Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) on the consultation on *Strengthening monitoring of medicines in Australia – Enhanced medicines vigilance*.

PSA understands the scope of proposed reforms impact on all medicines (listed and registered complementary, over-the-counter and prescription medicines) including vaccines and biological medicines.

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.

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Summary of PSA’s recommendations

PSA is supportive of the proposal to introduce a symbol relating to a ‘Black Triangle Scheme’. PSA can assist in the implementation of such a Scheme through resources for pharmacists such as the Australian Pharmaceutical Formulary and Handbook and other clinical guidance and practice support materials.

PSA advocates for a holistic, nationally-coordinated and outcomes-focussed pharmacovigilance program. PSA suggests 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. Pharmacists are core partners in and contributors to pharmacovigilance activities.

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 these reforms.

Background

The following outcomes and activities are relevant to the context of this submission.

Medicines and Medical Devices Regulation Review

The Medicines and Medical Devices Regulation Review (the ‘Review’) recommendations\(^2\) aimed at enhancing post-marketing monitoring processes currently undertaken by TGA were as follows:

**Recommendation 27:** 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

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5. Enhanced collaboration with overseas National Regulatory Authorities to share information relating to safety or efficacy.

**Government response**

The Australian Government accepted the recommendations listed above (with the exception of part 2, which was deferred) as outlined in the response to the Review released in September 2016. It noted that "the development of a more comprehensive post-market monitoring scheme will enhance consumer protection and complement existing post-market monitoring processes".

**Comments on specific issues**

**Adverse event reporting**

**Black triangle scheme**

PSA notes the information relating to the Black Triangle Scheme and is supportive of the proposal to introduce the symbol in:

- approved Product Information and Consumer Medicine Information
- advertising, promotional and educational materials produced by the sponsor for health care professionals
- relevant texts such as Australian Medicines Handbook (AMH) and MIMS, and
- prescribing and dispensing software.

PSA recommends that the Australian Pharmaceutical Formulary and Handbook (APF) is also considered in the implementation of a Black Triangle Scheme. The APF published by PSA contains clinical guidance and practice support information including Cautionary and Advisory Label (CAL) recommendations for specific substances/medicines. The ‘current’ edition of the APF is a primary reference cited by the Pharmacy Board of Australia in its list of essential reference texts that pharmacists must be able to readily access during the clinical assessment, reviewing, dispensing and counselling processes.

The two types of CALs are ‘ancillary labels’ and ‘additional instructions’. Ancillary labels are important tools for pharmacists in their interaction with consumers and are used to warn about possible undesirable effects of a medicine or interactions with other medicines or foods, or to advise on the best way to use or take a medicine for optimal effect. Additional instruction labels are used to inform about appropriate use and storage of a medicine.

PSA is the custodian of the CALs (as published in the APF) in relation to the design and wording of the CALs as well as the recommendations of specific CALs provided for each medicine (substance). The CALs in the APF are determined through a rigorous risk-based review process.
involving experts where a range of factors have been considered, including: evidence from published literature, current clinical best practice and statutory requirements of Appendix K of the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons).

PSA would seek to ensure it has a role in informing pharmacists about the Black Triangle Scheme (through the APF or other channels or resources) and further, is committed to providing appropriate guidance and resources to pharmacists who have a role and responsibility to advise consumers about their medicines including relevant warnings.

As the peak body for pharmacists in Australia, PSA is recognised for the broad membership base and general reach it has within the profession and to the public in communicating important professional practice and medication safety information. PSA also has expertise and a track record in developing and delivering practice support tools and professional development resources for pharmacists as well as consumer health and medicine information materials.

Thus PSA would be pleased to work with relevant stakeholders in the implementation of a Black Triangle Scheme.

**Improved collection and use of data**

PSA strongly supports the plan to enhance data analytics capabilities to better support pharmacovigilance monitoring and compliance activities – proposed to be achieved through better data collection, linking of health datasets and implementation of analytic IT software. PSA has highlighted in previous submissions the importance of developing a more comprehensive post-market monitoring scheme for medicines, which is consistent with Recommendation 27 of the Review.

The requirements for post-market surveillance activities are already 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 component of medication safety, pharmacovigilance encompasses the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. PSA advocates for pharmacovigilance activities to be designed to, not only improve medication safety, but inform quality use of medicines decisions and guide improvements in consumer health outcomes. There needs to be a focus on better use of ongoing surveillance data, clinical information and medical literature which can inform policy makers, health professionals and consumers.

Pharmacists are core partners in and contributors to pharmacovigilance activities. As such, PSA welcomes the opportunity to work in partnership with Government and other stakeholders on relevant reforms in this area.

PSA also notes the Review made a separate recommendation to enhance post-market monitoring activities of listed medicinal products, including complementary medicinal products (Recommendation 49). The consultation paper states that the scope of post-marketing activities outlined extends across listed and registered complementary, over-the-counter and prescription medicines.

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medicines as well as vaccines, biologicals and medical devices. However, there does not appear to be specific mention of Recommendation 49 of the Review.

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 Review in fact suggests integration and timely analysis of datasets could "provide a more streamlined and cost-effective approach to post-market monitoring". PSA therefore believes there is an opportunity to consider Recommendation 49 of the Review in the proposal around Recommendation 27.

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1 May 2017

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