MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Proposed changes to the classification of vitamin D pursuant to the Medicines Regulations 1984

Consultation outcome

July 2026

Contents

Executive Summary

From 5 March to 2 April 2026, Medsafe sought feedback on the proposal to increase the amount of vitamin D that is permitted in a general sale medicine from 25 micrograms (1,000 IU) to 50 micrograms (2,000 IU). This proposal was informed by an independent expert opinion, based on a comprehensive review of current literature.

This report provides a summary and assessment of the submissions received, and a final decision on the classification of vitamin D.

We would like to thank everyone who contributed to this consultation. Medsafe received 25 submissions to the consultation.

Most respondents agreed that the classification of vitamin D should change to increase the general sale medicine limit from 25 micrograms (1,000 IU) to 50 micrograms (2,000 IU).

Based on the independent expert report, consultation feedback, and advice from Medsafe, the Minister of Health's delegate (Group Manager, Medsafe) has made the decision to reclassify vitamin D as follows:

- *Prescription: for internal use in medicines containing more than **50** micrograms per recommended daily dose **except** in parenteral nutrition replacement preparations*
- *General sale: for external use; for internal use in medicines containing **50** micrograms or less per recommended daily dose; in parenteral nutrition replacement preparations*

This classification was implemented on 19 August 2026.

Background

From 5 March to 2 April 2026, Medsafe sought feedback on the proposal to increase the amount of vitamin D that is permitted in a general sale medicine from 25 mcg (1,000 IU) to 50 mcg (2,000 IU). This proposal was informed by an independent expert opinion, based on a comprehensive review of current literature.

Products containing vitamin D may be regulated pursuant to the Medicines Act 1981 and Medicines Regulations 1984, or pursuant to the Dietary Supplements Regulations 1985, depending on the amount of vitamin D they contain and whether they are for a therapeutic purpose.

Under Schedule 1 of the Medicines Regulations 1984, the general sale limit of vitamin D is 25 mcg (1,000 IU). This is currently aligned with the maximum daily dose limits for dietary supplements defined under the Dietary Supplements Regulations 1985.

When products containing vitamin D are not for a therapeutic purpose, they are not medicines. When a vitamin D product is not a medicine, it may be marketed as supplementing the diet and be regulated by the Dietary Supplements Regulations 1985, provided it meets the definitions and requirements of those regulations.

This consultation relates only to the classification of medicines pursuant to the Medicines Regulations 1984, not to an amendment to the Dietary Supplements Regulations 1985. For further information, please refer to the consultation documents on the Medsafe website.

For further information relating to medicines classification, dietary supplements containing vitamin D, and classification decisions, please refer to the vitamin D consultation documents on the Medsafe website.

Consultation results

Thank you to everyone who responded to this consultation.

Medsafe has analysed your responses and summarised the feedback provided.

The results are divided into seven parts:

1. Overview of respondents
2. Question 1: Maintenance of normal, healthy serum vitamin D levels
3. Question 2: Risks and benefits of a maximum daily dose for vitamin D of 2,000 IU
4. Question 3: Risks and benefits of a maximum daily dose for vitamin D of 3,000 IU
5. Question 4: Self-selection of vitamin D products with a daily dose of 2,000 IU
6. Other comments
7. Final decision

Part 1 summarises the respondent demographics by individual or organisation, location and respondent category.

Parts 2 to 5 contain tabulated summaries of respondents' agreement or disagreement with the questions provided, and a summary of respondents' comments. Medsafe has reviewed the responses and relevant supporting literature. Medsafe has considered whether the feedback is strong enough to depart from the expert opinion.

Part 6 summarises the other comments that were received for this consultation.

Part 7 details the final decision on the classification of vitamin D.

1. Overview of respondents

Medsafe received a total of 25 responses to this consultation. 22 submissions were received via the Citizen Space consultation tool, and three were received by email. Responses received by email did not give answers to each consultation question, rather they provided overall feedback on the proposal and included some comments which were out of scope of the consultation. These responses are summarised in the Other Comments section of this report.

As shown in Table 1, most responses were submitted as individuals (84.0%), and the remaining responses were submitted on behalf of an organisation or group (16.0%), including three natural health industry organisations and one government agency.

Table 1: Respondent types

Respondent	Total	Percent
As an individual	21	84.0%
On behalf of an organisation or group	4	16.0%

The majority of respondents were based in New Zealand (96.0%) (Table 2).

