

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

TRIM: D18-13348

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John

Dear Professor Skerritt

Consultation Response on Management and communication of medicines shortages: Submission to Therapeutic Goods Administration

I am writing in regards to the Therapeutic Goods Administration's Consultation: Management and communication of medicines shortages (March 2018).

The Australian Commission on Safety and Quality in Health Care (the Commission) welcomes the opportunity to participate in this important consultation and strongly supports further regulation around medicines shortages to promote patient safety.

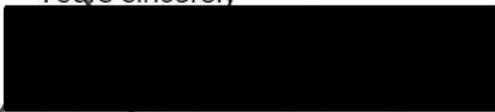
I enclose the Commission's response to the consultation for your consideration (**Attachment 1**). The Commission's response includes five recommendations:

1. Determine a detailed process for categorising medicines for potential inclusion in the Medicines Watch List
2. Include ALL medicines with an 'extreme' patient impact in shortage on the Medicines Watch List
3. Broaden the Medicines Watch List to include all medicines with a 'high' patient impact in shortage
4. Reflect the consumer impact of medicine shortages with increased consumer communication
5. Provide stricter parameters to define a 'resolved' medicine shortage.

If you have any questions regarding the consultation feedback, please contact:


eHealth and Medication Safety


Yours sincerely


Adjunct Professor Debora Picone AM
Chief Executive Officer

29 April 2018

Attachment 1 - Management and communication of medicines shortages – TGA consultation
Response from the Australian Commission on Safety and Quality in Health Care, April 2018

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TRIM: D18 - 13481

April 2018

Management and communication of medicines shortages – TGA consultation

**Response from the Australian Commission on
Safety and Quality in Health Care**

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Version Control (Document Revision History)

Version	Date	Comment
0.1	23 April 2018	Prepared by [Redacted]
0.2		
0.3		
1.0		Final

Distribution

Date Issued (version)	Issued to
16/04/2018 (0.1)	[Redacted]
27/04/2018 (1.0)	D Picone

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Adjunct Professor Debora Picone, AM

Chief Executive Officer

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Summary

The Therapeutic Goods Administration (TGA) proposes changes to the management and communication of medicines shortages. The Australian Commission on Safety and Quality in Health Care (the Commission) strongly supports this important initiative for patient safety with recommendations and feedback outlined in this paper.

Introduction

On 27 March 2018, the TGA published two papers for open consultation:

- Management and Communication of medicines shortages – proposed implementation approach- Consultation paper (**Appendix A**);
- Management and communication of medicine shortages in Australia – A new protocol (**Appendix B**)

In response the Commission has five key recommendations:

1. Determine a detailed process for categorising medicines for potential inclusion in the Medicines Watch List (**Appendix A**)
2. Include ALL medicines with an ‘extreme’ patient impact in shortage on the Medicines Watch List (**Appendix A**)
3. Broaden the Medicines Watch List (**Appendix A**) to include all medicines with a ‘high’ patient impact in shortage
4. Reflect the consumer impact of medicine shortages with increased consumer communication
5. Provide stricter parameters to define a ‘resolved’ medicine shortage

Context

Medicine shortages are a global issue. In Australia, the issue is exacerbated by the high percentage of imported, rather than locally manufactured, prescription medicines (90%). Options for alternative medicines may be unavailable or limited. This has an impact on the quality of consumer care. It also impacts patient safety with introduction of medication errors with potentially serious outcomes.

The TGA, with the involvement of other key stakeholders, proposes improvements to the management and communication of medicines shortages. The Commission supports this initiative and its potential impact on improving medication safety and delivering safer patient care.

Background

The worldwide issue of medicine shortages is worsening with time¹. The International Federation of Pharmacists (FIP) has taken an active role in defining, raising awareness and making recommendations to alleviate the issue of medicine shortages. FIP provides advice to the World Health Organization and the resolutions align with those of the 2016 World Health Assembly resolution “Addressing the global shortage of medicines and vaccines” (69.25)².

