Professor Hilary Powers
Chair of SACN Vitamin D Working Group
Scientific Advisory Committee on Nutrition
Public Health England
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10th September 2015

Dear Professor Powers,

Scientific consultation on the draft Vitamin D and Health report

The Council for Responsible Nutrition UK (CRN UK) is the UK trade association representing the leading manufacturers and suppliers of food supplements such as vitamins, minerals, botanicals, fish oils and other substances. We are pleased to have the opportunity to respond to the SACN consultation on the draft Vitamin D and Health report.

Our comments are provided in the attached Annex I and cover the following points:

a. *Risk assessments of vitamin D status of the UK population*
Quantitative information on dietary intakes and nutritional status should be highlighted in the Executive Summary, for the reasons detailed in Annex I.

b. *Vitamin D requirements during pregnancy and lactation*
The SACN should reconsider the appropriateness of its recommendation for the vitamin D RNI for pregnant and lactating women, for the reasons detailed in Annex I.

c. *Vitamin D recommendation for infants, children and adolescents*
The recommended level of vitamin D should be reconsidered for all ages from infants to adolescents aged up to 18 years, for the reasons detailed in Annex I.

d. *Older and institutionalised people*
The recommendations in the Executive Summary do not address the issues raised by the scientific evidence and specific at-risk groups, as highlighted in Annex I.

e. *Photobiology*
The Executive Summary provides little direction regarding effective strategies. Points that could assist risk managers are given in Annex I.

f. *Assay methods*
Initiatives to progress efforts to overcome the stated methodological limitations would be welcomed.

g. *Potential adverse effects of high exposure to vitamin D*
The substantial differences between levels of vitamin D in different food supplements, and the benefits to public health, are not appropriately covered. Annex I provides more detail on this issue.

h. *Nutrient-drug interactions*
The report fails to include vitamin D recommendations for individuals taking drugs that can induce vitamin D deficiency, as explained in Annex I.

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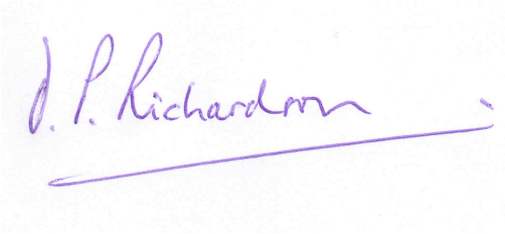
i. *SACN recommendation for considerations to be given to strategies for the UK population to achieve the RNIs*
The report does little to point risk managers toward effective strategies to improve vitamin D intake and nutritional status in the UK, as outlined in Annex I.

We trust that consideration will be given to our comments in the attached Annex I before the SACN finalise the report on vitamin D and health.

Should you require any further information on the above, please do not hesitate to contact us.

Yours sincerely,



Professor David Richardson
Scientific Advisor to CRN UK

ANNEX I

Observations and comments on the UK Scientific Advisory Committee on Nutrition (SACN) consultation on its draft report on Vitamin D and Health

a. Risk assessments of vitamin D status of the UK population

The terms of reference of the SACN report (Paragraph 8) includes a statement that to make the recommendations required a risk assessment of the vitamin D status of the UK population and the consideration of biochemical indicators of vitamin D status.

The Executive Summary sets out comprehensively the background to the report, the purpose and scope of the current review, biology and metabolism, photobiology, vitamin D and health outcomes and the selection of health outcomes to be used as the basis for setting Dietary Reference Values (DRVs) for vitamin D. However, the section on vitamin D intakes and serum 25 (OH) D concentrations as measures of nutritional status in the UK population merely describes the sources of the data (e.g. National Diet and Nutrition Survey (NDNS), the Low Income Diet and Nutrition Survey (LIDNS)) and refers the reader to Chapters 8 and 10 and Appendix 2 of the 159 page report. Whereas useful qualitative and quantitative information is given in the Executive Summary for topics other than dietary intakes and biochemical indicators, there is no factual information about the substantial proportions of the population (6–53% of some population groups quoted in paragraph 707 of the full report) with serum levels of 25 (OH) D < 25 nmol/L in the summer. The full report on nutritional status includes data showing, for example, that the serum 25 (OH) D concentrations during pregnancy < 25 nmol/L are 29% in summer and 49% in winter. In Aberdeen, the percentage of pregnant women with levels below 25 nmol/L was 25% in summer, 43% in spring, 60% in autumn and 76% in winter. In paragraph 663, the levels below 25 nmol/L are quoted as 80–72.7%. (There is probably a typographical error in the numbers.)

