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**Introducing Vitamin D<sub>3</sub> 1.25mg In Australia**

**BACKGROUND**

**The Problem**

Vitamin D deficiency is an emerging public health problem <sup>1</sup>.

Vitamin D is a hormone that is produced in the skin by the action of sunlight. Vitamin D is important in the maintenance of muscle and bone health and may also have broader effects on wellbeing in general.

Despite Australia sometimes being referred to as the “sun burnt” country, a significant number of Australians are deficient in Vitamin D. Indeed, it is a fallacy that Australians receive adequate Vitamin D from casual exposure to sunlight <sup>2</sup>.

Vitamin D deficiency increases the risk of major illness and adverse health outcomes especially osteoporosis, falls and fracture in the elderly. It is also associated with other conditions including, autoimmune diseases (rheumatoid arthritis, multiple sclerosis and type 1 diabetes) cardiovascular disease and some cancers <sup>1</sup>.

A disturbing proportion of the population has Vitamin D deficiency to such a degree that the bones become soft, weak and are more likely to fracture (break). This is especially evident in residential care facilities, where it has been shown from Australian studies that the majority of aged care residents (55-86%) have Vitamin D deficiency to such an extent <sup>3</sup>. In Sydney, 16% of “healthy” elderly men have Vitamin D deficiency, in Melbourne 20% in the age group 20-39 years, increasing to 53% in older age groups and in South East Queensland 23% of men and women are Vitamin D deficient <sup>4</sup>. In Tasmania there is evidence to suggest that 50% of the adult population is vitamin D deficient <sup>5</sup>.

Vitamin D deficiency is not the only cause of fractures, however, it is a significant contributory factor through making the bones weaker and the elderly more likely to fall. Direct costs associated with osteoporotic fractures and the total annual cost for Australia was estimated to be \$779,000,000 in 1992 <sup>6</sup>. More recent estimates, taking into account all types of fractures and all types of costs, both direct and indirect, have been estimated at about \$7 billion annually <sup>7,8</sup>.

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The problem of osteoporotic fractures is already large and is increasing with the ageing of the population. In 1994, there were 14,600 hip fractures in Australia. If nothing is done to reduce risks, it is estimated that in 2010 there will be 20,900 hip fractures in Australia <sup>6</sup>.

Apart from the elderly other people at high risk of Vitamin D deficiency include people with skin conditions where avoidance of sunlight is advised, those with dark skin (particularly if veiled) <sup>9</sup> and people on certain drugs i.e. anti-epileptic medications, that increase the excretion of Vitamin D.

To prevent and treat Vitamin D deficiency everyone should expose their face, hands, arms or legs to modest amounts of sunlight each day. In many cases, such as the elderly in residential care, those with dark skin and those with cultural or religious beliefs that prevent this exposure, this is not always practical.

It is alarming that Australia has the highest reported rates of non-melanoma skin cancer (NMSC) in the world. While it is necessary to attain a balance between avoiding an increase in the risk of skin cancer and achieving enough ultraviolet radiation exposure to maintain adequate Vitamin D levels, in Australia, where ultraviolet radiation levels are in the high to extreme range for most of the year, sun protective measures to reduce the incidence of skin cancer must continue as a high public health priority <sup>10</sup>.

Low dose Vitamin D is available over the counter from community pharmacies; it requires 3-5 tablets a day for 6-12 weeks to correct a Vitamin D deficiency. Higher dose formulations, that are 50 times the strength of over the counter preparations, could correct a vitamin D deficiency with one tablet a day for ten days.

High dose preparations that enable less frequent dosing are likely to be effective, cheaper and have a better compliance. Unfortunately, these preparations while available in New Zealand and other countries are not available in Australia.

From the manufacturer's point of view, there are a number of obstacles that would make the likelihood of potentially useful high dose Vitamin D preparations, in Australia, unlikely in the near future. These reasons include the unpatentable nature of Vitamin D, the unknown market potential, and high cost of registration of prescription medicines (\$200,000-\$300,000) and the low retail cost of approximately \$2 per month make the financial viability of marketing such products difficult <sup>11</sup>.

