Medicines Australia's response to the TGA's consultation: 'Medicine shortages and discontinuations: Proposed changes to reporting requirements'

Submitted via online consultation survey here on 13 January 2025

Issue 1: Monitoring medicine shortages

Q1. What is your preferred option from the following:

1. Add all current registered non-prescription medicines on the ARTG into the Reportable Medicines Determination, which would require affected sponsors to report any shortage or discontinuation to the TGA.

2. TGA PROPOSAL: Balance regulatory burden on sponsors with the need to improve TGA's monitoring of medicine shortages by:
   a. Adding 23 registered, non-prescription medicines that are critical to the health of patients in Australia, to the Reportable Medicines Determination (as outlined in Attachment A), and
   b. Including a provision in the Act to require sponsors of any approved medicine to provide the TGA, on request, with detailed supply information (i.e. not limited to reportable medicines).
3. No change to the current reporting requirements under the medicine shortages regulatory framework.

Q1 response:

Our preferred Option is # 2

Q2 Why is this your preferred option?

While members of Medicines Australia primarily focus on the development and supply of prescription medicines, some sponsor companies also have non-prescription medicines in their portfolios.

Medicines Australia does not have any objections to the proposed changes in Option 2, given the potential clinical impact of shortages of the 23 registered non-prescription medicines proposed to be included within the *Reportable Medicines Determination*. We note and support the inclusion of 'Sodium chloride 0.9% (normal saline) solution for injection' on the Reportable Medicines Determination due to its use as a vehicle for the administration of injectable medicines.

In addition, we do not object to Option 2b, which will require sponsors of any approved medicine to provide the TGA, on request, with detailed supply information (i.e. not limited to reportable medicines) for the purpose of managing medicine shortages.

Option 1 is not our preferred option due to the potential to increase the TGA's regulatory burden and adversely impact shortage publication timelines. An increase in regulatory burden could reasonably be expected to strain TGA resources. This could impact publication timeframes, and consequently adversely impact the primary objective of medicine shortages reporting to ensure prescribers and consumers receive timely notice of supply disruptions.

Furthermore, the regulatory burden for the TGA and sponsors is likely to outweigh the benefits of Option 1. That is, the majority of over the counter medicines (OTC) will not have the same level of clinical/medical impact for a shortage as prescription only medicines (schedule 4) and there are often alternative products available with similar clinical outcomes (either generics or analogues).

Q3. What impact would the TGA's preferred option (Option 2) have on your or your organisation?

Medicines Australia members are expected to have medicine shortage reporting procedures in place to support their prescription medicine portfolios, and any impact relating to the proposed Reportable Medicines Determination revision is expected to be limited.

However, we acknowledge that Option 2 may introduce shortages reporting burden for a limited number of organisations impacted by the addition of the 23 registered, non-prescription medicines to the Reportable Medicines Determination.

Medicines Australia members report having well established internal Standard Operating Procedures, Work Instructions and other tools and/or guidance in place to ensure the TGA's medicine shortage reporting requirements are met, as well as those of other comparable jurisdictions in which medicine shortages are reportable. The introduction of a formal request for information mechanism for all registered medicines (including non-reportable products) may prompt the revision of a number of internal procedural documents, at local and/or global levels. Therefore, adequate lead time for sponsors to prepare for the changes should be provided.

Sponsors of innovative medicines are familiar with the current Section 31 request for information mechanism. Medicines Australia therefore does not believe extending the

Section 31 mechanism (or introduction of a similar request-for-information mechanism) represents a significant increase in regulatory burden for our members.

Issue 2: Medicine discontinuations

Q4. What is your preferred option from the following:

1. Include additional medicines in the Medicines Watch List, such as oral opioids, to require sponsors of those medicines to notify the TGA of their permanent discontinuation at least 12 months before ceasing supply (or as soon as practicable after the decision is made).

2. TGA PROPOSAL: Update the Act to require sponsors of all reportable medicines to provide 12 months' notice of a decision to permanently discontinue the medicine (or as soon as practicable after the decision is made).

3. No changes to current mandatory periods for sponsors to notify the TGA of a decision to permanently discontinue a reportable medicine in Australia.

Q4 Proposed response:

Medicines Australia prefers Option 2.

Q5. Why is this your preferred option?

Medicines Australia does not have any objections to Option 2, provided the caveat of "as soon as practicable after the decision is made" is explicitly included in the Act. The caveat is important to retain as it accounts for the complexity of medicines supply chains. It allows sponsors practical and reasonable time to assess and navigate their internal processes and systems, at a global and local affiliate level, and consider any external factors as part of the discontinuation notification process.

We acknowledge and support the purpose of the proposed changes such as:

- To remove the distinction between reportable medicines with critical and non-critical impact for discontinuations as some "non-critical" medicines are used for certain special patient populations where there are no alternatives.
- To provide more lead time for alternative manufacturer(s) to ramp up manufacture and supply in anticipation of potential increased demand.

- To allow TGA and other sponsors more time to register alternative medicines and/or arrange supply of overseas substitute medicines under Section 19.
- Provide more time for communicating to patients and health care professionals (HCPs) to enable patient treatment plans to be reviewed and updated.

Medicines Australia considers Option 2 has more merit than Option 1 where specific medicines are proposed to be added to the Medicines Watch List. We agree with the consultation paper's assessment that adding specific medicines to the Watch List may be impractical due to the dynamic nature of medicine supply and administratively burdensome for both the TGA and sponsors to implement.

Q6. What impact would the TGA's preferred option (Option 2) have on your or your organisation?

