Pharmaceutical Society of Australia

Consultation on the regulatory framework for advertising therapeutic goods

MAR
2017

Purpose

The Pharmaceutical Society of Australia (PSA) takes this opportunity to make a submission to the Therapeutic Goods Administration (TGA) consultation on reforms to the regulatory framework for complementary medicines with regards to assessment pathways.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 29,000 pharmacists[1] working in all sectors and locations.

PSA's core functions relevant to pharmacists include:

- providing high quality continuing professional development, education and practice support to pharmacists;
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice; and
- representing pharmacists' role as frontline health professionals.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

[1] Pharmacy Board of Australia. Registrant data. Reporting period: 1 October 2016 – 31 December 2016. At: www.pharmacyboard.gov.au/documents/default.aspx?record=WD17%2f22786&dbid=AP&chksum=6tglf5%2b1PY5fnmPNgcDM0g%3d%3d

Summary of PSA's comments

Overall, PSA is supportive of the proposed reforms to complementary medicines regulation involving:

- *the introduction of a new pathway/class of assessment and the remit to move towards generation and use of evidence*
- *development of a permitted indications list and associated criteria but proposes more appropriate use of evidence*
- *the intention behind the use of claimers to enhance transparency for consumers, although there are concerns about possible unintended consequences*
- *encouraging innovation in the complementary medicines sector through incentives.*

PSA believes the proposals aimed at facilitating expansion of the evidence base for complementary medicines and increasing consumer access to evidence-based products are reasonable, noting that some aspects will require further consultation.

Background

The key outcomes and activities which are relevant to the context of this submission can be summarised as follows.

Expert Review of Medicines and Medical Devices Regulation

The following five Recommendations from the Expert Review of Medicines and Medical Devices Regulation (the 'Review')[2] are relevant to this submission.

Recommendation 38: The Panel recommends that the [TGA] establishes the list of Permitted Indications, from which sponsors must exclusively draw, for listed medicinal products in the ARTG.

Recommendation 39: The Panel recommends that that there be three options by which sponsors may seek entry into the ARTG of complementary medicinal products and other listed medicinal products for supply in Australia.

> ***Option One*** – Listing in the ARTG following self-declaration by the sponsor of the safety and quality of the product in circumstances where:
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> A. the product contains only ingredients that have been previously approved by the [TGA] for inclusion in listed medicinal products; and

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[2] Expert Panel, Review of Medicines and Medical Devices Regulation. Report to the Minister for Health on the regulatory framework for medicines and medical devices. 31 March 2015. At: **www.health.gov.au/internet/main/publishing.nsf/Content/8ADFA9CC3204463DCA257D74000EF5A0/$File/Review%20of%20Medicines%20and%20Medical%20Devices%20Stage%20One%20Report.pdf**

B. the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, comply with listing notices or similar documents issued or endorsed by the [TGA]; and

C. the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the [TGA]; and

D. the product is manufactured in accordance with PIC/S GMP; and

E. the sponsor only seeks to make claims regarding the indications for use of the product selected from the list of Permitted Indications (Recommendation 38 refers); and

F. the sponsor holds evidence to support these indications, consistent with requirements outlined in the evidence guidelines issued by the [TGA] from time to time.

Option Two – Listing in the ARTG following a self-assessment of the safety and quality of the product, and following assessment of the efficacy of the product by the [TGA], in circumstances where:

A. the product contains only ingredients that have been previously approved by the [TGA] for inclusion in listed medicinal products; and

B. the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, are compliant with listing notices or similar documents issued or endorsed by the [TGA]; and

C. the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the [TGA]; and

D. the product is manufactured in accordance with PIC/S GMP; and

E. the sponsor seeks to make health claims that fall outside the list of Permitted Indications but which are still appropriate for listed medicinal products; and

F. the sponsor can provide evidence acceptable to the [TGA] to support the safety and efficacy of the product for the proposed indication(s), commensurate with risk. This may include the submission of an un-redacted evaluation report(s) from a comparable overseas regulator.

Option Three – Registration of a complementary medicinal product in the ARTG following an assessment by the [TGA] of the product for safety, quality and efficacy in accordance with existing requirements for registration of complementary medicines (Recommendation 40 refers).

