Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Notice of final decision to amend (or not amend) the current Poisons Standard in relation to pyridoxine, pyridoxal or pyridoxamine (vitamin B6)

25 November 2025

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Notice of final decision to amend (or not amend) the current Poisons Standard

This web publication constitutes a notice for the purposes of regulation 42ZCZS of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulations 42ZCZS, this notice publishes:

- the decision made by a delegate[1] of the Secretary of the Department of Health, Disability and Ageing (the **Delegate**) pursuant to regulation 42CZR of the Regulations
- the reasons for the final decision and
- the date of effect of the final decision.

Defined terms

In this notice the following defined terms are used in addition to those above:

- the Therapeutic Goods Act 1989 (Cth) (the **Act**)
- the Scheduling Policy Framework 2018 (the **SPF**)
- the Scheduling handbook, Guidance for amending the Poisons Standard (the **Handbook**) and
- the Therapeutic Goods Administration (the **TGA**).

Note: additional terms are also defined for individual decisions.

[1] For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).

Final decision on a proposed amendment referred to the Advisory Committee on Medicines Scheduling (ACMS #46, November 2024)

Final decision in relation to pyridoxine, pyridoxal or pyridoxamine

Proposal

The applicant has proposed to amend the current Poisons Standard in relation to pyridoxine, pyridoxal or pyridoxamine which are different forms of vitamin B6. Under the proposal, human therapeutic preparations containing between 5 mg and 200 mg of pyridoxine, pyridoxal or pyridoxamine would be included in a new Pharmacist-only medicine (Schedule 3) entry. These preparations are currently not scheduled.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the delegate has decided to confirm the interim decision and amend the current Poisons Standard in relation to pyridoxine, pyridoxal or pyridoxamine as follows:[2]

Schedule 4

PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use **except:**

(a) when included in Schedule 3; or ~~in oral preparations containing 200 mg or less but more than 50 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose when compliant with the requirements of the required advisory statements for medicine labels;~~

(b) in oral preparations containing 50 mg or less of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.

Schedule 3 – New Entry

PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use in oral preparations containing 200 mg or less but more than 50 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.

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PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE

Schedule 4

Schedule 3

[2] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Materials considered

In making this final decision, the Delegate considered the following materials:

- The proposal to amend the current Poisons Standard with respect to pyridoxine, pyridoxal or pyridoxamine (the **Proposal**)
- The 21 public submissions, all with a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**)
- The advice received from the 46th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**)[3]
- The interim decision and the materials considered as part of the interim decision, as published on 26 June 2025
- The 248 public submissions, 215 of which included a written component, received in response to the public consultation on the interim decision under regulation 42ZCZP of the Regulations.
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health
- The SPF, and
- The Handbook.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to pyridoxine, pyridoxal or pyridoxamine. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have considered the material in the interim decision and the submissions received in response to the public consultation on the interim decision.

During the public consultation I received 248 submissions, including 231 from individuals and 17 from organisations. Submitters were also given choice of responding with or without written justification, and the majority provided justification. In total, 215 written justifications were provided from 199 individuals and 16 organisations.

Submissions were received from 17 organisations of which 8 supported the interim decision, 7 partially supported and 2 did not support it. Overall, the submissions presented a broad consensus on the need for further controls.

Of the individual submissions 115 supported the interim decision, 74 partially supported it and 42 did not support. However, a closer look at the justifications from the people who partially supported it or did not support the interim decision revealed that more than half of them (54 of 107 submissions with written justifications) favoured stricter regulation of vitamin B medicines than in the interim decision, including further reduction in the maximum recommended daily dose (RDD) of vitamin B6 that should be available for general sale. Further, 16 individuals supporting the interim decision also suggested further reduction in the maximum RDD above which vitamin B6 medicines should be available after

[3] Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

pharmacist consultation. In Australia, the estimated average requirement for vitamin B6 for adults is 1.1 to 1.3 mg/day and the recommended dietary intake (RDI) is 1.3 to 1.7 mg/day.[4]

