

Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
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23 April 2018

Re: Consultation: Management and Communication of Medicine Shortages in Australia – A new protocol

Medicines Australia (MA) welcomes the opportunity to respond to the TGA public consultation on the management and communication of medicines shortages.

MA, as the peak body representing innovative pharmaceutical companies in Australia, takes medicines shortages seriously and puts patient care at the centre of everything we do. Unfortunately, medicines shortages occur despite the best efforts of sponsors, manufacturers, distributors, pharmacies and government. Medicines shortages occur for various reasons including the increasingly globalised nature of the supply chain for medicines and the small Australian market for prescription medicines. However, there are other reasons for medicines shortages including state/territory procurement models, quality use of medicines and pricing policies. A comprehensive analysis of the causes of medicines shortages, recognising that government plays a role through signals to industry about the value of medicines in the Australian health system, is imperative to mitigate the immediate and long-term risk of medicines shortages.

In late 2017 MA was a member of a Government led working group involving the Medicines Partnership of Australia (MPA) and has been involved in the development of the revised MSII Protocol. We believe that there are many positive aspects to the protocol, however critical aspects of the proposals introduce too many uncertainties and risks for MA to support the new protocol. The key issues that MA has identified include (see Attachment 1):

- Definition of a medicine shortage – MA is not satisfied with the proposed definition of a medicine shortage, from which all shortage obligations will stem. The proposed definition is unclear and unworkable, especially in light of the proposed penalties including imprisonment.
- Criminal/civil prosecutions – There needs to be fair and reasonable defences to any criminal/civil prosecutions based on non-compliance with reporting obligations.
- Resourcing of the TGA – The application of the definition of a medicine shortage as currently proposed will result in increased regulatory burden due to overcompliance by sponsors to avoid penalty. It is unclear whether the TGA intends to manage every shortage report submitted by sponsors, and thus the ability of the TGA to effectively triage and manage shortage reports is questioned.
- Transition periods and formal review process - A transition period for the implementation of requirements to allow a fair opportunity for stakeholders to assess their feasibility should be considered. MA also proposes a review of the new system within 12 months post implementation to assess its effectiveness in achieving the objective of better communication and management of medicines shortages.

- We note the consultation paper does not specifically mention vaccines and how they would be handled in this situation. Some of our member companies will specifically raise this issue as warranting further consideration by the TGA. We would encourage the TGA to discuss this further with the Medicines Australia Vaccines Industry Group (MAVIG).

MA is aware that member companies may make their own submissions which highlight issues/ concerns as they see them. MA encourages the TGA to take their comments on board. Given the MPA was closely involved in the working group last year we propose the formation of a dedicated technical working group that takes into account the issues and opinions of relevant stakeholders to better inform the operationalisation of the new protocol. The group should be represented by expert operational staff and regulatory managers from sponsor companies, the Medicines Partnership of Australia, the TGA, clinicians and other relevant authorities involved in the supply of medicines.

Medicines shortages adversely impact patient health and the TGA proposals include severe penalties across the supply chain, some of which may be unreasonable. These very significant impacts dictate that any solution must be fair, reasonable and include appropriate implementation strategies to prevent unintended failures and ensure supply continuity.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Elizabeth de Somer', written in a cursive style.

Elizabeth de Somer
Interim CEO

Attachment 1

Consultation issue 1: Proposed Definition of a Medicine Shortage

Q: Is the definition of a medicine shortage clear and appropriate, noting that it will be required to be stated in the Therapeutic Goods Act through the proposed amendments? (See appendix 1)

Response: The definition of a medicines shortage is unclear and unworkable and is not feasible given the potential penalties involved for non-compliance. MA believes the definition needs to be further clarified with respect to:

- The definition of partial availability – The definition is not precise and could be variously interpreted, including as insufficient stock in the supply chain or a geographically localised shortage.
- There must be a clear definition with regards to “other constraints on the medicine’s availability”, which specifically identifies the types of constraints to avoid confusion.
- The definition of an anticipated medicine shortage – The anticipated period in advance of a shortage must be defined and the level of certainty of a shortage specified.
- Clarity on whether the protocol applies to supply constraints as a result of a recall is required, including the responsibilities of the sponsor.