Recommendation 40: The Panel recommends that where a sponsor seeks to include a complementary medicinal product in the ARTG that the sponsor is able to do so utilising registration Pathways One or Two, namely:

Pathway One – Submission of a complete dossier for de novo assessment. This assessment may be undertaken in full by the [TGA] or via a work-sharing arrangement between the [TGA] and a comparable overseas regulator.

Pathway Two – Submission of an un-redacted evaluation report from a comparable overseas regulator, along with a copy of the dossier submitted to the comparable overseas regulator and Australian specific data similar to that provided by sponsors in Module 1 of the Common Technical Document, for assessment by the [TGA]. The [TGA] to make a recommendation regarding registration of the complementary medicinal product once it has considered the data within the Australian context.

Recommendation 45: The Panel recommends that where a medicinal product is listed in the ARTG following an assessment by the [TGA] of an application under Option Two, the sponsor is able to indicate on all promotional materials and on the product label, that the efficacy of the product has been independently assessed for the approved indication(s).

Recommendation 50: The Panel recommends that the Australian Government gives consideration to improving the competitiveness of the Australian complementary medicines industry by providing incentives for innovation.

Government response

PSA understands that the Australian Government accepted[3] Recommendations 38, 39 and 40, noting that implementation may require legislative amendment and be subject to consultation with consumers, sponsors and health professionals. The Government accepted-in-principle Recommendations 45 and 50, noting further careful consideration by other Departments and stakeholders will be necessary.

PSA comments on consultation questions

PSA has provided comments on specific consultation topics and questions as outlined below.

A risk-based hierarchy for therapeutic indications

3.1 Do you agree with the proposed indication hierarchy and the criteria proposed to distinguish the three medicine pathways?

PSA believes the proposed three-tiered risk-based hierarchy of indications is consistent with the existing risk-based approach to regulation, noting that the intermediate level is the proposed new pathway between Listed and Registered Medicines. PSA notes that over time the new pathway may result in improvements to the overall standard of complementary medicines registered in Australia due to the additional criteria of efficacy assessment.

Current practice is that pharmacists must use their professional judgement to prevent the supply of products with no reliable evidence or evidence of no effect. Pharmacists will welcome the introduction of greater numbers of complementary medicines on the Australian market which can be shown to have been independently assessed for efficacy.

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[3] Australian Government Department of Health. Australian Government response to the Review of Medicines and Medical Devices Regulation. May 2016. At: **www.health.gov.au/internet/main/publishing.nsf/Content/CCB4916435683A5BCA257FA100839F95/$File/govresp.pdf**

3.2 Do you envisage any difficulties with criteria used to include or exclude products from the new pathway?

Given this is a new proposal, PSA suggests inclusion or exclusion criteria will most likely need to be tested and reviewed during a transition period.

The pool of complementary medicines that make intermediate indications outside the list of low level permitted indications, but not high level indications, and which are supported by high quality scientific evidence may be quite small. Nevertheless PSA supports the intent and purpose of this proposal as it is moving towards generation and application of evidence rather than sole reliance on self-certification of safety and quality.

3.3 What other considerations may need to be taken into account in implementing the new pathway?

Since the current pathway for compliance with requirements for Listed Medicines is through self-certification, there may be some hesitation to apply for assessment under the new pathway. Any additional requirements may be perceived as a burden, particularly for existing Listed Medicines.

Approaches to establishing efficacy

3.4 Do you agree with the proposed methods to establish efficacy for products included via the new pathway?

For complementary medicine products to be eligible for inclusion on the ARTG via the proposed new pathway, PSA agrees that efficacy data required on the product must be at a similar standard that applies to Registered complementary medicines. PSA supports the methods proposed to establish efficacy.

3.5 Is the proposed approach to establish efficacy for current listed products that have a restricted representation exemption appropriate?

PSA believes the proposed approach (outlined on p. 16 of the consultation paper) for current Listed products that refer to a restricted representation to establish efficacy is appropriate, noting that reasonable transition arrangements will be needed.

Evidence requirements

3.6 Are the evidence requirements appropriate for the new pathway?

In Table 2, *Proposed categories of evidence*, the category labels of A to D run from lowest to highest level of evidence. PSA notes that generally, in other references and systems, level A or level I (one) would refer to the highest level of evidence.

