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Department of Health, Disability and Ageing
Therapeutic Goods Administration

High-moderate risk changes to permissible ingredients – Vitamin B6 (pyridoxine hydrochloride, pyridoxal 5-phosphate, and pyridoxal 5-phosphate monohydrate)

Consultation paper

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Introduction

The [Therapeutic Goods \(Permissible Ingredients\) Determination \(No. 2\) 2026](#) (the Permissible Ingredients Determination) is a legislative instrument made under section 26BB of the *Therapeutic Goods Act 1989* (the Act). This instrument specifies all the ingredients that are available for use in [listed and assessed listed medicines](#) and their associated requirements. Listed medicines, except for assessed listed medicines, are low-risk products that are not pre-market assessed by the TGA for their quality, safety, and efficacy. To ensure listed medicines¹ can be used safely by consumers, they may only contain pre-approved low-risk ingredients included in the Permissible Ingredients Determination. This Determination is continually reviewed by the TGA to ensure that all ingredients and their requirements are appropriate for use in low-risk medicines.

Purpose

The proposed ingredient changes outlined in this consultation have been categorised as being of high-moderate risk. A [high-moderate risk change to the Permissible Ingredients Determination](#) is where a delay in changing an ingredient could cause serious or immediate harm. The reclassification of pyridoxine, pyridoxal, or pyridoxamine (i.e. vitamin B6)² in the [Poisons Standard](#) will be implemented from 1 June 2027. Under this, oral preparations for human therapeutic use providing between 50 mg and 200 mg daily doses of pyridoxine will be included as Pharmacist Only medicines (Schedule 3). Having regard to the [Notice of interim decision](#) (the Interim Decision) and the [Notice of final decision](#) (the Final Decision) to amend (or not amend) the current Poisons Standard in relation to pyridoxine, pyridoxal, or pyridoxamine, the TGA is proposing to update the relevant entries for pyridoxine hydrochloride, pyridoxal 5-phosphate, and pyridoxal 5-phosphate monohydrate to ensure appropriate risk-mitigation controls within the Permissible Ingredients Determination remain aligned with the Poisons Standard.

In addition, to support the safe use of vitamin B6-containing listed medicines and ensure that labelling requirements remain effective for risk communication, the TGA is proposing amendments to strengthen label-based risk mitigation measures. These include the introduction of a standardised label statement for all vitamin B6-containing listed medicines, amendment of the existing mandated warning statement, and a reduction in the dose threshold at which the warning statement is currently required on product labels.

Furthermore, clarification of 2 age-based dose categories is proposed. This includes clarifying the specific requirement for infants under 12 months of age, as well as

¹ For the purpose of this consultation paper, the term “listed medicines” is used collectively from this point to refer to both listed and assessed listed medicines.

² For the purposes of this consultation paper, “vitamin B6” is used as a collective term for the forms considered across relevant regulatory frameworks and committee evaluations. This includes the substances pyridoxine, pyridoxal and pyridoxamine as referenced in the Poisons Standard, as well as the listed medicine ingredients pyridoxine hydrochloride, pyridoxal 5-phosphate and pyridoxal 5-phosphate monohydrate included in the Permissible Ingredients Determination.

correcting the wording of the 14-18 years dose category to remove ambiguity within the Permissible Ingredients Determination.

The TGA is seeking public comment on the issues and proposed amendments outlined in this consultation paper. Feedback received will be considered to help inform the decision-maker whether the proposed amendments are appropriate and support the safe use of vitamin B6-containing listed medicines.

We invite you to provide your feedback by responding to the consultation questions through the online survey available on the [Consultation Hub](#) from 14 October 2026.

If you have any questions relating to this consultation, please email: nonprescriptionmedicines@health.gov.au.

Vitamin B6 and its association with peripheral neuropathy

Background

Vitamin B6 is currently permitted for use in listed medicines in Australia in the forms of pyridoxine hydrochloride, pyridoxal 5-phosphate, and pyridoxal 5-phosphate monohydrate under the Permissible Ingredients Determination.

The use of vitamin B6 ingredients is regulated by their equivalent pyridoxine content, with age-based maximum recommended daily dose (MRDD) limits. A warning statement is also mandated for products that provide more than 10 mg equivalent pyridoxine per day, directing consumers to “*Stop taking this medication if you experience tingling, burning or numbness, and see your healthcare practitioner as soon as possible*”. The mandated warning statement outlines symptoms that may be associated with peripheral neuropathy, a known adverse effect of excessive vitamin B6 intake.

Despite these measures, the recent scheduling decision highlighted concerns regarding consumer awareness of vitamin B6 content in listed medicines, cumulative exposure from multiple sources, and the effectiveness of existing labelling requirements in supporting early recognition and response to symptoms of vitamin B6 toxicity.

As at 18 September 2026, 333 reports of peripheral neuropathy and related neuropathy and polyneuropathies for products containing vitamin B6 had been recorded in the TGA’s Database of Adverse Event Notifications (DAEN). This indicates a need for further regulatory measures.

Development of the current vitamin B6 requirements

Safety Review

In 2017, the TGA initiated a safety review following an Australian adverse drug reaction report of peripheral neuropathy and elevated serum B6 levels linked to long-term use of a listed medicine delivering 41 mg pyridoxine per day. At the time, listed medicines could provide up to 200 mg equivalent pyridoxine per day, and warning statements were only required for products providing more than 50 mg equivalent pyridoxine per day³. The reported medicine was therefore not required to carry a warning statement.