Table 2: Respondent location

Location	Total	Percent
New Zealand	24	96.0%
Australia	1	4.0%

The majority of respondents self-identified as healthcare professionals (60.0%). These included nurses, general practitioners, nutritionists, naturopaths, and other natural health professionals. Several other respondents self-identified as researchers, industry representatives, members of the public, or government agencies (Table 3). One respondent self-identifying as a professional body and two respondents as 'other' were combined under the entry 'natural health industry' (Table 3).

For the purpose of response analysis, respondents were categorised as healthcare professional (HCP), industry, or other (Table 3).

Table 3: Respondent category

Respondent	Category	No.	Percent
Healthcare professional	HCP	15	60.0%
Member of the public	Other	3	12.0%
Natural health industry	Industry	3	12.0%
Researcher	Other	2	8.0%
Government	Other	1	4.0%
Pharmaceutical industry	Industry	1	4.0%

Medsafe notes that some responses to this consultation appeared to be in-part AI-generated. For example, some scientific articles cited by respondents either did not appear

to exist, had incorrect author names or article titles, or were improperly referenced. Medsafe has made best efforts to verify the validity of references where possible. For references where validity could not be verified, comments made surrounding these references were discounted when making a final decision on the classification of vitamin D. A summary of references provided by respondents can be found in **Appendix 1**.

2. Maintenance of healthy serum vitamin D levels

Question 1

The expert report notes that research has identified normal, healthy serum vitamin D levels as ranging from 50 to 75 nmol/L. It also indicates that a daily intake of 50 mcg (2,000 IU) of vitamin D is sufficient to maintain serum levels above 50 nmol in the general adult population. Do you agree with this assessment?

Table 4: Summary of responses to question 1

	Respondent category							
	All (n=25)		HCP (n=15)		Industry (n=4)		Other (n=6)	
Response	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Yes	17	68.0%	12	80.0%	3	75.0%	2	33.3%
No	5	20.0%	3	20.0%	0	0.0%	2	33.3%
Did not address	3	12.0%	0	0.0%	1	25.0%	2	33.3%

17/25 (68.0%) respondents agreed that healthy serum vitamin D levels range from 50-75 nmol/L, and that a daily intake of 2,000 IU of vitamin D would be sufficient to maintain healthy serum levels. One respondent who agreed provided further comment, noting that whilst 2,000 IU is generally sufficient, this is dependent on individual needs, and that this level may not be sufficient for all population groups.

Most respondents who agreed self-identified as healthcare professionals (12/17), with the remainder self-identifying as industry representatives, researchers, or members of the public.

Question 1.1

If not, please provide evidence in the form of peer-reviewed published literature.

5/25 (20%) respondents disagreed with the assessment in the expert report. Some of these respondents disagreed with both components of the assessment (healthy serum levels and sufficient daily intake levels), whilst others disagreed with only one component.

We have summarised the comments received into core themes below.

Optimal serum vitamin D levels range from 75-100 nmol/L, not 50-75 nmol/L

Some respondents disagreed that optimal serum vitamin D levels range from 50-75 nmol/L, and considered that optimal levels range from 75-100 nmol/L, or possibly as high as 150 nmol/L. Several articles were cited to support a range of 75-100 nmol/L (**Appendix 1**).

Medsafe consideration

The literature describing optimal serum vitamin D levels is mixed. The terminology used regarding serum nutrient levels is complex, with 'deficient', 'insufficient', 'sufficient' and 'optimal' serum levels all referring to different values.

The European Food Safety Authority's 2023 review on the tolerable upper intake level for vitamin D considers 50 nmol/L to be a suitable target value for all age and sex groups. In addition, current guidelines from the Royal College of Pathologists of Australasia state that no randomised control trials have been performed to determine ideal levels of vitamin D, and advise target vitamin D levels of >50 nmol/L. This threshold is supported by the Australia and New Zealand Bone and Mineral Society, Endocrine Society of Australia, and Institute of Medicine in the United States.

In 2012 the Ministry of Health, Cancer Society of New Zealand, and Accident Compensation Corporation (ACC) released a consensus statement on vitamin D and sun exposure in New Zealand. This statement noted that serum vitamin D levels of 50 nmol/L or over (and no higher than 125 nmol/L) are recommended.

The 2024 Endocrine Society Clinical Practice Guideline (Demay et al. 2024) states that there is no clinical trial evidence to support establishing distinct vitamin D thresholds tied to outcome-specific benefits. The society also state that they no longer endorse a target vitamin D level of 75 nmol/L, nor any specific levels to define vitamin D sufficiency, insufficiency, or deficiency.

