Submission for medicine reclassification for consideration by the Medicines Classification Committee

This form should be completed in conjunction with the directions in the guidance document 'How to change the legal classification of a medicine in New Zealand'.

Please also complete an introduction summarising the intention of the submission and provide any relevant background.

Once completed, this application should be sent to the MCC Secretariat (committees@health.govt.nz) by the deadline on the dates and deadlines page on the Medsafe website.

By submitting this form, you are confirming that all information is true and accurate, and understanding that this information and any appendices and/ or supporting information that is not considered commercially confidential under the Official Information Act 1982 will be published on the Medsafe website.

Introduction

Please provide background context for the submission

Vitamin D above 1000IUs is classified as a medicine but under 1000IUs it is classified as a dietary supplement. Since this division occurred, there is ample evidence that vitamin D insufficiency is a growing problem internationally, with about 5% of New Zealanders likely deficient with a further 25% below the recommended levels of vitamin D (source: www.ehinz.ac.nz). These rates are higher in Pacific adults, those who live in more socially deprived area,s and those who are identified as obese. One of the easiest ways to address deficiency and insufficiency is to supplement. To effectively achieve this, one need to take more than the current allowance of 1000IUs (Liu et al., 2025). Indeed, the current best practice guidelines indicate that we should be consuming between 2-3000IUs of vitamin D daily (Grant et al., 2025; Pludowski et al., 2024). Given the erosion of diets over the last 50 years along with increasing consumption of inflammatory foods, we can no longer rely on diet alone to provide the micronutrients that our bodies need. As such, I ask the committee to raise the limit for vitamin D to 3000IUs and change the classification of vitamin D to be a medicine about 3000IUs. In doing so, the Ministry of Health would be signalling to the

population that adequate vitamin D is essential for maintaining good health and for improving population resilience (Ahmad et al., 2023).

Please note that some of the information contained in this application came from previous applications submitted to the MCC by the natural products industry. However, I have not consulted with them on this application – I come from the perspective of supporting New Zealanders to manage and support their health with safe dietary options. I am not funded by the industry and have never received any funding from companies that make natural health products.

Part A- Regulatory Context and Proposed Classification

1. International non-proprietary (INN) name of the medicine

Vitamin D [includes vitamin D3, colecalciferol (alternative spelling cholecalciferol) and vitamin D2, ergocalciferol (alternative name calciferol)].

2. Proprietary names (if applicable)

N/A

3. Name and contact details of the company/ organisation/ individual requesting a reclassification

Contact details can be removed from the form prior to publication of the Medsafe website if requested.

Prof Julia Rucklidge
[redacted]

4. Dose form(s) and strength(s) for which a change is sort (if applicable)

N/A

5. Pack size, storage conditions and other qualifications (if applicable)

N/A

6. Indications for which change is sought (if applicable)

N/A

7. Present classification of the medicine

At the present time, Vitamin D is:

- Unscheduled when in products for external use.
- Unscheduled when in products for internal use containing 25 micrograms or less per recommended daily dose [ie equivalent to 1000 IU or less].
- Unscheduled when in parenteral nutrition replacement preparations.
- A prescription medicine except in the situations above

8. Classification sought

It is proposed that the classification of Vitamin D is changed to:

- Unscheduled when in products for external use.
- Unscheduled when in products for internal use containing 75 micrograms [ie 3000 IU] or less per recommended daily dose.
- Unscheduled when in parenteral nutrition replacement preparations.
- A prescription medicine except in the situations above

9. Classification status in other countries (especially Australia, UK, USA and Canada), and any justification for harmonisation

As far as I know:

Australia

Vitamin D is:

• Unscheduled when in products for external use.

• Unscheduled when in products for internal use containing 25 micrograms or less per recommended daily dose.

• Unscheduled when in parenteral nutrition replacement preparations.

• A prescription medicine except in the situations above.

Canada

Vitamin D is:

• Unscheduled in in oral dosage form containing 1,000 International Units [ie equivalent to 25 micrograms] of Vitamin D per dosage form or less, or where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by the person of less than 1,000 International Units of Vitamin D.

• Prescription drug in oral dosage form containing more than 1,000 International Units of Vitamin D per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by the person of more than 1,000 International Units of Vitamin D.

UK

Vitamin D is a pharmacy medicine above 10 micrograms [or 400 IU].

Below this, Vitamin D is unscheduled.