Alongside international surveillance concerns, the review identified Australian reports of neuropathy-type events associated with daily intakes under 50 mg per day of pyridoxine, often involving polypharmacy-related cumulative exposure, limited consumer awareness of vitamin B6 toxicity, and inconsistent application of the required warning statements. The review recommended lowering the warning statement threshold, for example to 10 mg per day, or to mandate the warning statement for all vitamin B6-containing listed medicines. It also recommended reassessing the maximum permissible daily dose in listed medicines with reference to the Upper Level of Intake (UL)⁴ specified in the Nutrient Reference Values (NRV) for Australia and New Zealand established by the National Health and Medical Research Council (NHMRC)⁵ (including paediatric limits), and to review label compliance.

As a result, the TGA published a [safety alert](#) on 5 May 2020, to warn consumers and healthcare professionals of the potential for peripheral neuropathy from products containing less than 50 mg equivalent pyridoxine per day and from polypharmacy of vitamin B6-containing products.

Advisory Committee on Complementary Medicines

In March 2021, the TGA presented the safety review, including updated Australian adverse event data and international regulatory assessments, to the Advisory Committee on Complementary Medicines (ACCM) at its 27th meeting. ACCM advised that additional risk mitigation was warranted for listed medicines providing less than 50 mg equivalent pyridoxine per day. ACCM recommended that these products carry

³ The warning statement requirements for vitamin B6 were specified in [Therapeutic Goods \(Permissible Ingredients\) Determination No. 3 of 2017](#). If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose, the medicine requires the following warning statement on the medicine label:

- (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6]'

⁴ Upper Level of Intake (UL): The highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. National Health and Medical Research Council 2006. Nutrient Reference Values for Australia and New Zealand: Introduction. Page 1. Available at: <https://www.nhmrc.gov.au/about-us/publications/nutrient-reference-values-australia-and-new-zealand-including-recommended-dietary-intakes>

⁵ National Health and Medical Research Council 2006. Nutrient Reference Values for Australia and New Zealand: Vitamin B6. Pages 75-80.

warning statements that make specific reference to adverse effects such as tingling and numbness, together with a direction to seek healthcare advice if symptoms occurred. ACCM also recommended reducing the maximum daily dose for listed medicines from 200 mg to 50 mg equivalent pyridoxine and aligning paediatric dosage limits with NHMRC NRV. Further, ACCM encouraged education for consumers and health professionals, as well as sponsor reviews of product content, dose, and labelling.

Annual low-negligible risk changes 2021-2022

Following consideration of these recommendations and a public consultation, amendments to vitamin B6 requirements were made through the [2021-2022 Annual low-negligible risk changes](#) to the Permissible Ingredients Determination. The amendments were implemented on 1 March 2022, with a one-year transition period instated to allow sponsors of existing products to ensure product compliance by 1 March 2023. These amendments extended the application of the existing warning statement to products delivering more than 10 mg equivalent pyridoxine per day, introduced age-based dose limits based on NHMRC NRV, and reduced the permitted maximum daily dose for individuals aged 19 years and above from 200 mg to 100 mg.

To reinforce risk communication, the TGA issued a [safety update](#) on 4 October 2022 and a [safety alert](#) on 10 November 2022. These communications advised consumers and healthcare professionals that vitamin B6 may cause peripheral neuropathy, including at intakes below 50 mg per day and in the context of polypharmacy, and outlined the updated requirements to the Permissible Ingredients Determination.

Reclassification of pyridoxine, pyridoxal, or pyridoxamine in the Poisons Standard

The [Poisons Standard](#) is a legislative instrument that lists medicines and chemicals into schedules according to the risk of harm and the level of access control required to protect public health and safety. Pyridoxine, pyridoxal and pyridoxamine are currently included in Schedule 4 of the Poisons Standard for human therapeutic use, except in oral preparations containing 200 mg or less but more than 50 mg per recommended daily dose when compliant with the required advisory statements for medicine labels, or in oral preparations containing 50 mg or less per recommended daily dose.

In July 2024, the TGA received an application to amend the current Poisons Standard in relation to pyridoxine, pyridoxal, or pyridoxamine, proposing that human therapeutic preparations containing between 5 mg and 200 mg be included in a new Schedule 3 entry (Pharmacist Only medicine). The scheduling process included a [public consultation](#) in September 2024 before the proposal was referred to the Advisory Committee on Medicines Scheduling (ACMS) for advice.

On 26 June 2025, following consideration of the submissions received, ACMS advice, recent safety data and international regulatory trends, the TGA made an [Interim Decision](#) that:

- oral preparations providing more than 50 mg but less than 200 mg of pyridoxine per day be included in Schedule 3 (Pharmacist Only medicine) of the Poisons Standard
- oral preparations providing 50 mg or less pyridoxine per day remain unscheduled, and
- oral preparations providing more than 200 mg pyridoxine per day remain in Schedule 4 (Prescription Only medicine) of the Poisons Standard.

The Interim Decision considered several matters relevant to the safe use of vitamin B6. These included the Australian UL of 50 mg pyridoxine per day for adults set by the NHMRC, the widespread availability of vitamin B6 across dietary sources, fortified foods and beverages, vitamins and supplements, the potential for consumers to obtain vitamin B6 from multiple sources without recognising their combined intake and resulting cumulative exposure, and the challenges associated with estimating total vitamin B6 intake.

