Palliative Care Australia
Matters of life and death

Medicine shortages and discontinuations

Proposed changes to reporting requi

Submission to the Therapeutic Goods Administrati

January 2025

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About Palliative Care Australia

Palliative Care Australia (PCA) is the national peak advocacy body for palliative care. PCA represents all those who work towards high-quality palliative care for all Australians who need it. Working closely with consumers, our Member Organisations and the palliative care workforce, PCA aims to improve access to and promote palliative care.

Summary and recommendations

PCA is grateful for the opportunity to comment on options presented by the Therapeutic Goods Administration (TGA) to reform reporting requirements for medicines in shortage or being discontinued.

This submission is provided in the context of ongoing concerns in the palliative care sector regarding discontinuation of key medicines on the PBS Palliative Care Schedule. These concerns led a group of seven organisations to develop an **11-point plan to resolve shortages of palliative care medicines**. A copy of the plan is included in this submission.

The TGA's consultation paper suggests that "six months is not enough notice to plan for the discontinuation of some reportable medicines." We strongly agree - recent experiences have conclusively shown that a six-month notice period is highly insufficient to avoid disruptions in supply and flow-on impacts for patients and clinicians.

On both issues under consideration (shortages and discontinuations), PCA supports the TGA's preferred options.

Issue 1: medicines shortages

PCA supports the TGA's proposal to "Include[e] 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). We hope this will provide the TGA with sufficient powers should a shortage emerge of non-prescription products commonly used in palliative care settings (e.g., artificial saliva products for dry mouth and glycopyrronium bromide for secretions or severe drooling).

For this new provision to work as intended, there must be clear mechanisms to allow additional medicines to be included in the Reportable Medicines Determination as issues arise. This should include processes to respond to on-the-ground intelligence from clinicians and an obligation on sponsors to keep and disclose accurate information on stock and availability.

Issue 2: medicine discontinuations

PCA prefers the proposal to "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)."

PCA takes this one step further by calling for **all medicines on the PBS Palliative Care Schedule to be added to the Medicines Watch List**, given the growing list of discontinuations of opioid analgesics and the disproportionate impact on patients. This option would result a lower regulatory burden for sponsors than the TGA's preferred option (to "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)").

PCA also supports the TGA's preferred option, because it would achieve the desired extension of reporting timeframes for all reportable medicines, not only palliative care medicines.

Additional feedback

Issue 2 (discontinuations) is more relevant for palliative care stakeholders, so the bulk of our advice below relates to Issue 2. These include observations drawn from recent experiences with the current 6-month reporting timeframe, including:

- The need for S19A substitutes would arise less often if notice periods were longer.
- Sponsors have a track record of not disclosing important information about supply until they are legally required to, even where it would be in the interest of clinicians and patients if they did so earlier.
- It appears that some sponsors are compliant to the point of only meeting minimum legal reporting requirements and no further, which does not always ensure smooth transitionary arrangements for prescribers and patients. A different approach could involve asking sponsors to prioritise patient interests over and above a putative concern for commercial confidentiality

A timely consultation

Over recent years several opioid analgesics on the PBS Palliative Care Schedule have been discontinued in the Australian market. Because the list of clinically appropriate substitutes or alternatives is shrinking, these withdrawals are having a disproportionately high and growing impact on palliative care patients and clinicians.

The TGA's consultation on notice periods for reporting medicine shortages and discontinuations takes place at a time of growing concern among palliative care stakeholders about the continuity of supply of critical palliative care medicines. While the TGA has done admirably within its powers to address emerging supply problems, it appears much more can be done both within the TGA's scope of action and beyond.

Against this background, a group of seven organisations have agreed on an **11-point plan** to resolve shortages of palliative care medicines and provided this plan to the Australian Government. Supporting organisations include:

- Palliative Care Australia
- Australia New Zealand Society of Palliative Medicine
- Advanced Pharmacy Australia
- Pharmaceutical Society of Australia
- Palliative Care Nurses Australia
- Pain Australia
- Aged and Community Care Providers Association

The 11-point plan is presented below. Notably, **points 1 and 8 pertain directly to the TGA's current consultation on reporting requirements**. Points 6,7 and 9 are also relevant to the TGA's work though out of scope for the current consultation.

Supporting organisations have written a joint letter to the doctors in the Australian Parliament asking for their support to take forward the actions in the 11-point plan.

11-point plan to resolve shortages of palliative care medicines

PBS Palliative Care Schedule

1. Add medicines on the PBS Palliative Care Schedule to the Medicines Watch List as critical medicines.

2. Review and update the PBS Palliative Care Schedule, based on clinical advice, to include all medicines commonly used in palliative care.

3. Waive application fees for sponsors seeking to list medicines on the PBS Palliative Care Schedule and/or opioid analgesics (for pain management in people with palliative care needs or cancer) on the PBS.

