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RACP Submission to TGA Consultation: Medicine shortages and discontinuations - Reportable medicines and timeframes for reporting discontinuations

January 2025

About The Royal Australasian College of Physicians (RACP)

The RACP trains, educates and advocates on behalf of over 22,200 physicians and 9,800 trainee physicians across Australia and Aotearoa New Zealand.

The RACP represents a broad range of medical specialties across 33 specialty areas with significant depth of knowledge of pharmacological supply and access issues, including clinical and experimental pharmacology and toxicology, adult, child, adolescent and young adult medicine, rehabilitation medicine, geriatric medicine, occupational and environmental medicine, and public health 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, the medical profession and the community.

Improving access to and quality use of medicines (QUM) initiatives are core RACP priorities, as enshrined in our Evolve Program aiming to reduce low value and unnecessary care.

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.

Opening remarks

The RACP welcomes the opportunity to comment on the TGA's regulatory reform proposals outlined in the Consultation Paper on *Medicine shortages and discontinuations - Reportable medicines and timeframes for reporting discontinuations.* This response follows our initial submission to the March 2024 TGA Consultation Paper: *Medicine shortages in Australia – Challenges and opportunities*. We acknowledge the important contribution of our members and RACP-affiliated societies, particularly the Australia and New Zealand Bone and Mineral Society, Endocrine Society of Australia, Haematology Society of Australia and New Zealand and Internal Medicine Society of Australia and New Zealand to this submission.

The RACP offers expert voice on quality use of medicines via our Evolve Program and on medicines shortages and potential solutions via its advocacy and policy work such as ongoing engagement with the TGA and other regulators and policy makers. The most recent Evolve list of low-value recommendations developed by the RACP and the Australian Society of Clinical and Experimental Pharmacologists and Toxicologists directly tackles harmful and ineffective prescribing practices.

We regularly contribute toward national debate on medicine management, including recent media releases and an opinion piece by RACP President Professor Jennifer Martin, clinical pharmacologist and physician, on the need for expanding Australia's medicine production capacity. Some recent media commentary on these activities, including medicine shortages, is available here, here, here , here and here.

As the TGA is well aware, population ageing and increasing co- and multi morbidities will continue to drive the demand for medications. I It is vital to act now to protect, promote and secure our medicines supply for the health of our communities and priority populations.

We consider the direction of the TGA's regulatory reform proposals to be an excellent initial step, aligned with a key recommendation the RACP made in March 2024 to reduce the significant time spent by physicians on managing medication shortages and discontinuations, and dealing with their negative impacts on patient care and physician wellbeing. We asked that:

- *Medication manufacturers and sponsors advise the TGA of a shortage or discontinuation and expected end date well in advance of the shortage or discontinuation.*

We also asked the TGA to, in the short term, focus on the following supporting performance measures:

- *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*.

We continue to encourage the TGA in its work to expand its reforms in streamlining medicines approval processes, continuous system improvement, growing domestic production capacity and enhancing import arrangements, as outlined in our earlier submission.

Minimum timeline for advising TGA of a shortage or discontinuation

The RACP and associated RACP specialty societies strongly support the TGA's intention to update the Therapeutic Goods 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).

We consider this to be a vast improvement over current requirements for sponsors and manufacturers, only requiring notification to the TGA of any decision to permanently discontinue the supply of a reportable medicine in Australia 12 months before discontinuation if it is likely to be of critical impact, or as soon as practicable after the decision is made, or six months before the discontinuation is proposed to occur in all other cases - or as soon as practicable after the decision is made.

We again underline the need for regulation to be coupled with appropriate early, broad and coordinated communication arrangements from the TGA to the RACP and its members, affiliated specialist societies and other health practitioners to maximise benefits for patient care and welfare and reduce the impost on already busy physicians and other healthcare workers.

'Reportable medications' for inclusion in the proposed TGA reporting arrangements

We lend our support to the TGA preferred regulatory reform option, Option 2 (inclusive of 2a and 2b), which seeks to balance regulatory burden on sponsors with the need to improve TGA's monitoring of medicine shortages by:

- Adding 23 registered, non-prescription medicines that are critical to the health of patients in Australia, to the Reportable Medicines Determination (per attachment one of the related TGA discussion paper); and

- 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).

Additionally, we strongly encourage the TGA to make a minor amendment to the list to include these two non-prescription medicines crucial to appropriate sub-specialty care for specific and complex health conditions in our communities:

Non-prescription medication	**Indication**
Benzyl benzoate, noting the inclusion of permethrin, but that benzyl benzoate is similarly needed	crusted scabies – a condition with high mortality and strong links with acute rheumatic fever/rheumatic heart disease
Lugol's Iodine	severe cases of hyperthyroidism

In determining future non-prescription medicines to add to the Reportable Medicines Determination, an audit of historical shortage and discontinuation data could guide the process.

Enhanced supply side information request powers for the TGA

We concur with the TGA's proposal to expand its supplier information request powers relating to the key non-prescription medicines and other medicines, whether prescription and non-prescription, that have historically been in shortage or have been discontinued. This will improve our country's pharmacovigilance.

In particular, we see a key opportunity for the TGA's proposed expanded information seeking powers for proactive gathering and monitoring of supply-side information for a range of mainly prescription medicines listed in our initial submission, particularly those medicines with a history of shortages.

The table below lists additional medication we propose should be included in the list, due to their importance managing health risks and conditions in priority patients and their continuing shortages, discontinuations and substitution concerns.

Priority patient group	**Medication shortage**
Children with neurodevelopmental disorders	Lisdexamfetamine, methylphenidate, concerta, Fluoxetine 10mg tablets
Children and adults with diabetes, complex obesity or endocrine issues	GLP-1 receptor agonists, semaglutide
Children with infections	Liquid Keflex, Benzylpenicillin
Patients in palliative care	Opiates – Hydromorphone immediate release, Jurnista (long-acting hydromorphone), Ordine (liquid morphine) cholesytramine (temporarily not available) and Oxynorm and Sevredol to discontinue soon
Patients with cardiac disease	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, varenicline, oral thiamine

Closing remarks

We commend the TGA for the regulatory reform proposals outlined in the Consultation Paper.

The proposal, coupled with other recommendations included in our 2024 submission, will deliver enhanced transparency, continuity and contingency planning of medicines supply and improve access to medicines for the patients across Australia.

The RACP sees itself as a trusted advisor to the TGA and we are looking forward to further collaboration.

Please contact Mr Peter Lalli, Senior Policy & Advocacy Officer for further information or inquiries related to this submission and broader RACP engagement on medicines supply via: policy@racp.edu.au.