

Consultation: Management and communication of medicine shortages

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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) to provide comments on the proposed implementation approach to the management and communication of medicine shortages.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 30,000 pharmacists¹ working in all sectors and locations.

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
- 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 2017 – 31 December 2017. At: www.pharmacyboard.gov.au/About/Statistics.aspx

Summary

PSA supports the proposal to enhance reporting and management of medicine shortages based on risk assessment and levels of likely patient impact. PSA supports the mandatory reporting of all shortages initially by sponsors to the TGA on a confidential basis, and assessment and decision making by TGA of appropriate actions.

PSA strongly advocates for sponsors to make available information relating to all other shortages not subject to mandatory reporting. This will ultimately be in the best interests of patient care.

PSA suggests that development of more specific criteria for the inclusion of non-prescription medicines in the Medicine Shortages Information Initiative should be explored.

PSA supports a graduated, risk-based approach to enforcement of compliance obligations. PSA also strongly suggests that education resources and activities are provided to help raise awareness of compliance obligations and how to meet reporting requirements and associated actions.

PSA seeks to work in partnership with the Australian Government and other stakeholders to facilitate implementation of a timely response to managing medicine shortages and supporting clear communication to pharmacists, prescribers and other members of the health care team, including patients, carers and families.

Introduction

PSA welcomes the review of management of medicine shortages in Australia. As mentioned in the consultation paper, Australia is heavily impacted by global manufacturer and supply chain issues, and therefore needs to have a well-coordinated system involving all stakeholders to manage and communicate information about prescription medicine shortages in an accurate and timely manner.

Despite the launch in 2014 of the Medicine Shortages Information Initiative (MSII) to assist with information on prescription medicine shortages, generally pharmacists have not found it to be the most helpful resource in terms of the currency and timeliness of information. It has not adequately supported professional practice for pharmacists who have a core role in assisting with continuity of therapy and care for patients.

Repeatedly pharmacists have reported of a mismatch between information made available through the MSII and the actual medicine stock availability situation they have encountered through wholesalers. Issues pharmacists have raised with PSA included:

- medicines indicated as 'out of stock' through wholesaler portals were not on the current shortages list of the MSII
- the expected supply date listed on the MSII was often inaccurate (e.g. did not reflect

the expected stock availability date indicated by wholesalers)

- updating of information on the MSII appeared to be infrequent.

As the primary point of contact with patients in the supply (dispensing) of medicines, information relating to the availability of a prescription medicine and the reasons behind any shortage situation are critical for pharmacists. Patients, carers and families can experience significant stress when they cannot receive their medication in a timely manner. The situation is worsened if the pharmacist is unable to provide accurate information regarding the expected length of shortage period or steps that could be taken to source an alternative medicine. Accurate and timely communication with the prescriber is also critical in such circumstances, particularly where decision-making around change in ongoing therapy may be required.

General comments on the proposed implementation approach

PSA acknowledges the significant work completed prior to this current consultation involving the Minister for Health, the Hon Greg Hunt MP, the TGA, organisations of the Medicines Partnership of Australia and a dedicated working group.

PSA understands there has been considerable discussion and negotiation involving various regulatory, health professional and industry stakeholders to improve the reporting, management and communication of medicine shortages. The likely impact of a medicine shortage on patients has been a key consideration in determining the way forward around mandatory notification, public reporting and actions.

PSA agrees with and supports the development of a “more transparent and action-oriented approach to the management of confirmed and serious medicines shortages”. Thus, PSA supports the proposed new requirements for:

- mandatory reporting by sponsors of all medicine shortages to the TGA on a confidential basis
- determination by the TGA, based on the protocol and in consultation with identified stakeholders, as relevant, of the level of patient impact
- mandatory publication of shortages which have been deemed (by the TGA) as being of ‘extreme’ or ‘high’ patient impact.

PSA regards these requirements to be enhancements to the current management and reporting requirements of medicine shortages. With the timely availability of medicine shortage information PSA would also be able to more effectively support the TGA’s actions through direct communication with its member pharmacists.

PSA would also strongly advocate for sponsors to publish information of other shortages (not subject to mandatory reporting) through the MSII. This aspect of medicine shortage management will continue to be particularly important for pharmacists as it impacts on their ability to assist patients and carers as well as prescribers.