3.8 What other considerations may need to be taken into account in implementing the new pathway?

PSA sees the introduction of a new (intermediate level) pathway and associated requirements to be a step in the right direction.

PSA would like to see improvements in the self-certification process that currently applies to Listed products as it appears that this assessment process will remain unchanged. PSA

appreciates that changes to this sector need to be implemented in a staged manner. Where data is required to be held by a sponsor but not submitted to the TGA, PSA strongly believes more rigorous compliance audit processes should be implemented and, greater penalties applied if there have been any breaches. While introduction of the new pathway is likely to result in better standards overall, it does not impact on any substandard practices that may occur at the lower end of the spectrum.

Criteria for permitted indications

4.1 Are the proposed criteria for inclusion of an indication on the permitted indications list appropriate?

As an initial starting point, PSA believes the proposed criteria for inclusion of an indication on the list of permitted indications to be reasonable, pending further development and consultation with stakeholders.

4.2 What other considerations should be taken into account in implementing the permitted indications list?

The proposed mechanism to maintain and update a permitted indications list is mentioned briefly in the consultation paper (p. 21). It is stated that applications for new indications to be added to the list will be assessed by the TGA against eligibility criteria but that the "indications will not be evaluated per se and there will be no requirement to submit supporting data". It is also suggested that a mechanism will be developed "to allow indications to be removed from the list where there is scientific evidence that supports their removal". PSA suggests that the use of evidence should inform any changes made to the list, whether it is adding an indication to or removing one from the list.

Implementation of the permitted indications list

4.3 Is Option 2 for selecting indications for inclusion on the ARTG and on product labels and promotional material suitable to address the objectives for permitted indications?

Option 2 appears to provide a balance between compliance with regulatory requirements and providing some flexibility in implementation. We support the TGA's commitment to consult further on a possible list of indications and qualifiers.

Use of a claimer

5.3 Will the use of a claimer on complementary medicines have any unintended consequences?

PSA supports the principle around the use of claimers in improving the transparency of efficacy claims for consumers. Pharmacists are aware that currently there is a great deal of consumer confusion, for example, about what is classified as a food or supplement, or around the difference between a complementary medicine with, or without, evidence of efficacy. PSA welcomes measures that contribute to an increase in consumer awareness of the ingredients, efficacy, limitations and safety of all medicines.

PSA notes however that the current proposal may have the potential to challenge a level playing field in medicines regulation since claimers are not permitted in other Listed or Registered (over-the-counter and prescription) Medicines. It may appear to provide an advantage to complementary medicines that have undergone pre-market efficacy

assessment over other medicines which have been subjected to a similar process and for which there may be higher levels of evidence available.

Therefore, further consideration is likely to be warranted on how such a measure might be implemented but in particular, PSA believes a comprehensive consumer awareness and education campaign will be vital in facilitating consumer understanding and support.

Protection for new ingredients and efficacy data

PSA supports the proposal to incentivise innovation within the complementary medicines sector as we believe this would provide greater transparency, confidence and potential benefit to consumers.

PSA is committed to evidence-based practice. Our advice to pharmacists is that, when discussing the use of complementary medicines, they must ensure consumers are provided with the best available information about the current evidence for efficacy. Generating a larger pool of evidence will support pharmacists to better assist consumers around informed decision-making in the use of complementary medicines.

Whatever mechanism is adopted (i.e. period of data protection and/or market exclusivity), the period to be granted must be fair and reasonable.

Transition arrangements

7.1 Do you agree with the proposed principles to support transition arrangements?

As with any proposed reforms, the short- and long-term impacts on parties likely to be affected by changes must be considered carefully and stakeholders consulted widely. Appropriately balanced transition arrangements are important for industry to be able to meet new requirements without unnecessarily delaying implementation of improvements. Logistics for consumers and health professionals must also be taken into account as therapeutic goods legislation changes can impact on decisions relating to prescribing and decision to supply, product availability and procurement policies, and informed decision-making around use of complementary medicines.

PSA believes the principles guiding the development of transition arrangements are logical and fair. However, we believe industry is best placed to provide detailed feedback.

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28 March 2017