21st September 2015

SACN Secretariat
By email

Paul Tredwell
COO – Internis Pharmaceuticals
Thornton and Ross Limited
Linthwaite Laboratories
Manchester Road
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH

Dear Sir or Madam,

**Re: Draft vitamin D and health report**

My name is Paul Tredwell, I am Chief Operating Officer of Internis Pharmaceuticals and I am contacting the SACN Secretariat in order to provide the company's perspective on the *Draft vitamin D and health report* published 22nd July this year.

I'd first like to congratulate the Secretariat on producing such an extensive and well-researched report. We're acutely aware of the many difficulties inherent in defining clear and universal parameters where vitamin D is concerned. Internis Pharmaceuticals supports the Secretariat's recommendation of a reference nutrient intake of 10mcg / 400iu per day for people over 1 year old. We would also like to submit the following observations for your consideration in drafting the final report:

A. There is a consensus among influential bodies (The British Geriatric Society, American Geriatric Society and National Osteoporosis Society) that 800iu (equivalent to 20mcg) vitamin D in a daily dose is necessary for most ***at risk groups***.[1,2] Internis assumes that the SACN recommendation of a 400iu (10mcg) daily dose is intended for members of the general public who fall outside of the at risk groups identified by the DoH[3]?

B. On pages 100-101 of the draft report, the Committee on Toxicity comments on Toxic Upper Limits (TULs). Internis is aware of instances of British children who have been (possibly permanently) damaged by ultra-high doses of vitamin D. Anyone could purchase a product which claims to contain 30,000iu (equivalent to 750mcg) vitamin D, seventy five times the recommended maximum paediatric dose and fifteen times the European Food Safety Authority upper safe limit for children between 1 and 10 years old. Given the dose variation which characterises this product category and has been demonstrated on numerous occassions[4,5,6] the actual dose could be significantly higher.

C. To date all calcium / vitamin D combined therapies have included 800iu (equivalent to 20mcg) vitamin D in each daily dose.

Internis recommends that:

1. The Secretariat makes a clear distinction between the 400iu / 10mcg per day reference nutrient intake recommended for the prevention of deficiency in the ***general population*** and the existing, widely accepted[1, 2] recommendations for the prevention of deficiency in most ***at-risk groups***, which is 800iu / 20mcg. It is our strongly held view that this can be best achieved through the use of an MHRA licensed product in every case and the use of an MHRA licensed ***prescription*** product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).

2. Secondly, that the Secretariat recommends vitamin D supplementation doses exceeding 400iu / 10mcg are provided only on prescription. This is particularly important as a public health and safety issue because of the current regulatory inconsistency in, on the one hand:
    - The regulator (MHRA) demanding a fully supported package of data to demonstrate adequate quality, safety and efficacy for a licensed product,

    At the same time as;

    - Allowing the distribution and supply of highly variable, potentially dangerous, unregulated products.

3. Vitamin D supplementation should be available in a ***'mono'*** formulation, rather than being combined with a variety of other vitamins. This will ensure that the most appropriate dose of vitamin D (and other supplements) can be delivered in every case. Mono formulations are vital where dose titration is required to establish the most effective dose for an individual patient.

Internis would be delighted to meet directly with representatives of the SACN Secretariat to clarify any of the points in this letter or to provide supplementary evidence to substantiate our recommendations.

Yours sincerely

Paul Tredwell

COO, Internis Pharmaceuticals Ltd

**References:**


1. American Geriatric Society / British Geriatric Society Clinical Practice Guidelines for Prevention of Falls in Older Persons http://www.bgs.org.uk/index.php?option=com_content&view=article&id=320:bgsagsfalls2010&catid=47:fallsandbones&Itemid=307
2. National Osteoporosis Society (NOS) Guidelines published April 2013, Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management http://www.nos.org.uk/document.doc?id=1352
3. Department of Health. NHS Choices. Vitamins and Minerals. Vitamin D. http://www.nhs.uk/Conditions/vitamins-minerals/Pages/Vitamin-D.aspx
4. Company-led drug recall: Dekristol/Dektristol Capsules - Jumbogate Ltd. (Quvera livery) - CLDA(12)A/10 http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/DrugAlerts/Company-ledrecalls/CON172253
5. Garg S, et al. Evaluation of vitamin D medicines and dietary supplements and the physicochemical analysis of selected formulations. The Journal of Nutrition, Health & Aging. 2013; 17(2), 158–61. doi:10.1007/s12603-012-0090-4Leblanc ES, Perrin N, Johnson JD, Ballatore A, Hillier T. Over-the-Counter and Compounded Vitamin D: Is Potency What We Expect? JAMA Intern Med. 2013 Apr;173(7):585–6.
6. Khadgawat R, Ramot R, Chacko KM, Marwaha RK. Disparity in cholecalciferol content of commercial preparations available in India. Indian J Endocrinol Metab [Internet]. 2013 Nov [cited 2014 Jan 14];17(6):1100–3. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3872693&tool=pmcentrez&rendertype=abstract