Reviews by Bischoff-Ferrari et al. (2006) and Grant et al. (2025) consider optimal serum vitamin D levels as being at least 75 nmol/L. The provided summary of meta-analyses by Ekmekcioglu and Poteser (2025) concluded that, whilst determining a generally applicable optimal vitamin D serum level is difficult, serum vitamin D levels below 75 nmol/L were associated with the lowest risks.

Considering the inconsistency of both data and opinions surrounding optimal vitamin D levels, Medsafe supports the recommendation of the independent expert that serum levels of vitamin D >50 nmol/L are sufficient.

Daily intake of 2,000 IU of vitamin D is not sufficient to maintain healthy serum levels

Some respondents stated that a daily intake of 2,000 IU of vitamin D is not sufficient to maintain healthy serum levels. Some respondents reasoned that this is because healthy serum levels are higher than 50-75 nmol/L, whilst other respondents expressed that 2,000 IU would not be sufficient to maintain 50-75 nmol/L levels. Several articles were cited to support this view (**Appendix 1**).

Medsafe consideration

Medsafe acknowledges the references provided by respondents. The literature describing the amount of daily vitamin D needed to maintain healthy serum levels is mixed. Suitable daily vitamin D intakes cited throughout the literature can range from 400 IU to 8,000 IU or higher.

The European Food Safety Authority's 2023 review considers an adequate daily intake of vitamin D to be 15 micrograms per day (600 IU) in order to achieve serum levels of 50 nmol/L or higher. This is in agreement with the recommended dietary allowance cited by the Institute of Medicine in the United States.

The Grant et al. (2025) review suggests that 2,000 IU of vitamin D per day would be sufficient to maintain optimal serum levels over 75 nmol/L, and the Bischoff-Ferrari et al. (2010) review concluded that 1,800-4,000 IU of vitamin D per day can achieve optimal vitamin D levels.

The narrative review by Pludowski et al. (2024) summarised data from randomised control trials and concluded that 2,000 IU of vitamin D per day is sufficient to maintain serum vitamin D levels above 50 nmol/L in >99% of the population, and above 75 nmol/L in >90% of the population.

Overall, Medsafe considers that the information provided by respondents is not sufficient to depart from the expert opinion, which supports the recommendation to increase the general sale limit for vitamin D from 1,000 IU to 2,000 IU.

The safe upper limit for vitamin D is 4,000 IU, so the general sale limit should be higher than 2,000 IU

Some respondents felt that, since the safe upper limit for vitamin D is 4,000 IU, a higher general sale medicine limit would be more appropriate. One respondent proposed a general sale limit of 3,000 IU, and three respondents proposed a level of 4,000 IU. Several articles were cited to support these limits (**Appendix 1**).

Medsafe consideration

4,000 IU is the safe daily upper limit specified by both the National Institutes of Health Office of Dietary Supplements and the European Food Safety Authority, amongst others.

Medsafe's position is that in determining an appropriate level for general sale medicines, important considerations include the severity of the clinical deficiency and/or disease the product would be designed to treat, and the level of oversight needed from a healthcare professional in safely diagnosing or managing the disease. This includes consumer self-selection behaviour and associated risks.

Medsafe acknowledges the references provided by respondents. The Grant et al. (2025) review suggests that whilst 2,000 IU of vitamin D per day would be sufficient to maintain optimal serum levels over 75 nmol/L, daily doses of 4,000-6,000 IU would provide additional benefits.

The 2024 Endocrine Society Clinical Practice Guideline (Demay et al. 2024) however cautions against high doses of vitamin D, and the systematic review and meta-analysis by Zittermann et al. (2023) concluded that supplemental vitamin D doses of 3,200 IU to 4,000 IU per day appear to increase the risk of hypercalcaemia and other adverse events in some individuals.

Overall, Medsafe considers that the information provided by respondents is not sufficient to depart from the expert opinion, which supports increasing the general sale limit for vitamin D from 1,000 IU to 2,000 IU.

New Zealand-specific considerations

Some respondents provided statistics around vitamin D deficiency in New Zealand, noting that Māori, Pacific peoples, older people, people with obesity and/or diabetes, and other groups have higher vitamin D deficiency rates.

Some respondents noted that public health messaging around sun exposure and skin cancer is enhancing vitamin D deficiency rates, resulting in a greater need for vitamin D supplementation in the New Zealand context and thus warranting a higher general sale limit.