As outlined in the Interim Decision, as of 4 June 2025, 174 reports of peripheral neuropathy and related polyneuropathies for products containing vitamin B6 had been recorded in the TGA's Database of Adverse Event Notifications (DAEN). The Interim Decision also noted that vitamin B6 in multi-ingredient products is not always obviously identified, and that consumers may not consistently read or understand label information. A further public consultation on the Interim Decision was undertaken in June 2025.

On 25 November 2025, the TGA published the [Final Decision](#), which affirmed the Interim Decision and confirmed implementation of the Schedule 3 entry from 1 June 2027. As outlined in the Final Decision, as at 31 October 2025, 250 reports of peripheral neuropathy and related neuropathy and polyneuropathies for products containing vitamin B6 had been recorded in the DAEN. The Final Decision noted widespread agreement among consultation submissions for clearer labelling of vitamin B6, including mandatory front-of-pack statements, particularly for multi-ingredient products. Many submissions described being unaware that vitamin B6 was present in various products, resulting in cumulative exposure from multiple sources. Submissions also repeatedly called for stronger warnings regarding neurotoxicity and for educational programs to raise awareness of possible overexposure to vitamin B6, particularly from multiple sources, and its associated adverse effects.

On 19 February 2026, the TGA published a [medicine safety update](#), outlining the forthcoming scheduling changes, reiterating the risk of peripheral neuropathy, and providing guidance for health professionals.

Recommendations for other actions to complement the scheduling decision

The [Interim Decision](#) noted that scheduling is only one part of the regulatory framework for managing risks from the use of medicines, and that the scheduling of vitamin B6 intersects with other regulatory controls that warrant consideration alongside the scheduling amendment.

Accordingly, the Interim Decision recommended that the Delegates responsible for the Permissible Ingredients Determination and the *Therapeutic Goods (Medicines Advisory Statements) Specification* review the appropriateness of the relevant vitamin B6 entries to address conflicting requirements and consider whether to:

1. *require all forms to include the term vitamin B6 in the ingredient list; for example, vitamin B6 (pyridoxine hydrochloride)*
2. *consider whether ingredient labels should also express the amount of vitamin B6 present (in pyridoxine equivalents) and provide the total amount of vitamin B6 in the case of medicines containing more than one vitamin*
3. *consider a limit on the duration of use*
4. *simplify and strengthen the warnings; for example,*
 - *Excess consumption of vitamin B6 can cause nerve damage. Stop use and see a doctor if you experience tingling, burning or numbness. OR*
 - *Stop use and see a doctor if you experience tingling, burning or numbness [contains vitamin B6]*
5. *consider whether the required statements for pyridoxine and pyridoxal in single and multi-ingredient preparations should be aligned*
6. *consider whether the current threshold of 10 mg per RDD for requiring warning statements should be reduced to a level closer to the recommended dietary intake (e.g., 2 mg)*

The TGA is proposing amendments to the Permissible Ingredients Determination to address all of the above recommendations in relation to vitamin B6-containing listed medicines. The proposed amendments are outlined below.

Consultation

Listed medicines cannot contain a substance included in a Schedule to the Poisons Standard⁶. The specific requirements for pyridoxine hydrochloride, pyridoxal 5 phosphate and pyridoxal 5 phosphate monohydrate in the Permissible Ingredients Determination will be updated to align with the implementation of the Schedule 3 entry for vitamin B6 in the Poisons Standard from 1 June 2027. This amendment will reduce the MRDD for individuals aged 19 years and older will be reduced from 100 mg to 50 mg pyridoxine. As such, changes reflecting this alignment is not within the scope of this consultation paper; however, these changes will be reflected in the [Proposed changes](#) to allow foreshadowing of the changes ahead of time.

⁶ Items 3 and 8 of Schedule 4 to the [Therapeutic Goods Regulations 1990](#).

Taking into account the recommendations in the Interim Decision, this consultation seeks feedback on proposed amendments to strengthen label-based risk communication for vitamin B6-containing listed medicines. The changes in this proposal are to support safer use, particularly where vitamin B6 may be obtained from multiple therapeutic and dietary sources, helping to reduce the risk of cumulative exposure and improve early recognition of potential neurotoxicity.

The Interim Decision outlined several steps consumers would need to take to estimate their total vitamin B6 intake, including:

- knowing which products they use contain vitamin B6, including the different ingredient forms captured by that term
- knowing how frequently they take each source of vitamin B6
- considering how long they have been taking each product, noting that some supplements are advised for long-term use, and
- calculating total daily vitamin B6 intake from all sources.

The UL for vitamin B6 in adults is 50 mg per day. Accordingly, vitamin B6 intake from all sources may be relevant to the development of signs and symptoms of toxicity, including peripheral neuropathy.

A further concern is that many products on the market do not clearly indicate on the main label that they contain vitamin B6. Consumers may therefore be unaware that a product contains vitamin B6, particularly where vitamin B6 is not identified using its common name and/or where vitamin B6 is not the only active ingredient in a multi-ingredient preparation. In many cases, a consumer would not know that vitamin B6 is present unless they read the ingredient list and also understand that pyridoxine hydrochloride, pyridoxal 5-phosphate or pyridoxal 5-phosphate monohydrate are forms of vitamin B6. While the full chemical name and ingredient quantity are required on the label, there is currently no requirement to display the common name 'vitamin B6', the equivalent amount expressed as pyridoxine, the total amount of vitamin B6 in the medicine, or information prompting consumers to consider other vitamin B6-containing products they may be taking.