USA

In the USA, many vitamin D products are marketed as dietary supplements which do not have to undergo a pre-approval process. There are at least 5,000 products containing Vitamin D on the US market. The vitamin content of these products ranges from 400 IU to 5000 IU (125 micrograms vitamin D)

10. Extent of usage in New Zealand and elsewhere (e.g. sales volume) and dates of the original consent to distribute

N/A

11. Local data or special considerations relating to New Zealand (if applicable)

N/A

12. Labelling or draft labelling for the proposed new presentation(s) (if applicable)

When used as an active ingredient in oral or sublingual products: Vitamins can only be of assistance if the dietary vitamin intake is inadequate [OR] Vitamin supplements should not replace a balanced diet. These are the same statements currently used in Australian for products containing Vitamin D.

13. Proposed warning statements (if applicable)

Vitamin D at 3000 IUs is very safe and below the Tolerable Upper Limits. Vitamin D toxicity is a rare event caused by inadvertent or intentional ingestion of excessively high amounts of vitamin D (Holick et al., 2011). See below for more information.

14. Other products containing the same active ingredient(s) which would be affected by the proposed change

Manufacturers of current dietary supplement-type products will likely increase the quantity of Vitamin D in their products or change their dosing instructions to deliver the maximum daily dose allowed. This kind of change would benefit the health of all New Zealanders through reducing the likelihood of deficiency and increasing resilience.

As far as I know, approved medicines containing Vitamin D as the active ingredient:
Vitalipid N Adult emulsion for injection
Vitalipid N Infant emulsion for injection
Cernevit powder for injection
Products for injection are not permitted under the NHP regulatory scheme.
Caltrate with Vitamin D tablets general sale
Calvid effervescent granules general sale
Caltrate 600mg with 400 IU Vitamin D tablets general sale
Elevit with Iodine tablets pharmacy medicine

Fosamax Plus tablets prescription medicine
Vit. D3 capsules prescription medicine

Part B- Clinical Context and Implications

15. Indications and dose

- *What is the medicine indicated for, and for which indication(s) is the reclassification application for?*
- *What is the evidence that the proposed indication is an OTC indication ie, that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?*
- *What is the treatment population for the indication (age, gender etc.)?*
- *What is the dose and dose frequency of the medicine for this indication?*

N/A

16. Presentation

- *What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?*
- *What disposal considerations need to be made for the medicine?*
- *How practical and easy to use is the proposed presentation?*

N/A

17. Consumer benefits

- *What is the history of this medicine's use for the proposed indication(s) ie, number of users; number of countries used in?*
- *To what extent is this medicine used for the proposed indication(s) ie, duration of use; frequency of use?*
- *What is the evidence that improved access is beneficial for the individual?*
- *What is the evidence of improved consumer involvement in their health?*
- *What are the benefits from a consumer viewpoint?*

Multi-ingredient supplements such as trace elements and essential nutrient formulations are usually taken to complement dietary intake of essential vitamins and

minerals. Such products are generally regarded as dietary supplements. At the present time, under the current Dietary Supplements Regulations 1985 regime, therapeutic claims are not permitted for dietary supplements. This creates a peculiar situation where, for example, iron supplements are recognised to aid in the treatment of iron deficiency and iron deficiency anaemia, and are taken for these purposes, yet such products cannot provide advice on their labels on how they should be used. The same applies to Vitamin D.

Vitamin D, calciferol, is a fat-soluble vitamin. It is found in food but also can be made in the body after exposure to ultraviolet rays from the sun. Vitamin D exists in several forms, each with a different activity. Some forms are relatively inactive in the body and have limited ability to function as a vitamin. The liver and kidney help convert vitamin D to its active hormone form. The major biologic function of vitamin D is to maintain normal blood levels of calcium and phosphorus. Vitamin D aids in the absorption of calcium, helping to form and maintain strong bones. It promotes bone mineralization in concert with a number of other vitamins, minerals, and hormones. Without vitamin D, bones can become thin, brittle, soft, or misshapen. Vitamin D prevents rickets in children and osteomalacia in adults, which are skeletal diseases that result in defects that weaken bones.

