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Australian Government Department of Health Therapeutic Goods Administration

Consultation: Options for the future regulation of "low risk" products

submission for consideration on homœopathic products

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This submission may not be altered, and is made solely with respect to *homœopathic medicine and medicines*, and with the understanding that the role of the *Therapeutic Goods Administration* [TGA] is limited to a consideration of goods intended for therapeutic use, more especially to ensure safety of therapeutic *substances* and *devices*, and that TGA has neither expertise nor statutory authority to make determinations on *homœopathic therapy or its practitioners*. For the purposes of transparency and to ensure wider dissemination we will make this submission available outside TGA.

Overview:

TGA's Consultation paper [CP] correctly identifies *homœopathic products* as low-risk,[1] and following the recommendations of the *Expert Review Panel…* (MMDR) that "*there are a range of products listed in the ARTG that are subject to a level of regulation which is not commensurate with the risk posed by these products to Australian consumers"* are exploring options statedly for reducing control by TGA.

TGA have consequently put forward for discussion four options (CP pp.46-49):

1. Maintain the status quo regulation of homœopathic products
2. Serious therapeutic claims must be supported by scientific evidence
3. Exemption from listing in the ARTG and/or GMP
4. Declare homœopathic products not to be therapeutic goods

Reasoning:

Our attention is immediately drawn to option 4 as the one with the most significant potential consequences for the *practice* of homœopathic medicine in Australia. TGA here recruits the provision of Section 7AA of the *Therapeutic Goods Act 1989* ["the Act"] in proposing this option. But that cited instrument allows only for the Minister to determine exclusion of *specified goods* – it does not provide for a blanket, *en masse* exclusion of an entire armamentarium of *varying* products associated simply by their peculiar method of pharmaceutical preparation.

The Act indeed stipulates[2] medicines are to be taken as separate and distinct in each case wherever they have a different active ingredient, dose, name, indications, container, etc.[3] *Therefrom we read no legal provision for TGA's proposed option 4* which would indiscriminately group all products manufactured using homœopathic pharmaceutical methods, ignoring their *significant individual differences*.[4]

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[1] TGA is here entirely consistent with the larger scientific international community, as seen in the WHO report *Safety Issues in the Preparation of Homœopathic Medicines* (2009) which recruited around 400 reviewers from 105 countries including experts and regulatory authorities from 101 countries, intended as a support document for regulatory authorities, and which clearly stated "Adverse events occurring during homeopathic treatment are rarely attributed to the homeopathic medicine itself."

[2] Part 3-2, clause 16.

[3] Part 3-2, clause 16 (2) allows for exclusion to apply to a group of therapeutic goods only when they have "common characteristics" – meaning of the therapeutic goods themselves, not of the therapeutic modality under which they are applied. For the same reasons grouping cannot apply *en masse* to say *herbal*, *ayurvedic*, etc.

[4] As for example the sources of substances which may derive from poisons such as *Aconite*, *Arsenic*, *Belladonna*, *Conium* (hemlock), *Dulcamara*, *Hyoscyamus*, *Mercury*, *Nux vomica*, *Veratrum*, etc., or from relatively harmless substances such as *Arnica*, *Chamomilla*, *Lycopodium*, *Natrum muriaticum*, etc. This would be like treating all drugs listed in the *British Pharmacopœia* as equal in terms of preparation, risk, and safety, and requiring identical controls.

What is of great concern is the wording of Option 4 which *declares* homœopathic products *en masse* to be non-therapeutic, and by extension therefrom infers Homœopathy a non-therapy.[5] The implications of this extend beyond the statutory provisions for TGA, and are in direct contrast to most other countries around the world where Homœopathy and homœopathic medicines are under legislative control.[6]

The reason for TGA extending themselves into a declaration affecting an entire therapy, hinges upon their reference to the report of NHMRC (2015),[7] comprising 'cherry-picking' *pseudo-findings* against Homœopathy, itself made without clear understanding of what constitutes or defines the very subject sought to be examined, and without undertaking a single medicinal trial, instead merely repeating their pre-positioning given in an earlier position paper.[8] TGA's citing of that report evidences an inability to evaluate on such matters outside their own areas of learning. It is for this reason that consultation with those *learned in the field* being examined must be a matter of necessity.