Q: Is the proposed scope for covered medicines clear and appropriate? (See appendix 2)

Response: MA believes that the proposed scope for covered medicines is clear and appropriate, noting that some medicines not covered in the scope of this paper can be assessed on a case by case basis.

Consultation issue 2: Reporting Obligations

Q: Do you support the suggested timeframes? Do you have an alternative proposal? (See appendix 3)

Response: MA supports the proposal that sponsors report a medicines shortage as soon as practicable after becoming aware of it. This not only provides patients with the most benefit in the timeliest fashion, but also is particularly important for those products with a significant lead time and where there are limited suppliers in the market.

However, MA does not believe that reporting within two business days after being contacted by the TGA regarding a report of a medicines shortage is feasible. This reporting timeframe does not allow enough time for comprehensive verification of an out of stock report especially when it has occurred further down in the supply chain.

MA does not agree with the suggested timing for sponsors to report a discontinuation. It can be difficult for sponsors to establish the reasons for discontinuation, as often a large proportion of medicines will be imported, and this can make it challenging to predict so far in advance. Thus there is a constant risk of non-compliance for these sponsors. In addition, for those products with a medium or low impact level, which have a number of alternatives in the market already, a shorter timeframe for reporting discontinuations of these products is most practicable. It should also be noted that increased reporting of shortages is not equivalent to improved management of shortages.

It is imperative that the TGA have sufficient resourcing to triage and manage all mandatory information, which may be significantly increased in volume due to potential over-compliance by sponsors to avoid penalties.

Q: Do you support the required notification content? (See appendix 4)

Response: MA supports the required notification content; however, confirmation is needed with regards to:

- Which fields are available in the “reasons for the shortage” drop box?
- The definition of “shortage type”, whether it refers to a partial or complete shortage, or a resolved/current/anticipated/discontinuation shortage type.
- Whether a “confidence level” will be included in the “estimated duration of shortage” field.

Additionally, an appropriate subset of the notification content also needs to be available to all health professionals (and potentially the whole supply chain) in order for it to be useful.

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

Q: Is the list comprehensive/adequate? Are there other products that would have an extreme or high patient impact if they were in short supply?

Response: MA agrees with the development of a Medicines Watch List. MA believes that products on the Medicines Watch List should take into account the number of sponsors supplying the product and the number of other presentations/strengths available. The proposed Medicines Watch List is comprehensive; however sponsors recommend that insulin should be added; bearing in mind the different insulins available would have different impacts on patients.

Q: What would be the best mechanism to add or remove medicines from the list?

Response: MA suggests that the list be regularly reviewed to ensure alignment with best practice and the most up to date evidence. We suggest that a formal review be undertaken on a regular basis by the TGA in consultation with the Chief Medical Officer. The relevant stakeholders should be given the opportunity to make a submission prior to the review, and they should also be able to appeal prior to the publication of the revised list.

Consultation issue 4: Compliance Obligations and Options

Q: Which option, or combination of options, do you believe would be the most effective? (see appendix 5)

Response: MA strongly opposes the severe and disproportionate penalties in option 3, which are not appropriate in this circumstance. Particularly considering the lack of clarity with respect to a sponsor’s obligations in relation to medicines shortages and the lack of recognition of other root causes of shortages outside the sponsor’s control.

Whilst some of our member companies may comment on the detail contained within the penalty options, MA believes it is premature to discuss support for any penalty option at this stage. This is particularly so given the unclear definition of a medicine shortage and the required reporting timeframes, of which have yet to be finalised.

In addition, there needs to be fair and reasonable defences for non-compliance. For example, there are situations whereby sponsors are not in direct control of shortages, however the protocol defines the sponsor as liable for the shortage; this can occur when a supplier of an active ingredient is unable to supply to the sponsor. MA believes that industry should be given enough time to adjust to the implementation of the new requirements, and we note the TGA’s proposal that allows sponsors an opportunity to comply with the requirement in the first instance before enforcement proceedings commence. MA also recommends that the effectiveness of the penalty system be formally assessed after 12 months post implementation of the new protocol.

