Consultation submission cover sheet

This form accompanies a submission on:

The document 'Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)'	
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I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.	☐ Yes ☒ No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: *(tick all that apply)*

Business in the therapeutics industry *(please tick sector):*

☐ Prescription medicines ☒ Complementary medicines ☐ OTC medicines

☐ Medical devices ☐ Blood, tissues, biological ☐ Other

☐ Sole trader ☐ Business with employees

☐ Importer ☐ Manufacturer ☐ Supplier ☐ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☐ Consumer organisation ☐ Institution (e.g. university, hospital)

☐ Regulatory affairs consultant ☐ Laboratory professional

☐ Health professional – *please indicate type of practice*:

☐ Other - *please specify*:

It would help in the analysis of stakeholder comments if you provide the information requested below.

Comments

An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Please see attached response
Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.
Any additional information on issues not asked in the above questions. If your comments relate to specific parts of the document please provide the page number and reference.

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Thankyou for the opportunity to provide comment on the second version of the consultation document *"Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)"*.

Health World Ltd is a TGA approved manufacturer and distributor of complementary medicines within Australia, and are a leading supplier of supplements to the Health Practitioner and Retail market. Health World is also a significant exporter of complementary medicines.

We are broadly supportive of the intent of regulatory reform to provide clarity and certainty for industry in the area of health claims, and to protect consumers from unwarranted or irresponsible claims. We also acknowledge the changes that have been made to the document between versions, especially with regards to the removal of the requirement for an expert to prepare the evidence review, and the creation of the SEE process. However we are still concerned that the proposed document provides for a significant increase in regulatory burden, without the certainty of a beneficial outcome for the consumer. We are also concerned that the proposed changes to the weight loss and biomarker area will result in a significant loss of products that are currently legally marketed, to the detriment of industry and consumer choice. We are also disappointed that a number of suggestions put forward in the industry (CHC) and our submission to the first consultation have been overlooked, so we reiterate some of them in this response.

We support the industry response

Health World is a member of the CHC and is aligned with and supportive of the responses generated by both the CHC and ASMI to this consultation. The comments in this submission are intended to be in addition to the comments made in the industry submissions.

We are concerned about increased regulatory burden without a guaranteed benefit to the consumer

We see that the proposal as it stands will increase the regulatory burden on companies operating in the listed medicine area. This will mainly be from the additional time required to substantiate indications for a product (estimated to be 3-4 times the work currently required), plus the loss of access to current claims (or ingredients for which no claims will be available).

We are concerned that this increased regulatory burden will not lead to an effective change in the marketplace, especially with regards to the reduction of unsupportable or irresponsible claims. Without an effective deterrent mechanism in place, it is likely that sponsors, who deliberately or unknowingly break the current rules, will continue to do so under future arrangements. The issue of enforcement is not addressed by this document or any current consultation.

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It is proposed that a simpler and more elegant solution would be for a sponsor registration system to be introduced, which would allow for education of individuals before they can become sponsors, and also allow for the deregistration of individuals who continue to break the rules. This would target the areas of concern, without increasing the overall regulatory burden.

Another reason we are concerned that these changes will not have the desired outcome, is that they may have the unintended effect of driving offending sponsors out of the listed medicine environment into the foods environment. There are currently many foods making illegal claims in the market, and the enforcement of the food claims regulations is minimal. Also with the impending arrival of a new food claims environment, many sponsors may take the opportunity to move their products to what is perceived to be the lower regulatory burden of foods. The ultimate consequence of this may be that the same (or similar) products continue to be market with the same (or similar) claims as foods. This will no longer be the TGA's problem, but it will do nothing to improve outcomes for the consumer, and could actually make things worse, as the products will no longer be made under TGA GMP, which would allow for a reduction in product quality. As an overall government response this would then be inadequate and not produce the desired change in sponsor behaviour.

The Sources of Established Evidence list is inadequate and needs to be kept current

Whilst we commend the TGA on the creation of the SEE mechanism in response to the first round of comments, we are concerned that the list produced is inadequate and does not accurately reflect the documents currently used by industry to support indications. We also do not understand the reasoning behind the removal of currently approved texts from the list. We would strongly recommend that the TGA adopt the revised list as provided by the CHC.

As science evolves and as new authoritative documents are produced regularly, it is also essential that a mechanism is created whereby sponsors can apply to have new documents added to the list of SEE over time, in a timely manner. We would suggest that the TGA create and publish a mechanism for new documents to be included on the list.