Submissions from individuals included personal testimony of lived experience, professional opinions, clinical insights, and suggestions. More than 100 individuals (103) reported severe, sometimes permanent, health effects from vitamin B6 toxicity including peripheral neuropathy, nerve damage, muscle weakness, and significant impacts on daily life and employment. Thirty-eight of these individuals were diagnosed by general practitioners (GPs) or other specialists using vitamin B6 blood tests. Many stated that medical professionals did not initially recognise B6 toxicity as the cause of their symptoms resulting in significant delay to diagnosis, cost and personal adversity. Toxicity occurred at doses lower than the daily upper level of intake (UL) of 50 mg in 31 individuals, of which 12 were diagnosed or tested for blood vitamin B6 levels. These submissions strengthen my view, expressed in the interim decision, that there is sufficient evidence to conclude peripheral neuropathy may occur in some individuals with vitamin B6 intake of 50 mg/day or even lower.

As of 31 October 2025, there were 250 reports of peripheral neuropathy, peripheral sensory neuropathy, peripheral sensorimotor neuropathy, small fibre neuropathy, polyneuropathy or chronic polyneuropathy for products containing vitamin B6 on the TGA's Database of Adverse Event Notifications (DAEN). Of these, 152 also reported 'Hypervitaminosis B6' and/or 'Vitamin B6 increased'. There were another 162 reports of 'Hypervitaminosis B6' and/or 'Vitamin B6 increased' with less specific reaction terms such as paraesthesia, burning sensation etc. possibly suggestive of neuropathies. A majority of the 250 adverse events in DAEN were reported since 1 January 2023 (208 events, 83%), with 130 events being reported in 2025 until 31 October 2025.

Between 1 January 2024 and 30 June 2025, the NSW Poisons Information Centre received 14 calls from patients experiencing symptoms of neuropathy. Patients reported adverse effects after taking daily pyridoxine doses between 25 mg to 400 mg for as little as 2 weeks, but up to as long as 10 years. Of these 14 patients, 2 were taking 50 mg or less of pyridoxine daily, and 8 reported blood tests results with higher-than-normal levels of pyridoxine (110 mg per day, 120 mg per day, other 6 unknown dosage).

The above reports contrast with industry submissions claiming that neurological adverse events from vitamin B6 only occur at high dose and with long-term usage. Notwithstanding the limitations of self-reporting of adverse events, and the possibility of some overlap in reporting channels, the considerable number of adverse events, difficulties in diagnosis and ensuing hardships on sufferers justify the scheduling restrictions on vitamin B6 medicines available for general sale.

I have adhered to the 50 mg per maximum RDD as the cut-off for exemption from scheduling foreshadowed in my interim decision. This cut-off is in alignment with the current UL of vitamin B6 for adults 19 years and over set by the National Health and Medical Research Council (NHMRC) of 50 mg/day.[4] Decreasing the limit of unscheduled preparations from 200 mg to 50 mg of vitamin B6 should reduce the toxicity risk from use of a single product, and from combined exposure from multiple sources. Submissions from individuals and organisations including professional associations, universities and industry broadly agreed with the 50 mg maximum RDD for unscheduled medicines.

Two submissions, one from a manufacturer and the other from a peak body, referred to a recent report recommending a RDD of 50 mg of vitamin B6 to be the tolerable maximum dosage for long term use with doses over 50 mg to 100 mg to be suitable for shorter durations.[5] I note that all authors of the paper received honorarium from various major manufacturers of vitamin B6 products. Further, the

[4] National Health and Medical Research Council, Australian Government Department of Health and Ageing, New Zealand Ministry of Health. Nutrient Reference Values for Australia and New Zealand. Canberra: National Health and Medical Research Council; 2006.

[5] Schellack N, Yotsombut K, Sabet A, Nafach J, Hiew FL, Kulkantrakorn K. Expert Consensus on Vitamin B6 Therapeutic Use for Patients: Guidance on Safe Dosage, Duration and Clinical Management. Drug Healthc Patient Saf. 2025 Apr 7;17:97-108. DOI: 10.2147/DHPS.S499941.

authors noted peripheral neuropathy risk even at 50–100 mg/day in susceptible individuals and recommended regular monitoring by healthcare professionals for patient consuming more than 50 mg/day of vitamin B6 for longer than 6 months.

