Pharmaceutical Society of Australia

Inquiry into the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

MAR 2017

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Standing Committee on Community Affairs Legislation Committee inquiry into the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016.

PSA has commented on proposed amendments relating to a future post-market monitoring scheme for medicines and medical devices in Australia.

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
- 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=6tgIf5%2b1PY5fnmPNgcDM0g%3d%3d

Summary

PSA agrees with those amendments in the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 that will support the implementation of a strengthened and more comprehensive post-market monitoring scheme for medicines and medical devices in Australia.

PSA supports a holistic, nationally-coordinated and outcomes-focussed pharmacovigilance program. Better use of post-market surveillance data can not only improve medication safety but can also inform quality use of medicines decisions and guide improved health outcomes.

PSA believes that the amendments to support the implementation of Recommendation 27 of the Expert Panel Review of Medicines and Medical Devices Regulation may also support, or are of relevance to, the implementation of Recommendation 49. Therefore PSA suggests it may be appropriate to also consider the latter recommendation as part of this Bill.

Background

The Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 (the 'Bill') consists of a number of amendments to the *Therapeutic Goods Act 1989* (the 'Act') including those that will support the implementation of eight key recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation (the 'Expert Review').

Of particular interest to PSA is Recommendation 27 of the Expert Review,[2] viz.:

> *The Panel recommends that the Australian Government develop a more comprehensive post-market monitoring scheme for medicines and medical devices. Such a scheme to include:*
>
> 1. *Better integration and timely analysis of available datasets, including analysis of matched de-identified data from the Pharmaceutical Benefits Scheme, Medical Benefits Scheme, eHealth records, hospital records, private health insurance records and device and other relevant registries and datasets;*
> 2. *Establishment and maintenance of registries for all high-risk implantable devices;*
> 3. *Implementation of a scheme to alert practitioners and consumers that a drug is newly registered and to encourage reporting of any adverse events;*
> 4. *Provision for electronic reporting of adverse events; and*
> 5. *Enhanced collaboration with overseas NRAs to share information relating to safety or efficacy.*

[2] Sansom L, Delaat W, Horvath J. Expert Panel Review of Medicines and Medical Devices Regulation. Recommendations to the Minister for Health on the regulatory frameworks for medicines, medical devices, complementary medicines and advertising of therapeutic goods. 2015; Jul.

In accepting this recommendation (with the exception of part 2), the Australian Government noted[3] that "the development of a more comprehensive post-market monitoring scheme will enhance consumer protection and complement existing post-market monitoring processes".

Implementation of Recommendation 27

Comments on Items in the Bill

The amendments to the Act designed to support the implementation of Recommendation 27 are set out in *Schedule 8 – Record-keeping etc*. PSA's comments on Items 1–3 and 5 are as follows (Item 4 appears to be a minor change to align terminology).

Item 1 – While record-keeping requirements are already stipulated in current legislation, it is important to be able to verify compliance with those requirements. PSA agrees with the proposed amendment under this Item.

Item 2 – PSA also agrees with this consequential amendment which would permit an authorised person to inspect and make copies of records kept in order to comply with the requirements.

Item 3 – In order to be able to respond to future changes in record-keeping requirements, it is anticipated that additional requirements may need to be prescribed from time to time. PSA therefore concurs with the amendments outlined in Item 3 and, in particular, agrees with having the requirements in the regulations.

Item 5 – The Explanatory Memorandum to the Bill clarifies that this Item will enable authorised officers to enter and search a range of premises which may be necessary if a sponsor undertakes a range of activities (including a separate administrative centre where records are kept) at or across a number of sites. PSA has no objections to this amendment.

Further enhancing the pharmacovigilance system

PSA considers the Items outlined above to be minor but essential amendments to the Act in the context of commencing development of a more comprehensive post-market monitoring scheme for medicines. PSA believes they are likely to represent a small set of initial changes and that more substantive changes will be necessary to further strengthen the post-market monitoring scheme.

Requirements for post-market surveillance activities are in place for sponsors and these are essential from a medication safety and public health perspective. However, PSA believes it is essential that we move towards a holistic, nationally-coordinated and outcomes-focussed approach to undertaking pharmacovigilance activities.

As a core underpinning element of medication safety, pharmacovigilance encompasses the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.[4] PSA believes Australia could become leaders in this arena if pharmacovigilance

---

[3] Australian Government Department of Health. Australian Government response to the Review of Medicines and Medical Devices Regulation. 2016.

[4] World Health Organisation. Pharmacovigilance: ensuring the safe use of medicines. WHO Policy Perspectives on Medicines. October 2004: 1

activities are designed to, not only improve medication safety, but inform quality use of medicines decisions and guide improvements in consumer health outcomes. There should be a focus on better use of ongoing surveillance data, clinical information and medical literature which can inform policy makers, health professionals and consumers.

As pharmacists are core partners in and contributors to pharmacovigilance activities, PSA as the peak body representing pharmacists would welcome the opportunity to work with Government and other stakeholders on future initiatives.

Recommendation 49

PSA notes that the Expert Review made a separate recommendation to enhance post-market monitoring activities of listed medicinal products, including complementary medicinal products (Recommendation 49). However, the current Bill does not include considerations of that particular recommendation.

PSA notes there is substantial overlap between parts of Recommendation 49 and Recommendation 27 including, for example, integration and analysis of datasets such as eHealth and hospital records, and provision for electronic reporting of adverse events. Recommendation 49 of the Expert Review in fact suggests integration and timely analysis of datasets could "provide a more streamlined and cost-effective approach to post-market monitoring".[5]

PSA therefore believes there is an opportunity to include in this Bill the implementation of Recommendation 49 of the Expert Review.

Submitted by:

Pharmaceutical Society of Australia
PO Box 42
Deakin West ACT 2600
Tel: 02 6283 4777
www.psa.org.au

Contacts:

Dr Lance Emerson, Chief Executive Officer

3 March 2017

[5] Sansom L, op. cit. Delaat W, Horvath J. Expert Panel Review of Medicines and Medical Devices Regulation. Recommendations to the Minister for Health on the regulatory frameworks for medicines, medical devices, complementary medicines and advertising of therapeutic goods. 2015; Jul.