Proposed amendments to warning statement and labelling requirements

Having regard to the matters identified above, and in line with the recommendations set out in the Interim Decision, the TGA proposes to:

1. introduce a standardised statement on the main label for all medicines containing vitamin B6, regardless of dose (the standardised label statement), so that consumers can readily identify vitamin B6 and its amount:

'This medicine contains X mg (expressed as pyridoxine equivalents) vitamin B6 per [dosage unit]. Consult your healthcare practitioner if taking more than one product containing vitamin B6 and/or if using for

longer than one month.'
(or words to that effect)

This statement would:

- identify the presence of vitamin B6 using the common name 'vitamin B6'
 - state the amount of vitamin B6 present per dosage unit, expressed as pyridoxine equivalents
 - provide precautionary advice relating to the concurrent use of multiple vitamin B6-containing products
 - advise consumers to consult a healthcare practitioner if taking more than one product containing vitamin B6 and/or if using the product for longer than one month, and
 - apply consistently across single-ingredient and multi-ingredient medicines.
2. simplify and strengthen the existing warning statement by amending it to state:
(VITB6SX) 'WARNING – Vitamin B6 may cause nerve damage. Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.'
 3. reduce the dose threshold for requiring the warning statement, from above 10 mg per day to more than 2 mg per day of pyridoxine.

Required advisory statements for registered medicines containing vitamin B6 are specified in the *Required Advisory Statements for Medicine Labels (RASML)*, as incorporated in the [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2021](#). The existing RASML requirements for vitamin B6 require updating to align with the current requirements in the Permissible Ingredients Determination, and adoption of the proposed amendments will require further changes to maintain alignment.

Rationale for need to recognise medicines that contain vitamin B6 and increase awareness about cumulative exposure

Clear expression of vitamin B6 on medicine labels will assist consumers to identify whether a medicine contains vitamin B6 and how much it contains.

Recent Australian pharmacy sales data indicate that high-risk vitamin B6 purchasing behaviours are widespread, including cumulative exposure from multiple lower-dose vitamin B6 products⁷. The authors concluded that these patterns may not be fully addressed by implementation of the Schedule 3 changes and highlighted the need for strengthened risk communication and improved consumer awareness, noting that

⁷ Chan W-JJ, Hunter J, Lee VY, Cairns R, Mathews S, Harnett JE. *Vitamin B6: too much, too little, too late? An analysis of sales trends in Australia from 2023 to 2025*. Intern Med J. 2026. Available at: <https://doi.org/10.1111/imj.70589>

regulatory reform alone is unlikely to adequately mitigate high-risk vitamin B6 use in Australia.

The TGA proposes a standardised label statement for all vitamin B6-containing listed medicines that readily identifies the presence of the ingredient using the common name 'vitamin B6' and states the total amount present, expressed as pyridoxine equivalents per dosage unit.

Applying this statement to all vitamin B6-containing medicines, regardless of dose, is intended to improve visibility of vitamin B6 at the point of selection and use, and to assist consumers in identifying products that contribute to their total vitamin B6 intake.

The proposed statement would also advise consumers to consult a healthcare practitioner if taking more than one product containing vitamin B6 and/or if using the product for longer than one month. This is intended to support consumers to discuss their total vitamin B6 intake and the appropriateness of ongoing use with a healthcare practitioner, including consideration of cumulative exposure from multiple sources over time, reducing the burden on consumers to independently assess cumulative intake, which can be complex in some situations.

Applying a consistent standardised statement on the main label across both single-ingredient and multi-ingredient medicines is also intended to align communication across product types, improve visibility of vitamin B6 content and increase consumer awareness.

Rationale for seeking healthcare practitioner advice when using vitamin B6-containing medicines

A duration of use of vitamin B6 at which peripheral neuropathy can develop has not been clearly established and is complicated by the widespread use of vitamin B6 in medicines and fortified food and beverages, together with the long-term use of many of these products by consumers. As risk increases with increased duration of use, health practitioner advice is advisable with any extended supplemental use.

The proposed standardised label statement would advise consumers to consult a healthcare practitioner if taking more than one product containing vitamin B6 and/or if using the medicine for longer than one month. While adverse event data is limited, available data indicates that a maximum duration of one month provides an appropriate point at which consumers should be prompted to seek advice. This enables an informed discussion of risks that can consider the individual's current and past intake of vitamin B6.

A review of recent (1 January 2024 - 29 April 2026) adverse event reports of elevated blood B6 levels and peripheral neuropathy or symptoms consistent with peripheral neuropathy associated with vitamin B6 containing medicines⁸ identified 112 cases

⁸ Search of adverse event management system (AEMS) QLIK app for cases up to 29 April 2026 (extract date 07/05/2026). Filter applied from 1 January 2024.

Reaction term 1: Hypervitaminosis B6, Vitamin B6 abnormal (narratives confirmed elevated), Vitamin B6 increased, and

with information on latency⁹. Of these, 19% (21/112) reported onset of symptoms within the first 3 months of commencing the suspected medicine. In 9% (10/112) of cases, onset was less than one month. In 15% (17/112) onset was more than 3 months up to 12 months, while in 66% (74/112) of cases onset occurred more than 12 months after commencing the suspected medicine.

A statement advising consumers to seek health care practitioner advice if using a vitamin B6-containing medicine for longer than one month is therefore considered an appropriate time point at which to prompt review of use and is supported by the adverse event data, which indicates that it could have potentially mitigated neuropathy risk in over 90% of cases included in the analysis.