Medsafe consideration

Medsafe acknowledges these comments. Medsafe agrees that the impacts of classification on at-risk groups, including Māori, Pacific, older people, and people with obesity and/or diabetes, are important considerations when making a final decision on the classification of vitamin D.

Medsafe has considered the expert opinion and references provided by respondents. The narrative review by Pludowski et al. (2024) summarised data from randomised control trials and concluded that 2,000 IU of vitamin D per day is sufficient to maintain serum vitamin D levels above 50 nmol/L in >99% of the population, and above 75 nmol/L in >90% of the population.

The 2024 Endocrine Society Clinical Practice Guideline (Demay et al. 2024) however cautions against high doses of vitamin D, and the systematic review and meta-analysis by Zittermann et al. (2023) concluded that supplemental vitamin D doses of 3,200 IU to 4,000 IU per day appear to increase the risk of hypercalcaemia and other adverse events in some individuals.

The 2012 Ministry of Health, Cancer Society of New Zealand, and ACC consensus statement on vitamin D and sun exposure in New Zealand states that at-risk groups may benefit from vitamin D supplementation with one high-dose (50,000 IU) cholecalciferol tablet per month, available on prescription.

Overall, Medsafe considers that the information provided is not sufficient to depart from the expert opinion, which supports which recommends to increasing the general sale limit for vitamin D from 1,000 IU to 2,000 IU.

3. Risks and benefits of a maximum daily dose of vitamin D of 2,000 IU

Question 2

The expert report indicates that the benefit of increasing the maximum daily dose of general sale vitamin D medicines to 50 mcg (2,000 IU) outweighs any risks. Do you agree with this assessment?

Table 5: Summary of responses to question 2

	Respondent category							
	All (n=25)		HCP (n=15)		Industry (n=4)		Other (n=6)	
Response	No.	%	No.	%	No.	%	No.	%
Yes	22	88.0%	15	100%	3	75.0%	4	66.6%
No	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Did not address	3	12.0%	0	0.0%	1	25.0%	2	33.3%

All respondents who submitted responses via the consultation platform agreed that the benefits of increasing the maximum daily dose of general sale vitamin D medicines to 50 mcg (2,000 IU) outweighs any risks.

Three respondents who agreed provided further comments. We have summarised these comments into core themes below.

Emphasising support for the proposal

Of the three respondents who provided further comments, one respondent emphasised their support for the proposal, noting that a daily intake of vitamin D of 2,000 IU presents minimal risk to the general adult population when used as directed.

Agree that the benefits of 2,000 IU of vitamin D per day outweigh any risks, but that the limit should be higher

Two respondents who provided further comment noted that, whilst they agree that the benefits of increasing the maximum daily dose of general sale vitamin D medicines to 2,000 IU outweigh the risks, they believe the limit should be higher. One respondent proposed 3,000 IU and one proposed 4,000 IU.

Medsafe consideration

Overall, Medsafe considers that the information provided by respondents is not sufficient to depart from the expert opinion, which supports increasing the general sale limit for vitamin D from 1,000 IU to 2,000 IU.

4. Risks and benefits of a maximum daily dose of vitamin D of 3,000 IU

Question 3

The expert report indicates that the benefit of increasing the maximum daily dose of general sale vitamin D medicines to 75 mcg (3,000 IU) or higher do not outweigh the risks associated with this change. Do you agree with this assessment?

Table 6: Summary of responses to question 3

	Respondent category							
	All (n=25)		HCP (n=15)		Industry (n=4)		Other (n=6)	
Response	No.	%	No.	%	No.	%	No.	%
Yes	8	32.0%	6	40.0%	1	25.0%	1	16.7%
No	14	56.0%	9	60.0%	2	50.0%	3	50.0%
Did not address	3	12.0%	0	0.0%	1	25.0%	2	33.3%

8/25 (32.0%) respondents agreed with the assessment that the benefits of increasing the maximum daily dose of general sale vitamin D medicines to 3,000 IU or higher do not outweigh the risks associated with this change. Of respondents who agreed, six self-identified as healthcare professionals, one as a member of the pharmaceutical industry, and one as a member of the public.

Question 3.1

If not, please provide evidence in the form of peer-reviewed published literature.

14/25 (56.0%) respondents disagreed with the assessment. Of respondents who disagreed, nine self-identified as healthcare professionals, two as members of the natural health industry, two as researchers, and one as a member of the public.

Nine respondents who disagreed provided further comments. We have summarised the comments received into core themes below.