18. Contraindications and precautions

- *What are the contraindications for the medicine and how easy are they to identify and prevent?*
- *What are the precautions for this medicine and how easy are these to understand?*
- *Does the medicine have a low therapeutic index?*
- *What class effects need to be considered and what are the risks?*
- *What are the risks of the medicine being used in an OTC environment?*
- *What other drug interactions need to be considered?*
- *What food and/ or drink interactions need to be considered?*
- *Are there any other restrictions when taking the medicine ie, driving restrictions or operating machinery?*
- *Are there any special populations where exposure to the medicine needs to be restricted?*

Alkundi et al (Alkundi et al., 2022) state that vitamin D should not be given to patients with hypercalcemia. It should be used with caution in infants, who may have increased sensitivity to its effects, and patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcemia occurred. It is also advised that plasma phosphate concentrations should be controlled during vitamin D therapy to reduce the risk of ectopic calcification and that patients receiving

pharmacological doses of vitamin D should have their plasma-calcium concentration monitored at regular intervals, especially initially or if symptoms suggest toxicity (Holick et al., 2011). Similar monitoring is recommended in infants if they are breast-fed by mothers receiving pharmacological doses of vitamin D. However, supplementation is different from treatment and the doses suggested for a DS are substantially lower than treatment doses.

The data sheet for Cal.D.Forte® lists the following contraindications:
• Colecalciferol is contraindicated in patients with hypersensitivity to any component of this product.
• Except under special circumstances, this medication should not be used when the following medical problems exist:
o Hypercalcemia o Hypervitaminosis D
o Renal osteodystrophy with hyperphosphatemia (risk of metastatic calcification; however, vitamin D therapy can begin once serum phosphate levels have stabilised).
• Risk-benefit should be considered when the following medical problems exist:
o Arteriosclerosis or cardiac function impairment (conditions may be exacerbated due to possibility of hypercalcemia and elevated serum cholesterol concentrations).
o Hypersensitivity to effects of vitamin D (may be involved in causing idiopathic hypercalcemia in infants).
o Renal function impairment (toxicity may occur in patients receiving vitamin D for nonrenal problems, although toxicity is also possible during treatment of renal osteodystrophy because of increased requirements and decreased renal function).
o Sarcoidosis, and possibly other granulomatous diseases (increased sensitivity to effects of vitamin D).

Warnings and Precautions listed in the data sheet include:
• Use in pregnancy. Maternal hypercalcemia during pregnancy in humans may be associated with increased sensitivity to effects of vitamin D, suppression of parathyroid function, or a syndrome of peculiar (elfin) faces, mental retardation and congenital aortic stenosis in infants
• Vitamin D should not be administered to patients with hypercalcemia
• Use with care in patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcemia occurred.
Adverse effects listed in the data sheet include:
• Chronic vitamin D-induced hypercalcemia
• Growth arrest in children (especially after prolonged administration of 45µg (1800 IU) of colecalciferol per day).
• Death (as a result of renal or cardiovascular failure caused by vitamin D toxicity).
Interactions listed in the Cal.D.Forte® data sheet include:
• Increased risk of hypercalcemia if co-administered with thiazide diuretics and calcium.

• Vitamin D requirements may be increased by some antiepileptics (e.g. carbamazepine, phenobarbitone, phenytoin, and primidone), barbiturates, cholestyramine, colestipol, hydantoin anticonvulsants, mineral oil, and primidone. These types of warnings and precautions would all need to be included on the labelling or a package insert if the classification of vitamin D was to be down-scheduled (although note the discussion below on the growth warning for children).

19. Undesirable effects

- *What are the known undesirable effects and the frequencies of these? Do these vary for special populations?*
- *What are the risks and consequences of known undesirable effects?*
- *Are there any significant safety concerns for the medicine under review?*
- *Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)?*
- *Are there any withdrawal effects following cessation of use of the medicine?*

Toxicity information

There is a high health risk associated with consuming too much vitamin D (Marcinowska-Suchowierska et al., 2018). Vitamin D toxicity can cause nausea, vomiting, poor appetite, constipation, weakness, and weight loss. It can also raise blood levels of calcium, causing mental status changes such as confusion. High blood levels of calcium also can cause heart rhythm abnormalities. Calcinosis, the deposition of calcium and phosphate in soft tissues like the kidney can be caused by vitamin D toxicity. Consuming too much vitamin D through diet alone is not likely unless you routinely consume large amounts of cod liver oil. It is much more likely to occur from high intakes of vitamin D in supplements. The NZ Ministry of Health (National Health and Medical Research Council, 2006) considers an intake of 25 mcg (1,000 IU) for infants up to 12 months of age and 80 mcg (3,200 IU) for children, adults, pregnant, and lactating women to be the tolerable upper intake level (UL), meaning it would be safe to take at this dose.

The AI levels recommended by the Ministry of Health are generally below those recommended by the National Institutes of Health.

