RACGP
Royal Australian College of General Practitioners

Healthy Profession.
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12 January 2018

Senate Community Affairs Legislation Committee
Additional Committee Support
PO Box 6100
Parliament House
Canberra ACT 2600
committee.sen@aph.gov.au

Dear Committee Secretariat,

Re: Inquiry into the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and the Therapeutic Goods (Charges) Amendment Bill 2017

The Royal Australian College of General Practitioners (RACGP) is Australia's largest medical college representing over 35,000 members working in or towards a career in general practice. We thank the Senate Community Affairs Legislation Committee for the opportunity to comment as part of the inquiry into the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and the Therapeutic Goods (Charges) Amendment Bill 2017.

Under these Bills, the TGA will introduce a list of permitted indications from which sponsors must exclusively draw when listing their medicine on the Australian Register of Therapeutic Goods (ARTG). The stated purpose of establishing the list of permitted indications is to:

- Ensure that listed medicines can only make low level indications that are suitable for medicines that do not undergo pre market assessment.

- Provide transparency for sponsors on what indications are suitable for listed medicines to help prevent inadvertent non-compliance.

The RACGP is concerned that including numerous 'traditional' indications on this list encourages industry to evade the requirement to have scientific proof of efficacy for their products, endorses pseudoscience and will mislead and confuse consumers.

Our recommendation summary:

We ask the Senate Community Affairs Legislation Committee to:

1. Recommend that the TGA creates a mandatory obligation that all tradition-based health claims must be accompanied by a statement that there is no scientific evidence to justify that health claim.

2. Recommend that the range of goods covered by the Therapeutic Goods Advertising Code be broadened to include other products, including foods.

Background:

Take, for example, a product 'X' which is completely inert – that is, it has no benefit to health whatsoever. Consumers have every right to still buy and consume product X, but should clearly not be misled into believing that it will be of specific health benefit.

Yet the proposed Bills will allow the manufacturer to claim that X nourishes or rejuvenates, or assists weight reduction or jet lag. Manufacturers can simply state that X is a traditional product that has at some point been recommended by various alternative practitioners.

This justification is so vague that it is hard to see any product failing to meet that low bar. It would be extraordinarily difficult to refute the statement that some tradition has recommended product X for whatever therapeutic benefit the manufacturer chooses to advertise.

To base the regulation process merely on manufacturer claims about tradition entirely ignores the question 'Does it work'?

Regardless of whether X was a powdered bean, a jelly bean or a drop of water, very little in the proposed Bill would prevent the manufacturer continuing to claim that X may help arthritis, insomnia or anxiety, based on tradition. No application of the scientific method could ever thwart such an advertising claim, because although the health claim itself is testable by science, any negative outcome of that test would be irrelevant under the proposed Bills.

Our proposal:

The RACGP preferred 'default' position would be to restrict therapeutic claims to those supported by scientific evidence.

However, we are aware that such a regulatory outcome is unlikely, and that the vast majority of indications that have been proposed by industry (879 out of 1019) fail to meet this criterion.

We therefore propose instead that a 'lack-of-evidence disclaimer' must immediately follow any unsupported health claim.

This concept is similar to US Federal Trade Commission regulation – for example, their Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs states, "The promotion of an OTC homeopathic product for an indication that is not substantiated by competent and reliable scientific evidence may not be deceptive if that promotion effectively communicates to consumers that: (1) There is no scientific evidence that the product works and (2) the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts." [ref: FTC]

1. We strongly recommend that the TGA mandates that manufacturers must include a statement to accompany all non-scientific therapeutic claims, in close proximity and in the same font as the health claim.

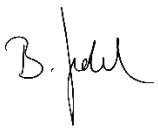
The mandated statement should read similarly to the US FTC example quoted above:

'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'.

We note that this recommendation will not impede any manufacturer from choosing to market their product to people with a particular health condition. It merely provides the consumer with information that protects them from being led to believe that the health claim is backed by scientific evidence.

2. The lack of regulation around therapeutic claims for foods provides an inappropriate alternative pathway for manufacturers to promote unsubstantiated health claims. Rather than trying to create an entirely new regulatory system for foods, it makes more sense to protect consumers from unjustified claims by broadening the scope of the Therapeutic Goods Advertising Code to include foods and other products.

Yours sincerely



Dr Bastian Seidel
President

[FTC] Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs. Federal Register/Vol. 81, No. 239/Tuesday, December 13, 2016/Notices