Inappropriate consumption by consumers raises the risk of 3,000 IU per day

One respondent considered there to be no difference in the risks of 2,000 IU of vitamin D per day versus 3,000 IU, particularly given the safe upper limit is 4,000 IU. This respondent also noted that the purported additional benefits of 3,000 IU of vitamin D per day versus 2,000 IU are minimal, and that levels of 1,000-2,000 IU are sufficient to reach serum levels >50 nmol/L.

However, this respondent considered that risk associated with 3,000 IU versus 2,000 IU of vitamin D per day is increased due to inappropriate consumption and wider consumer behaviour patterns. The respondent provided several references to support this view (**Appendix 1**).

Medsafe consideration

Medsafe acknowledges the comments and references provided by the respondent, and the concerns raised regarding risks surrounding consumer behaviour. Medsafe agrees that consumer behaviour is an important factor that should be considered when making a final decision on the classification of vitamin D.

As the safe upper limit for vitamin D is 4,000 IU per day, there are no more risks associated with 3,000 IU per day than 2,000 IU per day

Several respondents considered that 3,000 IU per day of vitamin D is not associated with any higher risk than 2,000 IU per day, as theses doses both fall below the safe upper limit of vitamin D of 4,000 IU per day. These respondents noted that available research does not identify increased harm at 3,000 IU per day compared with 2,000 IU. Several references were provided to support this view (**Appendix 1**).

Medsafe consideration

4,000 IU is the safe daily upper limit specified by both the National Institutes of Health Office of Dietary Supplements and the European Food Safety Authority, amongst others.

Medsafe acknowledges the references provided by respondents. The Grant et al. (2025) review suggests that whilst 2,000 IU of vitamin D per day would be sufficient to maintain optimal serum levels over 75 nmol/L, daily doses of 4,000-6,000 IU would provide additional benefits.

The 2024 Endocrine Society Clinical Practice Guideline (Demay et al. 2024) cautions against high doses of vitamin D. The systematic review and meta-analysis by Zittermann et al. (2023), concluded that supplemental vitamin D doses of 3,200 IU to 4,000 IU per day appear to increase the risk of hypercalcaemia and other adverse events in some individuals.

In determining an appropriate level for general sale medicines, important considerations include the severity of the clinical deficiency and/or disease the product would be designed to treat, and the level of oversight needed from a healthcare professional in safely diagnosing or managing the disease. This includes consideration of how consumers self-select products and the potential risks associated with products containing higher levels of vitamin D.

Overall, Medsafe considers that the information provided by respondents is not sufficient to depart from the expert opinion, which supports increasing the general sale limit for vitamin D from 1,000 IU to 2,000 IU.

In clinical practice settings, it can be necessary to provide higher doses

Several respondents noted that, in some clinical settings, doses of vitamin D higher than 2,000 IU can be necessary, and that this warrants increasing the general sale limit of vitamin D further.

Medsafe consideration

Medsafe acknowledges that, for treatment of some diseases, doses of vitamin D higher than 2,000 IU may be necessary. There is one vitamin D medicine approved in New Zealand containing 5,600 IU of vitamin D, and one medicine containing 50,000 IU. These medicines are indicated for the treatment of osteoporosis and vitamin D deficiency, respectively which are appropriately classified as prescription medicines and prescribed with healthcare professional oversight.

5. Self-selection of vitamin D products with a daily dose of 2,000 IU

Question 4

The expert report does not identify significant risks associated with consumers self-selecting products containing a daily dose of 50 mcg (2,000 IU) of vitamin D. Do you agree that there are no significant risks at these doses?

Table 7: Summary of responses to question 4

	Respondent category							
	All (n=25)		HCP (n=15)		Industry (n=4)		Other (n=6)	
Response	No.	%	No.	%	No.	%	No.	%
Yes	21	84.0%	15	100%	3	75.0%	3	50.0%
No	1	4.0%	0	0.0%	0	0.0%	1	16.7%
Did not address	3	12.0%	0	0.0%	1	25.0%	2	33.3%

21/25 (84.0%) respondents agreed with the assessment that there are no significant risks associated with consumers self-selecting products containing a daily dose of 2,000 IU. Of respondents who agreed, 15 self-identified as healthcare professionals, three as industry, and three as researchers or members of the public.

Two respondents who agreed with the assessment provided further comments. We have summarised these comments into core themes below.

2,000 IU of vitamin D per day presents no safety risk when used as directed

One respondent agreed that 2,000 IU per day of vitamin D presents no significant safety risk for the general population when used as directed, emphasising that this level is below the tolerable upper level of 4,000 IU and therefore maintains a good margin of safety.