Some researchers argue that the UL has been set too low: "Except in those with conditions causing hypersensitivity, there is no evidence of adverse effects with serum 25(OH)D concentrations < 140 nmol/L, which require a total vitamin D supply of 250 µg (10,000 IU)/day to attain. Published cases of vitamin D toxicity with hypercalcaemia, for which the 25(OH)D concentration and vitamin D dose are known, all involve intake of ≥ 1000 µg (40,000 IU)." (Vieth, 1999). Indeed, research with healthy adults has established that taking vitamin D3 daily at a dose of 100 µg (4000 IU) has been

determined to be safe (Vieth et al., 2001). While earlier recommendations suggested much lower intakes, research over the last decade indicates that vitamin D can be tolerated at much higher doses. Indeed, sunshine can provide an adult with vitamin D in an amount equivalent to daily oral consumption of 250 µg (10,000 IU)/day, this is intuitively a safe dose (Vieth, 2007).

One of the concerns of excess vitamins D intake is hypercalcaemia. The weight of published evidence on toxicity shows that the lowest dose of vitamin D causing hypercalcaemia in some healthy adults is 1000 µg (40,000 IU)/day of the vitamin D2 form. Based on the evidence, Vieth concluded: "The overwhelming bulk of clinical trial evidence supports the conclusion that a prolonged intake of 250 µg (10,000 IU)/d of vitamin D3 likely poses no risk of adverse effects in almost all individuals in the general population" (Vieth, 2007). Collectively, the absence of toxicity in trials conducted in healthy adults that used vitamin D dose > or = 250 µg/day (10,000 IU vitamin D3) supports the confident selection of this value as the UL (Hathcock et al., 2007). Indeed, many studies are using doses of vitamin D at 25,000 IU [or 625 mg/day].

There are many studies on vitamin D safety as well as studies showing the risks of vitamin D deficiency in children (Wheeler et al., 2015). Indeed, in our research to date, we have noted about ~20-30% of participants (both adults and children) are deficient in vitamin D (Rucklidge et al., 2018; Rucklidge et al., 2014).

The committee might also be interested in the article by Drury et al (Drury et al., 2015) highlighting the importance of supplementing children with vitamin D and the one by Hathcock and colleagues (2007) that discusses the risks of vitamin D and the low risk of adverse effects (Hathcock et al., 2007).

In the past, Medsafe has raised concerns about the harm associated with giving vitamin D at 3000IUs to children, specifically, "Growth arrest in children (especially after prolonged administration of 45µg (1800 IU) of colecalciferol per day)."

Although I was unable to find the source of this fact in the information on the Medsafe website, I came across an article by Hypponen et al (Hypponen et al., 2011). This study refutes the idea that vitamin D supplementation has a negative impact on growth. It is based on a large sample of 12,000 live births in Finland and follows the children to 31 years of age.

In this article, the authors discuss the commonly held assumption that taking vitamin D above 45 mcg a day affects growth and development in children and cite a 1938 article as the original source of that statement by Jean et al (Jeans & Stearns, 1938).

I am not sure if this article is the source of that statement made in the fact sheets but I couldn't find anything else. If it is, then it is based on a sample of 9 infants not children. Further, the study is confounded by the fact that they gave both vitamin D and vitamin A to the infants. In addition, there is no control group so we can't determine if the observations on growth were caused by supplementation.

Here is a discussion from the Finnish study about the impact of vitamin D on growth and development:

"Importantly, as illustrated by the inclusion in the recent Institute of Medicine risk assessment on vitamin D, this relative lack of data has left a small uncontrolled case study to influence the conception of vitamin D toxicity at concentrations that are far below those associated with more severe symptoms of vitamin D overdosing. The message of potential adverse influences of vitamin D supplementation at dosages of ~1800 IU/d was based solely on this 1 case study including 9 children that reported associations between vitamin D supplementation and reduced growth. Findings of that case study published in the 1930s have not been subsequently replicated, and also we found little evidence for a shorter stature of children who received vitamin D supplementation compared with others."

I do hope that this newer information puts Medsafe and the MCC at ease about concerns of vitamin D on the growth and development of children.

20. Overdose

- *Is there a potential for overdose of the medicine?*
- *What are the consequences of overdose of the medicine?*
- *Are there any reports of overdose of the medicine?*

There is risk of overdose currently when sold at 1000IUs per day. This risk doesn't change if 3000IUs is allowed (given 3000IUs isn't toxic).

