

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

There is concern that many suggestions to improve the Code made by non-industry stakeholders in previous consultations have been ignored. The most important omissions in the draft Code are:

1. Removal of reference to the Australian Quality Use of Medicines (QUM) policy from the objects of the new Code despite it being in the 2015 Code.

The 2000 [National Medicines Policy document](#) notes (page 3),

'Medicines should be used judiciously - whether prescribed, recommended, and/or self-selected should be used only when appropriate, with non-medicinal alternatives considered as needed' and

'Medicines must achieve the goals of therapy by delivering beneficial changes in actual health outcomes' (especially relevant to complementary medicines as most don't).

While QUM policy has been mentioned in the latest Guidance Document my own view is that it should remain in the objects of the Code and consideration of issues below, such as advisory statements, warnings, testimonials, celebrity and other endorsements, should all be assessed against the principle, do they promote QUM

2. Ignoring submissions from civil society that wanting advisory statements on products with "traditional indications" to assist consumers making an informed choice, for example,

'This product's traditional claims are based on alternative health practices that are not accepted by most modern medical experts' &/or

'No scientific evidence has been provided that this product works'.

The TGA allowed industry to provide the list of Permitted Indications which resulted in 1019 indications of which 86% can be supported by traditional evidence, for example from Traditional Chinese Medicine, Ayurveda, Unani, Western herbalism and Homoeopathy.

These include indications such as, 'softens hardness', 'replenishes gate of vitality' and 'moistens dryness in the triple burner' and [have been ridiculed by the media](#). TGA advisory statements for some traditions, but not others, has also been controversial.

Submissions to the TGA (and Senate Inquiry) pointed out that including numerous traditional indications on this list will encourage industry to evade the requirement to have scientific proof of efficacy for their products, endorses pseudoscience and will confuse the average consumer as the terms used will not be understood. We are already seeing a market increase in advertisements for products claiming traditional indications (Appendix).

Regardless, the [Therapeutic Goods \(Permissible Indications\) Determination No.1 2018](#) has ignored submissions advocating an advisory statement for homeopathic medicines while nevertheless requiring advisory statements for other traditions, for example: 'Seek advice from a registered Chinese medicine practitioner or Ayurvedic medicine practitioner to ensure this medicine is right for you'. Why not, 'Seek advice from a Homeopath or Western herbalist'? Or, more appropriately, 'Seek advice from a registered pharmacist or medical doctor to ensure this medicine is right for you'?

3. Refusing to strengthen mandatory warnings on products containing vitamins, minerals and food extracts to support critical public health messages, for example,

'Vitamins, minerals and other supplements are NO substitute for a healthy balanced diet. Except in special circumstances, vitamins, minerals and food extracts are best obtained from food'.

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

4. Refusing to eliminate testimonials. These are not allowed in the [Health Practitioner Regulation National Law \(s.133\)](#), and if health professionals cannot use them to advertise health services why should advertisers of therapeutic goods?
5. Refusing to prohibit celebrity endorsement and recommendations by scientists or healthcare professionals. It was suggested the new Code should adopt the same stance on prohibition that is used in the [United Kingdom](#):

'Advertisements to the general public should **NOT** contain material which refers to recommendations by scientists or healthcare professionals, or which refers to recommendations by celebrities who, because of their celebrity, could encourage consumption of products'.
6. Refusing to consider steps to broaden the focus of the new Code and complaint system to encompass all therapeutic claims, including those made about food, not just therapeutic goods.

