Submission to Senate Community Affairs Legislation Committee on Therapeutic Goods Amendment (2017 Measures No.1) Bill

Dear Committee Members,

My name is Michael Dong. I am a medical student interested in the regulation of complementary alternative medicines. I appreciate this opportunity to participate and express my concerns to this senate enquiry.

I have significant concerns that this Bill (Schedule 6 - Advertising) fails to protect the public from misleading and deceptive homeopathic products. Increasingly, products are being promoted under the guise of homeopathy, despite not conforming to homeopathic traditions or definitions.

An egregious example is the promotion of homeopathic melatonin illustrated above. These $25-$22 homeopathic melatonin products claim to have the same therapeutic effect as the $99 prescription product (Circadin). The companies involved are exploiting the lack of knowledge of consumers about homeopathic dilutions. A 6X dilution of 400 mg of melatonin is a dilution of 10^6 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.

In addition, these products are not in accord with definition of a homeopathic preparation as outlined in Part 1(2) (Interpretation) of the Therapeutic Goods Regulations 1990 (Compilation no. 77):

> ***"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…"

Melatonin, produces sleep, not insomnia; it is therefore not a homeopathic preparation in accord with the homeopathy "Law of Similars" (like cures like). Coffee, not melatonin, is traditionally used in homeopathic preparations to treat insomnia.

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Furthermore, this use of melatonin is not in accord the TGA evidence guidelines on traditional evidence. These state:

> "Traditional indications are based on evidence of a history of medicinal use of the ingredients or medicines that exceeds three generations (75 years) of use."

Melatonin was first discovered in 1958 by dermatology professor Aaron B. Lerner and colleagues at Yale University and thus cannot be used for a "traditional indication".

Another example is Biomedica "homeoceuticals" that are being marketed to practitioners to be dispensed and sold to patients. In the "Anxiostat" example illustrated below, the product contains three prescription drugs: Alprazolam, Diazepam and Chlorpromazine (albeit at dilutions that will have no therapeutic effect). Once again, this company (and practitioners who prescribe and sell these products) are not only breaching the regulations governing homeopathic products, they are also deluding and ripping off consumers.

I submit that products invoking "traditional indications" should require a mandatory disclaimer like that used by the US Federal Trade Commission for homeopathic products.

> "This product's traditional claims are based on alternative health practices that are not accepted by most modern medical experts. There is no good scientific evidence that this product works".

This would protect the public from misinformation, deception and exploitation.

Lastly, the urgency behind this submission comes from a consistent display of inaction from the TGA. Homoeopathic preparations are currently exempt from regulation if they are more dilute than a one-thousand-fold dilution of a mother tincture (4X and above); are not

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required to be sterile, do not include ingredients of human or animal origin and do not refer to serious diseases or conditions.

Regardless, there have been long-standing concerns by consumers and health professionals about the regulation of these products by the TGA and the claims they make.

In 2003, the Expert Committee on Complementary Medicines in the Health System recommended that homoeopathic medicines that make therapeutic claims should be regulated to ensure they meet appropriate standards of safety, quality and efficacy. No action was taken.

In 2008, the TGA held a consultation on the regulation of homoeopathic and anthroposophic medicines in Australia. Numerous submissions were received but no action eventuated.

In 2015, the NHMRC released a statement concluding that there is no good quality evidence to support the claim that homeopathy is effective in treating health conditions. Once again, the TGA did nothing.

This amendment bill is an opportunity to enact meaningful change that will protect consumers from the misleading and deceptive claims promulgated by the purveyors of homeopathic and other traditional medicines.

I urge the Senate Community Affairs Legislation Committee to require the TGA to add to their list of permitted indications (see 26BF of the Bill) a requirement that all indications citing traditional evidence must include the following statement (or words to that effect):

> "This traditional indication is not in accordance with modern medical knowledge; there is no scientific evidence this product is effective".

Yours sincerely,

Michael Dong
Monday 11 December 2017