Of the recent cases with a latency period of up to 3 months (range: 19 to 92 days), the TGA was able to establish the daily dose consumed for 20 cases: 16/20 cases specified the daily dose consumed while 4/20 cases included sufficient information to estimate a dose consumed using the maximum recommended daily dose in the Australian Register of Therapeutic Goods (ARTG) entry or online label (range: 21 mg to 100 mg)¹⁰. Figure 1 shows that most (90% [18/20]) of these 20 cases were associated with doses below the new Schedule 3 daily dose (over 50 mg per day). Doses exceeded the new Schedule 3 daily dose in only 2 cases, noting that in both cases, a higher dosage estimate was applied due to a range on the label (1-2 dosage units/day) or varying doses reported throughout the latency period. This data supports the view that the scheduling changes alone are unlikely to mitigate risks of neuropathy associated with the use of vitamin B6 containing listed medicines, and that neuropathy can occur at lower doses and after short durations of use.

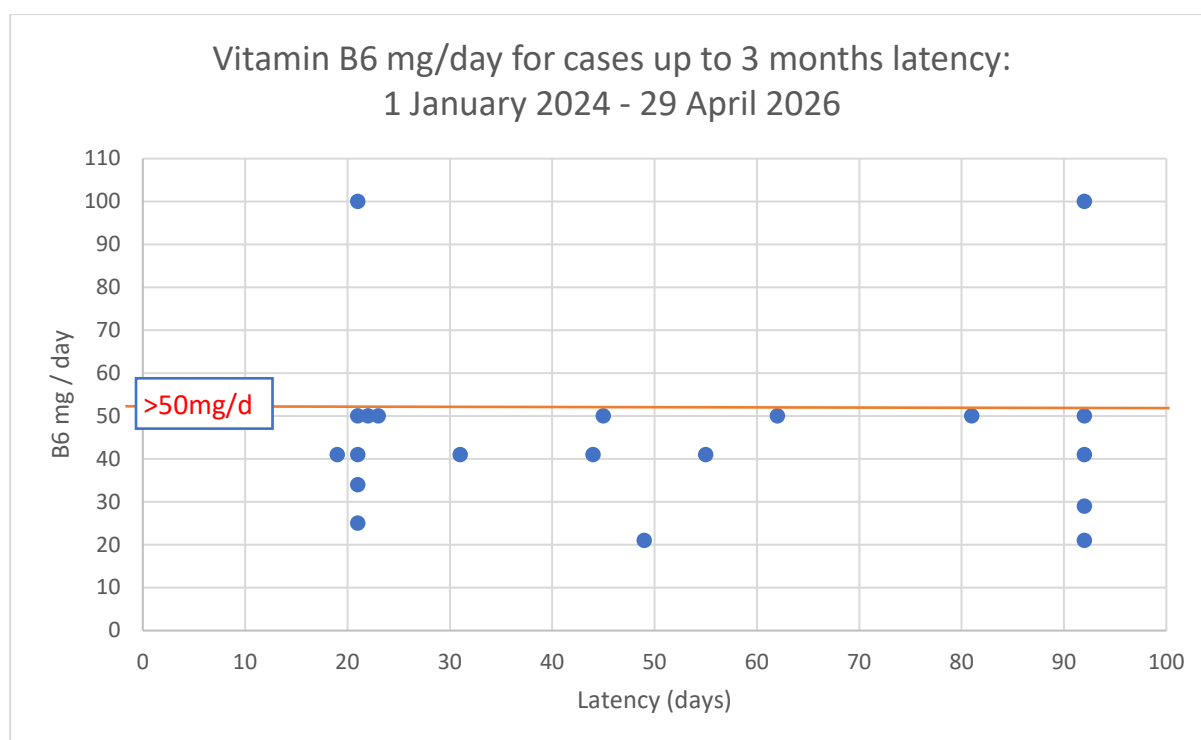
Reaction Term 2: Burning feet syndrome, Burning sensation, Hypoaesthesia, Neuropathy peripheral, Paraesthesia, Peripheral sensorimotor neuropathy, Peripheral sensory neuropathy, Polyneuropathy, Sensory disturbance, Sensory loss, Skin burning sensation, Small fibre neuropathy, Acute polyneuropathy, Hypotonia.

Ingredient Name: pyridoxal 5-phosphate, pyridoxal 5-phosphate monohydrate, pyridoxal hydrochloride, pyridoxine, pyridoxine hydrochloride.

Exclusion criteria: medicine start date/duration of use up to symptom onset/vitamin B6 blood test could not be identified/determined or if it was unclear from case narrative that vitamin B6 blood test was conducted.

⁹ Latency - Time to onset of symptoms associated with peripheral neuropathy from commencement of suspected medicine. If time to symptom onset from commencement of medicine was not clearly stated, the reported time to confirmed elevated blood B6 was used, noting only cases with reported symptoms that also reported vitamin B6 blood tests were included in the review. Where reported onset was not specific, the highest estimate of the latency period was applied. For example, a latency reported as 'after taking for 2-3 months', the longest possible latency value (3 months/92 days) was used.

¹⁰ As with latency, where reported dose consumed was not specific, the highest estimate has been applied. For example, where varying doses during the latency period were reported, such as mostly one tablet a day increased to 2 tablets a day for a period, the dose of 2 tablets per day has been applied. Where reported doses were not daily, the average daily dose has been calculated. For example, 41 mg consumed for 5 of 7 days each week was represented as a daily dose of 29 mg, noting non-daily use was reported in 3 cases only.