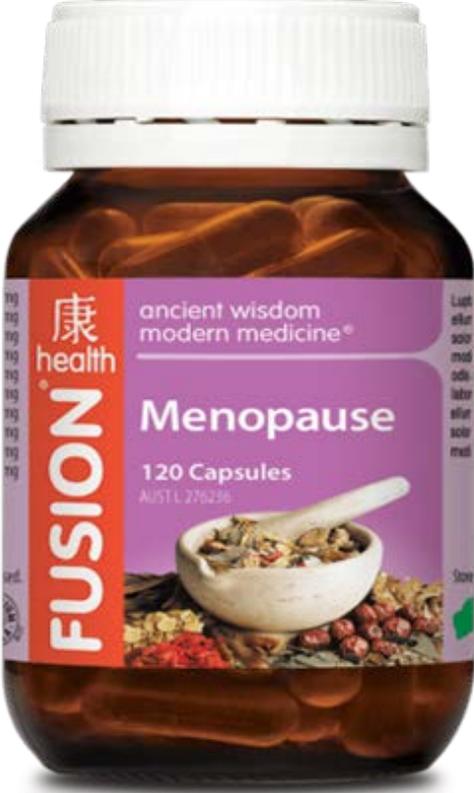
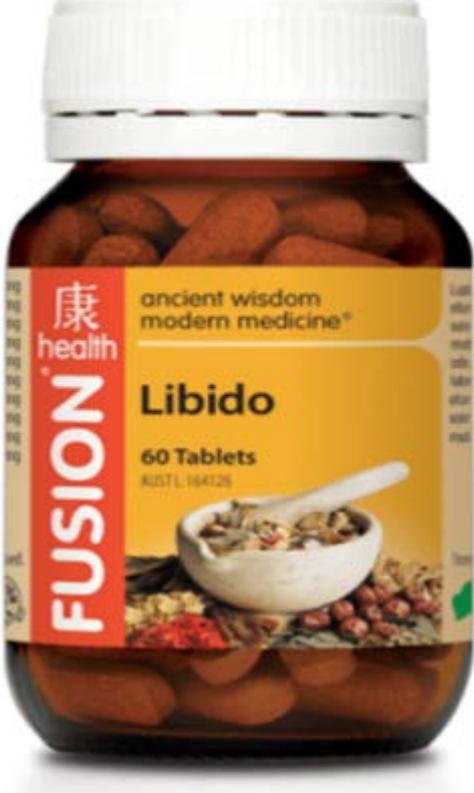
For more detail see:

[Dr Ken Harvey and Dr Prasad Ranaweera, with the assistance of Ms Eleonora Kay, TGA Consultation: Therapeutic Goods Advertising Code, 13 October 2017. Submission endorsed by Friends of Science in Medicine.](#)

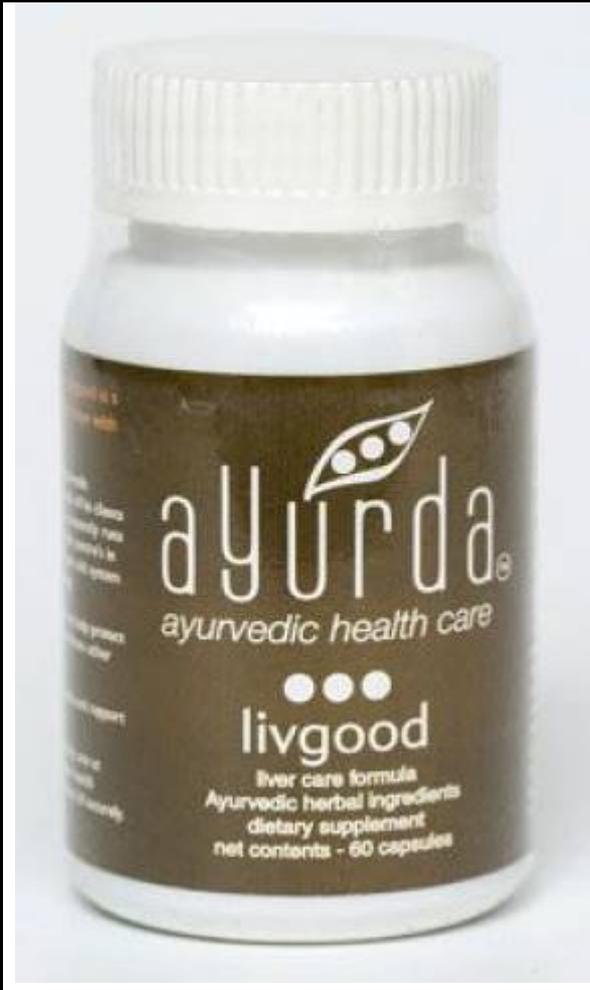
Dr Ken Harvey
12 April 2018

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

Appendix: Examples of complementary medicines invoking 'traditional' indications currently marketed in Australia