The association between medicine shortages and harmful medication errors is well documented. A survey undertaken by the Institute for Safe Medication Practices (ISMP) recorded approximately one in three (35%) respondents experienced a near miss during the past year due to a medicine shortage. One in five reported adverse patient outcomes over the year due to medicine shortages³.

A number of issues are associated with medicine shortages which have the potential to impact safe and effective use of medicines. These include:

- Using alternative medications (or alternative concentrations, strengths or dosage forms of the same medicine) may introduce errors in prescribing, preparing, administering, and monitoring medicines
- Standardising product formularies and concentrations may become difficult or impossible with an unreliable product supply
- Clinicians may be more prone to make errors with unfamiliar products, concentrations, or dosage forms
- Pressure to conserve medicines in short supply may lead to unsafe practices. Organisations or individuals may adjust policies or processes to conserve supply without full consideration of safety impacts
- Alternative medicines, concentrations, and dosage forms may be unavailable in electronic medication management systems, including the clinical decision support tools of computerised prescriber order entry systems, and pharmacy information systems, or smart pump libraries
- Procuring or preparing alternative products may introduce look-alike, sound-alike medicine name confusion
- Management of medicine shortages generates additional workload for health services.

These issues have a significant impact on clinical care. The Society of Hospital Pharmacists of Australia report 32% of actions in response to medicine shortages directly impact patient care⁴. This may have implications for length of hospital stay. For example, using a less efficacious medicine may extend the treatment period; alternative therapies may increase exposure to more adverse effects; and using injectable medicines when oral formulations are unavailable exposes the patient to increased risk of infection.

Medicine shortages are not able to be prevented completely. Therefore, processes for health services to manage shortages are required to be in place under the National Safety and Quality Health Service (NSQHS) Standards. Standard 4: Medication Safety requires hospitals implement policies and procedures for medication management and manage risks associated with medication management⁵.

These processes are compromised when medicine shortages arise without adequate warning. The response by health services to develop plans, identify therapeutic alternatives, and implement necessary safety measures may be limited. A well managed and communicated system of shortage notification will help minimise the potential for medication error and patient harm.

Medicine shortages are a global issue and Australia can benefit from international learnings. In the US, early notification of availability issues and proposed discontinuations has positively impacted the steps taken by the Food and Drug Administration to manage and communicate the impact of these changes⁶.

Feedback

Comments and feedback to **Appendices A (Consultation paper) and B (New protocol)** are provided in two parts; Recommendations and editorial comments.

Recommendations

1. Determine a detailed process for categorising medicines for potential inclusion in the Medicines Watch List (**Appendix A**)

A classification system based on the risk matrix set out in Tables 1, 2 and 3 should be developed so that medicines associated with clinically serious medicines shortages (page 10, **Appendix B**) are included in the regulations for mandatory reporting and communication. An enhanced, well defined classification would also enable maintenance and currency of the list. An algorithm may support the process.

The majority of the other classes of medicines associated with clinically serious medicines shortages (page 10, Appendix B) are considered ‘high risk medicines’ by the Commission www.safetyandquality.gov.au/our-work/medication-safety/high-risk-medicines/, such as:

- Inhaled anaesthetics, anticonvulsants, antipsychotics, antidepressants, opioids, steroids – alternatives in these classes may potentially be interchangeable; likewise
- Specific oncology medicines - require individual patient assessment as to whether alternatives are appropriate and switching is possible.

The potential for medication error from the substitution of high risk medicines is heightened in the context of shortages. These medicines should be included as having a ‘high’ impact in shortage necessitating inclusion in the reporting and communication regulations. The proposed protocol understates the potential for patient harm. For example, a chemotherapy regimen is complex, often with multiple medicines with multiple dependencies and a critical schedule. The impact of changes to this regimen requires clear communication and enhanced collaboration across disciplines to avoid medication error and adverse events.

In addition, there are broader health impacts to decisions on alternative medicines in areas such as antibiotics, where increasing levels of antimicrobial resistance need to be considered.