As paragraph 675 states, the summer synthesis of vitamin D in the skin is clearly not occurring for a great many individuals in the UK. Whereas the previous recommendations by the Committee on Medical Aspects (COMA) assumed that enough vitamin D is synthesised in the skin, the draft SACN report does address this issue. However, the data on dietary intakes (paragraphs 624–629 in the full draft SACN report) demonstrates the appallingly low intakes in breastfed infants, non-breastfed infants, children and adolescents. Similarly, the intakes of adults (19–64 years), adults 65 years and over and adults in institutions are substantially below the RNI.

The failure to highlight any quantitative information on dietary intakes and nutritional status in the Executive Summary should be addressed by SACN. The need to rectify this omission is necessary in order to fulfil the terms of reference of the report to undertake a risk assessment of the vitamin D status of the UK population. Moreover, many readers of the draft report may miss the vital information contained in the lengthy report but not included in the Executive Summary.

b. Vitamin D requirements during pregnancy and lactation

Paragraph 709 states that data are not available to suggest the requirement for an additional increment. Paragraph 713 states that the SACN has assumed that maternal

vitamin D supplementation during pregnancy will provide infants with enough for the period of exclusive breastfeeding. The needs of pregnant and lactating mothers are not mentioned in the recommendations in the Executive Summary. Paragraph 624 states that, for breastfed infants, intakes of vitamin D from all sources (excluding breast milk) were below the RNI at 41% (4–6 months), 52% (7–9 months), 54% (10–11 months) and 37% (12–18 months). For non-breastfed infants aged 12–18 months, the mean intakes were 55% RNI from all sources.

The Executive Summary (paragraph ES47 states that the RNI of 10 µg/day vitamin D proposed for the general population includes pregnant and lactating women. The key scientific question that the SACN report needs to consider is how much vitamin D does the mother need so as to ensure an adequate amount in her milk? In most nursing mothers, human milk contains very little vitamin D, and the NDNS data demonstrate that, during the first year of life and infancy, large numbers of breastfed infants are not meeting the requirements. It is a paradoxical situation in which, on the one hand, health authorities stress that human milk is the best source of nourishment for babies, but on the other hand, they seem to ignore the fact that human milk does not contain the vitamin D babies need.

Bearing in mind the limited exposure to sunlight and the small amounts of vitamin D in breast milk, the SACN needs to consider the amounts of vitamin D that would be necessary to ensure an adequate amount in a mother's breast milk. Ensuring an adequate vitamin D input to the mother during pregnancy and lactation could be the best way to meet the needs of both mother and child. If the recommendation is 10µg/day for nursing mothers and 8.5 to 10 µg/day for the baby, there appears to be a disconnect between the physiological facts and the proposed recommendations. The SACN, therefore, is urged to reconsider the appropriateness of its recommendation for the vitamin D RNI for pregnant and lactating women.

c. Vitamin D recommendation for infants, children and adolescents

The pragmatic use of a serum concentration of 25 (OH) D as the population protective concentration rather than an indicator of deficiency is understandable, given the ongoing scientific debate about the classification of vitamin D status by 25 (OH) D concentration. The NDNS data highlight the fact that vitamin D deficiency occurs commonly among UK (and European) infants, children and adolescents, especially in certain at-risk groups, which include breastfed infants, not adhering to the recommendation for vitamin D supplementation, those with dark skin, those without adequate sun exposure and obese children.

The European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN Consensus Statement "Vitamin D in the healthy European Paediatric Population" by Braegger et al., JPGN 56 (6) June 2013: 692–701) recommends a daily oral supplement of 10 µg/day (400 IU) for all infants during the first year of life. This measure will ensure prevention of vitamin D deficiency-associated diseases for infants.