	
<p>Relieve the physical and emotional symptoms of menopause. Contains a carefully formulated blend of Chinese herbs traditionally used to balance Yin and Yang during menopause. .</p>	<p>Promotes sexual vitality in men and women. Rejuvenating aphrodisiac formula containing herbs traditionally used in Chinese medicine to enhance sexual vitality, libido (sex drive and desire), sexual potency, sensitivity and physical performance.</p>

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

	
<p>A unique combination of Ayurvedic herbs which are known for their protective action on the liver. This preparation helps expel the build-up of toxins from the liver which accumulate from a diet that includes fried & highly processed foods. Useful in the treatment of: Acne, Gastritis, Gout, Liver disorders, Psoriasis. Also protects liver from the impact of overindulgence.</p>	<p>Ashwagandha is an adaptogen herb that has traditionally been used in Ayurveda as Rasayana (a rejuvenative tonic) to help: Relieve stress and mild anxiety, Relieve mild nervous tensions, As a sleep aid, Support memory enhancement, Support rejuvenation.</p>

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

	
<p>This \$25 homeopathic melatonin product claims to have the same therapeutic effect as the \$99 prescription product (Circadin). A 6X dilution of 400 mg of melatonin is a dilution of 10⁶ or 1 in 1,000,000. Thus, each tablet only contains 0.0004 mg of melatonin. As a result, consumers are being deluded into purchasing a product that contains no therapeutically active ingredient. See also the products on the next page which also contain prescription drugs (highlighted) albeit at ineffective concentrations.</p>	<p>This \$17 homeopathic product claims to reduce jet lag. Each packet contains 32 tablets, said to be enough for 50 hours flying - equivalent to a round-the-world trip for one person. The ingredients are: Arnica Montana (Leopard's Bane) 30C; Bellis Perennis (Daisy) 30C; Chamomilla (Wild Chamomile) 30C; Ipecacuanha (Ipecac) 30C and Lycopodium (Clubmoss) 30C. At these dilutions the product will contain no molecules of the named ingredients.</p>

Anxiostat

May be supportive during anxiety



Anxiostat contains:

- Aconite 200x
- Borax 200x
- Kali phos 200x
- Ergotine 200x
- Alprazolam 12x
- Diazepam 12x
- Chlorpromazine 4c

Suggested dose:

4-5 sprays directly under tongue
2-3 times a day or as directed by a healthcare practitioner.
Frequency of dose can be increased during acute conditions.

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

Bactrol

May be supportive for bacterial infections



Bactrol contains:

- Hepar sulph 30x
- Myristica 30x
- Anthraxinum 30x
- Pyrogenium 30x
- Silicea 30x
- Streptococcin 30x
- Pneumococcin 30x
- Staphylococcin 30x
- Penicillinum LM9
- Streptomycin LM9
- Ciprofloxacinum LM9

Suggested dose:

4-5 sprays directly under tongue
2-3 times a day or as directed by a healthcare practitioner.
Frequency of dose can be increased during acute conditions.

Deprel

May be supportive for depression



Deprel contains:

- Ignatia LM3, 6c, 30c
- Natrum mur LM3, 6c, 30c
- Aurum met LM3, 6c, 30c
- Kali phos LM3, 6c, 30c
- Hyoscyamus LM3, 6c, 30c
- Haloperidol LM3, 7c
- Chlorpromazine LM3, 7c

Suggested dose:

4-5 sprays directly under tongue
initially once a day, then gradually
2-3 times a day or as directed by a
healthcare practitioner.
Frequency of dose can be increased
during acute conditions.