21. Medication errors and abuse/ misuse potential

- *Would reclassification affect the risk of unnecessary use?*
- *Should the medicine be provided with necessary tools to allow correct dosing eg, liquids supplied with a measuring device?*
- *What are the reported medication errors post-market?*
- *What are the reported cases of abuse/misuse/accidental overdose?*
- *How would reclassification affect import considerations?*

- *What is the addiction potential of the medicine?*

N/A

22. Communal harm and/or benefit

- *What are the possibilities of community harm resulting from wider use of the medicine in question (e.g., the development of antibiotic resistance in bacteria or increased immunisation rates)?*
- *What are the possibilities of community benefit resulting from wider use of the medicine in question (e.g., greater herd immunity as a result of improved access to a communicable disease vaccine)?*

The risk of harm is predominantly to individuals, as discussed in the previous sections of this report. Wider use of vitamin D in adults deficient in vitamin D or at risk of deficiency is unlikely to result in harm to the community, rather the resultant reduction in falls and improved mood could result in health and societal benefits.

23. Integrated benefit-risk statement

- *A summary of the reclassification benefits*
- *A summary of the reclassification risk of harm*
- *A summary of the need for the medicine at the classification proposed*
- *Precedent – how are other medicines in the same class classified?*

The research suggests some role for vitamin D in the prevention of falls and fractures. Given the prevalence of vitamin D deficiency, particularly in older individuals, there appears to be a need for high dose vitamin D products. This need is evidenced by the large number of patients using the Pharmac-subsidised vitamin D drug Cal.D.Forte. However, need does not necessarily mean that the classification of an ingredient should change. The safety of the ingredient is an important consideration. Vitamin D can generally be considered safe, with a UL ranging between 80-250 µg depending on the research group. With regards to a 1.25 mg dose taken monthly, this equates to a daily dose of 40.3-41.7 µg. Even based on the more conservative UL of 80 µg, this gives a safety margin of approximately two. When a 1.25 mg vitamin D tablet is used as intended (for individuals with vitamin D deficiency states), the safety margin would be higher.

The risks of adverse effects and/or the seriousness of those effects increases when individuals have certain medical conditions (e.g. heart disease, renal impairment, hypercalcemia, hyperphosphataemia) or are taking certain medications or supplements (e.g. thiazide diuretics, calcium). The appropriateness of the medication

for an individual therefore needs to be assessed against their medical history and blood tests and labelling products to indicate that consumers should be directed by their health care professional for advice. Deficiency is defined by serum 25-OHD levels which, once again, require a blood test to determine. As far as I am aware, prescribers are discouraged from testing for Vitamin D deficiency (perhaps because there is a high likelihood it will be detected). The data sheet also recommends monitoring patients during treatment, generally via results from blood tests.

The other risk factor to consider is patient confusion over daily versus monthly administration. This risk could be minimised by specific emphasis on dosage instructions on the supplement. With regards to a suitable daily dose, a quantity of 40.3-41.7 µg would be proportional to the once-a-month intake of 1.25 mg colecalciferol. It is also within the NRV's UL of 80 µg per day and within the UL of 100 µg per day suggested by the IOM. For scheduling purposes, the daily quantity could be rounded up to 45 µg. Increasing the adult daily dose to the 80 µg or 100 µg UL is also a possibility. However, it should be noted that no products are currently registered in New Zealand for this daily dose.

24. Risk mitigating strategies

- *Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required e.g., healthcare professional education; integration of care; consumer information to be provided etc?*
- *What is the evidence that these proposed risk mitigation strategies would be effective?*
- *What post-market surveillance activities would be carried out?*
- *Is the proposed reclassification supported by professional bodies?*

This reclassification has been supported by the industry for decades and indeed, they submitted for this exact change to occur in 2016.

Conclusion

A brief summary of the purpose of the submission and any concluding remarks

Summary comment:

In adults, Vitamin D toxicity usually does not occur unless intakes exceed 50,000 IU per day. There have been a few cases of adverse reactions reported at daily intakes around 12,000 IU/day. A proposed maximum daily dose 3000 IU (ie 75 micrograms) of Vitamin D is well within the [suggested] tolerable upper limit of 10,000 IU level. This would ensure that when

New Zealanders purchase dietary supplements to maintain good health, they will be receiving a dose that has been identified internationally as the recommended daily dose of vitamin D (Grant et al., 2025; Pludowski et al., 2024). At present, we are shortchanged by regulations and the result of that is increasing vitamin D deficiency in our country.

References

Please provide references for your submission

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