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TGA Consultation: Medicine shortages in Australia – Challenges and opportunities

March 2024

About The Royal Australasian College of Physicians (RACP)

The RACP trains, educates and advocates on behalf of over 21,000 physicians and 9,000 trainee physicians, across Australia and Aotearoa New Zealand. The RACP represents a broad range of medical specialties including general medicine, paediatrics and child health, cardiology, respiratory medicine, neurology, oncology, public health medicine, infectious diseases medicine, occupational and environmental medicine, palliative medicine, sexual health medicine, rehabilitation medicine, geriatric medicine, and addiction medicine. Beyond the drive for medical excellence, the RACP is committed to developing health and social policies which bring vital improvements to the wellbeing of patients and the community.

We acknowledge and pay respect to the Traditional Custodians and Elders – past, present and emerging – of the lands and waters on which RACP members and staff live, learn and work. The RACP acknowledges Māori as tangata whenua and Te Tiriti o Waitangi partners in Aotearoa New Zealand.



Introduction and key points

The RACP acknowledges the opportunity to contribute to this important consultation which aims to improve Australia's capacity for predicting, risk managing and ultimately preventing medication shortages and unplanned medicines discontinuations. This submission complements our 2021 [submission](#) to the National Medicines Policy Review.

This response addresses consultation questions of relevance to prescribing physicians and reflects the views of some of the RACP's subspecialties: paediatrics, developmental paediatrics, paediatric endocrinology, endocrinology, cardiology, addiction medicine, palliative care medicine and sexual health medicine. We appreciate and acknowledge the contributions of RACP affiliated specialty societies to this submission: the Australian Paediatric Society, the Australasian Society for Developmental Paediatrics, the Australia and New Zealand Society for Paediatric Endocrinology and Diabetes, the Cardiac Society of Australia and New Zealand and the Endocrine Society of Australia.

Key issues raised by respondent physicians include:

- Significant time can be spent by physicians on managing medication shortages and discontinuations.
- These situations can have significant impacts on patient care and wellbeing.
- The need for early communication by the TGA of anticipated shortages or discontinuations through a variety of channels.
- Need to accommodate additional physician information needs through the TGA website.
- Considering strategies to mitigate and prevent shortages, including increased key medications production in Australia.

Medicine shortages and medicines policy more generally are a key priority for RACP members and we look forward to continuing to engage with the TGA on these subjects.

Practitioner and patient experienced medicine shortages and related impacts (questions 6- 7, 19-22)

Practitioner experience

All responding RACP Fellows and specialty societies reported shortages of key medicines required in their subspecialties within the last 12 months. Shortages of the following medications that impacted the capacity of respondents to provide appropriate care to specific patient groups with high or complex healthcare needs have been identified:

Priority patient group	Medication shortage
Children with neurodevelopmental disorders	Vyvanse, Concerta, Ritalin LA, Fluoxetine 10mg tablets
Children and adults with diabetes, complex obesity or endocrine issues	GLP-1 receptor agonists, Ozempic, growth hormones
Children with infections	Liquid Keflex, Benzylpenicillin
Patients in palliative care	Opiates – Hydromorphone immediate release, Jurnista (long acting hydromorphone), Ordine (liquid morphine) cholestyramine (temporarily not available) and Oxynorm and Sevredol to discontinue soon
Patients with heart issues	Warfarin
Patients with sexually transmitted infections	Benzathine penicillin, Bicillin, pristinamycin, and limited available agent mycoplasma genitalium in general
Patients with a substance use disorder	Disulfiram

Respondents indicated various periods of time spent managing medicine shortages and discontinuations; their estimates ranged from a few hours per day to an hour each week through to ad hoc time on a weekly or fortnightly basis. Related time-consuming activities included facilitating additional consultations, identifying alternative management options, writing additional or new scripts, educating patients on new medications,

organising admission for collection or dispensation of new pharmacotherapies and calling pharmacies or the TGA for further information.

These activities were made more time consuming when:

- Physicians lacked an awareness of alternative pharmacotherapies and/or needed to complete an authority script.
- Patients needed to be risk stratified and prioritised for prolonged shortages or discontinuations and/or expectations about what medicines they should take.
- Extended psychological support to patients is also often needed.

