



Complementary Medicines Australia submission:

Permitted Indications Determination

Submission (4) of a multi-part submission:

Bach Flower; Tissue / cell salts; and additional Herbal Medicines tradition of use evidence qualifiers

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Bach flowers and Tissue Salts

This submission requests traditional context evidence qualifiers that are already used on therapeutic goods in Australia. The TGA already regulate these types of goods and where therapeutic claims are made for such goods under the therapeutic goods framework.

The TGA's consultation: '*Options for the future regulation of 'low risk' products*' ('the low risk consultation') did not introduce the concept of deregulating or otherwise removing Bach flower remedies or tissue salts, noting here that neither of these products are homoeopathics. Therefore, it is unclear as to why they have been excluded from the draft list of traditional context evidence qualifiers.

From the TGA's low risk consultation:

A 'homoeopathic product/preparation/medicine' is based upon the principles of homoeopathic pharmacy 'potentisation,' which is the serial dilution and succussion of a stock.

The Therapeutic Goods Regulations 1990 defines homoeopathic preparations as:

homoeopathic preparation means 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.

The *Therapeutic Goods Act 1989* defines homoeopathic preparations as:

3AA Homoeopathic preparations and homoeopathic standards

Homoeopathic preparation

- (1) For the purposes of this Act, a homoeopathic preparation is a preparation:
 - (a) manufactured from a mother substance; and
 - (b) manufactured in accordance with a manufacturing procedure described in a homoeopathic pharmacopoeia.

The preparation and use of Bach flowers and tissue salts do not meet the above definitions as further described in Table 1 below, but are traditional medicines. The World Health Organisation offers the following definition of traditional medicines:

‘Traditional medicine has a long history. It is the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses.’¹

The medicines used in the traditional paradigms described below are low risk medicines used for self-limiting conditions as well as enhancing wellbeing. Consumers have the right to access medicines based on tradition of use

The inclusion of a tradition of use qualifier is mandatory, therefore, the lack of a qualifier for this group of goods effectively removes them from supply, something that has not been examined in consultation or a regulatory impact statement.

Table 1. Proposed additional qualifiers.

Proposed additional traditional context evidence qualifiers & Discussion.
<p>Traditionally used in tissue salt / cell salt to/as</p> <p>Originating culture: Western / European</p> <p>Originating time: 19th Century</p> <p>Description:</p> <p>This system originated with Dr Scheussler in the 19th century, and has been used since to treat perceived mineral imbalances and cellular mineral malabsorption, as it relates to a certain subset of defined symptomology. Although there are some overlaps in preparation method with homeopathics, tissue salts / cell salts are considered a different paradigm of medicine to homeopathics as well as from nutritinal supplementation. They prepared differently from homeopathics (trituration, not succussion), are set to predefined dosage amounts, and are prescribed according their own unique paradigm. The definitions and qualifier for homeopathics is not applicable. The tradition of use fits the description provided by both WHO and that within the TGA’s evidence guidelines (3 or more generations).</p>

¹ World Health Organization 2013: ‘WHO traditional medicine strategy: 2014-2023’;
http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf?ua=1

Traditionally used as a Bach flower remedy to/as

Originating culture: Western / European

Originating time: 19th Century, Dr Bach

Description:

Bach flowers present insignificant risk, however the TGA have required sponsors to include them where they are being sold as finished goods to consumers with therapeutic claims. Bach flower remedies are a paradigm based upon assisting emotional and nervous wellbeing. They are prepared differently to and prescribed differently from homeopathic remedies. Thus the qualifier for homeopathics is not applicable. The tradition of use fits the description provided by both WHO and that within the TGA's evidence guidelines (3 or more generations).

Additional Herbal Medicine Qualifiers

The CMA would like to request additional Herbal Medicine tradition of use evidence qualifiers that are not included in the revised draft list published on the 24-10-2017:

- Traditional African medicine
- Traditional Korean medicine
- Traditional Yunani medicine
- Traditional Siddha medicine