Other Issues

MA calls on the Government to consider matters outside the scope of the original work, as they were clearly identified as contributing factors to the management of shortages. For example:

- 1. Analysis of the root causes of shortages** – MA calls for the government to undertake a comprehensive analysis of other causes of medicines shortages. Factors not identified in the protocol such as the misuse/overuse of medicines, inappropriate prescribing, aggressive pricing policies (such as mandatory price cuts and price disclosure), manufacturing requirements and state/territory procurement models; can all have an impact on medicines shortages. A root cause analysis needs to be taken into consideration in order to inform and proactively mitigate future risks, rather than relying on either reporting once a shortage has occurred or severe penalties.
- 2. Education of health professionals** – Lack of communication and information regarding medicine shortages can result in fragmented patient care. Pharmacists and prescribers may face uncertainty in recommending an alternative treatment if there is no clear information as to how long the shortage will last. It is important that health professionals not only be informed of, but also educated on medicines shortages and how to find the most current information, in order to effectively manage them. Organisations such as NPS Medicinewise and the Council of Australian Therapeutic Advisory Groups (CATAG) should be involved with the provision of this information.
- 3.** Other sections in the Therapeutic Goods Act 1989 that enable the use of unapproved products are noted as potential mechanisms to help address specific shortages. However, these sections need to be modified to avoid unnecessary use of resources (e.g. other registered suppliers may have capacity to assist in resolving the shortage which will minimise over-importation), and to allow these products to become more readily accessible (e.g. introduction of effective statutory processing times for Section 19A applications and Section 14 Exemptions).
- 4. Direct distribution** - Our members take their responsibilities to the Australian community and the people who use their medicines incredibly seriously. It is the fundamental position of Medicines Australia and our members that Australians are able to access the medicines they need when they need them. Medicines Australia supports the Community Service Obligation wholesalers, but we also support a manufacturer's ability to determine the most efficient, safe and cost-effective distribution channel, which may include arrangements to supply medicines directly to pharmacies through other appropriate logistics companies.

Appendix

1. 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.

Different types of medicine shortage are defined:

- **Anticipated** medicine shortage means a medicine shortage that is anticipated to commence at a future date;
- **Current** medicine shortage means a medicine shortage that has commenced;
- **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;
- **Discontinuation** means a decision by a sponsor to permanently cease the supply of a medicine.

2. 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:

- The medicine is critical to the ongoing health of the patient (an example would be salbutamol asthma inhalers); and/or
- Inclusion of the medicines is critical for public health (an example would be naloxone injections for opioid overdose).

3. Suggested timing for sponsors to report an anticipated or current shortage:

- Sponsors must report an anticipated or current medicine shortage: as soon as practicable after becoming aware of it, or within 2 business days after being contacted by the TGA regarding a report of a shortage of their medicine.
- Sponsors must report all resolved shortages as soon as practicable after it has resolved and within 5 working days of the day the shortage was resolved.
- A medicine is taken to be in shortage once patient care may need to be revised due to unavailability.

Suggested timing for sponsors to report a discontinuation:

Sponsor must report:

- 12 months prior to the discontinuation, for a discontinuation with an extreme or high impact level;
- 6 months prior to the discontinuation, for a discontinuation with medium impact level;
- 3 months prior to the discontinuation, for a discontinuation with low impact level.

It should be noted that these timeframes are those currently set out in the medicines shortages Interim Business Specifications and Guidance Supplement available in TGA's eBusiness Services (eBS) portal. The long lead times for reporting discontinuations of medicine shortages with extreme or high impact levels are needed because in many cases the sponsor of these medicines may be the sole supplier in Australia. The lead times enable TGA to identify alternative suppliers of the product for the Australian market, which may include seeking and reviewing an application for registration of the alternative medicine on the ARTG.

4. The information required when reporting a medicine shortage includes:

- Sponsor name and contact details
- Product active ingredient and trade name, strength, dose form and ARTG number
- Reason for the shortage (selected from a drop-down menu)
- Estimated duration of the shortage
- Shortage type
- Additional supply details about the medicine as appropriate
- Information about substitute medicines or therapeutic alternatives as appropriate.

It should be noted that this is the same content requested of medicines sponsors under the existing voluntary reporting scheme.

5. Penalties

- **Option 1:** Publicly identifying non-compliant sponsors, without additional sanction
- **Option 2:** Focus on civil penalties and infringement notices
- **Option 3:** Substantial civil penalties and criminal offence