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From: KELLY, Larry
Sent: Tuesday, 6 February 2018 1:12 PM
To: [REDACTED]; SKERRITT, John; HAWKINS, Ross
Cc: Minister McKenzie DLO; [REDACTED]
Subject: RE: Written material to support rebuttal against Greens' amendments [DLM=For-Official-Use-Only]

Hi [REDACTED]

Here are some rebuttal points and some further background if needed for the Greens' amendments.

Let me know if you need anything else.

Thanks

Larry

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Responses to Greens' Amendments to the Therapeutic Goods Amendment (2017 Measures No 1) Bill 2017

Following are rebuttal points to the Greens' concerns. More details and background to the permitted indications reforms is attached.

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Amendment 2 – Require products that use indications citing traditional evidence (ie not scientific) to have a label statement saying the indication is not in accordance with modern medical knowledge and there is no scientific evidence that this product is effective.

Response: The government agrees with providing consumers with the maximum amount of information to make informed choices. However, this proposal is not supported because:

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- Overseas experience shows it will be ineffective: The experience from the US (where such disclaimers have been mandated by the US Food and Drug Administration) is that these disclaimers are ineffective in assisting consumers make more informed choices when self-selecting medicines. A number of independent studies published in major consumer research and health policy journals have reached the same conclusion.

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- Offensive and disrespectful: The negative statement will be offensive to those traditional cultures that have a very long history of practising within a traditional medicine paradigm. Chinese medicine for example goes back 4000 years, has been extensively refined, practised, documented and incorporated into mainstream medicine. A statement required by the Australian government that the indication is not in accordance with modern medical knowledge and that there is no scientific evidence will be seen as arrogant and insensitive.
- Not consistent with WHO: Australia has endorsed the WHO position on the role of complementary medicines in national medicines frameworks. This position acknowledges that traditional medicines have a valid function in modern medicinal frameworks.
- Not consistent with AHPRA: Traditional Chinese medicine practitioners are recognised under the national law governing medical practitioners administered at Commonwealth level by the Australian Health Practitioners Regulatory Authority. This follows a detailed review by government of which modalities are evidence based and therefore have credibility.
- Compliance programs will be strengthened: Government has committed to increased compliance activity for listed medicines. Any sponsors found not have the evidence to support their indications will be removed from the ARTG.

Background to Key Issues – Permitted Indications for Listed Complementary Medicines:

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3. Concerns raised by some consumer advocates

- a. *A mandatory label warning statement (or 'disclaimer') should be enforced for sponsors who select indications based traditional evidence. The statement should say "This traditional indication is not in accordance with modern medical knowledge and there is no scientific evidence that this product is effective"*

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- Overseas experience: The experience from the US (where such disclaimers have been mandated by the US Food and Drug Administration) is that these disclaimers are ineffective in assisting consumers make more informed choices when self-selecting medicines. A number of independent studies published in major consumer research and health policy journals have reached the same conclusion.

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b. Use of traditional Chinese medicine terminology that is confusing for general consumers

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- As part of its Traditional Medicine Strategy, the WHO recommends that all member states appropriately include traditional medicine terms in their regulatory, legislative and policy initiatives around traditional and complementary medicine products and practices. The TGA's approach to implement the permitted indications reform is consistent with this strategy.

