation:

- 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
 - iii. presented in a dosage form defined in a recognised homoeopathic pharmacopoeia.



Conclusion

- Proposed definitions more clearly define the boundaries for regulation.
- There are objective criteria for determining eligibility for regulation as a complementary medicine.
- Allows for innovation, otherwise precluded by the criterion of traditional use.

Note: Medicinal products or ingredients determined NOT to be a complementary medicines can still be regulated as a Class I (low risk) medicine.