### **Safety**

- *The New Zealand Experience:*

Healthcare Manufacturing Group has manufactured and marketed the product, in a TGA approved manufacturing facility, in New Zealand since the 1960's. In the later 1990's HMG temporarily withdrew the product due to a lack of manufacturing and stability data that was not required when the product was first launched. In early 2000 the New Zealand Government asked HMG to recommence production of the product to address the health issues resulting from low Vitamin D<sub>3</sub> levels in the New Zealand community, most notably the high incidence of fractures.

Since 2000 there has been approximately 75,000 patient therapy years for Vitamin D<sub>3</sub> 1.25 mg (high dose) tablets in New Zealand. From 2000 there has only been one adverse reaction reported to the Centre of Adverse Reactions Monitoring (CARM) in New Zealand. In New Zealand vitamin D deficiency is treated by taking one tablet daily for ten days then maintained on one tablet per month.

From its initial introduction onto the New Zealand market in the 1960's there has only been two other adverse reactions reported. These adverse reactions were consistent with vitamin D intoxication. Both patients recovered without incident after the drug was withdrawn.

- Toxic effects of vitamin D are usually the result of over-supplementation, not acute ingestion which rarely results in toxicity<sup>12</sup>. Single doses of 25 mg or more have been administered without untoward effects but **prolonged** administration of 2.5 mg to 3.75 mg **daily** (60-90 times the maintenance dose of the New Zealand preparation) and 1 mg or more **daily** in children (20 times the maintenance dose for adults) is likely to give rise to toxic symptoms<sup>13</sup>. High dose 7.5 mg injections at intervals of not less than 3-6 months are generally not considered to be associated with toxicity<sup>9</sup>.

#### **Cost**

- In regards to the high dose vitamin D preparation, the drug cost of 1 to 2 years of maintenance therapy, depending on the dose, is \$12.50 to \$25 per annum.
- As this drug would be ineligible for reimbursement under the Pharmaceutical Benefits Scheme there will be no financial burden placed on the Federal Government, as it is currently not registered in Australia.

#### **Government Recognition**

The burden of osteoporotic disease in Australia is great. In recognition of this the Australian Governments Department of Health and Aging have classified osteoporosis as a national Health priority area. The Department has set up and funded an expert advisory body the National Arthritis and Musculoskeletal Advisory Group (NAMSCAG) to develop a National Action Plan to improve health related quality of life and reduce the burden of Disease and Disability for osteoporosis, osteoarthritis and Rheumatoid Arthritis. This expert committee has highlighted the need for vitamin D and calcium in all aspects of osteoporosis from controlling established chronic osteoporosis to disease prevention<sup>14</sup>.

This proposal, to introduce 1.25 mg vitamin D into Australia, complements NAMSCAG's "primary goals" and objectives.

The Department of Health and Aging has also funded a vitamin D and Calcium conference involving medical specialists in osteoporosis from all over Australia to address these issues and develop recommendations for vitamin D and calcium. These recommendations have recently been published<sup>1</sup>. The first of the recommendations highlighted the benefits of higher dose vitamin D (1.25 mg) preparations in treating vitamin D deficiency<sup>1,15</sup>.

The developed guidelines <sup>15,16</sup> were launched in Sydney on 26 April 2006 by the Federal Minister for Ageing, Hon Senator Santo Santoro, Osteoporosis Australia's media release is attached.

### **The Australian Opportunity**

The Healthcare Manufacturing Group (HMG) intend to register this product in Australia through the TGA in approximately 2 to 3 years once all the requirements of the TGA registering process have been met. HMG is currently reformulating their vitamin D formulation, to remove all animal products such as gelatin, a commonly used pharmaceutical ingredient. Ingredients such as gelatin can not be ingested by some members of the community on religious grounds. This section of the community is also commonly vitamin D deficient. Reformulating, any pharmaceutical is a time consuming process, with the stability testing for the determination of shelf life takes a minimum of 12 months with accelerated testing to acquire a normal shelf-life of 2 years. Adding the time taken to reformulate and undertake the process of registration takes 2 to 3 years.

However, HMG in New Zealand have been approached by the Australian and New Zealand Bone Mineral Society and Osteoporosis Australia to make Vitamin D<sub>3</sub> 1.25 mg available in Australia, in the interim to its registration, to address the deleterious broad health consequences associated with low vitamin D<sub>3</sub> levels in sections of the community.

To make this product available in the interim would require a regulatory exemption under the Therapeutic Goods Regulations 1990. Section 18 of the Therapeutic Goods Act 1990, allows Regulations that can exempt specified therapeutic goods or a specific class of therapeutic goods.

