Australian Commission on Safety and Quality in Health Care

GPO Box 5480 Sydney NSW 2001

Level 6, 255 Elizabeth Street, Sydney NSW 2000

RE: World Health Organization Global Patient Safety Challenge – Medication without harm – Medicines Australia response

Medicines Australia (MA) welcomes the opportunity to contribute to the World Health Organization Global Patient Safety Challenge on Medication without harm.

MA believes that medication safety is of utmost importance and our member companies are committed to promoting the appropriate and safe use of medicines.

A viable medicines industry, one of the objectives of the National Medicines Policy, is an important aspect in promoting the quality use of medicines. The medicines industry is involved in many activities that contribute to effective and appropriate medicine use. Our member companies provide educational materials for patients and healthcare professionals, they support ongoing research and development (via the development of new medicines and also via safety monitoring of existing medicines), and they are committed to abiding by regulatory standards which ensure the ethical and responsible promotion of medicines.

As the peak association representing the discovery-driven pharmaceutical industry in Australia, MA does not direct policies or activities towards specific groups of medicines; rather we focus on promoting the quality use of all medicines as all medicines have inherent risks, whether they are prescription medicines, over-the-counter or complementary medicines. Whilst the World Health Organization (WHO) has identified classes of medicines that are considered high-risk, MA believes that all medicines should be used in an appropriate manner once a risk-benefit assessment has been undertaken for each individual patient.

Therefore, the following summary of relevant policies and activities is applicable to the three identified focus areas for this initiative.

Education for healthcare professionals and patients

The medicines industry produces educational materials about their products for healthcare professionals and patients, including the approved Product Information (PI) and the Consumer Medicine Information (CMI) respectively. Industry also contributes to healthcare professional education through sponsorship of independent educational meetings. The provision of medicines information and education to patients and healthcare professionals assists in the quality use of medicines; ensures prescribers and other healthcare professionals can prescribe, dispense and administer products appropriately; and enables better health literacy for patients. The result is a reduction in the risk of adverse events due to medication error, subsequently resulting in improved health outcomes.

Medication Safety and Pharmacovigilance

The medicines industry is also heavily involved in pharmacovigilance and post-market safety monitoring. For all new prescription medicines and extensions of indications, our member companies work collaboratively with the regulator, the Therapeutic Goods Administration (TGA), to develop and update Risk Managements Plans (RMPs), which describe the safety profile of a medicine and include a set of product vigilance and risk minimisation activities designed to identify and manage risks relating to a medicine.

The medicines industry also supports the TGA Database of Adverse Event Notifications (DAEN) to monitor reports of medication related events. This publicly searchable database also supports ongoing safety and highlights any potential safety signals associated with medicines.

In addition, since January 2018, the PI and CMI of newly registered prescription medicines, provisionally registered medicines and extensions of indications have required the inclusion of an inverted Black Triangle symbol and advisory text. The Black Triangle Scheme provides a means for healthcare professionals and patients to identify certain types of new prescription medicines and to encourage the reporting of adverse events associated with their use.

Ethical conduct and promotion of medicines

The healthcare system in Australia is complex, and involves many participants delivering healthcare to Australians. MA and our member companies are committed to ensuring ethical conduct amongst organisations in the healthcare sector. The ethical promotion of prescription medicines to healthcare professionals is governed by the Medicines Australia Code of Conduct (the Code). The Code specifies requirements to ensure the ethical promotion of prescription medicines to healthcare professionals, including that only TGA-approved indications are promoted, and it requires that adequate safety information is readily available to healthcare professionals in the form of the PI. The marketing approval from the TGA requires all sponsors of registered prescription medicines to follow the Code when advertising a prescription medicine, even if the sponsor is not a member of MA. However, non-member companies are not obligated to participate in the Code disciplinary process for complaints. In cases of alleged non-compliance by a non-member company, where the company declines to have the complaint adjudicated under the MA Code, MA would refer the matter to the TGA for action.

MA has also recently signed the Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector; MA was a foundation collaborator in the Framework's development. The framework has been endorsed by the Federal Minister for Health, the Hon. Greg Hunt MP as well as by state and territory health ministers and was jointly signed by over 50 other peak health-related bodies in Australia. The development of the framework promotes transparency, cooperation and ethical conduct, whilst clearly articulating a commitment to promoting the best interests of patients first and foremost.

Other industry related issues relevant to medication safety

- The CMI is a counselling tool for further discussion between a healthcare professional and a patient, and it is important to ensure that this information is received by every consumer for their medicine. This means that CMIs need to be available from multiple sources to cater for all patients, including in print format. Industry is also involved in working towards improvements in CMI format, such as digital CMI that allows for the provision of the most up to date PI and CMI.

- The PI provides prescribers and healthcare professionals with important and relevant information on the selection, and quality use of medicines.
- Our member companies work with the TGA to ensure that medicine labels provide important information about the medicine that is clear and consistent and aligns with international best practice. The requirements for appropriate labelling are contained in the Therapeutic Goods Orders, which ensures that all label necessary information is included and is legible. Industry can also play a role in testing packaging with users, in order to avoid confusing medicine labelling and packaging. A number of ongoing consultations to continuously improve medicines information are welcomed.
- NPS MedicineWise is a valuable resource for healthcare professionals to promote quality use of medicines and rational prescribing. It also includes information on healthcare professional support and training.
- The introduction of the My Health Record will improve communication between healthcare professionals and patients by providing an integrated electronic system between primary, tertiary and social care. It will enable the reduction in medication errors via the accurate identification of medication related issues, and it will also assist with medication reconciliation and the smooth transition of patient care.

MA is keen to further engage with the Australian Commission on Safety and Quality in Health Care and other stakeholders as the national plan to respond to the World Health Organization Global Patient Safety Challenge develops.

For further correspondence on this matter, please contact Betsy Anderson-Smith on banderson-smith@medaus.com.au

Yours sincerely,

Elizabeth de Somer

CEO, Medicines Australia

Attachments / Links

National Medicines Policy:
http://www.health.gov.au/internet/main/publishing.nsf/content/national-medicines-policy

MA policy. Guide to QUM, May 2012.https://members.medaus.com.au/files/2012/03/20120614-pub-MA-QUM-Internal-with-disclaimer.pdf

Medicines Australia Code of Conduct Edition 18: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20150617-PUB-Code-Edition-18-FINAL.pdf

Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector:
https://www.aoa.org.au/docs/default-source/australian-consensus-framework/australian-consensus-framework-23-july_final.pdf?sfvrsn=64ec704_2

TGA Black Triangle Scheme: https://www.tga.gov.au/black-triangle-scheme

TGA Risk Management Plans for Medicines and Biologicals: https://www.tga.gov.au/publication/risk-management-plans-medicines-and-biologicals

NPS MedicineWise: https://www.nps.org.au/