Parastat

May be supportive for parasitic infections



Parastat contains:

- Kurchi 6c
- Ipecacuanha 6c
- Chaparo am 6c
- Candida alb 12x
- Emetine 12x
- Natrum phos 12c
- Entamoeba histolitica nosode 30c
- Norfloxacin 12x
- Metronidazole 12x
- Tinidazole 12x

Suggested dose:

4-5 sprays directly under tongue
2-3 times a day or as directed by a
healthcare practitioner.
Frequency of dose can be increased
during acute conditions.

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

Examples of traditional indications listed on the Therapeutic Goods (Permissible Indications) Determination and available products

Table 1 – Indications relating to general health / body parts

No.	Indication	Evidence	Other requirements	Product example
13	Aids/assists natural body cleansing / detoxification processes	Scientific or Traditional	Product presentation must only refer to detoxification in relation to natural body processes	Swisse Ultiboost Liver Detox See also CRP: 2015/07/020
18	Alterative/blood cleanser/depurative /purifier	Traditional	Product presentation must only refer to detoxification in relation to natural body processes	Schuessler Tissue Salts 6x Blood Cleanser

Table 2 – Indications relating to bone

No.	Indication	Evidence	Other requirements	Product example
5	Decrease/reduce/relieve mild joint pain/soreness	Scientific or Traditional	If symptoms persist, seek the advice of a healthcare professional	Rhus tox (Homeopathic)
9	Decrease/reduce/relieve symptoms of occasional episodes of gout	Scientific or Traditional	If symptoms persist, worsen or episodes become more frequent consult your medical practitioner.	Goutinex 59 ml (Homeopathic)

Table 3 – Indications relating to the cardiovascular system

No.	Indication	Evidence	Other requirements	Product example
5	Cardiotonic/strengthen heart	Traditional	Product presentation must not imply or refer to serious cardiovascular conditions	A.Vogel Heart Tonic

Table 4 – Indications relating to the endocrine system

No.	Indication	Evidence	Other requirements	Product example
2	Maintain/support healthy immune system function	Traditional	Product presentation must not imply or refer to any adrenal related diseases.	Pretorius DHEA 6X (Homeopathic) See also CRP: 2017/03/032

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

Table 5 – Indications relating to the gastrointestinal system

No.	Indication	Evidence	Other requirements	Product example
34	Decrease/reduce/relieve colic (wind/gas pain)	Scientific or Traditional	If symptoms persist, seek the advice of a healthcare professional	Brauer Baby & Child Colic (Homeopathic) See also CRP: 2017/06/019
47	Decrease/reduce/relieve symptoms of motion/travel/sea sickness	Scientific or Traditional	If symptoms persist, seek the advice of a healthcare professional	Jet Ease (Homeopathic)
104	Maintain/support healthy digestion	Scientific or Traditional	Nil	Bioglan Triphala (traditional Ayurvedic tonic)
127	Reduce/decrease/suppress hunger/appetite	Scientific or Traditional	Product presentation must not imply or refer to eating disorders	Swisse Ultiboost Hunger Control See also: 2013 ABC Checkout

Table 6 – Indications relating to the immune system

No.	Indication	Evidence	Other requirements	Product example
15	Maintain/support healthy immune system function	Scientific or Traditional	Product presentation must not imply or refer to serious immunological diseases	Brauer Baby & Child Immunity (Homeopathic) See also CRP: 2011-05-021

Table 7 – Indications relating to muscles

No.	Indication	Evidence	Other requirements	Product example
17	Helps decrease/reduce/relieve mild muscle spasms/twitches	Scientific or Traditional	If symptoms persist, seek the advice of a healthcare professional	Martin & Pleasance Restless Legs Relief See also CRP: 2016/09/006