Patient experience

Medication shortages and discontinuations cause a great deal of anxiety for patients. Our physicians identified several harmful consequences of medication shortages:

- Delays to key therapies
- Medication shift outside of a scheduled management review
- Withdrawal side effects
- Prescription of a less effective pharmacotherapy
- Symptom reoccurrence or relapse
- Non-participation in daily activities.

Some physicians report that patients become entangled in complex referral webs to obtain substitutes. Others noted patient compliance issues with substitute regimes. These impacts can cause patients to have serious concerns about their longevity and quality of life that physicians are left to manage.

Medication shortage and discontinuation information receipt, relay and the quality of TGA information (questions 14-18)

Physicians refer to a range of sources for information on medicine shortages or discontinuations; there is no single source of truth that respondents found most helpful

Physicians most value accurate information on acute shortages and pharmacotherapy substitutes well in advance of a shortage or discontinuation wherever possible; however, they would prefer to receive this information through a diverse range of channels to assure receipt.

Some respondents suggested that an email from the TGA is most helpful for hospital-based doctors with capacity to access alert emails while others valued the ability to refer directly to the TGA website; yet others appreciated cascaded feedback from the TGA Medicine Shortage Action Groups to accurately target affected practitioners and patients.

Some respondents have appreciated distribution of TGA shortage-related information via their specialty society. These respondents pointed to the value of involving their professional organisations in alert distribution. Updates directly from hospital-based pharmacists were found helpful by some hospital-based respondents. A small number of respondents indicated that they have received updates about shortages and substitutions from patients, social media or through repeat calls to community pharmacists. These respondents may not be aware of a shortage or discontinuation until a patient tells them or scripts cannot be dispensed, indicating clear capacity for improvement of the existing communication arrangements.

Fellows experienced information gaps in receiving and sharing medication shortages and discontinuations advice

Respondents reported often lacking the necessary details to communicate fully about shortages or discontinuations, both in their interactions with patients and partners in clinical care. They referenced the following information deficits:

- Lack of TGA explanation for a discontinuation.
- Lack of information about predicted or shifting timeframes for resolution.

- No information on available pharmacotherapy substitutes.
- Concerns over whether advice might be out-dated.

Some respondents critiqued the time lag between the commencement of medication shortages and discontinuations and the release of TGA updates.

The TGA medicines shortages website has untapped potential

Some respondents were supportive of the TGA medicines shortage website as is while others found it to be substantially lacking or had gradually lost trust in the provided advice for the reasons stated above. What the feedback clearly indicates is that there is scope to accommodate additional practitioner information needs through the website.

Following actions could establish the website as a reliable and trusted source of information:

- Promote the website directly to hospital pharmacies, specialty societies and individual practitioners.
- Notify prescribers of any updates via email, taking a proactive reach-out approach and including links to the website. Emails could be directed to Ahpra-registered pharmacists and medical practitioners.
- Improve the interface between medication shortage alerts and the medication shortage database.
- Segment/localise information to specific regions with a medicine shortage or discontinuation.
- Implement a surveillance system for provider, sponsor, patient, practitioner and sector feed-in, to capture and more broadly communicate early indicators of shortage risk. Refer to the National Immunisation Register, the National Communicable Disease Register or the Adverse Drug Reactions/Events for examples of such real-time surveillance systems.
- Include more information about alternative supply or mitigation options the TGA plans to put in place or has put in place.

The TGA should also consider another dedicated channel for real time information transfer, such as a phone hotline. Again, it is important that there are diverse sources of timely, reliable and comprehensive information on upcoming and existing medicine supply issues.

Systemic reforms to enhance the medicine supply chain and our discontinuation and shortage management processes (questions 23-24)

Limited local production and rigid approval processes for overseas sponsors restrict care options for patients and clinicians.

Respondents called attention to the 'thin' market for medicine production in Australia and the related overreliance on overseas manufacturers. Since Australia accounts for only 2% of the global market and imports over 90% of its medicines, it is likely more vulnerable than bigger markets which may be prioritised by suppliers in periods of shortage.¹

These conditions cause and are in turn exacerbated by the lack of timely collaboration between the industry and the Government to proactively manage supply issues and agree on contingencies. The COVID-19 pandemic demonstrated the severe limits of our undeveloped capacity for vaccine and medicines development. Continuing with the status quo of largely offshore medicines production could mean significantly more deaths in future pandemics when the global supply chain become strained yet again.²

Respondents offered the following potential strategies to enhance the medicines supply chain and improve availability:

- Develop or incentivise onshore manufacturing capabilities for medicines that are assessed as critical.
- For critical medicines, incentivise registration of equivalents, including generic formulations.