2. Include ALL medicines with an ‘extreme’ patient impact in shortage on the Medicines Watch List (**Appendix A**)

The ‘Medicines Watch List’ refers to medicines with ‘extreme’ patient impact in shortage. The Medicines Watch List should be expanded to include all medicines that would present ‘extreme’ patient impact in short supply include hyoscine, midazolam, glycopyrronium, potassium chloride, dopamine and thyroxin.

3. Broaden the Medicines Watch List (**Appendix A**) to include all medicines with a ‘high’ patient impact in shortage

The Commission strongly supports extending regulation to reflect the potential for harm where cases of medication error are known to have occurred. Medicines with ‘high’ patient impact in shortage are referenced in the new protocol. Such medicines include high risk medicines (HRMs) that have an increased risk of causing significant patient harm or death if they are misused or used in error.

The Commission has a number of resources related to HRMs including the Medication Safety Self Assessment for Australian Hospitals 2015⁷. This includes guidelines for alerting

practitioners to medicine shortages, selecting and using alternative products and doses, and educating practitioners about their safe use.

4. Reflect the consumer impact of medicine shortages with increased consumer communication

The Commission acknowledges the TGA's recent work in improving communication processes with consumers. The impact of medicine shortages on consumers can be alleviated with communication about the reasons for shortages and resultant impact on their individual treatments. Awareness of the likelihood of medicine shortages will help consumers to make informed decisions with health professionals.

Consumers are partners in healthcare planning and should have timely access to information when it impacts their healthcare and that of the people for whom they care. The role of health professionals and professional organisations in communicating information about medicine shortages is discussed (page 22, **Appendix B**). This section could be expanded to reflect the needs of consumers and could be aligned with the NSQHS Standards: Partnering with Consumers Standard requires systems be designed and used to support patients, carers, families. Reducing the impacts of shortages on consumers can be assisted through the content and availability of information for consumers.

5. Provide stricter parameters to define a 'resolved' medicine shortage

A 'resolved' medicine shortage (page 7, **Appendix A**) should be defined to manage consumer and clinician expectation. The following descriptions are suggested to accurately describe medicine availability after a confirmed medicine shortage:

- Partly resolved – limited stock is available which will be distributed in small quantities in a controlled manner until the shortage is resolved
- Resolved – medicine is freely available at all points in the supply chain with a low probability of becoming short again in a defined period of time.

Medicine shortages may be temporarily resolved such that limited stock is available but a shortage in the near future is probable. In this case, the description would be stated as partly resolved and revert to medicine shortage as appropriate.

Communication of the resolved medicine shortage should form part of determining resolution.

Detailed comments

Table 1: Editorial and detailed recommendations for Management and Communication of medicines shortages – proposed implementation approach- Consultation paper (**Appendix A**)

Page	Paragraph(P), Line (L), Bullet (B)	Recommendation
4; Background	L6	Replace 'manufacturing problem in any facility may simultaneously affect several Australian sponsors' With 'manufacturing problem in that facility may simultaneously affect several Australian sponsors of the same active ingredient'
5; Background	L18	Add ' It also allows consumers the opportunity to have a conversation with a health professional on impacts and alternatives where

		appropriate'
6; Enhancements etc.	P4	Split issue one into definition of medicine shortage and scope of covered medicines consistent with Scope on page 4
7; Proposed definition of a medicine shortage	B2	Delete 'Current medicine shortage means a medicine shortage that has commenced' ((Medicine shortage is defined above))
7; Proposed definition of a medicine shortage	B3	Replace 'Resolved medicine shortage means a medicine is now available because the supply of the medicine is no longer unavailable, partially available, or affected by other constraints' With 'Resolved medicine shortage means a medicine previously known to be in shortage is now available'
7; Proposed scope for medicines in this context	P1	Replace 'The kinds of medicines intended to be covered for the purposes of the proposed medicine shortage reporting requirements are prescription medicines that are entered on the Australian Register of Therapeutic Goods. However it is also proposed to include a small number of non-prescription medicines. The criteria for inclusion of a non-prescription medicine would be:' With 'The medicines covered by the proposed medicine shortage reporting requirements are prescription medicines on the Australian Register of Therapeutic Goods. A small number of non-prescription medicines would be included if:'
7; Proposed scope for medicines in this context	NA	State items that are out of scope. For example medical devices Specify the medicines excluded and included according to schedule
8; Suggested timing for sponsors to report an anticipated or current medicine shortage	P1	Consider splitting 'anticipated medicine shortage' and 'medicine shortage'
8; Suggested timing for sponsors to report an anticipated or current medicine shortage	P3	Delete 'A medicine is taken to be in shortage once patient care may need to be revised due to unavailability' ((This is repetition of definition))
8; Required content of notifications	B5	Add bullet ' <ul style="list-style-type: none"> • Anticipated date available from sponsor
9; Required content of notifications	B2 and B3	Separate these two bullet points as optional additional information

