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To whom it may concern,

Re: Reforms to the regulatory framework for complementary medicines: Assessment pathways

Thank you for the opportunity to comment on the '*Consultation: Reforms to the regulatory framework for complementary medicines: Assessment pathways*'.

Phytologic Holdings is a small Australian owned and operated company supplying quality Australian listed medicines. We were therefore concerned to read the proposed revisions to the regulatory framework for Australian complementary medicines.

There are three major aspects to our concerns around the proposed reforms as they are currently written. The first, and major, is that the proposal in its current form doesn't appear to achieve the stated primary aim, which is to provide 'transparency to consumers and healthcare professionals' on the regulation of medicines by the Therapeutic Goods Administration (the TGA).

Secondly, the proposal unfairly penalises small businesses with the introduction of new fees for commercial advantage, with no public health justification for their imposition.

And thirdly, the proposal as written is internally inconsistent and challenging to navigate, making it difficult to evaluate how it will be implemented, and therefore its impact on industry, or benefits for healthcare professionals and consumers.

To our first point, the main reason advanced for the need for change is 'healthcare professional and consumer confidence' in TGA regulation. In our opinion, this goal is best served by the TGA doing a consistent and transparent job of enforcing the current regulations; and by the TGA communicating effectively to consumers and healthcare professionals about the regulatory system and its operation in Australia.

Sponsors are rightly responsible for ensuring that they communicate clearly and accurately about their products, and don't exaggerate their benefits or mislead consumers. However, they are not responsible for educating consumers about the regulatory framework for medicines. If the TGA are of the view that consumers are confused, then the TGA needs to address this; it's neither appropriate nor reasonable that industry do so. We cannot find provision in the proposal for the TGA itself to alter or increase its communication and education of the relevant groups to address this need, nor for there to be any increase in transparency of how the TGA will determine and enforce the regulatory requirements. It is not appropriate for industry to be the primary source of education for consumers about the TGA; the TGA itself should be working to ensure transparency and consistency across the board in their operations. To our reading, this proposal consistently shirks the TGA's obligations and attempts to inappropriately redirect the responsibility to industry.

The proposal also notes at several points throughout that listed medicines are considered 'low risk', and don't warrant heavy regulation. At the same time, though, the revisions provide a heavy-handed system of restrictions that, if implemented as written, take away sponsors' ability to accurately state

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a medicine's benefits unless they pay an as-yet undisclosed fee. The public health intent behind the current system of regulation is to allow consumers to self-select low risk medicines for minor and self-limiting conditions. This proposal seems to go beyond that, but if listed medicines are 'low risk', what is the justification for reducing consumer choice and sponsors' ability to communicate, and imposing an unfair burden on small businesses?

The proposal also does not consider the likely effect of the reforms on complementary medicines sitting on the food/medicine boundary. Under the Australia New Zealand Food Standards Code (the Code), eligible food products are already able to make stronger claims than listed medicines, with far fewer quality requirements and far less scrutiny and enforcement action. The proposed revisions put more barriers in the way of compliant sponsors, and push non-compliant sponsors towards launching their products as 'foods'. Given the lower costs of manufacture and regulatory compliance of 'food' products compared to medicines, this makes it more difficult for compliant sponsors to compete, as well as limiting the ways in which they can communicate about their product. We cannot see how this creates a public health benefit for consumers, or lessens confusion with regards to medicine regulation.

We also struggle to understand how adding an 'intermediate' tier of medicine that is able to (effectively) claim TGA endorsement provides any sort of clarity to consumers or public health benefit. Registered medicines, although subject to greater scrutiny, will not be able to make this claim, leading to confusion about what medicines are 'stronger' or more 'evidence based'. If a consumer can choose between an intermediate tier medicine with the TGA endorsement 'claimer', and an OTC medicine, surely the intermediate medicine will appear to have greater credibility. We cannot see how this assists with the transparency of regulation of medicines.

Given that there is also no facility for 'general level' indications to be approved by the TGA for this intermediate tier, a perverse incentive may be created that encourages consumers to select products indicated for more severe conditions instead of general ones for the maintenance of health. Given the aim of listed medicines is to allow safe self-selection of products for self-limiting conditions, this seems counter-intuitive, and counterproductive.

We are also disappointed by the proposal to remove the ability for the Health Minister to approve the use of claims including what the TGA defines as 'restricted representations, where a public health benefit exists. Under the current framework, listed medicines may use claims for restricted representations if the Health Minister specifically approves the claim and its conditions under Section 42DE of the Therapeutic Goods Act 1989, due to the demonstration of a benefit to public health from the communication. Under the revised framework, the TGA are proposing to remove this facility, including for claims for restricted representations that have previously been approved by the Minister.

This seems to be in contrary of the clear public health goals of these approvals, and to be unfairly punitive of the sponsors of products compliantly using the claim. Given that the approval process requires the applicants to demonstrate a clear health benefit to the approval, and for the Minister to evaluate each on a case by case process, on what grounds can the TGA justify this?

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On our second point, the proposed changes will unfairly advantage larger sponsors, while making it harder for small sponsors to compete.