¹ Morris S. Medicine shortages in Australia - what are we doing about them? Aust Prescr. 2018 Oct;41(5):136-137. doi: 10.18773/austprescr.2018.047. Epub 2018 Oct 1. PMID: 30410206; PMCID: PMC6202294. [Medicine shortages in Australia – what are we doing about them? - PMC \(nih.gov\)](#)

² Simon Quilty, Arnagretta Hunter, COVID-19: access to medicines that Australians need, MJA Insight, Issue 30 / 3 August 2020 [online]; [COVID-19: access to medicines that Australians need | InSight+ \(mja.com.au\)](#)

- Introduce taxation or fiscal incentives to ensure supply of critical medications that may not be financially viable to introduce to the Australian market without further incentives.
- Review the system of statutory price reductions for older medications with a view to tempering price reductions to avoid PBS delisting.
- Introduce regulations requiring pharmaceutical companies to maintain minimum medication stockpiles in Australia to allow time for organisation of medication contingencies.
- Enhance regulatory powers for the TGA to redistribute scarce medicines to priority patient groups at risk of poorer health outcomes in consultation with TGA Medicine Shortage Action Groups, noting that patient groups with a higher incidence of chronic and complex disease are most likely to require specialist care and are more vulnerable to shortages and discontinuations; they may also have diminished capacity to advocate for alternative scripts, find remaining supply and source it privately.
- Simplify the Special Access Scheme application for unapproved medicines and therapeutic goods.

Management of medication discontinuations and shortages is rarely seamless

This response has already highlighted the issue of limited lead times for the planning and communication of discontinuations and shortages and the consequences of these delays on continuity of care. Some respondents urged the TGA to introduce earlier notification systems that might help weather the impacts of medication shortages, including where manufacturers plan to withdraw from the market. One solution would be for the TGA to extend the timeframe in which manufacturers are required to report a planned cessation or supply barrier to the TGA to allow time to organise viable and affordable options.

Indicators of a successful national system (question 25)

A successful national system will better predict, communicate and mitigate the risks of medication shortages and discontinuations

Multiple pressure points will require reform to achieve this goal and TGA leadership on this front is greatly needed. Noting that the next significant public health event may be around the corner, it is vital that the issues raised in this submission are reflected in the workplan of the TGA and in its ongoing work on innovative solutions to medicines supply issues.

Indicators of success in supply chain reforms may include:

Communication of a shortage or discontinuation - short term

- Medication manufacturers and sponsors advise the TGA of a shortage or discontinuation and expected end date well in advance of the shortage or discontinuation.
- Practitioners are advised well in advance of a medication shortage/discontinuation and alternative substitutes by the TGA, via the Medicines Shortages Working Party, specialty societies, professional networks, hospital pharmacists, the TGA website, and direct correspondence to prescribers.
- The TGA website is regularly and rigorously updated to give real-time information on shortages and discontinuations, expected end dates and alternative medications for substitution.
- Practitioners spend significantly less practice time to following up information on a medicine shortage or discontinuation.

Mitigation of impacts of shortages for priority groups - short to medium term

- The Special Access Scheme approval process is simplified for improved timeliness and responsiveness to real-time requirements in patient care.
- Timeframes for the approval of medications for priority groups are streamlined for access to the Australian market, especially where international efficacy and safety data exists or a medication is accessible abroad per the approval of a competent regulatory authority.
- A list of critical, life sustaining medications in Australia is developed and minimum stock levels are maintained for potential national public health crises.
- Logistical strategies are developed to support the redirection of critical life sustaining medications to priority groups through clear and targeted distribution chains.
- Duplication of registration is incentivised by the TGA for medicines deemed critical to public health, safety or clinical management of priority groups to ensure adequate planning for contingencies.

Preventing shortages - medium term

- Local production of medications is stimulated and incentivised.
- International suppliers of medicines critical to the health of Australians are encouraged to enter and remain within the Australian market through TGA-driven incentives.
- System-wide and nationally coordinated approach among supply chain partners and the Government to reduce the risk of medicine shortages through the use of artificial intelligence technologies such as big data analytics.