Pharmaceutical companies operate in a global market which requires them to navigate and adhere to multiple international regulatory frameworks. Any Australia-specific regulatory changes will require pharmaceutical companies to assess and update their procedures and processes accordingly, at the global and local affiliate level. Sponsor burden is expected to vary depending on internal process(es) maturity and governance complexity. In addition, the proposed 12-month notice period is more stringent than the 6-month requirement in other major markets such as the US and most European countries, and therefore, sponsor burden is expected to vary depending on internal process(es) maturity and governance complexity.

Medicines Australia members strive to provide as much notice as possible for all medicine discontinuations to minimise the impacts on patients and health care professionals. Whilst Medicines Australia does not object to Option 2, there may be commercial and manufacturing factors where the 12-month notice period is not feasible. It is therefore critical that the caveat of "as soon as practicable after the decision is made" is explicitly retained in the Act.

<u>Additional comments regarding medicines shortages and discontinuations</u>

With the accelerating growth of the innovative medicines pipeline and a competitive global medicines market, there is a likelihood that more products may face commercial viability issues, complicating efforts to manage shortages and discontinuations. Medicines Australia is committed to working with the TGA and other stakeholders to ensure the timely reporting of medicine shortage and discontinuations to minimise the impact to patients and HCPs.

While reporting is an important aspect of managing medicine shortages and discontinuations, it is imperative to minimise such events occurring in the first place, wherever possible.

We note the TGA's Medicines Shortages Report in 2024 which reported manufacturing (63%) and commercial changes/ viability (16%) as the most common reasons for a medicine shortage.

Consistent with the TGA's report, Medicines Australia has previously highlighted that the pricing and reimbursement environment in Australia can increase the risk of shortages.[1] For example and as previously noted, "A genericised multi-brand competitive market, coupled with F1/F2 PBS price reductions, has driven down prices which creates challenges for sponsors' buying power. Low prices create an unsustainable commercial environment that can lead to market failure and medicine shortage in an internationally competitive market."

Health Technology Assessment (HTA) evaluation policies for government reimbursement on the Pharmaceutical Benefits Scheme (PBS) may also exacerbate the impacts of medicines discontinuations by reducing the potential number of innovative medicines being supplied in Australia. The policies and methods used during HTA evaluations in Australia result in some of the lowest medicines prices in the world, making it difficult for some sponsors to commercialise their innovative medicines here. If a sponsor chooses to discontinue a medicine and there is no alternative because it is commercially unviable to bring the alternative to market (despite being available internationally), patients are impacted. The relationship between medicines reimbursement cost containment measures and the market viability of innovative medicines in Australia are discussed in detail in Medicines Australia's response to the Australian National Audit Office (ANAO) review of the PBS Administration 2023-24.[2]

While the TGA may not have direct control of many of these factors, we suggest that it is important that it considers the changing medicines discovery landscape and raises relevant policy issues with other relevant areas of the Department of Health and Aged Care. We believe it is vital to ensure a whole of system approach is taken for mitigating and managing medicines shortages and discontinuations.

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[1] Medicines Australia submission: Building a more robust medicines supply: Proposals to help prevent, mitigate and manage medicine shortages (2021). Available at https://www.medicinesaustralia.com.au/policy/submissions/?t=2021

[2] Medicines Australia's submission 2 to the ANAO audit of PBS Administration 2023-24 https://www.medicinesaustralia.com.au/policy/submissions/

Appendix A – Background information

Medicines shortage reporting

Current reporting requirements

- Registered medicines are considered ***reportable*** under Section 30EH of the *Therapeutic Goods Act 1989* (the Act) if:
  - they contain one or more Schedule 4 (Prescription Only Medicine); or
  - Schedule 8 (Controlled Drug) substances; or
  - if they are included in the *Therapeutic Goods (Reportable Medicines) Determination 2018* (known as the Reportable Medicines Determination).
- The Reportable Medicines Determination currently lists 11 reportable medicines that are non-prescription registered medicines considered critical to the health of Australians.
- Sponsors of reportable medicines must report all shortages or discontinuations to the TGA. These details are then published on the TGA's Medicine Shortage Reports Database.
- For non-reportable medicines on the Australian Register of Therapeutic Goods (ARTG), sponsors are not required to report shortages or discontinuations to the TGA.
- However, the TGA can request sponsors to provide information about *whether* the medicine is being supplied, imported into, or exported from Australia. However, the Act only provides a clear requirement for sponsors to provide more detailed data in relation to reportable medicines (e.g. data on the volume of products being imported, exported or supplied).

Medicine discontinuations

Current requirements:

Sponsors must advise the TGA of any decision to permanently discontinue the supply of a reportable medicine in Australia either:

- 12-months before the discontinuation is proposed to occur if it is likely to be of critical impact - or as soon as practicable after the decision is made, or
- 6-months before the discontinuation is proposed to occur in all other cases - or as soon as practicable after the decision is made.

A decision to permanently discontinue a reportable medicine will be of '**critical impact**' where either:

- the medicine is listed on the Medicines Watch List, signalling that a shortage or permanent discontinuation of the medicine could cause significant morbidity or death for patients in Australia; or
- at the particular time:
    - there are no registered goods that could reasonably be used as a substitute for the medicine or – that these substitutes are not likely to be available in sufficient quantities to meet the demand and
    - the discontinuation has the potential to have a life-threatening impact on, or a serious impact on the physical or mental health or functioning of, persons who take, or who may need to take, the medicine.

There are 96 medicines, plus vaccines listed in the National Immunisation Program Schedule (as at 1 July 2018), listed in the Medicines Watch List.

For medicines not listed in the Medicines Watch List, sponsors are required to assess the potential impact of a discontinuation to determine whether 6- or 12- months' notice of the discontinuation must be given to the TGA.