

28 July 2025

Department of Health, Disability and Ageing
Therapeutic Goods Administration (TGA)
Medicines Scheduling

Via email: medicines.scheduling@health.gov.au

Dear Advisory Committee on Medicines Scheduling (ACMS),

Re: Public consultation on the interim decision to amend the Poisons Standard in relation to pyridoxine, pyridoxal or pyridoxamine (vitamin B6)

The Royal Australian College of General Practitioners (RACGP) welcomes the opportunity to provide comment on the interim decision to amend the Poisons Standard in relation to pyridoxine, pyridoxal or pyridoxamine (vitamin B6).

General practitioners (GPs) play an important role in supporting safe, evidence-based use of medicines and products. They are often the first point of contact in the healthcare system, with nearly nine in 10 Australians visiting a GP at least once a year.¹ GPs provide ongoing, coordinated care that considers an individual's broader health needs, ensuring safe and appropriate treatment across a range of health issues. This places GPs in a strong position to help people navigate health claims, assess potential risks, and provide guidance on safe and informed use of medicines and products, including those containing vitamin B6.

The RACGP supports the interim decision to amend the Poisons Standard in relation to vitamin B6 to classify preparations containing 50-200 mg/day as Pharmacist Only (Schedule 3), above 200 mg/day to remain prescription only (Schedule 4), and less than 50 mg/day exempted from scheduling. This is a positive step towards reducing the risk of harm from excessive vitamin B6 intake and improving safety and awareness.

We agree scheduling is only one part of the regulatory framework for managing risks associated with medicines. Scheduling changes alone will not address the multiple sources through which individuals may be exposed to vitamin B6, including through diet, fortified foods, and supplements. Many people are unaware these combined sources can lead to excessive cumulative intake and potential health risks. Clinical deficiency of vitamin B6 is rare, and there is limited evidence supporting supplementation benefits in individuals who are not deficient. The RACGP, therefore, also supports the recommendations for other actions to complement the interim decision as outlined on pages 15 -16 of the interim notice, including:

- public education campaigns to raise awareness of overconsumption
- consistency in ingredient naming on product labels
- strengthening labelling requirements through stronger wording of warning statements and clarity on the presence of vitamin B6
- a review of by the Food Standards Australia New Zealand (FSANZ) of the appropriateness of the 10 mg limit for formulated caffeinated beverages, given the risks from the use of multiple products containing vitamin B6.

In addition, the RACGP recommends health claims made on vitamin B6 containing products be subject to stronger regulations and permitted only when robust evidence demonstrates the benefits clearly outweigh the potential risks.



RACGP
Royal Australian College
of General Practitioners

Healthy Profession.
Healthy Australia.

If the interim decision is confirmed, the proposed 18-month implementation period (starting 1 February 2027) is appropriate to provide time for industry and healthcare professionals to prepare for changes, and for the TGA to review other regulatory controls on vitamin B6 and align the timing of any additional actions accordingly. The RACGP welcomes the opportunity to provide further input as needed to support effective implementation.

Thank you again for the opportunity to provide feedback. If you have any questions regarding our feedback, please contact Mr Stephan Groombridge, National Manager, e-health, Quality Care & Standards at stephan.groombridge@racgp.org.au or (03) 8699 0544.

Yours sincerely

Dr Michael Wright

President

References

1. Australian Institute of Health and Welfare. General practice, allied health and other primary care services. Australian Government;2025. Available at <https://www.aihw.gov.au/reports/primary-health-care/general-practice-allied-health-primary-care> [Accessed 22 June 2025]