When used unsupervised, 2,000 IU of vitamin D per day can increase risks in certain contexts

One respondent noted that, whilst they broadly agree with the assessment, unsupervised self-selection of vitamin D at doses of 2,000 IU per day can carry a clinically meaningful risk for certain population groups, including in patients with granulomatous disease, patients taking thiazide diuretics, and patients with undiagnosed primary hyperparathyroidism.

Medsafe consideration

Medsafe acknowledges the concerns raised regarding consumer self-selection risks. Medsafe considers that consumer behaviour and self-selection practices are important factors that should be considered when making a final decision on the classification of vitamin D.

Medsafe acknowledges that, for treatment of some diseases, doses of vitamin D higher than 2,000 IU may be necessary. There is one vitamin D medicine approved in New Zealand containing 5,600 IU of vitamin D, and one medicine containing 50,000 IU. These medicines are indicated for the treatment of osteoporosis and vitamin D deficiency, respectively which are appropriately classified as prescription medicines and prescribed with healthcare professional oversight.

Question 4.1

If not, please provide evidence in the form of peer-reviewed published literature.

One respondent (4.0%) disagreed with this assessment and provided further comment. We have summarised this comment into core themes below.

Consumer self-selection can lead to inappropriate consumption

The respondent considered that consumer self-selection of vitamin D products may involve inappropriate consumption and possible over-consumption of vitamin D. The respondent noted that consumers can be resistant to education on adverse effects from dietary supplements, natural health products, and similar products. The respondent also noted that consumers who are more likely to take natural health products are members of the population who likely do not require supplementation, increasing their vulnerability to over-consumption. The respondent provided several references to support this view (**Appendix 1**).

Medsafe consideration

Medsafe acknowledges the comments provided by the respondent, and the concerns raised by the respondent regarding risks surrounding consumer behaviour.

The change in the classification of vitamin D proposed in this consultation would impact the upper limits of vitamin D permitted in general sale medicines.

Given general sale medicines are available for self-selection, Medsafe acknowledges the references provided and agrees that consumer behaviour is an important factor that should be considered when making a final decision on the classification of vitamin D.

6. Other comments

Question 5

Do you have any further comments to add regarding the classification of vitamin D?

Table 8: Summary of respondents who provided further comments

	Respondent category							
	All (n=25)		HCP (n=15)		Industry (n=4)		Other (n=6)	
Response	No.	%	No.	%	No.	%	No.	%
Yes	18	72.0%	11	73.3%	2	50.0%	5	83.3%
No	7	28.0%	4	26.7%	2	50.0%	1	16.7%

Of the feedback provided via the consultation platform, several other themes that did not directly relate to the questions were raised. These are summarised below.

Updates to the Dietary Supplements Regulations 1985

Many respondents expressed a desire for the Dietary Supplements Regulations 1985 to be updated, to align with the proposed general sale medicine limit for vitamin D. As noted in the consultation overview, the Dietary Supplements Regulations 1985 are promulgated under the Food Act 2014, which is administered by the Ministry of Primary Industries. Any changes would be Government decisions and follow parliamentary process. This is outside the scope of this consultation.

Natural health product regulation

Several respondents provided comments surrounding the regulation of natural health products and dietary supplements. Some respondents considered that risks associated with vitamin D product self-selection could be mitigated through regulatory activities, such as labelling requirements. As noted in the consultation overview, policy development regarding natural health product legislation is outside the scope of this consultation.

As noted previously, three respondents provided comments outside of the consultation platform, giving broad feedback on the proposal. This feedback is summarised below.

Feedback from the Therapeutic Goods Administration (Australia)

Overall, the Therapeutic Goods Administration (TGA) in Australia expressed that they are not supportive of the proposed reclassification of vitamin D to increase the general sale limit from 1,000 IU to 2,000 IU.

The TGA noted that current permitted limits for medicines providing 1,000 IU coincide with the upper limit for infants, as defined by the National Health and Medical Research Council's nutrient reference values for vitamin D. The TGA notes that the current limit of 1,000 IU already exceeds the recommended daily intake for all population groups.

The TGA considers there to be no benefit in increasing general sale limits to 2,000 IU, as vitamin D status is generally maintained by sun exposure and dietary intake.