Figure 1 – Vitamin B6 mg/day for cases up to 3 months latency: 1 January 2024 - 29 April 2026

Rationale for revision of the warning statement threshold and wording in the existing warning statement

The Interim Decision outlined that the NHMRC's estimated average requirement for vitamin B6 for adults is 1.1-1.3 mg per day and the recommended dietary intake (RDI) is 1.3-1.7 mg per day.

Both the Interim Decision and Final Decision noted that the risk of peripheral neuropathy cannot be excluded for intakes below 50 mg per day. Accordingly, the TGA proposes to lower the current dose threshold for requiring the warning statement from more than 10 mg to more than 2 mg equivalent pyridoxine per day. The proposed threshold is intended to capture medicines that contribute to supplemental vitamin B6 at amounts above typical dietary requirements and that may be relevant to cumulative intake.

The TGA notes that the NHMRC recently concluded a public consultation on proposed revision to the Nutrient Reference Values for vitamin B6, including recommended changes to the RDI and UL¹¹. As the NHMRC's recommendations are yet to be finalised, the proposed dose threshold for requiring a vitamin B6 warning statement may be reviewed and amended, where appropriate, to align with the final NHMRC recommendations.

¹¹ Nutrient Reference Values - Public Consultation on Draft Recommendations - Vitamin B6 - NHMRC consultation hub - Citizen Space. Available at: <https://consultations.nhmrc.gov.au/public-health/nrv-public-consultation-vitamin-b6/>

In addition to the lower threshold, the existing warning statement is proposed to be amended to clearly identify that vitamin B6 may cause nerve damage, while retaining advice directing consumers to cease use and seek healthcare advice if symptoms such as tingling, burning or numbness occur.

The proposed standardised label statement would apply regardless of MRDD, while the amended warning statement would apply where the MRDD provides more than 2 mg of pyridoxine.

This approach distinguishes between:

- a standardised label statement, intended to support recognition of vitamin B6 content, cumulative exposure and duration of use considerations, which applies to all vitamin B6-containing listed medicines, and
- a symptom-based warning statement, intended to communicate the potential risk of nerve damage and the actions consumers should take if symptoms occur, which applies where the medicine provides more than 2 mg per day of pyridoxine.

The proposed statements are outlined above.

Proposed amendments to warning statement and labelling requirements consultation questions



- 1a. Do you support the proposed introduction of a standardised statement on the main label for all listed medicines containing vitamin B6?
- 1b. Do you support the proposed amendments to warning statement VITB6SX to simplify and strengthen the existing wording?
- 1c. Do you support reducing the dose threshold for requiring warning statement VITB6SX from more than 10 mg per day to more than 2 mg per day of pyridoxine?
- 1d. Please provide any comments relating to the proposed warning statement and labelling amendments.

Additional variations to the Permissible Ingredients Determination

In addition to the proposed amendments to the warning statement and labelling requirements, this consultation also seeks feedback on age-based requirements relating to the permitted use of vitamin B6.

Following review of the current age-based dose categories and their implementation, the TGA proposes to:

- clarify the specific requirements so that vitamin B6-containing listed medicines must not be directed for use in infants under 12 months of age, and

- clarify the 14-18-years age category to ensure the intended age range is accurately reflected.

Rationale for not permitting use in infants (0-12 months)

It has come to the TGA's attention that the current specific requirements, which do not explicitly specify a maximum daily dose limit for vitamin B6 in relation to infants under 12 months of age, are ambiguous. This ambiguity arose following the implementation of age-based dose restrictions introduced through the [2021–22 Annual low-negligible risk changes](#).

In developing those restrictions, the TGA sought to implement advice provided by the ACCM at its 27th meeting. The ACCM advised that the age-based limits for vitamin B6 should align with the Australian NRVs established by the NHMRC. These values are shown in Table 1 below.

Table 1: UL of intake of Vitamin B6 as pyridoxine (NHMRC, 2006)

Population	UL of Vitamin B6 as pyridoxine (mg/day)
Infants (0-12 months)	Not possible to establish; source of intake should be breast milk, formula or food only
1-3 years	15
4-8 years	20
9-13 years	30
14-18 years	40
Adults (19+ years)	50

As shown in Table 1, the NHMRC did not establish an upper level of intake for infants aged 0–12 months, stating that intake for this age group should be limited to breast milk, formula and/or food. While the intent of the ACCM advice was reflected in the age-based restrictions that were introduced, the wording ultimately adopted in the Permissible Ingredients Determination does not clearly give effect to that intent in relation to infants under 12 months of age.

To clarify the original intent and maintain alignment with the NHMRC guidance and ACCM advice, the TGA proposes to amend the specific requirements to expressly not permit the use of vitamin B6 in this population.

The TGA is aware that vitamin B6 may be used in infants under healthcare practitioner supervision in certain clinical circumstances. However, listed medicines are intended to be low-risk, self-selected medicines, and the inclusion of directions relating to healthcare practitioner-supervised use is not considered appropriate within the listed medicines framework.

Rationale for minor typographical change to individuals aged 14-18 years

It has come to the TGA's attention that the current wording for the 14-18 years age group in the current age-based dose restrictions for vitamin B6 in the Permissible Ingredients Determination refers to "*individuals aged 14 and 18 years (inclusive)*". This may be mistakenly interpreted as applying only to individuals aged 14 years and 18 years, inadvertently excluding those aged 15 to 17 years. To correct and ensure the intended population group is clear, the TGA proposes to amend the wording to reflect the full age range of "*individuals aged *between* 14 and 18 years (inclusive)*".