Table 2: Editorial and detailed recommendations for Management and communication of medicine shortages in Australia – A new protocol (Appendix B)

Page	Paragraph(P), Line (L), Bullet (B)	Recommendation
5; The new protocol	P5, L4	Replace 'having Extreme of High patient impact' With 'having Extreme or High patient impact'
8; Figure1	Last line,	Include 'consider as appropriate' against 'additional public communication' under High risk
8; Figure1		Provide full definitions for low, medium, high and extreme categories of risk in addition to the risk matrix (Table 1)
9; Reporting of a shortage	P2, L4	Specify with whom the information is verified, presumably sponsors
9; Reporting of a shortage	12a	Replace ' a potential shortage' With 'shortage or anticipated shortage'
9; Reporting of a shortage	12b	Delete 'actual'
11	Table 1	Define low, medium, high and extreme categories more specifically and with reference to scheduling
13; Investigation of alternative products	P4, L2	Specify the communication processes in the event information cannot be verified in a timely manner
13; Response	Bullets	Add bullet point for link to Australian Digital Health Agency for inclusion in EMM systems and My Health Record
14; Response	P4, L1	Advice on the relative importance of obtaining alternative product (s) overseas needs expansion
15; TGA and the sponsor coordinate...	P1, L1	Should this read 'extreme and high'?
16; The medicines shortage initiative...	B1	This was previously stated on page 5 (P3, L3) as prescription medicines on the ARTG (PBS or non PBS). Check inclusions against scope.
22; Health professionals.		Add 'Role of to health professionals

Discussion

The Commission is responsible for the development and support of the NSQHS Standards including standards for medicines management. In addition, medication management in the event of medicines shortages and the impact on health services has been tabled and reviewed by two of the Commission's advisory groups; the Medication Reference Group and the Health Services Medication Expert Advisory Group. These groups advise the Commission from a major stakeholder and a jurisdictional perspective on issues relating to medication safety.

Processes for medication management in situations of medicines shortage are important elements of health service governance⁵. Facilitating these processes will be enhanced by increasing the time for health services to plan for the response to the medicine shortage, consider alternative medicines and measures to procure these medicines and determine the impact on safety of these alternatives.

The Commission supports the mandatory reporting of all medicine shortages by the TGA and the communication of these shortages with as much notice as possible. The Commission welcomes further opportunities to review any revisions to the TGA's proposal and offers support with discussion on medication safety impact.

Appendices

A: Therapeutic Goods Administration. Management and Communication of medicines shortages – proposed implementation approach- Consultation paper. Version 1.0, March 2018. www.tga.gov.au/sites/default/files/consultation-management-and-communication-of-medicines-shortages.pdf

B: Therapeutic Goods Administration. Management and communication of medicine shortages in Australia – A new protocol. Protocol for Australian Product Sponsors, the Therapeutic Goods Administration and supply chain stakeholders. Version 1.0, March 2018. www.tga.gov.au/sites/default/files/consultation-management-and-communication-of-medicine-shortages-in-australia-a-new-protocol.pdf

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www.ismp.org/Newsletters/acutecare/articles/20100923.asp
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7. Medication Safety Self Assessment® for Australian Hospitals (2015). The Clinical Excellence Commission. Sydney: CEC 2015
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