The TGA noted the classification of vitamin D in Australia:

- *Prescription (Schedule 4)* ***except***
    - *in preparations containing 25 micrograms or less of vitamin D per recommended daily dose*
    - *when included in Schedule 3*
- *Pharmacist-only (Schedule 3) in preparations containing 175 micrograms or less of vitamin D per recommended single weekly dose* ***except*** *in preparations containing 25 micrograms or less of vitamin D per recommended daily dose*

The TGA considers that patients who require preparations of vitamin D exceeding 25 micrograms per day or 175 micrograms per week should seek medical attention.

The TGA also notes that well-conducted randomised controlled trials at 2,000 IU have not consistently demonstrated clinically meaningful benefits.

The TGA were of the view that the risks of excess vitamin D over long-term exposure without medical supervision outweighs the benefits of increasing general sale vitamin D levels to 2,000 IU, noting that consumers may take multi-ingredient formulations containing vitamin D across multiple products.

Feedback from a natural health industry organisation

A natural health industry organisation provided feedback, noting that whilst an increase in the level of vitamin D available at general sale is welcome, higher doses are preferable. The respondent noted the upper intake level for vitamin D of 4,000 IU per day, and felt that this should be the limit for general sale vitamin D medicines. The respondent considered that several references cited in the expert report were not appropriately considered, conflating the toxicity profile of vitamin D.

They noted that, in the New Zealand context, public health messaging surrounding sun exposure is exacerbating vitamin D deficiency, warranting higher general sale limits for vitamin D. The respondent also made broader comments regarding medicines regulation in New Zealand.

Feedback from a member of the public

A member of the public provided feedback, noting that the upper intake level for vitamin D is 4,000 IU per day, and reasoned that there is no justification to set limits below this level.

The respondent considered that several references cited in the expert report were not appropriately considered, conflating the toxicity profile of vitamin D. The respondent also made broader comments regarding medicines regulation in New Zealand.

7. Final decision

The Minister of Health's Delegate (Group Manager, Medsafe) has made the final decision to reclassify vitamin D as follows:

- *Prescription: for internal use in medicines containing more than **50 micrograms** per recommended daily dose **except** in parenteral nutrition replacement preparations*
- *General sale: for external use; for internal use in medicines containing **50 micrograms** or less per recommended daily dose; in parenteral nutrition replacement preparations*

This classification was implemented on 19 August 2026.

This information was based on the following:

1. The independent expert report, which undertook a comprehensive review of current literature surrounding vitamin D.
2. The feedback provided by respondents to this consultation.
3. Previous discussions by the Medicines Classification Committee regarding vitamin D.
4. Advice provided by Medsafe.

Appendix 1 – References provided by respondents

Author (Year)	Title	Type	Relevant Question(s)	Comments
Amrein et al. (2020)	Vitamin D deficiency 2.0: an update on the current status worldwide	Narrative review	5	
Bacha et al. (2021)	Vitamin D_3 dose requirement that raises 25-hydroxyvitamin D to desirable level in overweight and obese elderly	Post-hoc analysis	1	This reference was cited as Alnasrallah (2025) in the respondent submission
Barry (2018)	Patients' perceptions and use of natural health products	Survey	3, 4, 5	
Bickle et al. (2023)	Unknown	Unknown	1	This reference could not be verified
Bischoff-Ferrari et al. (2006)	Estimation of optimal serum concentrations of 25-hydroxyvitamin D for multiple health outcomes	Review	1	
Bischoff-Ferrari et al. (2010)	Benefit-risk assessment of vitamin D supplementation	Review	3, 4, 5	
Cashman et al. (2008)	Estimation of the dietary requirement for vitamin D in healthy adults	Clinical trial	3, 4, 5	
Chandler et al. (2014)	Risk of hypercalcemia in blacks taking hydrochlorothiazide and vitamin D	Clinical trial	4	This reference was cited as Michos et al. (2014) in the respondent submission
Cui et al. (2023)	Global and regional prevalence of vitamin D deficiency in population-based studies from 2000 to 2022: A pooled analysis of 7.9 million participants	Meta-analysis	5	