4. Ensure that any medicines prescribed under the PBS Palliative Care Schedule that require an authority are available via a streamlined authority.

5. Abolish co-payments for medicines prescribed through the PBS Palliative Care Schedule.

Managing long-term supply risks

6. Expand the powers of the TGA to more proactively anticipate shortages and discontinuations of critical medicines and intervene more proactively, including by initiating the creation of stockpiles of identified medicines in need.

7. Establish a fund (with an initial commitment of $10 million) to enable the Australian Government to create and manage a stockpile of palliative care medicines through the established network of Community Service Obligation (CSO) distributors.

8. Extend the timeframe for notifying the TGA of any anticipated shortage, discontinuation or disruption to supplies of medicines on the Palliative Care Schedule from 6 months to at least 12 months and enforce civil penalties against sponsors who do not meet their obligations under the Medicine Shortage Reporting Compliance Framework.

9. Commission an independent evaluation of whether arrangements through Section 19A of the Therapeutic Goods Act 1989 are achieving the intended purpose and how they could be strengthened to mitigate temporary medicines shortages.

Managing temporary supply disruptions

10. Expand incentives for domestic pharmaceutical manufacturing to essential medicines in common clinical use, including opioid analgesics.

11. Commission an objective assessment of the factors contributing to the longer-term decline in the availability of opioid analgesics in Australia. This should include consideration of the comparative conditions of the Australian versus other markets with respect to factors such as price, costs of registration, compliance with regulations for Schedule 8 medicines (e.g. security, medicines handling, administration, distribution).

Comments on current notice periods for medicines being discontinued

Six months is insufficient

The TGA's consultation paper suggests that "six months is not enough notice to plan for the discontinuation of some reportable medicines." We strongly agree - recent experiences have shown that a six-month notice period is quite insufficient to avoid disruptions in supply and flow-on impacts for patients and clinicians.

The need for S19A substitutes would arise less often if notice periods were longer

Section 19A approvals have proven necessary even where a discontinued product will be replaced by a new permanent substitute, because six months is not long enough for the new sponsor to go through both the ARTG and PBS approvals processes. The TGA has endeavoured to fill the gap in supply via its powers under Section 19A – something that would be needed less often if notice periods were longer

Sponsors have a track record of not disclosing important information about supply until they are legally required to

Even where there is a minimum reporting period, sponsors have admitted of being aware that a product was likely to be withdrawn from the Australian market well before they notified the TGA of their intention to do so. PCA is aware of one case where a sponsor knew of these risks **three to four years in advance** and yet notified the TGA and prescribers only six months ahead of time, because that was all they were required to do (PCA can provide the TGA with further details if that is of interest).

These situation resulted in gaps in supply that might have been avoided if the notice period were longer, and/or if sponsors were felt sufficient incentive notify the TGA as soon as they become aware of a likely discontinuation, even ahead of the required notice period.

Notice periods for new products

It is not clear how current notice periods are applicable or enforceable apply for products which are newly ARTG-registered or newly PBS-listed products. This is important in the context of discontinuations especially where a new product will replace a discontinued product and prescribers are keenly awaiting supply updates.

This situation arose where a sponsor recently took over the license to supply a product on the PBS Palliative Care Schedule. There was a gap in the availability of the product between suppliers, and the information on the TGA website (presumably from the new sponsor) indicated that clinicians could expect the new product to arrive on a given date in August 2024. The anticipated date for supplies to arrive had been on the TGA website for many months, and PCA had informed our stakeholders that the supply situation would resolve once the new product arrived. **Two days** before that date, we learned that there would be a further 1-3 months until the new products would arrive. The further delay at very late notice added further challenge to an already frustrating situation for prescribers and consumers.

In PCA's view, the situation described above was entirely avoidable.

A compliance approach versus a patient-centric approach

The above experiences raise questions about the value of a solely compliance-driven approach to reporting of medicines supply disruptions (both shortages and discontinuations). Information on the medicines shortages database is often unreliable, with the actual dates provided by sponsors often proving inaccurate or changed at late notice. In at least some instances, sponsors have access to information about medicines supply that they are not disclosing to the TGA until they are legally required to, and, even then, that information is not necessarily reliable.

With respect to the examples cited above, it is hard to imagine that the information disclosed so belatedly was commercially sensitive; instead it appears that **some sponsors are taking their reporting obligations only as seriously as they are legally required to – and no further**.

All this is occurring even with a Medicine Shortage Reporting Compliance Framework in place, under which there are (at least notionally) penalties for sponsors who don't provide sufficiently timely information.

This is why PCA calls on all stakeholders with the ability to improve information about medicines supply disruptions, to think about a different approach that goes beyond mere compliance and respects the need for clinicians and patients to receive up-to-date information as and when it becomes available. That should include **asking sponsors to prioritise patient interests over and above a putative concern for commercial confidentiality** – concerns that have proven, in at least the cases PCA cites in this submission, to be highly questionable.