

## Consultation on proposed changes to the classification of vitamin D pursuant to the Medicines Regulations 1984

This consultation asks for feedback to a proposal to increase the amount of vitamin D that is permitted in a general sale medicine. Currently, general sale medicines can contain up to 25 micrograms (1,000 IU) of vitamin D per daily dose. This consultation considers increasing this to 50 micrograms (2,000 IU) per daily dose. This proposal is informed by an independent expert opinion, based on a comprehensive review of current literature.

The outcome of this consultation may, in the future, enable supply of dietary supplements that contain higher amounts of vitamin D. This is discussed later in this consultation document. However, policy development relating to the Dietary Supplements Regulations 1985 is outside the scope of this consultation. Any change to the classification of vitamin D pursuant to the Medicines Regulations 1984 does not guarantee a change to the Dietary Supplements Regulations 1985.

Policy development for natural health products legislation, led by the Ministry of Health, is also outside the scope of this consultation. Further information on policy development in this area can be found [here](#).

Key definitions relating to this consultation are outlined in the table below.

Terminology	Definition
Medicine	<a href="#">Medicines Act 1981, section 3(1)</a>
Therapeutic Purpose	<a href="#">Medicines Act 1981, section 4</a>
Prescription Medicine	<a href="#">Medicines Act 1981, section 3(3)</a>
General Sale Medicine	<a href="#">Medicines Act 1981, section 99</a>
Dietary Supplement	<a href="#">Dietary Supplement Regulations, regulation 2A</a>

### Medicines Classification Committee

The Medicines Classification Committee (MCC) is an advisory committee established under section 8 of the Medicines Act 1981 whose terms of reference are to make recommendations to the Minister of Health (or their delegate) regarding the classification of medicines as prescription, restricted (pharmacist-only), pharmacy-only, or general sale.

### Current classification of medicines containing vitamin D

Medicines containing vitamin D are classified under the Medicines Regulations 1984 as either prescription or general sale depending on how much vitamin D they contain:

- Prescription: in medicines containing more than 25 micrograms (mcg) per daily dose
- General sale: in medicines containing 25 mcg or less per daily dose

## Recent vitamin D classification reviews

In 2016, a series of submissions were to be discussed at the [56<sup>th</sup> meeting](#) of the MCC. These submissions proposed the reclassification of several substances that are also commonly used in dietary supplements, including vitamin D. These proposals were made when the Natural Health Products Bill was progressing through parliament. However, just prior to the MCC meeting, the Bill stalled, causing a postponement of the 56<sup>th</sup> meeting. The proposed reclassifications were not progressed, following the Bill lapsing in 2017.

More recently, the classification of vitamin D was considered by the MCC at its [74<sup>th</sup> meeting](#), following a new submission proposing reclassification. Based on the information available in that submission, the MCC recommended that no change be made.

## Medicines containing vitamin D

The following medicines containing vitamin D are approved in New Zealand:

### Prescription medicines

- Fosamax Plus alendronate anhydrous 70 mg and vitamin D 140 mcg. This product is indicated for '*the treatment of osteoporosis in select patients where vitamin D supplementation is recommended.*'
- Vit D3 1.25 mg (50,000 IU). This product is indicated for '*the treatment of vitamin D deficiency in adults and the prevention of vitamin D deficiency in high-risk adults.*'

### Pharmacy-only medicines

- Elevit film-coated tablet. This product is indicated to '*supplement maternal dietary intake during pregnancy and lactation.*' This product contains vitamin D at general sale levels (25 mcg) but is classified as pharmacy-only due to the presence of other active ingredients at pharmacy-only level.

### General sale medicines

- There are currently no approved general sale medicines that contain only vitamin D.