Consultation with relevant experts on aspects requiring clinical input is mentioned in the TGA papers, specifically around the assessment of impact of a medicine shortage and the

identification of alternative products. PSA would like to seek further detail on how health professionals with specific expertise will be identified and/or engaged, for example, through consultation with professional organisations on an as-needed basis, or establishment of a list or database of names of individuals with specific expertise.

Comments on listed consultation issues

Consultation issue 1: The definition of a medicine shortage

Proposed definition of a medicine shortage

PSA broadly supports the proposed definition of a medicine shortage presented on p. 7 of the consultation paper viz.:

*A **medicine shortage** covers all instances where a patient's care may need to be revised as a result of:*

- (a) the unavailability of a medicine from a sponsor, wholesaler or manufacturer; or*
- (b) the partial availability of a medicine from the sponsor, wholesaler or manufacturer; or*
- (c) other constraints on the medicine's availability.*

Although we understand the intent of the definition, PSA believes the following wording of the lead-in text may provide better clarity, particularly in the context of implementing amendments to the *Therapeutic Goods Act*:

*A **medicine shortage** covers all instances where the care of a patient who is prescribed that medicine may need to be revised as a result of...*

PSA agrees with the definitions of different types of medicine shortage which are outlined on p. 7 of the consultation paper.

Proposed scope for covered medicines

PSA believes the proposed scope for medicines to be covered for the purposes of the medicine shortages reporting requirements in relation to prescription medicines is clear and appropriate.

PSA understands it is also proposed to include within scope a small number of non-prescription medicines. Given the MSII provides information about prescription medicine shortages, PSA believes the expansion of scope (if confirmed) will need to be considered carefully.

For example, PSA notes the criteria for inclusion of a non-prescription medicine are listed as "critical to the ongoing health of the patient" and/or "critical for public health". We consider these criteria to be broad and generic. PSA would query what mechanism or process would be used to apply these criteria in determining whether a particular non-prescription medicine is

within the scope of this initiative. Perhaps the development of criteria with greater specificity could be explored.

PSA also seeks further information on how relevant stakeholders or expertise would be engaged in this process. We note the new protocol includes plans for the engagement of expertise where clinical input is required, although this is not mentioned in the context of identification of non-prescription medicines for inclusion within scope of covered medicines.

Consultation issue 2: Reporting obligations

Reporting timeframes

As referred earlier, PSA agrees with the proposal for sponsors to report all medicine shortages to the TGA. Pharmacists are supportive of this occurring at the earliest opportunity but PSA acknowledges that sponsors need to be consulted closely to determine what the most appropriate specified time period is for implementation purposes.

PSA also believes it would be helpful to have specific timeframes associated with the implementation of other measures which are triggered by the mandatory reporting of a medicine shortage or discontinuation. For example consideration of steps in identifying alternative therapeutic options, assessing the availability of those alternative medicines and sourcing supply in a timely manner should be initiated as soon as practicable. Early communication of what plans are being put in place is also fundamentally important.

Content of notifications

PSA supports the inclusion of “estimated duration of the shortage” as required information when reporting a medicine shortage. A question which has been raised is when and how this parameter would be monitored, reviewed and/or updated particularly if the shortage is not likely to be resolved as originally anticipated. This relates, in part, to the experience of some pharmacists where a medicine shortage was not resolved by the expected supply date listed on the MSII and this information was not updated in a timely manner thereby leaving pharmacists unable to provide accurate advice to patients and prescribers.

Consultation issue 3: Which products should be on the ‘Medicines Watch List’ defining an ‘extreme’ risk shortage

In the interests of improving the responsiveness to medicine shortages, PSA supports the establishment of a ‘Medicines Watch List’ of critical products to help facilitate decision-making around ‘extreme’ or ‘high’ patient impact shortages.

A consensus review of existing state hospital emergency medicines lists or life-saving drugs registers and the WHO Model Lists of Essential Medicines relevant to Australia seems to be a logical basis for the proposed Medicines Watch List. PSA also supports the need to review the Medicines Watch List periodically. PSA notes the WHO list is reportedly updated every two years.

Consultation issue 4: Compliance obligations and potential penalties

PSA supports a graduated, risk-based approach to enforcement of compliance obligations as referred through options 2 and 3 in the consultation paper. We believe such an approach is more likely to encourage compliance and minimises the potential for unintentional non-compliance.

PSA also supports the provision of education resources and activities to raise awareness of compliance obligations and how best to meet them.

(End of submission)

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