Weight loss guidelines

We have reviewed our current portfolio of weight loss products and under the proposed regulations we would be forced to stop marketing 100% of our products, as we would not be able to make any weight loss claims. We have also reviewed the available evidence on ingredients with weight loss activity and we believe that there are no ingredients available on the current Aust L list of approved substances that would meet the new criteria, meaning that under the new rules, there would be no weight loss products available within the listed medicine category. Many of the products in this category have been successfully on the market for many years now, which argues for a history of safe use and consumer acceptance. Many also have a substantial body of clinical research to support them; however this research does not meet the proposed

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criteria. We therefore make the point in the strongest terms possible that the effect of the changes will be to decimate the weight loss category, reducing consumer choice and seriously harming the companies that currently produce weight loss products.

Our recommendations are as follows:

- Reduce the period of clinical trial required to 3 months
- Replace the specific requirements for a percentage weight loss with the requirement that the indication/claim matches the evidence, as assessed by the individual preparing the evidence report
- Allow the use of surrogate markers related to weight loss (such as reduces appetite etc), so long as there is no attempt to imply that a surrogate marker may cause weight loss. These markers are of interest to consumers and are clinically meaningful and should be allowed to be included in product indications.

Biomarker guidelines

We are disappointed that our recommendations as relates to biomarkers in our previous submission went largely unheeded in the second version of the guidelines. As with the weight loss guidelines, we have reviewed our current product range against the new biomarker rules and we have great concern that the rules as currently written would lead to the loss of a significant percentage of the range, and a substantial diminishment in the sales of the surviving products. We are also concerned that the changes would lead to consumer confusion over the use of these products, as the claims that would be available would not allow the clear explanation of the use of the products. Once again, these are products and ingredients that have been on the market for many years, arguing for safety and consumer acceptance. We make the point that there is no significant consumer safety issue that is necessitating that increase in regulatory burden in this area.

The issue that is of greatest concern when it comes to biomarkers is the need to use healthy populations to generate supportive evidence. A healthy population is defined in the document as those with a biomarker level only slightly above normal. Although there is substantial clinical evidence to support the action of many natural medicines on biomarkers, very little of this is in healthy populations. The reason why is obvious – if there is nothing wrong with the biomarker in the first place, then how do you design a clinical trial to show a benefit?

Our recommendation is:

- Remove the need to use a healthy population for biomarker claims, and instead use a disclaimer on the bottle that educates the consumer that the product is designed for the maintenance and prevention aspects of health, not for the treatment of serious disease. An example currently in use is that of Iron supplements, which carry the warning that they are not for the treatment of anaemia (even though the exact same iron supplement if sold as an Aust R would be able to make that claim). The evidence for iron

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supplementation comes from 'diseased populations" – ie those with iron levels low enough to be classed as anaemic.

- Any product carrying a biomarker claim could carry the following warning *"This product is not for the treatment of serious disease, it is for the maintenance of normal health and the reduction of risk of disease."* This allows then the use of relevant evidence, without the risk of deceiving the consumer.

Restriction of inappropriate claims

We are concerned that unless there is significant enforcement of the evidence rules, the new guidelines will only serve to punish the companies that are already largely compliant, as they will be the ones who invest the time and resources to meet the new rules. Companies that are deliberately non-compliant now or those who do not understand the rules will not change their behaviour based on these new guidelines unless there is a significant disincentive to break the rules.

- We propose that the TGA require at the time of listing that companies provide to the TGA a copy of the evidence summary. This should be held commercial in confidence by the TGA, but not reviewed unless the product is subject to a post market review. This would be a substantial incentive for sponsors to follow the new guidelines as they know the TGA holds their evidence summary and is able to review it at any time.
- We also propose that the TGA create a system of sponsor registration with a mandatory education component to ensure that all sponsors have an understanding of the rules before they begin listing medicines

Guidance on marketing claims vs indications

- We request specific guidance on what is an indication compared to what is a marketing claim, and how they should be treated.
- What needs to be on the ARTG
- What wording can be used for various levels of claim, given the new levels structure proposed (examples)
- What freedom is there to move away from the indication in marketing claim wording, and especially when coded indications are developed, we believe industry should be able to make a marketing claim that is in the spirit of the indication, not verbatim.
- Structure-function claims, nutrient content claims and statements of fact - are they indications or claims, what are the guidelines around their use. We propose that they do not need to be included on ARTG, but evidence provided for advertising approval/ review on request. <u>However, it needs to be ensured that the advertising approval officers are working to the same standard as industry in this regard.</u>

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Claims relating to safety, such as contraindications with a generic class of pharmaceutical, or contraindication in people with a serious health condition, should be able to be mentioned on the product label to enhance the safe and quality use of complementary medicines

Thankyou for the opportunity to comment, we look forward to working with the TGA to ensure the final document is one that provides industry with clarity, incentive and some certainty, without creating an unnecessary administrative burden that has a negative impact on product cost and consumer choice.

Sincerely,

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