Pharmaceutical Society of Australia

Senate Community Affairs Legislation Committee

Inquiry into the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017

JAN
2018

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Senate Community Affairs Legislation Committee's inquiry into the ***Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017*** (the 'Bill'). PSA has not provided any comments on the Therapeutic Goods (Charges) Amendment Bill 2017.

PSA understands the purpose of this Bill is to amend the *Therapeutic Goods Act 1989* to enable the implementation of several recommendations from the Expert Panel Review of Medicines and Medical Devices Regulation (the 'Review'). PSA has previously provided comments to the Review as well as through consultations hosted by the Therapeutic Goods Administration (TGA).

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 30,000 pharmacists[1] working in all sectors and locations.

PSA's core functions 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
- 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 July 2017 – 30 September 2017. At: **www.pharmacyboard.gov.au/About/Statistics.aspx**

PSA's comments on specific issues

In this submission, PSA has commented in relation to the following schedules of the Bill:

- Schedule 1 – Provisional registration of medicine
- Schedule 6 – Advertising.

Provisional registration of medicine (Schedule 1)

PSA supports the implementation of a provisional approval pathway to allow earlier access to medicines by patients with significant unmet clinical needs for serious conditions. We understand strict conditions will apply given this will capture medicines with only preliminary efficacy data and that comprehensive efficacy and safety data will need to be submitted by the sponsor within a predetermined timeframe for a provisionally registered medicine to be considered for ongoing approval or full registration.

PSA has previously stated that it is vitally important to provide relevant information about this pathway to health professionals as well as patients and carers. For health professionals, there must be clarity and transparency about what data are available and their limitations so that clinical decision-making is adequately supported. For patients and carers, it must be clear that a provisionally approved medicine is at a stage where full registration has not been granted, and what impact this may have on their treatment.

In the ***Addendum to the Explanatory Memorandum*** to this Bill (p. 1), PSA is pleased to note the intention to provide appropriate information to health professionals and consumers to support transparency of the provisional registration decision-making process. PSA will also consider in due course any amendments that need to be made to the *Therapeutic Goods Regulations 1990*.

PSA notes that provisions under the *Therapeutic Goods Act 1989* will apply to ongoing provisional registration decisions if any safety concerns arise with a provisionally registered medicine. While this is likely to be based on safety data submitted by the sponsor of the medicine, it is not clear to PSA whether there will be additional pharmacovigilance requirements for prescribers and pharmacists apart from their usual professional role around adverse event monitoring and reporting. For example, pharmacists are aware that the TGA particularly requests reports of suspected adverse events involving new medicines.[2]

Advertising (Schedule 6)

Removal of requirement for advertisements to be approved (Part 2)

PSA has supported the decision to cease vetting and pre-approval of therapeutic goods advertising in favour of a more self-regulatory arrangement. This was felt to be a logical option given the Review outlined that complexities and inconsistencies existed in the pre-approval arrangements.

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[2] Therapeutic Goods Administration. Reporting adverse events to medicines and vaccines: information for health professionals. 2014;May. At: **https://www.tga.gov.au/sites/default/files/problem-medicine-reporting-reactions.pdf**

PSA has been pleased overall to see changes being made or proposed as suggested in our previous submissions. PSA understands these include proposed measures to clarify advertising rules and support compliance, the strengthening of penalties and sanctions for advertising breaches, and a transparent and responsive complaints management process.

Education program

In relation to supporting compliance, the ***Explanatory Memorandum*** (p. 71) to this Bill states that:

> *…changes in Schedule 6 will be accompanied by an education program to assist industry, sponsors and advertisers in understanding their obligations under the new regulatory framework so that they have the appropriate information to allow them to comply with the advertising requirements.*

As mentioned in a previous submission, PSA fully supports this proposed approach and strongly recommends the inclusion of pharmacist-specific guidance materials in the education program. The advertising of therapeutic goods is relevant to pharmacists and their obligations can be complex particularly for those who have a dual role as a health service provider and a retailer.

PSA has a core remit of developing and advocating standards and guidelines to inform and enhance pharmacists' practice and a longstanding track record for producing high quality education and practice support resources for pharmacists. PSA would welcome the opportunity to work with the TGA to assist in designing and implementing information and support materials for pharmacists.

(End of submission)

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