Our position is that option 4 has no legal provision according to the Act, and is further entirely inappropriate in its inference and possible ramifications affecting an entire profession and the choices of their patients, and *must necessarily be vigorously opposed.*

Other Options 1,2,3:

Option 1 (status quo) is perfectly acceptable should *change* be deemed unnecessary, but it does not address the impetus for change reasoned by MMDR.

Option 3 which represents a great concern given the relatively few homœopathic products listed on the *Australian Register of Therapeutic Goods* (ARTG) cannot be considered an undue regulatory burden on the resources of TGA, and exempting such homœopathic preparations (below the 4x dilution) introduces the real risk that products, unchecked, may be introduced with significant quantities of restricted substance undetected until after adverse reactions have been reported. We therefore oppose this option, and are left to wonder why it was posted given the risks are known to TGA already.[9]

Option 2 is acceptable as most appropriate given homœopathic medicines are not to be prescribed merely upon a 'named' condition, rather, for the individual response of the patient in that condition.[10]

Lastly, we have attached an appendix of definitions to remove much of the evident misunderstandings from Government authorities, stemming from a failure to closely examine the homœopathic literature.

Sincerely,

[redacted]

Wednesday, 10 May 2017

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[5] Perhaps NHMRC & TGA would press our *Governor General* (General Peter Cosgrove) to communicate this *opinion* of the non-therapy (for not a single drug-trial has been commissioned by the authorities reaching this conclusion) to the UK Royal Family to impress the delusion in having trusted their health to Homœopathy over the past 150 years or more?

[6] As for example Europe, UK, Canada, USA, Mexico, India, South Africa, etc. Many of these countries allow registered medical practitioners who have undertaken specialised homœopathic training to practice Homœopathy.

[7] https://www.nhmrc.gov.au/guidelines-publications/cam02.

[8] DRAFT NHMRC Public Statement on Homœopathy" NHMRC, by its own admission therein, adopted a (*pre-*) *position*, and then sought a non-transparent and *selective consensus* from those already known to be of the same view; all without undertaking a single medicinal trial. It is for this reason the NHMRC report warrants disregard and must be rejected.

[9] We are lead to consider TGA has decided their preference, offering only unviable other options as a semblance of due process. Thus options 1 and 3 are readily seen as unacceptable – option 1 because it does not address the impetus for change, option 3 because of the increased risk to public health. And the wording of option 2 also raises suspicion that is has just been "thrown-in", for the term "serious therapeutic claims" is not defined (serious to whom?: to public health, to the individual patient, to select consumer or professional groups?).

[10] Hence the greater variety of medicines indicated for different patients even in the same 'diagnostic' condition.

APPENDIX

definitions

Homœopathy (Gr. *όμοιον* [*omoion,* similar] + πάθος [*páthos,* suffering]):

A method of medical therapy developed by Samuel Hahnemann (1755-1843), based on the reproducible observation that *effects* produced by a substance (both *toxicologies* & *methodical substance trials* [*provings*]) may be removed by that substance when given for a patient presenting *similar* symptoms.[i] This observable and reproducible phænomenon is referred to as the *Law of Similars* (L. *Similia Similibus Curantur*).

The Practice of Homœopathy:

Requires a practitioner prescribe a substance which is known to produce (the most) *similar* effects (regardless of mechanism) to those presented by the patient in their illness.

Homœopathic medicine [*preparation/product*]:

Any substance prepared according to the method of serial *dilution + succussion* (known as *potentisation*) singular to Homœopathy, as described in standardised pharmaceutical works (*homœopathic pharmacopœiæ*).

Homœopathic remedy:

Any substance, irrespective of its preparation methods,[ii] prescribed upon the basis of the *similarity of its known effects* with the *effects of disease* in a patient. We thus distinguish a *medicine* (prepared) from a *remedy* (applied) – a remedy is thus only rightly described as *homœopathic* to the case, i.e., when prescribed strictly according to symptom similarity (of medicine/disease).

