Australian Greens' Dissenting Report

1.1 The Australian Greens referred the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 to the Senate Community Affairs Legislation Committee for inquiry in report due to the significant concerns raised about the stakeholder consultation associated with the bill, as well as specific concerns relating to Schedule 2 and Schedule 6 of the bill.

Consultation

1.2 The Australian Greens note the concerns raised about the consultation on the measures in this bill. Many submitters to the inquiry have highlighted that while there has been some consultation associated with reform options prior to the bill being introduced into Parliament, the wide range of views and concerns have not been adequately represented in the drafting of the bill.

1.3 It is noted that while the Department has categorised all the amendments in this bill as arising from the Expert Review of Medicines and Medical Device Regulation (the Sansom Review), some elements of the bill go further than what was recommended in the report of that review, and indeed seem not to have taken into account the legitimate concerns of some stakeholders about the implications of these reforms.

1.4 The Senate inquiry has provided a further opportunity for stakeholders to highlight their concerns, and yet the majority report has once again disregarded these concerns and recommends that the bill pass the Senate in its current form.

1.5 The Australian Greens recognise that the concerns of stakeholders require consideration given the significant implications of the proposed changes to the regulation of complementary medicines for Australian patients and consumers. These stakeholders include the Consumers Health Forum, Choice, and Associate Professor Harvey and Professor Braithwaite.

Permitted indications and lack of disclaimer

1.6 Schedule 2 of the bill would enable the Minister to determine a list of 'permitted indications' that can be made for medicines listed in the Register (complementary medicines).

1.7 Currently, the process for 'listing' a complementary medicine on the Australian Register of Therapeutic Goods (ARTG) allows the sponsor company to include a 'free text' description of the indications for that product. Schedule 2 proposes to remove the 'free text' option and replace it with a power for the Minister, via legislative instrument, to establish a list of pre-approved 'permitted indications' which sponsors can use to promote their products, without any assessment from the Therapeutic Goods Administration (TGA).

1.8 The Australian Greens share the concerns of a number of stakeholders who have raised concerns in their submissions about the implementation of this proposed new approach, in particular given that the Sansom review had made a supplementary

recommendation for a prominent disclaimer to also appear on the pack of complementary medicines, alerting consumers of the lack of testing for efficacy.[1]

1.9 For example, in the submission from the Consumers Health Forum it is stated that:

> Our concern is that the limitations of this list of permitted indications may not be understood by many consumers and it may give them some misplaced confidence in the evidence behind the list. If the proposal [had been adopted] from the Review of Medicines and Medical Device Regulation that there should be a disclaimer on all listed complementary medicines making it clear that the efficacy claims had not been independently verified, then this would not be such a problem.[2]

1.10 This call is echoed in a range of submissions including the Royal Australian College of General Practitioners (RACGP) who state that:

> 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.
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> The mandated statement should read similarly to the US FTC example…:
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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'.*
>
> 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.[3]

1.11 The Sansom Review recommended that:

> …where a medicinal product is listed in the ARTG under Option One (self-assessment), the sponsor is required to include a prominent disclaimer on all promotional materials relating to the product, including product information on websites, to the effect that the efficacy claims for the product have not been independently assessed and/or are based on traditional use.[4]

1.12 This recommendation was made to work in correlation with the introduction of a permitted indications list, to ensure that consumers have the information they

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1 See, for example, Choice, *Submission 38*; Consumers Health Forum, *Submission 19*; Access 2: Foundation for Effective Markets and Governance, *Submission 32*; and additional information provided to the Committee by the Friends of Science in Medicine.

2 Consumers Health Forum of Australia, *Submission 19*, pp. 5–6.

3 Royal Australian College of General Practitioners, *Submission 39*, pp. 2–3.

4 Recommendation 44, Lloyd Sansom, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation – Stage Two: Report on the Regulatory Frameworks for Complementary Medicines and Advertising of Therapeutic Goods*, July 2015, p. 38.

need to understand the level of regulatory oversight that is applied to the efficacy claims for listed, or complementary medicines. The Australian Greens are disappointed that this recommendation was rejected by the Government in its response to the Sansom Review. As a consequence of this decision, the bill proposes to introduce a lengthy list of permitted indications without the accompanying disclaimer.

Recommendation 1

1.13 The Australian Greens recommend that Schedule 2 of the TGA Bill be amended to require that sponsors include a disclaimer on their ARTG listed medicines under Option One, as set out in Recommendation 44 of the Expert Review of Medicines and Medical Devices Regulation Report.

Deregulation of advertising and removal of preapprovals

1.14 Schedule 6 of the TGA Bill proposes to remove the current system of pre-approvals for advertisements of therapeutic goods. Currently, proposed advertisements are submitted to a pre-vetting process, under a power delegated to the Australian Self Medication Industry (ASMI) and Complementary Medicines Australia, to ensure they meet the approved standards.

1.15 Numerous submitters to the inquiry have raised concerns about the removal of this current layer of oversight. The current system guards against the distribution or broadcast of advertisements in breach of the relevant regulations and protects consumers from misinformation about the efficacy or indications of products.

1.16 The current need for the pre-approvals process is outlined in the submission from ASMI:

> ASMI estimates that 60 – 70% of advertisements submitted to the ASMI Advertising Services Office for pre-approval, require some form of amendment, ranging from relatively small amendments to major reviews of advertisements. Without pre-approval 2 serious adverse consequences arise:
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> - First, consumers would have been exposed to those non-compliant advertisements and may suffer adverse health or economic impacts.
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> - Secondly, sponsors face potentially very expensive revisions to marketing campaigns after launch. Campaign costs range from $200,000 to $10,000,000 and while large member companies have the resources for extensive compliance checking, a significant burden will fall on firms at the smaller end who have limited regulatory and compliance resources and have come to rely on ASMI providing a review function.[5]

5 ASMI, *Submission 43*, p. 5.

1.17 The Australian Greens concur with the concerns of stakeholders including CHF, Choice, Friends of Science in Medicine, Access 2, Public Health Association of Australia (PHAA), ASMI[6], that there is little sense in removing this layer of regulatory protection, at the very least until the effectiveness of the new sanctions for breaches have been assessed and reviewed through the formal three year review of the reforms.[7]

Recommendation 2

1.18 The Australian Greens recommend that the removal of pre-approvals for therapeutic goods advertising be delayed at least until after the three year review of the broader reform package.

Senator Rachel Siewert
Deputy Chair

6 See, for example, Associate Professor Ken Harvey, *Submission 2*; Centre for Research in Evidence Based Practice, *Submission 13*; Consumers Health Forum of Australia, *Submission 19*, Public Health Association of Australia, *Submission 22*; Mr Allan Asher, *Submission 31*; CHOICE, *Submission 38*.

7 The TGA has committed to an 'external review of the complaints model after three years'. See Department of Health, *Submission 46*, p. 19; Therapeutic Goods Administration, *TGA business plan 2017–18*, https://www.tga.gov.au/book-page/regulatory-reform-0 (accessed 1 February 2018).