The Pharmacy Guild of Australia

THERAPEUTIC GOODS ADMINISTRATION

Consultation: Reforms to the regulatory framework for complementary medicines

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INTRODUCTION AND GENERAL COMMENTS

The Pharmacy Guild of Australia (the Guild) welcomes the opportunity to provide further comment on reforms to the regulatory framework for complementary medicines.

The Guild has focussed its responses mainly to issues of direct relevance to community pharmacy, providing comments on the specific questions where applicable.

The Guild believes that:

- Consumers have access to objective, informed advice about complementary medicines.
- All health professionals have immediate access to product-specific, evidence-based information about complementary medicines.
- Since complementary medicines are therapeutic goods they should be held to similar standards as registered medicines regarding evidence of claims and other compliance frameworks.

The Therapeutic Goods Administration (TGA) should implement transparent and stronger licensing and marketing processes for complementary medicines sold in Australia to provide the community with confidence with regards to safety, efficacy and responsible marketing.

The Guild believes the majority of complementary medicines are responsibly marketed in Australia and supported by evidence. While the Guild would support the TGA revising the licensing and marketing arrangements for complementary medicines, the complementary medicines industry must be supported to research and publish the necessary evidence so that only credible products are marketed in Australia and consumers and all Australian supply outlets have confidence in the Australian complementary medicines market. Furthermore, there should be appropriate surveillance. Strong action needs to be taken in instances where it is found that therapeutic claims are not supported by evidence.

IMPLEMENTING A LIST OF PERMITTED INDICATIONS

The Guild supports the intent of removing the free text field provision in the Electronic Listing Facility. A list of permitted indications will strengthen the regulatory framework and reduce the likelihood of the presentation/advertising of indications and claims that are not supported by evidence. The Guild reserves its final position pending the finalisation and publishing of the permitted indications list.

The Guild also seeks further information regarding the mechanism that will allow indications to be removed from the list where there is scientific evidence that supports their removal. In terms of consistency, it should also be a requirement to submit scientific evidence when an application is made to add an indication to the list.

Options for implementation of the permitted indications list

The Guild supports the TGA's view that option 2 (core permitted indications which can be modified with pre-approved qualifiers) strikes the best balance between flexibility for industry and compliance with regulatory requirements. However, if sponsors wish to include indication qualifiers for a product, they should be required to supply evidence to support these claims.

Claiming evidence of efficacy

The implementation of a mechanism to allow sponsors to present that the efficacy of their product has been assessed via a claimer on the medicine packaging is supported. The proposed conditions regarding the display of such a claimer appear reasonable and balanced. The Guild has previously suggested the following options for a claimer:

- an appropriate statement or symbol (e.g. tick) for products shown to be efficacious by well conducted trials; and
- a statement such as 'this product has been evaluated by the Australian regulator for efficacy'.

While either option would be acceptable, a symbol may be preferable in terms of simplicity as well as the ability for consumers to understand and recognise the key messaging. Many consumers would already be familiar with a tick symbol to highlight a 'positive' attribute of a product in the context of food.[1] A key consideration is that any proposed symbol must be able to be easily differentiated from existing symbols to avoid confusion or misrepresentation.

The main challenge in implementing such a mechanism is ensuring that such a claimer does not cause confusion or distress amongst consumers who use registered over the counter and/or prescription medicines. Such risks can be mitigated by having Aust L and Aust R numbers more prominently displayed on medicine labels and the TGA running an awareness campaign to inform consumers regarding the implementation of the new claimer. This campaign should also outline the key differences between medicines that have an Aust R number compared to products with an Aust L number.

Incentives for Innovation

The Guild supports proposals that encourage sponsors of listed complementary medicines to conduct research that supports the quality, safety and efficacy of new products and to promote this information to healthcare professionals and consumers in a manner that does not compromise their commercial investment.

However, pharmacists and pharmacy staff should be able to access evidence-based, product-specific information held by sponsors that support indications for their listed complementary medicine(s). Transparency of information must take priority over other considerations. Sponsors should be required to provide evidence-based, product-specific information, which can be accessed by healthcare professionals such as pharmacists who can inform consumers regarding whether a particular complementary medicine is suitable.

[1] https://www.heartfoundation.org.au/healthy-eating/heart-foundation-tick