As a result HMG request the temporary approval or exemption, via a regulatory change, to supply the Vitamin D<sub>3</sub> 1.25 mg tablets into Australia until the product is registered or another registered product becomes available. This is in order to address what is recognized as a National health priority.

### **Initial Nation Wide Support**

- Professor Geoff Nicholson - Barwon Health, Victoria
- Professor Peter Ebeling – Chair Medicine, Western Hospital, University of Melbourne
- A/Prof Rebecca Mason
- Graeme Jones – Menzies Research Institute, Hobart
- Professor Ian Reid – Head Dept Medicine, University of Auckland, New Zealand
- Osteoporosis Australia



John Barker

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## Minister launches new Guides addressing health risks posed by calcium and vitamin D deficiency

Australians are being urged to review their intake of calcium and vitamin D to avoid the onset of brittle bones and fractures, according to new Guides launched in Sydney today by the Federal Minister for Ageing, The Hon. Senator Santo Santoro.

The Calcium, Vitamin D and Osteoporosis Guides<sup>1,2</sup> recommend increasing calcium intake and exposure to limited sunlight in order to reduce the risk of developing osteoporosis.

"More than half of all Australian adults do not get their recommended daily intake of calcium for healthy bones, even though it is easily available from foods," said Senator Santoro.

"And despite living in a sun-drenched country, many of us do not receive adequate vitamin D due to our limited exposure to sunlight.

"These Guides will help address the situation, and improve the health and wellbeing of older Australians."

The Guides feature revised existing Nutrient Reference Values or NRV\* for calcium and vitamin D, with a higher calcium intake recommended for all Australians, especially 5 to 9 year olds, postmenopausal women and adults over 70 years of age<sup>1</sup>.

The Guides also recommend periods of limited sunlight exposure outside peak ultraviolet (UV) activity to achieve sufficient vitamin D production in the body (although sun-baking is not recommended).

People at risk of vitamin D deficiency include:

- the elderly, especially those who are house-bound or in residential care
- people with dark skin, particularly those who wear veils or cover most of their body
- people with chronic illnesses, especially those with skin conditions who are advised to avoid sunlight
- pregnant and breastfeeding women with vitamin D deficiency risk factors, and their children<sup>1,2</sup>.

"Calcium and vitamin D are essential for building and maintaining strong bones and protecting against osteoporosis, falls and fractures," said Senator Santoro.

"The Guides recommend that Australians urgently review their calcium and vitamin D levels."

The recommendations include:

- Australian men and women achieve an NRV\* of 1000mg of calcium each day (previous NRV was 1000mg for women and 800mg for men)
- All Australians over 70 years of age increase their calcium NRV to 1300mg per day
- The average (fair skinned) Australian adult achieves an NRV of 10-15 micrograms (400-600IU) of vitamin D per day, which equates to 6-8 minutes of sunlight in Sydney and Melbourne in summer, up to 28 minutes in Sydney in winter and up to 52 minutes in Melbourne during winter
- Darker skinned Australians achieve a daily NRV of vitamin D of at least three times that of fair skinned Australians<sup>1,2</sup>.

According to Professor Peter Ebeling, Chair of the Department of Medicine and Head of Endocrinology at the University of Melbourne, Western Hospital, Melbourne, calcium intake and vitamin D capacity tend to decrease as we age and deficiencies are a real risk, particularly for the frail and home-bound.

"Vitamin D deficiency is an emerging public health problem in Australia.

"While limited exposure to the sun on most days is often enough to maintain adequate vitamin D levels among fair skinned people, longer exposure is required in more pigmented individuals and in those belonging to the 'at risk' groups, such as the elderly," said Professor Ebeling.

"Adequate vitamin D intake is particularly important for pregnant women with deficiency risk factors due to the long-term effects of foetal deficiency, and also for their breastfed children.

"Maternal vitamin D deficiency leads to low bone mass and an increased risk of osteoporosis in their offspring," Professor Ebeling said. more#

"At Sunshine Hospital in Victoria for instance, we are witnessing the paradoxical re-emergence of rickets.

"Many other Australians who, for religious or cultural reasons are required to cover up their bodies, are also at significant risk of vitamin D deficiency," said Professor Ebeling.