Posology (Gr. πόσον [*póson,* how much] + λόγος [*lógos,* reason, consideration]):

The above singular definition for what constitutes Homœopathy makes no mention of *dose* (Gr. δόση [*dósy,* to give]), and it remains remarkable that many in the general scientific community seem ignorant of this basic fact, to the point they identify Homœopathy solely with *potentisation* (something which was developed much later). In fact during the formative years of Homœopathy, practitioners employed *substantial doses* (though generally smaller than the often (too) large even 'heroic' doses common in medicine at that time), and a large portion of the information on substance effects used in homœopathic practice derive from *toxicologies* (accidental, deliberate poisoning, and medical overdose).[iii] Hence even a medicine prepared using methods different to those described in standard homœopathic pharmaceutical works may still be applied *homœopathically* (according to symptom similarity) in a particular case.

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[i] Hahnemann was not the first to observe 'similars', but was the first to then systematically develop an entire method of medical practice. We note numerous authors reporting on "similars" in medicine prior to Hahnemann, as for example:

- Hippocrates (460-370BC), Περὶ τόπων τῶν κατ' ἄνθρωπον [On the Places in Man], §42:

  "Another principle is the following: a disease arises because of similars, and, by being treated with similars, patients recover from such diseases. For example, the same thing produces strangury when it is not present, and stops it when it is present; cough, in the same way as strangury, is engendered and is halted by the same things. … Phlegmasia [inflammation]… is stopped by the things that produce it, and produced by those that stop it."

- Thomas Sydenham (1624-1689), *Opera Medica*, Genevæ, 1769, p.271 – writes that burns are best treated with spirits
- Georg Ernst Stahl (1660-1734), In Jo. Hammelii, *Commentatio de Arthritide tam tartarea*, quam scorbutica, seu podagra et scorbuto, Budingæ, 1738, viii, pp.40-42 – the following translation provided by J.McNoughton, President of the Medical Society of the State of New York, in his *Annual Address*, Feb.6, 1838 (Transactions of the Medical Society of the State of New York, vol.4, 1838-40, p.8):

  "The rule adopted in medicine of treating diseases by remedies which produce effects contrary to those of the disease (*contraria contrariis*) is entirely false and absurd. I am persuaded on the contrary, that disease yields to remedies which produce an analogous affection (*similia similibus*) – burns are cured by keeping the parts affected before the fire – frostbite by applying snow or cold water – inflammations and contusions by spirituous lotions. It is in this manner that I have succeeded in correcting a tendency to acidity by very small doses of sulphuric acid, in cases where a multitude of absorbents had been exhibited to no advantage."

- Anton von Störck (1731-1803) – first used *Stramonium* (known to produce convulsions) in Epilepsy, giving ½ - 1 grain doses of the extract multiple times daily. which results were confirmed by others (refer *A Dictionary of Practical Medicine*, vol.2, 1833).
- Benjamin Bell (1749-1806), *A System of Surgery*, Edinburgh, 1787, vol.5, Chapter 36, of burns, he writes (p.360):

  "One of the best applications to every burn of this kind is strong brandy or any other ardent spirits: it seems to induce a momentary additional pain; but this soon subsides, and is succeeded by an agreeable soothing sensation."

[ii] Medicines which are not prepared according to homœopathic pharmaceutical methods are not considered *homœopathic products* according to the Act, 3AA (1).

[iii] Without wishing to extend the scope of this submission with specific and lengthy citation, we may nevertheless mention (alphabetically) just a few such reporters in the medical literature: Abano, Alexander, Alston, Baylies, Beddoes, Bergius, Boerhaave, Cullen, Duncan, Fabricius, Falconer, Fallopio, Geoffroy, Gmelin, Greding, Hamilton, Hoffmann, Hufeland, Hunter, Mead, Monro, Morgagni, Orfila, Sennert, Störck, Sydenham, Tralles, Wepfer, Withering, etc. etc.