January 9, 2018

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President/ Secretary

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Submitted to: https://www.aph.gov.au/Parliamentary_Business/Committees/OnlineSubmission

Exposure Draft of Therapeutic Goods Amendment (2017 Measures No. 1) Bill and related measures

Dear Members of the Senate inquiry,

My name is Dr Paulina Stehlik and I am writing on the behalf of the Gold Coast Skeptics, a branch of the Australian Skeptics. I am also a practicing community pharmacist, and Senior Research Fellow at the Centre for Research in Evidence Based Practice, Bond University.

The Gold Coast Skeptics is an evidence-based organisation run by volunteer members. We encourage thoughtful, rational exploration of the world around us and encourage people to think carefully and seek appropriate evidence before coming to a conclusion on any issue.

Our primary concern is that the Bill does not adequately protect the public from misleading claims regarding product effectiveness and safety. In saying this we provide the following commentary to the Senate Community Affairs Legislation Committee regarding the proposed Bill:

1. Advertising pre-approval

The current Bill recommends the abolishment of advertising pre-approval in favour of self-regulation. Currently the pre-approval process is the main barrier to misleading advertising to consumers. We recommend that the abolishment of the pre-approval process be postponed until the 3-year review of the reform to allow for adequate data collection to determine the success of any advertising reforms.

2. Division 6 Subsection 42DKB (1):

> *"If a representation in an advertisement about therapeutic goods is false or misleading, the Secretary may, by notice given to a person apparently responsible"*

We propose that the word *may* be replaced with *must* to improve transparency in TGA processes.

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3. Division 6 Subsection 42DV:

> *"…regulations, the Secretary may, in writing,…"*

We propose that the word *may* be replaced with *must* to improve transparency in TGA processes.

4. Division 2 Subsection 26BF Permissible Indications

Be required to provide a disclaimer for all listed medications that site "traditional use" as evidence of efficacy along the lines of:

> *"This traditional indication is not in accordance with modern medical knowledge; nor there is there scientific evidence this product is effective"*

Patients frequently are misled into believing that therapies that have been used for a long time have more evidence of efficacy than those supported by the scientific literature. My personal experience as a community pharmacist has been that patients often do not understand the premise on which many traditional therapies base their claims (e.g.: homeopathy, chakras, Qi, meridians, etc.) and are often horrified when I explain what these terms mean.

Indeed, there have been well publicised cases of harm caused by these products despite their listing as "low-risk", due to the products not working as claimed, side-effects, or poor product quality-control.

We therefore strongly recommend that the absence of scientific evidence and/ or contradiction to modern medical knowledge of these products be made clear to consumers.

5. Focus of new Code and complaint System

We believe that the focus of the code and complaint system, and required legislative changes, should be broadened to encompass *all therapeutic claims*, including those made about foods and other modalities, not just therapeutic goods.

Yours sincerely

[redacted]

Dr Paulina Stehlik

President/ Secretary Gold Coast Skeptics

On behalf of the Gold Coast Skeptics Advisory Committee: Mr Paul Heeren (Treasurer), Mr Max Clixby, Mr Casey Shannon, Mr Harley Stansfield, Mr Simon Leonard