"Exposure to sunlight should be limited and timed for the morning or afternoon, outside peak radiation times such as midday when the risk of developing skin cancer is high."

The Guides stipulate that older people should be exposed to sunlight 5-6 times a week, while darker skinned individuals need longer exposure times, 3-4 times greater than those with fairer skin.

Exposure times are dependent upon the time of year and location in Australia. The body's levels of vitamin D are lower in winter than in summer and depending on where you live, it would take not much longer to achieve NRV in Cairns in winter, but almost five times longer in Melbourne.

**"While it's necessary to maintain adequate vitamin D levels, sun protective measures to reduce the incidence of skin cancer must continue to be a public health priority,"** said Professor Ebeling.

"It needs to be a balanced approach."

According to Osteoporosis Australia CEO, Ms Judy Stenmark the balance between sun exposure and sun risk protection is also of concern for children.

"Vitamin D deficiency can cause rickets in children, resulting in muscle weakness and bone deformities.

"The national 'no hat, no play' policy in school playgrounds should be reassessed in Canberra and Tasmania during winter for instance, because children aren't being exposed to sufficient sunlight," said Ms Stenmark.

"While vitamin D is found in small quantities in a few foods such as fatty fish, liver, margarine and eggs, for most Australians, especially children, adequate vitamin D is unlikely to be achieved through diet alone.

"Although some milk is fortified with vitamin D, the majority is not," Ms Stenmark said.

**Current statistics indicate 1 in 2 women and 1 in 3 Australian men over 60 years will suffer an osteoporotic fracture.**

Vitamin D helps to increase the absorption of calcium and phosphorus from the small intestine; to regulate the amount of calcium in the blood, and to strengthen the skeleton<sup>2</sup>.

Calcium is a building block deposited as crystal to maintain healthy bone strength. Low dietary calcium intake results in leeching of stored bone calcium for use in other bodily functions<sup>2</sup>.

"The only way to check your levels of calcium and vitamin D is to have your GP do a blood test," said Ms Stenmark.

"People who think they may be at risk of calcium and vitamin D deficiency should see their doctor."

The Calcium, Vitamin D and Osteoporosis Guides were developed by a Scientific Committee comprising leading medical experts from Australia and New Zealand, Osteoporosis Australia, key stakeholders and consumer representatives. The Guides were based on Recommendations from the Vitamin D and Calcium Forum held in Melbourne during 2005 with support from the Australian Government. NHMRC Guiding Principles were followed in developing the Recommendations and Guides.

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**\* NRV – nutrient reference value, previously known as recommended dietary intake or RDI**

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**For more information about the Guides or to organise an interview with the Hon. Senator Santoro, Professor Peter Ebeling or Judy Stenmark, please contact Kirsten Bruce or Ruby Archis from viva! communications on m. 0401 717 566 / 0413 834 906.**

**Reference**

1. *Calcium, Vitamin D and Osteoporosis – A Guide for Consumers 2006*. Written by OA in partnership with the Australian and New Zealand Bone and Mineral Society (ANZBMS). Publication funded by the Australian Government.
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15 May 2006

Hon Alex Somlay MP  
Chair  
Standing Committee on Health and Ageing  
House of Representatives  
Parliament House  
**Canberra ACT 2600**

Dear Mr Somlay

Good day. I enclose a proposal advocating the introduction of high dose Vitamin D<sub>3</sub> into Australia.

I am representing the Healthcare Manufacturing Group (HMG) a New Zealand based pharmaceutical company with strong Australian links.

The proposal addresses what is recognized as a National health priority and it has considerable support from leading clinical practitioners and relevant health service organisations.

The proposal highlights the very significant incidence and need to address Vitamin D deficiency in Australia. Unfortunately the process to enable introduction into Australia is quite difficult.

HMG and its supporters are seeking temporary approval or exemption by a regulatory amendment under S18 of the Therapeutic Goods Act 1990, to supply Vitamin D<sub>3</sub>, 1.25mg tablets in this country.

HMG intends to continue to undertake the full qualifying process to meet TGA requirements while temporary approval is in place.

Importantly the product has been available in New Zealand since the 1960's and has a very positive 75,000 patient year history to support introduction in Australia.

Representatives of my clients, supporters and I would welcome an opportunity to present to the Committee and are available to discuss the matter further with you.

I look forward to your consideration and response.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'John Barker', with a stylized flourish at the end.

John Barker