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# 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.

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**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.