choice

Friday 12 January 2018

Senate Community Affairs Legislation Committee
By email: committee.sen@aph.gov.au

RE: Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and related bill

CHOICE is Australia's leading consumer advocacy organisation. We represent over 160,000 members and 126,000 campaign supporters in our mission to achieve fair, just and safe markets. On this basis, we have concerns about the exposure draft of the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 (the Bill) and welcome the opportunity to comment.

We appreciate changes in the Bill stem from recommendations within the Expert Panel Review of Medicines and Medical Devices Regulation (the Review). Several of these measures will address long-standing concerns with the regulation of complementary medicines and advertising of therapeutic goods. However, CHOICE shares the concerns of other consumer representatives and academics that the Bill in its current form will create adverse outcomes for consumers.

Our primary concerns are in relation to the broad number of proposed permitted indications, many of which are not backed by scientific evidence, and the ceasing of the pre-approval process for advertising therapeutic goods. We therefore recommend that;

1. Indications based on traditional use display a prominent disclaimer stating that the product's claims are not based on scientific evidence.
2. The pre-approval process for advertising therapeutic goods continues until a formal independent review of the system is completed.

Permitted indications on complementary medicines should be supported by scientific evidence

As part of the reforms to regulate complementary medicines, the Bill supports Recommendation 38 from the Review which states that the Therapeutic Goods Administration (TGA) should establish a list of permitted indications for listed complementary medicines, from which sponsors of these products must exclusively draw.[1] CHOICE believes that indications on complementary medicine should be better regulated and we support a list of pre-approved claims. However, there is a clear need for any pre-approved claims to be backed by independently-assessed scientific evidence.

The current list contains an overwhelming 1,019 permissible indications, with the majority lacking sufficient evidence. Of these, the list contains;

- 140 indications which must be supported by scientific evidence.
- 879 indications that can be supported by a tradition of use such as traditional Chinese medicine, ayurveda and homeopathy.[2]

Including numerous traditional indications such as 'balance Yin and Yang' or 'regulate Chong channels' allows companies to make claims without having scientific proof of efficacy of their products. It allows industry to evade the need to prove their products work illustrating that the proposed mechanism to 'regulate' complementary medicines does not work. This is best highlighted through the recent actions of Swisse (Appendix 1) whose 'Ultiboost Appetite Suppressant' was de-listed in 2013 due to 'insufficient evidence to support the indications for the product.'.[3] Within the same year, Swisse re-listed the exact same product, changing the label to

[1] Expert Panel Review of Medicines and Medical Devices Regulation http://www.health.gov.au/internet/main/publishing.nsf/content/8ADFA9CC3204463DCA257D74000EF5A0/$File/Review%20of%20Medicines%20and%20Medical%20Devices%20-%20Recommendations_Accessible.pdf

[2] TGA Draft Permitted Indications https://www.tga.gov.au/draft-list-permitted-indications

[3] Clone of Complementary medicines: Cancellations from the ARTG https://www.tga.gov.au/clone-complementary-medicines-cancellations-artg?field_date_cancellation_value%5Bvalue%5D%5Byear%5D=&sort_by=field_date_cancellation_value&sort_order=ASC&items_per_page=60

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include a ‘traditional use’ qualifier, to evade the requirement of being based on scientific evidence. The Checkout produced segments on this issue in 2013[4] and again in 2017.[5]

While a list of permitted indications that largely contains traditional use indications suits the needs of industry, it is to the detriment of consumers who are unable to determine between claims based on scientific evidence and those that are unfounded. This results in direct consumer harm in two ways: first, consumers spend money on products that they do not realise are not proven to fix their problems and second consumers may forego evidence-based products and spend money on a product with no proven efficacy.

This is further evidenced through Fusion’s ‘Menopause Free’ supplements (Appendix 2). Many women seek supplements to address the symptoms of menopause which can significantly affect women’s quality of life.[6] The menopause products produced by Global Therapeutics Pty Ltd claim to “relieve the physical and emotional symptoms of menopause.” The product contains a “carefully formulated blend of Chinese herbs [that are] traditionally used to balance Yin and Yang during menopause.” These claims exploit consumers who are not aware that the traditional Chinese concept of energy forces (Yin and Ying) has not been validated by scientific enquiry. In addition, the average consumer would not know that the traditional use claim means there is no scientific evidence that this product is effective.

Australia is a multicultural country and it is appropriate we respect and allow access to alternative medical traditions. However, it is also important that consumers are protected from misleading claims. For consumers to be able to make an informed choice about complementary medicines, products displaying traditional use indications must also be required to display a prominent disclaimer on the label to the effect of;

[4] The Checkout, 2013 https://www.youtube.com/watch?v=12ww26sQF7E
[5] The Checkout, 2017 https://www.youtube.com/watch?v=56tD0NTxnHM
[6] The Conversation https://theconversation.com/trick-or-treat-alternative-therapies-for-menopause-18007

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> *"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 is in line with disclaimers used by the US Federal Trade Commission for homeopathic products.[7] It is also in line with Recommendation 44 of the Review which advocated that a prominent disclaimer should be applied to all promotional material relating to listed complementary medicines, to the effect that the efficacy claims for the product have not been independently assessed.[8]

The TGA's updated guidance on permitted indications is unsatisfactory

Following a consultation on the TGA's draft permitted indications in October 2017, the TGA has sought comment on new guidance which recommends that traditional Chinese medicine and ayurvedic indications must include an advisory statement on their label with words to the effect of;

- '*Seek advice from a registered Chinese medicine practitioner to ensure this medicine is right for you'*
- *'Seek advice from an Ayurvedic medicine practitioner to ensure this medicine is right for you.'*

This requirement is deeply unsatisfactory - it does not address the underlying issue of potentially misleading claims and raises further issues. First, it only applies to a subset of permissible indications (206 of 1019) and therefore creates inconsistency between products. Why would a product with a Traditional Chinese Medicine indication recommend consultation with a practitioner but a product with Homeopathic indications or listed medicines with scientific indications do not?