Individuals aged 14-18 years and 19+ years

The TGA has received concerns from industry stakeholders in relation to the existing age-based dose limits for vitamin B6, noting that specifying MRDD for individuals aged 14-18 years differ from those aged 19 years and older, creating difficulties for sponsors regarding their product labels. Specifically, that label advisory statements, such as "*Adult use*" or "*Adults only*" are generally understood within industry as referring to individuals aged 18 years and older. This difference in MRDD is perceived to cause inadvertent compliance risk if sponsors interpret that individuals aged 18 years old may receive a higher dose, aligned with that of the limit for 19 years and older, despite the Permissible Ingredients Determination specifying a lower MRDD for individuals aged 18 years. It was also noted that, for medicines intended for adults only and under the current age-based dose restrictions, sponsors are required to include separate directions for use for individuals aged 18 years and for those aged 19 years and older.

After careful review, the TGA considers the existing age-based dose categories for vitamin B6 remain appropriate, as they are consistent with the defined age brackets set out in the NHMRC guidelines. The use of advisory statements such as "*Adults only*" does not negate the applicable dose restrictions specified in the Permissible Ingredients Determination. Accordingly, the current consultation does not cover a proposal to amend the Permissible Ingredients Determination or introduce additional instructions in this regard, as this would add unnecessary complexity. Sponsors remain responsible for ensuring that their product labels, directions for use, and MRDD limits comply with the age-based requirements set out in the Permissible Ingredients Determination, including where advisory statements are used.

Additional variations to the Permissible Ingredients Determination consultation questions



- 2a. Do you support the proposed amendment clarifying that vitamin B6-containing listed medicines must not be directed for use in infants under 12 months of age?
- 2b. Do you support the proposed amendment clarifying the 14-18 years age category?

2c. Do you have any comments regarding the proposed amendments to age-based dose requirements in relation to the 12 months age category or the individuals aged 14-18 years category?

As mentioned earlier, the TGA is aware of the NHMRC's recent public consultation on proposed changes to the NRVs for vitamin B6, including recommended changes to the RDI and UL¹². As the NHMRC's recommendations have not been finalised, the maximum recommended daily dose permitted for each population age group may be reviewed and amended, where appropriate, to align with the final NHMRC recommendations.

Transition expectations

If the proposed amendments to the specific requirements for vitamin B6 in the Permissible Ingredients Determination are adopted, a staged implementation approach is proposed to allow sponsors of existing listed medicines sufficient time to comply with the amended requirements.

The reduction of the maximum recommended daily dose for individuals aged 19 years and older from 100 mg to 50 mg of pyridoxine is intended to be effective from 1 June 2027, aligning with commencement of the new Schedule 3 entry in the Poisons Standard. As discussed in [Consultation](#), this change is not within the scope of this consultation.

Changes related to pyridoxine dose limit for individuals 19 years and older

From 1 June 2027, listed medicines released for supply must comply with the amended maximum recommended daily dose limit of 50 mg of pyridoxine for individuals aged 19 years and older. That is, products containing more than 50 mg but less than or equal to 100 mg of pyridoxine per maximum recommended daily dose will no longer be eligible for listing and cannot be released for supply as listed medicines from 1 June 2027. Sponsors can choose to:

- reformulate affected products to contain 50 mg or less of pyridoxine and list the new formulation in the ARTG; or
- seek to register affected products as Pharmacist-Only medicines.

This provides sponsors with sufficient time to ensure that their listed medicines comply with the new dose limit. As previously highlighted, changes reflecting alignment with the Schedule 3 entry for vitamin B6 in the Poisons Standard are not within the scope of this consultation.

¹² Nutrient Reference Values - Public Consultation on Draft Recommendations - Vitamin B6 - NHMRC consultation hub - Citizen Space. Available at: <https://consultations.nhmrc.gov.au/public-health/nrv-public-consultation-vitamin-b6/>

Changes related to labels

It is proposed that Vitamin B6-containing medicines listed in the ARTG on or after 1 June 2027 will need to comply with the new requirements discussed at [Proposed amendments to warning statement and labelling requirements](#) and [Additional variations to the Permissible Ingredients Determination](#), namely the requirement to:

- include the standardised label statement
- include the updated warning statement about the risk of nerve damage associated with vitamin B6 where it provides more than 2 mg per day of pyridoxine
- not be directed for use in infants under 12 months of age, and
- comply with the clarified age category for individuals aged 14-18 years.

Vitamin B6-containing medicines already listed in the ARTG prior to 1 June 2027 will be allowed a 9-month transition period to comply with the above requirements. These products can continue to be released for supply up until 1 March 2028. This provides sponsors with additional time to implement label and packaging changes through normal manufacturing and supply processes. Sponsors should note that this transition period applies only to the labelling and age-based requirements described above. Products must nevertheless comply with the above [Changes related to pyridoxine dose limit](#) from 1 June 2027.

Affected ingredients

- PYRIDOXAL 5-PHOSPHATE
- PYRIDOXAL 5-PHOSPHATE MONOHYDRATE
- PYRIDOXINE HYDROCHLORIDE

As at 15 September 2026, there are 1,471 listed medicines included in the ARTG that contain one or more of the above ingredients. Of these, 92 medicines providing more than 50 mg and up to 100 mg of pyridoxine equivalent per day will no longer be eligible for listing after 1 June 2027.

A total of 1,373¹³ medicines would be affected by the proposed standardised label statement requirements.

