

Submission

Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods

JUN
2013

About PSA

The Pharmaceutical Society of Australia (PSA) is the peak national professional pharmacy organisation representing Australia's pharmacists working in all sectors and locations. There are over 27,000 registered pharmacists,¹ of which approximately 80% work in the community sector.

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; and representing pharmacists' role as frontline health professionals.

Purpose

This submission is provided by PSA in response to the public consultation paper issued in May 2013 by the Therapeutic Goods Administration (TGA) on *Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods*.

Responses to issues identified in the consultation paper

Support for proposed new scheme

The Australian therapeutic goods sector has in place reasonably well established systems and processes for risk assessment and mitigation across the entire product lifecycle. However from a pharmacist's perspective based on their interactions with consumers, we believe public awareness is generally focussed more on how health professionals, regulators and consumers respond after a safety concern has been raised or an adverse event has occurred. Much of the other regulatory activities which occur during development and testing of new products or the ongoing post-market monitoring tend not to be visible to consumers resulting in a low level of understanding despite their importance in ensuring the safety, quality and efficacy of the medicines they take.

¹ Based on data published by the Pharmacy Board of Australia in April 2013.

PSA therefore welcomes and supports the TGA's proposal to establish a new-to-market risk communication scheme which is designed to signal to people that a particular therapeutic product is new, or is newly available for a particular use. We believe this can appropriately complement the TGA's other activities and should become an important component within Australia's regulatory processes for therapeutic goods.

Potential values and uses of a new scheme

As most people would recognise, communicating realistic information on risks and benefits of medicines to consumers can often be a challenge. In 2007, PSA contributed to an initiative of the Australian Self-Medication Industry to develop a consumer information brochure about side effects of medicines. We note that an updated version was released in 2011.²

There is also a tendency for consumers to attach a disproportionate value or high expectation to a new medicine even before they have been registered by the TGA. Pharmacists can attest to the enthusiastic enquiries they receive from consumers and carers immediately after a television story has been aired about a positive result from the earliest stages of a clinical trial.

Thus, in establishing a new-to-market risk communication scheme, PSA believes it will be important to provide the appropriate contextual information and explanations which will be acceptable to and understandable by consumers. We note the TGA's proposal includes the possibility of using a symbol next to the name of the product in various information sources. We believe that for this new scheme to realise its potential value, there will need to be an overarching document or resource for consumers and carers which provides a general overview about the scheme and associated issues as well as answers to some frequently asked questions that might be anticipated.

Impact on pharmacists

As frontline health professionals, a new-to-market risk communication scheme is likely to impact significantly on pharmacists. We anticipate pharmacies will be key sites where consumers might become aware of the scheme or wish to raise questions and discuss with a health professional. We envisage the impact on professional practice will mostly be in the time taken to explain the scheme to consumers and carers and to respond to their questions in a way that will be meaningful to their personal situation and health status.

Studies on the provision of written medicines information (e.g. Consumer Medicine Information leaflets) show that consumers welcome the tailoring of information,³ and this is consistent with the pharmacist's role in providing individualised medicine information to better meet the consumer's needs. PSA is a strong advocate for the role of pharmacists in pharmacovigilance. We therefore believe pharmacists are well placed to provide information about the new-to-market risk communication scheme and to tailor information if necessary.

² Australian Self-Medication Industry. Understanding the side effects of medicines. 2011, Jun. Available at: www.asmi.com.au/consumer/Side-Effects.aspx

³ Dickinson R, Hamrosi K, Knapp P, Aslani P, Sowter J, Krass I, Raynor DK. Suits you? A qualitative study exploring preferences regarding the tailoring of consumer medicines information. *Int J Pharm Pract* 2012. doi: 10.1111/j.2042-7174.2012.00252.x

Some of the general, overarching information could be presented in simple posters or brochures which could be made available in pharmacies and other health institutions. This type of resource would need to be logical and succinct to be useful for consumers rather than technical or long. We believe pharmacists would certainly welcome this type of tool to be made available for use by health professionals as well so that consistent information and messages can be communicated.

PSA would be pleased to assist the TGA to meet its objectives of a new-to-market risk communication scheme by disseminating information to our member pharmacists. We would also welcome the opportunity to work with the TGA around the design of any resources which could be used in a pharmacy setting and help facilitate understanding by consumers and carers.

Submitted by:

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

Contacts:

Liesel Wett, Chief Executive Officer

Kay Sorimachi, Director Policy and Regulatory Affairs
kay.sorimachi@psa.org.au

13 June 2013