Other submissions, including one from a manufacturer, proposed a more graduated approach with products containing 50–200 mg per day classified as Pharmacy medicine (Schedule 2) rather than Pharmacist only (Schedule 3). These submissions argued that a Schedule 2 classification would support early intervention for those at risk of vitamin B6 deficiency, improve public health outcomes, and reduce unnecessary strain on the healthcare system. However, I remain concerned that with the widespread availability of vitamin B6 through multiple sources classifying high-dose vitamin B6 products as Pharmacy medicines will continue to pose risks to the consumer as professional advice is not required to be provided at the point of sale. For those in clinical need of vitamin B6 supplementation, high-dose preparations will still be available with pharmacist consultation or a prescription.

One industry peak body, and several professional organisations, commented on the established use of vitamin B6 in various health conditions such as nausea and vomiting in pregnancy, premenstrual syndrome, and cardiovascular health. The peak body referred to various Australian clinical guidelines that recommend doses of up to 200 mg/day for the treatment of nausea and vomiting in pregnancy (NVP).[6,7,8] These guidelines are intended for medical professionals such as GPs and obstetricians, and not the public. These guidelines highlight the importance of ruling out other causes, diagnosing NVP using a formal scoring system, and distinguishing NVP from hyperemesis gravidarum as the management and potential maternal and foetal complications differ. While the maximum daily dose can be 200 mg, generally the recommended daily dose is 10–25 mg 3–4 times a day. Before taking medicines during pregnancy, you should get advice from your doctor or pharmacist.

With regards to the role of vitamin B6 in preventing cardiovascular disease, the evidence is weak and at best equivocal. While data from the United States (US) National Health and Nutrition Examination Survey showed that vitamin B6 was negatively associated with coronary heart disease and exerted protective effects, the strongest protective effect was observed with the daily intake of 1.703 to 2.466 mg vitamin B6.[9] Earlier studies in US and Japanese populations also observed lower risk of coronary heart disease in groups having higher intake of vitamin B6, but the protective effects were seen at daily intake levels of 4.6 mg/day (median value, US population) and 1.6 mg/day (mean value; Japanese population).[10,11] A recent scientific statement from the European Association of Preventive Cardiology and the Association of Cardiovascular Nursing & Allied Professions of the European Society of Cardiology stated that the effects of vitamin B supplementation on total cardiovascular disease independently of their effect on homocysteine reduction remain to be assessed.[12] Similarly, vitamin B6 may help with pre-menstrual symptoms and cognitive impairment, but evidence of efficacy is mixed.

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[6] Society of Obstetric Medicine of Australia and New Zealand. The SOMANZ Position Statement on the Management of Nausea and Vomiting in Pregnancy and Hyperemesis Gravidarum. Updated October 2023.

[7] NSW Health. NSW Health Guideline: Nausea and Vomiting in Pregnancy and Hyperemesis Gravidarum. July 2022.

[8] Safer Care Victoria. Nausea and Vomiting in Pregnancy: Clinical guidance. October 2024.

[9] Li, B., Hu, M., Ma, Y. *et al.* Association between Vitamin E, Vitamin B6, and Vitamin B12 with coronary heart disease. *Sci Rep* **14**, 19960 (2024). DOI: 10.1038/s41598-024-68413-8

[10] Rimm EB, Willett WC, Hu FB, et al. Folate and Vitamin B_6 From Diet and Supplements in Relation to Risk of Coronary Heart Disease Among Women. *JAMA.* 1998;279(5):359–364. DOI: 10.1001/jama.279.5.359

[11] Ishihara, J., Iso, H., Inoue, M., Iwasaki, M., Okada, K., Kita, Y. (2008). Intake of Folate, Vitamin B_6 and Vitamin B_{12} and the Risk of CHD: The Japan Public Health Center-Based Prospective Study Cohort I. *Journal of the American College of Nutrition*, *27*(1), 127–136. DOI: 10.1080/07315724.2008.10719684

[12] Panagiotakos D. Diet and nutrition in cardiovascular disease prevention: a scientific statement of the European Association of Preventive Cardiology and the Association of Cardiovascular Nursing & Allied Professions of the European Society of Cardiology. Eur J Prev Cardiol. 2025 Nov 11;32(16):1540-1552. DOI: 10.1093/eurjpc/zwaf310

The Australasian Society of Inborn Errors of Metabolism highlighted that certain rare genetic conditions (e.g. pyridoxamine 5'-phosphate oxidase (PNPO) deficiency, pyridoxine-dependent epilepsy) require high-dose vitamin B6 under specialist supervision. They recommended exceptions to the guidelines for these cases. PNPO deficiency and pyridoxine-dependent epilepsy are diagnosed and managed by medical specialists in neurology, genetics, paediatrics and neonatal care. My decision to schedule vitamin B6 preparations as above does not impact availability under specialist medical care.