As mentioned above, the fees for having an intermediate tier have not yet been proposed, but are stated to be likely to 'less than those for registered medicines', which range from $10,000 to $70,000, depending on the page count of the submission. The proposal also allows for a fee for the TGA to consider whether the medicine is eligible to apply for assessment for the intermediate tier, and the medicine must be listed as a general AUST L medicine before the sponsor can apply. This will require sponsors to spend thousands of dollars on products in regulatory fees before the sponsor can even determine if they have a viable marketing platform. Most small companies will be unable to sustain the cost burden, which will therefore act to stifle innovation, as well as discouraging competition and favouring larger sponsors.

The proposal also allows for a fee to add new permitted indications for general listed medicines once the free text facility is removed. Therefore, if a sponsor holds evidence for an appropriate indication that is not on the list, they will need to pay the fee in order to communicate the medicine's action, which, again, obviously disadvantages smaller sponsors.

Given that the TGA has provided a definition for permissible indications, and the proposal explicitly states that the TGA will not be evaluating any evidence for the indication, the addition of new compliant indications should be covered by the standard annual fees for listed medicines. Since any added indications would necessarily be available to all sponsors, how can a small company is unlikely to be able to justify paying the fee. To us, adding new permitted indications should be considered as part of the general regulatory burden of medicine recovered through the standard cost-recovery process.

The proposed 'innovations protection' mechanisms also appear to be poorly defined, and unfairly burdensome on smaller businesses. We also note that the TGA is willing to offer incentives such as data exclusivity to sponsors, but explicitly disclaims any role in enforcing them. If the TGA is willing to offer exclusivity for claims or ingredients not willing to penalise breaches of these agreements, it again thrusts an unfair burden onto small businesses, who will have to take expensive legal action to enforce rights the TGA should be policing, or at the very least, enforcing.

Finally, to our third point, the proposal as drafted suffers from a number of issues in clarity and internal consistency, as well as poorly defined scope. As an example, page 6 notes (emphasis added):

> The Panel did not consider the regulation of all low risk products in making recommendations relating to complementary medicines regulation. A range of products, including sunscreens, are not complementary medicines, but are currently listed on the ARTG. They are not being considered directly in this consultation but will be addressed in a separate consultation **along with homeopathic products and other complementary medicines such as low dose vitamins and minerals.**

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The TGA needs to provide clarity around which medicines it considers are affected by the proposed changes. What 'other complementary medicines' are not captured by this proposal, and what constitutes 'low dose vitamins and minerals'? If multivitamin supplements are not included in the proposal, how will they be regulated?

The scope of the proposed new 'endorsed' claims is similarly poorly articulated. On page 11, the proposal says that the determination of the level of an indication would be on the basis of 'risk factors', but then says that low level indications are equivalent to the current permitted indications for listed meds. It notes that these indications pose 'the lowest level of risk to consumers' and therefore TGA intervention is not warranted.

The proposal further goes on to state on page 21 (our emphasis):

> The proposed criteria **will not reduce the ability of sponsors to use indications which are currently appropriate for listed medicines**. Further, as the permitted indications list will include all indications that are appropriately structured and compliant with the eligibility criteria, it is unlikely that the list will affect currently compliant sponsors.

If this is the case, it is difficult to see what benefit will be provided by the new tier, other than an endorsement 'claimer'.

However, the examples of claims appear to contradict this. Page 14 says a low level claim would be 'may help manage symptoms of the common cold', which it claims could be 'upgraded' to an intermediate indication such as 'improves symptoms of common cold such as sore throat and runny nose within two days'. Page 11-13 state that indications for listed medicines may refer to 'a disease, ailment, defect or injury other than a serious disease'. Under that definition, there is no requirement for claims to automatically be qualified by 'may', and the second version of the indication is not precluded – in fact, page 22 specifically lists 'helps reduce common cold symptoms' as a compliant claim for listed medicines.

The proposal further discusses adding qualifiers such as 'in pregnant women' or 'in the elderly' to indications on page 26, while page 11 says that directing a claim at a target population is a 'risk factor' for whether a claim is low, intermediate or high. If adding a qualification around the appropriate target population is determinative of the level of claim, then the TGA needs to be clear on how this will be applied.

If the main issue driving the reforms is a lack of understanding of the Australian regulatory system, it is difficult to see how contradictions like this assist it, or help sponsors maintain complaint products.

The complementary medicine industry in Australia is well regarded internationally, with leading Australian-based companies and manufacturing facilities. This is in contrast to many other areas of Australian industry, where multi-national companies operate with little investment or tax contribution in this country and next to no manufacturing presence here in Australia, due to a mass outsourcing to off-shore sites resulting in local employment cuts.

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We have an enviable reputation worldwide for product quality and our regulatory environment. Today we have a successful industry, but these proposed new measures have the potential to stifle investment both locally and from overseas, making it still more difficult for others to enter the market here in Australia. We support the TGA's goals of increasing understanding of the regulatory system, and providing a level playing field for maintaining compliance from industry and ensuring safe consumer choice. We do not consider, however, that the proposal as currently put forward achieves either of these goals.

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