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[7] US Federal Register https://www.ftc.gov/system/files/documents/federal_register_notices/2016/12/homeopathic_drugs_frn_12-13-2016.pdf
[8] Expert Panel Review of Medicines and Medical Devices Regulation http://www.health.gov.au/internet/main/publishing.nsf/content/8ADFA9CC3204463DCA257D74000EF5A0/$File/Review%20of%20Medicines%20and%20Medical%20Devices%20-%20Recommendations_Accessible.pdf

Second, it is unlikely consumers will take heed of these advisory statements and if they do, seeking advice from a Ayurvedic or Chinese Medicine practitioner is unlikely the best defence against unfounded claims. Most importantly, this advice is ineffective and does not communicate to consumers that the claim is not backed by scientific evidence and will therefore not minimise the risk of consumers being misled.

The pre-approval process for advertising therapeutic goods should continue

The Bill incorporates a recommendation from The Review that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.[9]

In the Minister for Health's second reading of the Bill, he stated the aim of 'streamlining the advertising framework' was so that consumers will be 'better informed about the medicines and healthcare products they buy.[10] However, abandoning pre-approval of advertisements will result in consumers being less informed due to potentially misleading and even dangerous claims being made on mainstream media.

The responsibility for pre-vetting advertisements is currently split between two bodies; Australian Self Medication Industry (ASMI) and Complementary Medicines Australia. The Advertising Standards Manager at ASMI reported that in 2014/15, ASMI reviewed over 1,400 advertisements with an average turnaround time of 7 days.[11] She noted that during this period, the majority of new advertisements assessed required changes to avoid breaching the Therapeutic Goods Advertising Code, sometimes wholesale revisions. Considering this, it is evident that this process is essential in protecting consumers against false and misleading advertising. Ceasing pre-vetting opens a

[9] Expert Panel Review of Medicines and Medical Devices Regulation
http://www.health.gov.au/internet/main/publishing.nsf/content/8ADFA9CC3204463DCA257D74000EF5A0/$File/Review%20of%20Medicines%20and%20Medical%20Devices%20-%20Recommendations_Accessible.pdf
[10] Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 Second Reading
http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansardr%2F71dedd3e-cf9b-446c-a886-d27af6602161%2F0032%22
[11] MJA InSight https://www.doctorportal.com.au/mjainsight/2016/38/advertising-reform-watering-down-consumer-protection/

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floodgate of issues – advertisers can say anything they want and, while the TGA has enforcement powers, once an advertisement has been aired or published, the damage has been done and consumers are unwittingly misled.

Before any changes to this process are made, we strongly support a formal independent review of the system. Sufficient evidence should be collected that demonstrates that there is no need for pre-approval of adverts before such a decision is made.

In summary, any changes to the Therapeutic Goods Act should support a more robust system that effectively protects consumers from false and misleading information. While several measures in the Bill will address long-standing concerns, without appropriate amendments the proposed legislation will result in direct consumer harm.

For further information please contact CHOICE on kday@choice.com.au.

Yours sincerely,

Katinka Day,
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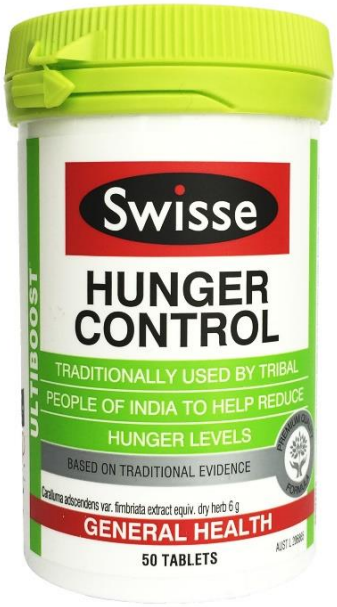
CHOICE

Appendix 1

Swisse Appetite Suppressant delisted from the Australian Register of Therapeutic Goods in 2013 due to insufficient evidence to support the product's indications.



Swisse Hunger Control listed on the Australian Register of Therapeutic Goods in 2013. The product is exactly the same as the delisted product however the label now includes the 'traditional use' qualifier.

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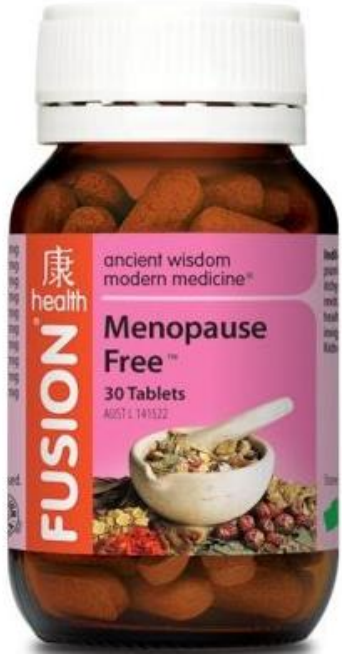
Appendix 2



FUSION Menopause Free claims to "relieve the physical and emotional symptoms of menopause. The average consumer would not know that the "traditional use claim" means there is no scientific evidence that this product is effective.

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