Several individual submissions raised the differential adverse effects of different vitamers of vitamin B6, and proposed dose restriction be limited to pyridoxine only, and not pyridoxal-5-phosphate. The different effects of different vitamers and individual variations in vitamin B6 metabolism were considered in my interim decision. However, these findings are preliminary and at best indicative of a possibly better safety profile for pyridoxine.[13,14] The TGA will continue to monitor the safety profile for all the vitamers of vitamin B6 that are approved for use in medicines.

Several naturopaths, nutritionists and one association (Australasian Association and Register of Practicing Nutritionists) raised that allowing only pharmacists to dispense medicines containing more than 50 mg of vitamin B6 is not optimal. These submissions argued that pharmacists may not have sufficient training in clinical nutrition to safely manage higher-dose vitamin B6 products. Instead, they recommended establishing a formal 'Practitioner Only' category for the supply of high potency or high-risk supplements under the guidance of a qualified health professional such as a registered herbalist, naturopath or nutritionist. Such a change is beyond the scope of the current scheduling framework. I acknowledge the need for adequate education, training and support for pharmacists for this decision.

There was widespread agreement in the submissions for the need for clearer labelling, including mandatory front-of-pack statements indicating the presence of vitamin B6, especially in combination products. Many people mentioned being unaware of vitamin B6 in various products resulting in cumulative exposure from multiple sources. There were also repeated calls for stronger warnings regarding neurotoxicity and educational programs to raise awareness of possible overexposure to vitamin B6, particularly from multiple sources, and associated adverse effects. To help address this health literacy gap, the TGA will run a public awareness campaign to educate consumers about the multiple sources of vitamin B6 and possible harms from cumulative dose and excessive intake. In the lead up to the changes taking effect, the TGA will run a further public awareness campaign. It is pleasing to note that several peak bodies, industry, and organisations are supportive of the need for further consumer and health professional educational material. I encourage the industry, professional organisations and consumer peak bodies to work together towards educating Australian consumers on the safe use of complementary medicines.

Currently, there are at least 125 medicines providing more than 50 mg but less than 200 mg vitamin B6 per maximum RDD. Of these, 116 are listed complementary medicines. To continue to be available on the Australian market, these medicines will need to be registered on the Australian Register of Therapeutic Goods and their labels updated. Further labelling changes may also be required, should the TGA decide to strengthen the warning statements required and change how vitamin B6 is labelled on products. Lastly, the Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2025 will also need to be amended to reflect the scheduling changes.

Recently, the NHMRC announced that it has decided to undertake a review of the UL of vitamin B6, anticipated to be completed by early 2027. As part of my decision is related to the current UL for

[13] Vrolijk MF, Opperhuizen A, Jansen EHJM, Hageman GJ, Bast A, Haenen GRMM. The vitamin B6 paradox: Supplementation with high concentrations of pyridoxine leads to decreased vitamin B6 function. Toxicol In Vitro. 2017 Oct;44:206-212. DOI: 10.1016/j.tiv.2017.07.009.

[14] Vrolijk MF, Hageman GJ, van de Koppel S, van Hunsel F, Bast A. Inter-individual differences in pharmacokinetics of vitamin B6: a possible explanation of different sensitivity to its neuropathic effects. PharmaNutrition. 2020;12:100188. DOI: 10.1016/j.phanu.2020.100188.

vitamin B6 in Australia, should there be a change following the NHMRC review, the appropriateness of the new limits in this Final Decision will be re-evaluated.

In consideration of the corresponding regulatory changes that need to be actioned outside of scheduling, and timeframes for industry to make decisions regarding affected products, I have decided to extend the implementation date from my interim decision.

Implementation date

1 June 2027.

Therapeutic Goods Administration

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