## **Dietary supplements containing vitamin D**

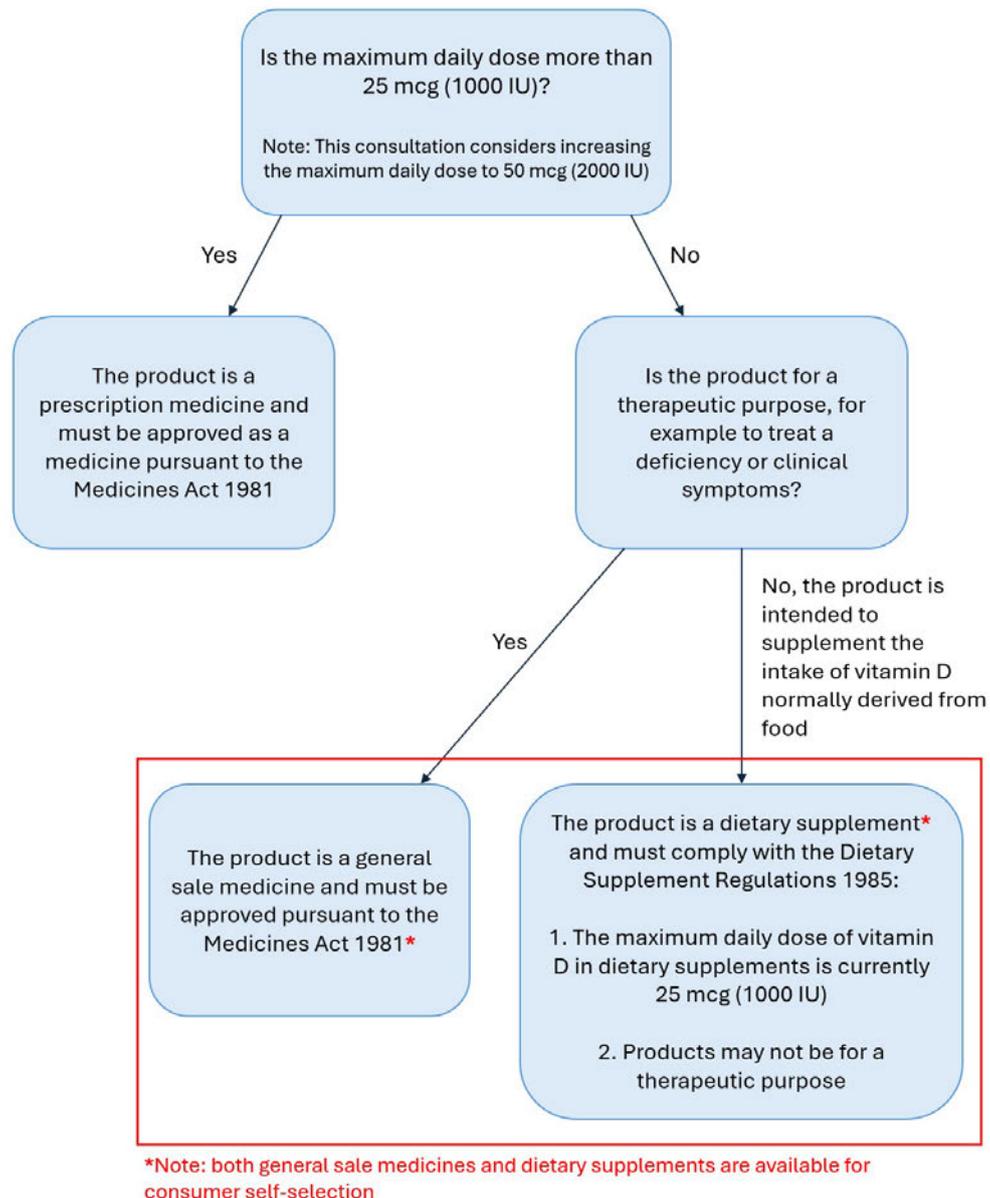
When products containing vitamin D are **not** for a therapeutic purpose, they are not medicines. When a vitamin D product is **not** a medicine, it may be marketed as a dietary supplement and be regulated by the Dietary Supplements Regulations 1985, provided it meets the definitions and requirements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

The Dietary Supplements Regulations 1985 place limits on the maximum daily dose allowed in dietary supplements. For vitamin D, this is up to 25 mcg (1000 IU). This is currently aligned with the general sale limit under the Medicines Act 1981.

As such, if a vitamin D product contains no more than 25 mcg **and** is not for a therapeutic purpose, **and** it meets the definitions and requirements of the Dietary Supplement Regulations 1985, it is a dietary supplement.

## Determining whether a Vitamin D product is a medicine or a dietary supplement

A guide to determining whether a product containing vitamin D is a medicine or a dietary supplement is provided below.



## Relationship between the Medicines Regulations 1984 and the Dietary Supplements Regulations 1985

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.

