Consumers Health Forum of Australia

SUBMISSION

Reforms to the Regulatory Framework for Complementary Medicines; Assessment Pathways

MARCH 2017

Consumers Health Forum of Australia (2017)
Submission on Reforms to the Regulatory
Framework for Complementary Medicines;
Assessment Pathways, Canberra, Australia

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Consumers Health Forum of Australia is funded by the Australian Government as the peak healthcare consumer organisation under the Health Peak and Advisory Bodies Programme

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Introduction

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems. CHF has a strong interest in the regulatory framework for medicines and medical devices: this is a key component in ensuring that Australian consumers can have confidence that the medicines and medical devices they use are safe and fit for purpose.

CHF welcomed the Expert Review of the regulatory framework chaired by Professor Lloyd Sansom (the Review) and has been an active participant throughout the review process. We put in a submission on complementary medicines and have participated in the stakeholder forums about the implementation of the Government's reform package.

CHF has always accepted the right of consumers to choose complementary medicines as part of the treatment regime for their illness or to promote health and well-being. Our concern has always been to ensure people have the right level of information available in a timely fashion in order to enable them to make informed healthcare decisions about the products they use based on a clear understanding of the evidence behind the claims that manufacturers and others make around the efficacy of such products.

At the moment we believe many people do not have a good understanding of the complementary medicines they use. We also believe that some of the claims made by sponsors are not supported by robust evidence and there has been a lack of clarity on the levels of evidence required from manufacturers when advertising their products and their efficacy. In this context it is useful to be reminded that around 60% of Australians have low health literacy, which points to the important need for consumer education as part of the Review's implementation.

We support the principles which are guiding the reforms and agree with all the objectives of the reform package as identified in the consultation paper, most importantly the commitment to maintaining consumer confidence in the TGA regulation of complementary medicines and the steps to improve standards of evidence regarding the efficacy of complementary medicines and avoidance of consumers being misled by indications on labels. These particular objectives are critical to consumers making informed decisions and receiving better value healthcare.

Issues

Assessment Pathways

Establishing a risk-based hierarchy for therapeutic indications

CHF supports the introduction of a three-tiered risk based framework for the regulation of complementary medicines. The introduction of the New Pathway bridges the substantial gap between the current self- assessment process for listing and the very rigorous evidence requirements for a registered product.

Proposal One, which identifies the hierarchy of indications appropriately stratifies the risks and makes it clear to sponsors which pathway is appropriate for the product and level of evidence they have.

CHF is pleased to see that the New Pathway is not designed to be a provisional pathway and that sponsors will need to have the appropriate evidence at the time of applying for assessment.

The New Pathway should provide an incentive for sponsors to seek out and provide more evidence on the efficacy of their products which should be of benefit to consumers. The current ATRG List and ATRG Registered terms are meaningless to most consumers.

There will need to be a naming hierarchy for the three pathways that is meaningful to consumers and we suggest that there should be some consumer testing of options before deciding on this.

Evidence requirements

One of the major problems with the current system is the lack of independent evidence on the efficacy of many complementary medicines. Many studies conducted or funded by the sponsor and are often on a very small scale which limits their usefulness. The evidence dossier requirements in Table 4 of the consultation paper set out a good framework. However we think assessment via the New Pathway must include a requirement for evidence from an independently randomised, placebo controlled clinical trial with blinding of outcomes. Information on the evidence should be in the public domain.

Implementing a list of permitted indications

CHF supports the move away from sponsors using unsubstantiated 'free text' indications to the introduction of a limited list of permitted indications. These free form indications are often used in advertising claims by sponsors. Moving to a permitted list of indications would help to eliminate this practice. We support these being limited to low level indications.

We support the criteria for inclusion on the list of permitted indications as outlined in the consultation paper. We also support the proposal that TGA will also be able to specify certain

indications that will not be permitted by creating a non-permitted list as this is important for consumer safety and confidence in the listing process. This may encourage sponsors who want to use an indication which is on the non-permitted list to go for a listing at a higher level, either New Pathway or registered which requires more evidence. This again would be in the consumer interest.

We understand there will be consultation on both the permitted indications and non-permitted indications list and would welcome the opportunity to be part of those consultations. There needs to be some consumer testing of the list to see if consumers understand the differences and what the indications actually mean.

One of the main benefits of the permitted indications list is to give clarity to consumers. Some of this clarity would be lost if there is too much flexibility in varying the wording of the permitted indications. For this reason CHF supports Option 1 for the implementation of the permitted indications as this gives maximum consistency and certainty for consumers. Option 2 shifts the balance too far away from the consumer interest and would undermine the usefulness of the permitted indications list in clamping down on unsubstantiated advertising.

Claiming evidence of efficacy

This introduction of the New Pathway and the other changes around permitted indications will only have a positive impact on helping consumers make informed decisions if they are aware of them and what they mean. Clearly there needs to be a process to ensure that consumers are able to distinguish they are made aware of the difference between listed medicines and those evaluated under the New Pathway.

CHF supports the introduction of a "claimer" for products assessed under the New Pathway and for registered products. We think it needs to be on the product packaging or labels and needs to be visual. It requires a symbol or logo that consumers can recognise. Getting recognition of the symbol would be part of the consumer awareness program that we believe must accompany these changes.

We agree with the criteria proposed in the paper around the placement of the claimer and conditions for its use. Whilst understanding sponsors issues around differentiating products in this way, particularly for those which are also exported, we believe this is an essential component of the reforms if consumers are going to benefit from them. Again potential logos/symbols need to be consumer tested.

Incentives for Innovation

It is in consumers ' interests for sponsors to collect evidence of efficacy and we would hope that a number of products are assessed under the New Pathway with its higher level of evidence. We understand that sponsors need to see some market benefits in doing this and so support the proposals to give them some protection from 'free-loading' competitors. We support proposals on time limiting that exclusivity and believe the time frames suggested are appropriate to encourage innovation but not totally stifle competition.

Conclusion

CHF supports the intent of the reforms and believe that they will enable consumers to make more informed choices about their use of complementary medicines. We believe they will make complementary medicines more suitable for self- selection by consumers and that the information provided would support consumer making more informed health decisions.

However these regulatory and legislative changes are only part of the solution. We will need a public education/awareness campaign to explain the changes to consumers so that the proposed changes have the desired effect of encouraging consumers to make informed decisions when managing their health and well-being.

CHF also looks forward to being involved in further consultations as the other recommendations around complementary medicines are developed and playing an active role in the implementation of the changes.