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

Table 8 – Indications relating to the nervous system

No.	Indication	Evidence	Other requirements	Product example
11	Decrease/reduce time to fall asleep	Scientific or Traditional	Nil	Pretorius Homoeopathic Melatonin 6X See also CRP: 2011-05-021
22	Decrease/reduce/relieve symptoms of mild anxiety	Scientific or Traditional	If symptoms persist, seek the advice of a healthcare professional	Bioglan Ashwagandha (Traditional Ayurvedic Medicine)

Table 9 – Indications relating to nutrition

No.	Indication	Evidence	Other requirements	Product example
6	Enhance/improve/promote/increase nutrient uptake	Scientific or Traditional	Nil	No traditional products found

Table 10 – Indications relating to the reproductive system

No.	Indication	Evidence	Other requirements	Product example
2	Aphrodisiac/Enhance /improve/promote healthy libido	Scientific or Traditional	Nil	Fusion Health Libido (Traditional Chinese Medicine)
4	Decrease/reduce heavy menstruation/periods	Scientific or Traditional	If symptoms persist, seek the advice of a healthcare professional	Fusion Health Tienchi Ginseng (Traditional Chinese Medicine)
8	Decrease/reduce/relieve hot flushes associated with menopause	Scientific or Traditional	If symptoms persist, seek the advice of a healthcare professional	Brauer Menopause Oral Spray (Homeopathic) See also CRP: 2011-04-026

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

Table 11 – Indications relating to the respiratory system

No.	Indication	Evidence	Other requirements	Product example
16	Decrease/reduce/relieve symptoms of common cold	Scientific or Traditional	If symptoms persist, seek the advice of a healthcare professional	Brauer Baby & Child Cold & Flu (Homeopathic) See also CRP: 2012/11/010

Table 12 – Indications relating to skin

No.	Indication	Evidence	Other requirements	Product example
13	Decrease/reduce/relieve bruise pain	Scientific or Traditional	If symptoms persist, seek the advice of a healthcare professional	Brauer Arnicaeze Kids' Bumps & Bruises (Homeopathic) See also: Dermatol Surg. 2002; 28:686-8

Table 13 – Indications relating to the urinary system

No.	Indication	Evidence	Other requirements	Product example
7	Helps decrease/reduce/relieve symptoms of medically diagnosed cystitis	Scientific or Traditional	If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect)	Fusion Health Cystitis (Traditional Chinese Medicine)
11	Kidney tonic	Traditional	Product presentation must not imply or refer to kidney disease.	Fusion Health Kidney Tonic (Traditional Chinese Medicine)

Table 14 – Traditional Chinese medicine indications

No.	Indication	Evidence	Other requirements	Product example
3	Balance Yin and Yang	Traditional Chinese medicine	Please seek the advice of a registered traditional Chinese medicine practitioner if you are unsure if this medicine is right for you.	Fusion Health Menopause

Consultation on the draft Therapeutic Goods Advertising Code 2018 and Associated Guidelines: Notes for Submissions

46	Eliminate/reduce/remove /resolve/dissipate blood stasis	Traditional Chinese medicine	Please seek the advice of a registered traditional Chinese medicine practitioner if you are unsure if this medicine is right for you.	Fusion Health Tienchi Ginseng
64	Nourish/tonify/replenish kidney Yin	Traditional Chinese medicine	Please seek the advice of a registered traditional Chinese medicine practitioner if you are unsure if this medicine is right for you	Fusion Health Kidney Tonic

Table 15 – Traditional Ayurvedic medicine indications

No.	Indication	Evidence	Other requirements	
49	Rasayan/rejuvenative tonic	Traditional Ayurvedic medicine	Please seek the advice of a traditional Ayurvedic medicine practitioner if you are unsure if this medicine is right for you	Bioglan Ashwagandha also Bioglan Triphala