Demay et al. (2024)	Vitamin D for the prevention of disease: An Endocrine Society clinical practice guideline	Guideline	1	
Dunlop et al. (2025)	A systematic review and meta-analysis of circulating 25-hydroxyvitamin D concentration and vitamin D status worldwide	Systematic review and meta-analysis	1	
EFSA (2016)	Dietary reference values for vitamin D	Scientific opinion	3, 4, 5	
EFSA et al. (2023)	Scientific opinion on the tolerable upper intake level for vitamin D, including derivation of a conversion factor for calcidiol monohydrate	Scientific opinion	2, 3	
Environmental Health Intelligence NZ	Vitamin D deficiency	Website	2	
Ekmekcioglu & Poteser (2025)	The optimal protective 25-hydroxyvitamin D level for different health outcomes in adults: A brief summary of dose-response meta-analyses	Opinion paper	1	This reference was cited as Zittermann et al. (2025) in the respondent submission
Forrest & Stuhldreher (2011)	Prevalence and correlates of vitamin D deficiency in US adults	Study	3, 4, 5	
Garland et al. (2009)	Vitamin D for cancer prevention: Global perspective	Review	1	
Goyal et al. (2009)	4,000 IU of Vitamin D daily is safe, but takes a year to plateau – Best-D RCT.	Unknown	3	This reference could not be verified
Grant et al. (2025)	Vitamin D: Evidence-based health benefits and recommendations for population guidelines	Review	1	
Greger et al. (2001)	Dietary supplement use: Consumer characteristics and interests	Opinion review	3, 4, 5	
Health Canada	Dietary reference intakes for vitamin D	Reference table	2, 3	

Holick et al. (2011)	Evaluation, treatment, and prevention of vitamin D deficiency: an Endocrine Society clinical practice guideline	Guideline	1, 3, 4, 5	
Institute of Medicine (2011)	Dietary reference intakes for calcium and vitamin D	Report	2, 3	
Johnson et al. (2022)	Safety and tolerability of high-dose daily vitamin D_3 supplementation in the vitamin D and type 2 diabetes (D2d) study – randomised trial in persons with prediabetes	Clinical trial	3	This reference was cited as Jones et al. (2022) in the respondent submission
Khan et al. (2024)	The dark side of the sunshine vitamin: A case of acute renal failure and hypercalcaemia from vitamin D overconsumption	Case study	3, 4, 5	
Koutkia et al. (2001)	Vitamin D intoxication associated with an over-the-counter supplement	Case study	3, 4, 5	
Lyle et al. (1998)	Supplement users differ from nonusers in demographic, lifestyle, dietary and health characteristics	Observational study	3, 4, 5	
Mifsud et al. (2023)	Thiazide diuretics and primary hyperparathyroidism	Review	4	This reference was cited as Kana et al. (2024) in the respondent submission
Ministry of Health et al. (2012)	Consensus statement on vitamin D and sun exposure in New Zealand	Consensus statement	2, 5	
Newman et al. (1998)	Dietary supplement use by women at risk for breast cancer recurrence	Descriptive study	3, 4, 5	
Ozkan et al. (2012)	Vitamin D intoxication	Review	3, 4, 5	
Papadimitiou (2017)	The big vitamin D mistake	Opinion review	3	

Papagerakis et al. (2017)	Unknown	Unknown	3	This reference could not be verified
Pludowski et al. (2024)	Vitamin D supplementation: A review of the evidence arguing for a daily dose of 2000 International Units (50 micrograms) of vitamin D for adults in the general population	Narrative review	1, 2	
Rizzoli (2021)	Vitamin D supplementation: upper limit for safety revisited?	Review	2	This reference was cited as Ambrosi (2021) in the respondent submission
Rockell et al. (2006)	Serum 25-hydroxyvitamin D concentrations of New Zealanders aged 15 years and older	Study	1	
Schoenmakers & Jones (2021)	Unknown	Unknown	1	This reference could not be verified
Scragg et al. (2010)	Burden of disease associated with low vitamin D status in New Zealand	Risk analysis	1	
Tebben et al. (2016)	Vitamin D-mediated hypercalcemia: Mechanisms, diagnosis, and treatment	Review	4	This reference was cited as Bilezikian et al. (2016) in the respondent submission
Tollitt & Solomon (2014)	Hypercalcaemia and acute kidney injury following administration of vitamin D in granulomatous disease	Case report	4	This reference was cited as Yong et al. (2014) in the respondent submission
Vieth (1999)	Vitamin D supplementation, 25-hydroxyvitamin D concentrations, and safety	Review	1	
Wimalawansa (2023)	Infections and autoimmunity – The immune system and vitamin D: A systematic review	Systematic review	5	
Wimalawansa (2025)	Vitamin D's impact on cancer incidence and mortality: A systematic review	Systematic review	1	This reference was cited as Moukayed (2025) in the respondent submission

Zittermann et al. (2023)	Long-term supplementation with 3200 to 4000 IU of vitamin D daily and adverse events: a systematic review and meta-analysis of randomized control trials	Systematic review and meta-analysis	3	This reference was cited as Pliz et al. (2023) in the respondent submission