Of these, 504 listed medicines currently provide more than 10 mg and up to 50 mg of equivalent pyridoxine per day and would be affected by the proposed amendments to the existing warning statement.

A further 505 listed medicines currently provide more than 2 mg and up to 10 mg of equivalent pyridoxine per day and would become subject to the warning statement requirements should the application threshold be reduced to more than 2 mg of pyridoxine per maximum recommended daily dose.

¹³ Excludes 6 products for which no maximum recommended daily dose data were available.

Proposed changes

Ingredient name	Existing purpose	New specific requirements ¹⁴
PYRIDOXAL 5-PHOSPHATE	A, E	Pyridoxine is a mandatory component of pyridoxal 5-phosphate. The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate. The medicine must not be directed for use in infants younger than 12 months of age. The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged between 14 and 18 years (inclusive); and (v) 400 50 mg of pyridoxine for individuals aged 19 years and older. Medicines that contain pyridoxal 5-phosphate must include the following statement, prominent on the main label: - (XXX) 'This medicine contains X mg (expressed as pyridoxine equivalents) Vitamin B6 per [dosage unit]. Consult your health care practitioner if taking more than one product containing vitamin B6 and/or if using for longer than one month' or words to that effect. If the maximum recommended daily dose of thea medicine provides more than 402 mg of pyridoxine, the following warning statement is required must be included on the medicine label: - (VITB6SX) 'WARNING – Vitamin B6 may cause nerve damage. Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
PYRIDOXAL 5-PHOSPHATE MONOHYDRATE	A	Pyridoxine is a mandatory component of pyridoxal 5-phosphate monohydrate. The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate. The medicine must not be directed for use in infants younger than 12 months of age. The maximum recommended daily dose of the medicine must not provide more than:

¹⁴ Current specific requirements are in black font, addition in green font and deletion strikethrough in red font.

Ingredient name	Existing purpose	New specific requirements ¹⁴
		(i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged between 14 and 18 years (inclusive); and (v) 400 50 mg of pyridoxine for individuals aged 19 years and older. Medicines that contain pyridoxal 5-phosphate monohydrate must include the following statement, prominent on the main label: - (XXX) 'This medicine contains X mg (expressed as pyridoxine equivalents) Vitamin B6 per [dosage unit]. Consult your health care practitioner if taking more than one product containing vitamin B6 and/or if using for longer than one month' or words to that effect. If the maximum recommended daily dose of the a medicine provides more than 40 2 mg of pyridoxine, the following warning statement is required must be included on the medicine label: - (VITB6SX) 'WARNING - Vitamin B6 may cause nerve damage. Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
PYRIDOXINE HYDROCHLORIDE	A, E, H	When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of pyridoxine hydrochloride. The percentage of pyridoxine from pyridoxine hydrochloride should be calculated based on the molecular weight of pyridoxine hydrochloride. The medicine must not be directed for use in infants younger than 12 months of age. The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged between 14 and 18 years (inclusive); and (v) 400 50 mg of pyridoxine for individuals aged 19 years and older. Medicines that contain pyridoxine hydrochloride must include the following statement, prominent on the main label:

Ingredient name	Existing purpose	New specific requirements ¹⁴
		- (XXX) 'This medicine contains X mg (expressed as pyridoxine equivalents) Vitamin B6 per [dosage unit]. Consult your health care practitioner if taking more than one product containing vitamin B6 and/or if using for longer than one month' or words to that effect. If the maximum recommended daily dose of the a medicine provides more than 40 2 mg of pyridoxine, the following warning statement is required must be included on the medicine label: - (VITB6SX) 'WARNING - Vitamin B6 may cause nerve damage. Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'

Making a submission

The TGA is seeking feedback on the proposed amendments to the requirements for medicines containing vitamin B6. To provide feedback on this consultation, please respond to the consultation questions using the available response options and comment boxes in the online survey available on the [Consultation Hub web page](#). Responses should be relevant to matters specifically raised in this consultation and must be received by the closing date.

All feedback will be considered after the consultation period ends and may be published on the Consultation Hub web page with your consent.

Privacy and your personal information

The TGA collects your personal information in this survey in order to:

- Clarify any issues raised in your responses or to confirm whether you consent to certain information that you have provided being made publicly available.
- Help provide context about your responses (e.g. to determine whether you are an individual or a director of a company or representing an interest group).

The TGA may disclose your full name, work title, company/organisation and submission on the internet (i.e. make this information publicly available) with your consent.

You may specify whether there is anything in your submission that you would prefer not to be published online (e.g. names, email addresses or proprietary information). Please clearly identify the relevant information at the end of your response.

Please do not include personal information about other individuals in your responses. Personal information in this context means, information or an opinion about an identified individual, or an individual who is reasonably identifiable, from the information or opinion. The TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

Timetable

This consultation opened 14 October 2026.

Interested parties should respond by close of business 25 November 2026. Please note that late submissions after this date may not be considered.

Following consideration of public submissions, and subject to any revisions of the proposals and consideration by the Delegate of the Minister, the outcome of this consultation paper will be published in [High-moderate risk changes to the Permissible Ingredients Determination](#).

The confirmed changes to the Permissible Ingredients Determination is expected to commence in June 2027.

The transition period of 9 months is anticipated to end in March 2028 unless otherwise specified.

Enquiries

Please contact us if you have any questions relating to this consultation at the following email address: nonprescriptionmedicines@health.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Complementary Medicines Evaluation Section, Complementary and OTC Medicines Branch	14 October 2026

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