## Medicines

Pursuant to sections 3 and 4 of the Medicines Act 1981, products for a therapeutic purpose are medicines. They may, for example, be to correct a clinical deficiency or to provide vitamin D over and above normal intake levels to ensure adequate serum levels for the prevention and treatment of disease. Medicines must be approved before being sold in New Zealand.

Should the classification of vitamin D be changed (pursuant to the Medicines Regulations 1984) to increase the maximum daily dose permitted as a general sale medicine to 50 mcg, applications could be made for approval of general sale medicines with up to 50 mcg vitamin D. Information on regulatory requirements relating to medicines approval can be found [here](#).

## Dietary supplements

In contrast, dietary supplements are to supplement the diet to ensure normal and adequate serum levels of vitamin D that would be present in a healthy diet.

To enable higher doses of vitamin D permitted in dietary supplements, two regulatory changes would be needed:

1. The classification of vitamin D pursuant to the Medicines Regulations 1984 would need to be changed to increase the maximum daily dose. This is a decision made by the Minister of Health's delegate. If the maximum daily dose was increased, products containing between 25 mcg (1000 IU) and 50 mcg (2000 IU) vitamin D would remain general sale medicines unless the Dietary Supplements Regulations 1985 are amended (point 2 below).
2. The Dietary Supplements Regulations 1985 would need to be amended to allow for a higher maximum daily dose of 50 mcg (2000 IU). These regulations are promulgated under the Food Act 2014, which is administered by the Ministry of Primary Industries (MPI). If amended, products at or below 50 mcg (2000 IU) would be dietary supplements, providing that they are not for a therapeutic purpose and that they meet the definition of a dietary supplement.

A change to the classification of vitamin D pursuant to the Medicines Regulations 1984 (point 1) enables a subsequent amendment to the Dietary Supplements Regulations 1985 (point 2) to increase the maximum daily dose of vitamin D permitted in dietary supplements to 50 mcg. However, it does not guarantee an amendment to the Dietary Supplements Regulations 1985, which would follow legislative processes.

**This consultation relates only to the classification of medicines pursuant to the Medicines Regulations 1984 (point 1), not to an amendment to the Dietary Supplement Regulations 1985 (point 2).**

## **Classification decisions**

The Minister of Health, or their delegate (the Group Manager, Medsafe), is responsible for classifying medicines in New Zealand. This consultation will inform a decision to be made by the Minister of Health's delegate on the classification of vitamin D.

A key principle for determining the appropriate maximum daily dose for products that may be prescription or general sale medicines is determining 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.

## **Expert Advice**

Medsafe has commissioned independent advice from an expert in the use of vitamin, mineral, and herbal products and their use as both medicines and dietary supplements. The resulting report focuses on:

- A review of the 2016 vitamin D submission to the 56<sup>th</sup> MCC meeting
- Medical uses of vitamin D
- An assessment on vitamin D needs for a healthy diet
- The benefits of supplementation of the diet with vitamin D to ensure adequate and normal levels of vitamin D, to maintain good health
- The risks of consuming too much vitamin D
- The risks and benefits of consumers self-selecting products containing vitamin D

The expert opinion is that the maximum daily dose for general sale vitamin D medicines should be increased from 25 mcg (1000 IU) to 50 mcg (2000 IU).

## **Consultation questions**

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 (2000 IU) of vitamin D is sufficient to maintain serum levels above 50 nmol in the general adult population. Do you agree with this assessment? If not, please provide evidence in the form of peer-reviewed published literature.
2. The expert report indicates that the benefit of increasing the maximum daily dose of general sale vitamin D medicines to 50 mcg (2000 IU) outweighs any risks. Do you agree with this assessment? If not, please provide evidence in the form of peer-reviewed published literature.

3. The expert report indicates that the benefits of increasing the maximum daily dose of general sale vitamin D medicines to 75 mcg (3000 IU) or higher do not outweigh the risks associated with this change. Do you agree with this assessment? If not, please provide evidence in the form of peer-reviewed published literature.
4. The expert report does not identify significant risks associated with consumers self-selecting products containing a daily dose of 50 mcg of vitamin D. Do you agree that there are no significant risks at these doses? If not, please provide evidence in the form of peer-reviewed published literature.
5. Do you have any further comments to add regarding the classification of vitamin D?