5 May 2017

Phillipa Olrick
Director
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

RE: Strengthening monitoring of medicines in Australia – Enhanced medicines vigilance

Dear Ms Olrick,

The Society of Hospital Pharmacists of Australia (SHPA) would like to express our appreciation to the TGA for the opportunity to comment on the strengthening monitoring of medicines in Australia. Our members provide clinical pharmacy services to the most unwell patients in a variety of healthcare settings, including the patients participating in clinical trials and using newly registered medicines. As such, hospital pharmacists are very adept at reporting adverse medicines events, however, recognise that the regulator can improve the systems, data collection and culture around medicines monitoring.

SHPA is the national professional organisation with more than 4,000 pharmacists, pharmacist interns, students, technicians and associates working across Australia’s health system. SHPA is the only professional pharmacy organisation with a strong base of members practicing in public and private hospitals and other healthcare settings.

Do the proposed criteria for inclusion in the Black Triangle Scheme appropriately target new medicines for which adverse event reports should be sought?

SHPA believes the proposed criteria for inclusion in the Black Triangle Scheme is appropriate. SHPA supports the Black Triangle Scheme which has been implemented in other international jurisdictions to encourage health professionals to report adverse events associated with medicines that are newly available or there has been an extension of the indication of the medicine with limited evidence.

What information, communication and education activities would assist health professionals and consumers to understand the Black Triangle Scheme and the importance of reporting adverse events for these medicines?

SHPA believes that messaging and communication activities will be critical to its success. The TGA should prepare guidance documents that explain the Black Triangle Scheme to medical and pharmacy stakeholders, as well as the importance of reporting adverse events related to medicines with a black triangle. A frequently asked questions document that will help health professionals to answer anticipated common questions from the patients they provide care for will also empower healthcare professionals to confidently advise their patients, and ensure consistent messaging.

Communication and education activities to consumers need to be strong enough for consumers to be aware of the scheme, but not too alarmist that it may discourage medicines compliance. There is an implicit risk that the notion of a ‘black triangle’ may lead consumers to think they are taking an unsafe medicine or not the most optimal medicine for their condition. It is imperative that consumers are not lead to believe these misconceptions, which in turn can also damage the trust and confidence they have for their healthcare providers, and in their confidence of the TGA as a regulator. Consumers should always be encouraged to have a discussion of their concerns with their pharmacist.
Are the proposed changes to the Product Information (PI) leaflet useful for health professionals?

The proposed changes to the PI leaflet are light on detail beyond its intent to reformat the PI and ensure important prescribing information is easily accessible to the prescriber. A common frustration amongst healthcare providers is that medical and dispensing software display too many ‘alerts’ and can often dilute the importance of certain alerts which are much more critical than others. It is important that these changes do not contribute to the alert overload experienced by clinicians.

Medicines Vigilance Framework and Adverse Events Management System (ADRS)

SHPA supports the proposed enhancements to data analytics capabilities of the Medicines Vigilance Framework, and linking datasets such as the Pharmaceutical Benefits System, Medicare Benefits Schedule and hospitals data, which will bring emerging issues to the fore in a more timely manner.

The move towards an online system to report adverse events is also welcomed by SHPA, as it is envisaged this will improve frequency of reporting through its the ease of use compared to current paper-based mechanisms. It will also collect information in a consistent and systematic manner which is a shortfall of the current system.

If you would like to discuss SHPA’s submission further, please do not hesitate to contact Johanna de Wever, General Manager, Advocacy and Leadership. (jdewever@shpa.org.au)

Yours sincerely,

Kristin Michaels
Chief Executive Officer