RACP comment: *Therapeutic Goods Amendment (Medicines Shortages and Other Measures) Bill 2026*

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to comment on the *Therapeutic Goods Amendment (Medicines Shortages and Other Measures) Bill 2026* (the Bill).

In our capacity as the peak body for Australia's trainee physicians and physicians and a member of the Therapeutic Goods Administration (TGA) Medicines Shortage Stakeholder Forum **we consider the draft provisions of the Bill vital to strengthening medicine surveillance and improving mechanisms for early, effective notification arrangements for medicines shortages and discontinuations in Australia.**

The Bill delivers core improvements to the communication responsibilities of medicines sponsors and manufacturers to enable better shortages preparation and supply change planning, as called for in our 2024 [submission](#) to the TGA consultation *Medicines shortages in Australia: Challenges and opportunities*.

The ability of Australia's physicians, as advanced prescribers for all patient populations, to plan for contingencies in medicines supplies is closely linked to the TGA's capacity to detect, capture and report supply fluctuations. The earlier and more effectively this is done, the better patient outcomes, especially given the complex processes and interactions involved in information flow from global medicines markets to local practice contexts.

The RACP offers its strong support to draft Bill provisions:

- Requiring sponsors to notify the Secretary of any decision to permanently discontinue the supply of reportable medicines in Australia at least 12 months in advance (or as soon as practicable after the decision is made).
- Requiring sponsors who give such notice to update the Secretary if there is a change in that approach (i.e. if the supply is no longer proposed to be discontinued, or if the discontinuation is to occur at a different time to that notified).
- Enabling the Secretary to require all sponsors of approved medicines to provide information about the availability, and any shortage or discontinuation, of their products in Australia.

The draft Bill's design will work some way toward mitigating the range of scenarios of disrupted care, avoidable exacerbations, lapsed patient adherence, insufficient or ineffective substitutes sourced at short notice and heightened patient anxiety that Australia's physicians frequently encounter when notice of a shortage or discontinuation is not issued well in advance of the event.

We note the TGA has also recently upgraded its [Medicine Shortages Reports Database](#) to improve user interface and searchability; the Bill will reinforce and increase the value of the database as a central accurate, reliable and rigorous system for patient treatment planning.

However, the Bill alone is unlikely to deliver a comprehensive solution to national medicines supply disruptions, being only one measure among a range of systemic reforms needed to improve Australia's medicines resilience.

As the Senate Community Affairs Legislation Committee would be aware, our medicines are generally sourced and imported from overseas, the Australian market reflects a minor share of overall global medicines demand, and our nation lacks the sovereign manufacturing base required for medicines production at scale to address shortages or supply downturns.

This makes Australia very vulnerable to supply shocks. With our population living longer and with higher levels of chronicity and morbidity, comprehensive and advanced national planning is necessary if we are to outperform the OECD average on population health indicators, especially avoidable deaths, preventable mortalities and chronic exacerbations.

The RACP brings to the attention of the Committee the following priority actions from its 2024 [submission](#) to the TGA for consideration in parallel with the Bill:

- The Special Access Scheme approval process needs to be simplified for improved timeliness and responsiveness to real-time requirements in patient care.
- Timeframes for the approval of medications for priority groups need to be streamlined for access to the Australian market, especially where international efficacy and safety data exists or a medication is accessible abroad per the approval of a competent regulatory authority.
- A list of critical, life sustaining medications in Australia needs to be developed and minimum stock levels maintained for potential national public health crises.
- Logistical strategies are needed to support the redirection of critical life sustaining medications to priority groups through clear and targeted distribution chains.
- Duplication of registration in Australia needs to be incentivised for medicines deemed critical to public health, safety or clinical management of priority groups to ensure adequate planning for contingencies.
- Further local production of medications must be stimulated and incentivised.
- International suppliers of medicines critical to the health of Australians should be encouraged to enter and remain within the Australian market through TGA-driven incentives.
- Use of artificial intelligence technologies such as big data analytics is needed for a system-wide and nationally coordinated approach among supply chain partners and the Government to reduce the risk of medicine shortages.

The RACP welcomes further involvement in this important public inquiry. Please contact Peter Lalli, Senior Policy and Advocacy Officer on policy@racp.edu.au for further engagement or follow up.