Paragraph 86 of the SACN report comments on the physiological requirements of infants only with respect to healthy skeletal development and not other potential benefits, and paragraph 712 refers to the SACN's use of the pragmatic term—"a safe intake" in a range of 8.5 to 10 µg/day for infants aged 0—11 months. This amount is quoted as accommodating current practice. A safe intake of 10 µg/day is recommended for 1—4 year olds. The Executive Summary (ES48) states that safe intakes are based on a precautionary approach

and reflect the insecurities of the data. The SACN proposal for a range of safe intakes from 8.5 to 10 µg/day cannot be justified on the basis of the scientific evidence, taking into account the factors that could affect endogenous vitamin D synthesis, storage and utilisation. The SACN proposal for a range of values from 8.5 to 10 µg/day is likely to create confusion among doctors, healthcare professionals and parents alike. From a practical point of view, it is difficult to give a baby a drop of a supplement that contains 8.5 µg.

The SACN is urged to reconsider the recommended level of vitamin D for infants during the first year of life as well as for infants older than 12 months and all children and adolescents aged 2–18 years.

d. Older and institutionalised people

The intake data for adults aged 65 years and over and for institutionalised adults show mean vitamin D intakes of 51% and 34% RNI, respectively. These observations are inadequately communicated in the Executive Summary and the report fails to draw sufficient attention to the subset of frail, older people with the highest likelihood of deficiency. The final recommendation in the Executive Summary, p. ES61, is that consideration should be given to strategies for the UK population to achieve the RNIs and safe intakes for the particular age groups. This recommendation is too vague and really does not address the issues raised by the scientific evidence and specific at-risk groups. The SACN needs to highlight the subsets of the UK population at real risk of deficiency, for example, to consider a focus on institutional care and pregnant and nursing mothers.

In view of limited resources and rising costs, the evidence base could inform better, effective strategies, including selective testing of at-risk groups (in the winter), the benefits of vitamin D with respect to reducing risk of falling and fracture, the relative contribution to vitamin D intake of certain foods and food supplements and from cutaneous synthesis. The scientific points that could inform strategies for vitamin D nutrition include the fact that the appearance of vitamin D in plasma is short lived, since it is taken up by adipose tissue and other tissues or metabolised in the liver, and the plasma half-life of the parent vitamin D is about 4–6 hours (paragraph 38); the half-life of 25 (OH) D is 2–3 weeks and the active metabolite 1,25 (OH)2 D is about 4–6 hours; mobilisation of vitamin D stores from adipose tissue; effects of ageing on dermal synthesis (paragraphs 118–121).

The SACN is requested to consider a sufficient amount of daily vitamin D to ensure stable circulating concentrations, and how the amounts of vitamin D can be affected by the short circulating half-life of this essential nutrient. For optimal benefits of vitamin D supplementation, enough vitamin D should be provided on a daily basis to ensure that stable circulating concentrations are maintained over time. The SACN report needs to highlight that effective strategies must take into account the need to sustain constant circulating vitamin D concentrations by daily supplements and/or chronic UVB exposure (Hollis & Wagner in J Clin Endocrinol Metab ((2013) 98 (12): 4619–4628). For elderly people, the SACN report does not adequately address the co-supplementation of vitamin D and calcium for elderly institutionalised individuals and the use of targeted supplementation to reduce risk of fracture.

e. Photobiology

Although the Executive Summary provides useful background information, there is little

direction regarding effective strategies. Points that could be highlighted for risk managers to re-evaluate sun protection strategies versus vitamin D status include the fact that vitamin D production may be completely abolished when the amount of sunscreen and sun protection factor advised by WHO is used, that dietary sources of vitamin D are scarce, and that the determination of the average percentage of vitamin D production from skin compared with vitamin D provided in food and food supplements is still an open question. As previously stated, the only known way to sustain constant circulating vitamin D is by daily supplementation and/or chronic exposure to UVB radiation/sunlight.

f. Assay methods

The SACN report affirms the use of 25 (OH) D as the best marker of vitamin D status and acknowledges that there is considerable variability in results between the current assay methods. This quantification of serum 25 (OH) D is included in the Executive Summary (ES12). Initiatives to progress efforts to overcome some of these methodological limitations are welcomed.

g. Potential adverse effects of high exposure to vitamin D

The formation of vitamin D in the skin slows once dietary vitamin D intakes are sufficient and blood levels of the activated forms are high. Hence, excess exposure to sunlight does not lead to vitamin D toxicity. This point could be useful to risk managers when assessing the risk and benefits of different sources of vitamin D. Dietary vitamin D can produce toxic effects when consumed in very large quantities. In most adults, a daily intake in excess of 1.25 mg is needed to produce toxicity. The US Institute of Medicine (2011) and EFSA (2012) established ULs of 100 µg/day of vitamin D for adults from all sources and the UK Expert Vitamin and Mineral Group set a guidance level for supplemental intake of 25 µg/day.

The traditional conservatism of vitamin D recommendations are being corrected somewhat in the SACN report based on evidence-based assessments by recognised authoritative scientific bodies around the world. These assessments indicate that larger amounts are now considered safe. In paragraph 77 of the SACN report, it is stated, “High doses of oral vitamin D supplements have, however, been shown to have toxic effects (Vieth, 2006)”. There is no mention of the level of vitamin D in the food supplements in question, whereas amounts used in food fortification and in other foods are included. In paragraph 309, the report refers to a single RCT, which increased the risk of fracture with a single high annual dose of 12,500 µg; paragraph 342 refers to increased risk of falls. The quantified levels of vitamin D in food supplements are mentioned in paragraph 563, but there is no mention by SACN of the huge difference between the levels found in food supplements and the amount to cause adverse effects.

The impression, therefore, about levels of vitamin D in food supplements given in the report does not reflect the substantial difference between amounts in food supplements and the benefits to public health. If strategies are to be considered to achieve the proposed RNIs and public health benefits, risk managers need to be reassured of the safety of food supplements. Currently, the SACN report emphasises the risks and does not provide either assurances of the safety of levels used in food supplements or public health benefits for the general population and at-risk groups.

h. Nutrient - drug interactions

The SACN report fails to include vitamin D recommendations for individuals taking drugs that can induce vitamin D deficiency. Many drugs can interfere with vitamin D metabolism, e.g. antiepileptic drug therapy and osteomalacia (anticonvulsant osteomalacia). Corticoids, tuberculostatic and antiretroviral drugs can also induce vitamin D deficiency. Drug-induced interactions may manifest as hyperparathyroidism and bone mineralisation disorders.

SACN may wish to consider additional scientific evaluation of drug/nutrient interactions, particularly in the elderly.

i. SACN recommendation for considerations to be given to strategies for the UK population to achieve the RNIs.

The SACN report provides a plethora of scientific data and information but does little to point the risk managers towards effective strategies to improve vitamin D intake and nutritional status. Indoor lifestyles encouraged by television, computers and other electronic entertainment, as well as the use of sunscreens have significantly reduced the synthesis of vitamin D in skin. The conflict between advice on prevention of skin cancer and on the health benefits of sunlight is still discouraging people from sun exposure. The SACN report should emphasise that intermittent sun exposure and sunburn increase risk of melanoma whereas high continuous patterns of sun exposure can be protective. The evidence from the NDNS demonstrates that large numbers of the population have suboptimal levels of vitamin D (25 (OH) D) even in summer. The evidence that limited exposure to the sunlight is not sufficient needs to be communicated to the public more effectively, based on the scientific evidence. The case for the use of vitamin D supplements at higher levels of intake than 10 µg/day, at least in the winter, in addition to careful sunbathing in summer, should form the basis of public health advice, especially for pregnant and nursing mothers and their babies. Fatty fish and fish oil supplements containing vitamin D can provide the vitamin D to achieve optimal levels of 25 (OH) D, in both summer and winter.

Advice to pregnant and lactating mothers for themselves and for their babies needs to be evidence informed, logical and coherent. The SACN report goes some way towards a complete reassessment of the vitamin D requirements of the UK population. Special attention should be given to careful sun exposure, the greater use of food supplements, food fortification and by provision of new vitamin D-containing products. However, this may prove difficult to achieve if the additives required for such products for infants and young children are not permitted in the proposed new category for this target population under the additives Regulation 1333/2008. This issue is under discussion at Commission level, and the current proposals by the Commission could lead to the majority, if not all, of the vitamin D-containing food supplement products produced for infants and young children being removed from the UK market.

The cost of improving vitamin D levels in the UK population is small compared to the likely gains to public health and the public purse.