John Dalli
Member of the European Commission

Brussels, 13. 04. 2011
CAB D (2011) Ares

Dear Mr Chichester,

Thank you for your letter dated 15 March 2011 including the letters from your constituents regarding Directive 2002/46/EC on food supplements and Directive 2004/24/EC on traditional herbal medicinal products.

As regards medicinal products, I would like to stress that it is an underlying principle of the European Union pharmaceutical legislation that patients should have access to the medicinal products of their choice, provided that all necessary measures are taken to ensure the quality, safety and efficacy of the products.

Directive 2001/83/EC[1] provides that no medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities. Accordingly, herbal products falling under the definition of a medicinal product have to be authorised in accordance with the above mentioned rules until the adoption of Directive 2004/24/EC[2].

Directive 2004/24/EC amends Directive 2001/83/EC and provides for a simplified registration procedure introduced to facilitate the placing on the market of traditional herbal medicinal products for all companies, including small and medium-sized enterprises (SMEs). Directive 2004/24/EC allows the registration of traditional herbal medicinal products, including Chinese or Indian ayurveda herbal medicinal products or herbal medicinal products from any other tradition, without requiring particulars and documents on tests and trials on safety and efficacy, which the applicant is obliged to provide under the marketing authorisation procedure of Directive 2001/83/EC. Instead the applicant has to provide sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the European Union.

As a consequence, the simplified procedure does not reduce access to Chinese or Indian ayurveda medicinal products or of products of companies with reduced financial capacity; the adoption of the simplified procedure facilitates the possibility to place specific traditional herbal medicinal products on the European market and does not introduce new requirements more burdensome than the ones following from the marketing authorisation procedures. On the contrary, the aim of these rules is to safeguard public health and at the same time facilitate the free circulation of traditional herbal medicinal products within the European market.

[1] JO L 311, 28.11.2001, p. 67
[2] JO L 136, 30.4.2004, p. 85.

European Commission, B-1049 Brussels - TELEPHONE: +32 2 298 65 13 - FAX: +32 2 298 84 94 - E-MAIL: john.dalli@ec.europa.eu

In addition, I would like to inform you that the Commission services have recently published a Q&A document regarding the end of the transitional period of the Herbal Directive that your constituent may find useful. Please find below the link to the Q&A document:

http://ec.europa.eu/dgs/health_consumer/docs/traditional_herbal_medicinal_products_en.pdf

As regards food supplements, Directive 2002/46/EC on food supplements[3] harmonises the provisions concerning the composition of these products only with respect to vitamins and minerals. It foresees the setting of maximum amounts of vitamins and minerals present in food supplements. They would apply only to food supplements which are classified as food under the European legislation. There is no link between the setting of such maximum amounts and the application of legislation on medicinal products, including the provisions of the Traditional Herbal Medicinal Products Directive.

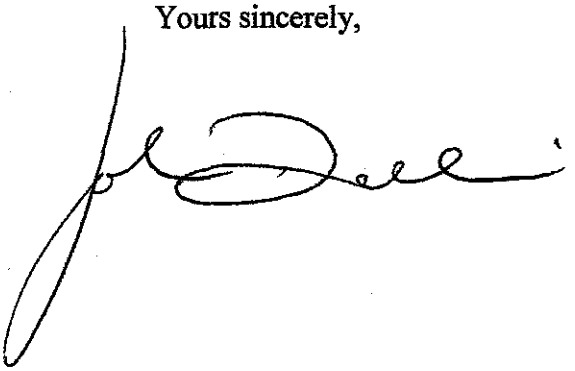
Vitamins and minerals are essential nutrients but in some cases excessive intakes can lead to adverse health effects. The maximum amounts are foreseen by Article 5 of the Directive and will be established on a safety basis taking into account scientific assessment carried out by the European Food Safety Authority[4] and by other recognized scientific assessment bodies.

The work on setting maximum amounts is ongoing; however no proposal has yet been presented. The Commission has consulted extensively with Member States and interested stakeholders on the issue. All the available data on the potential effects on economic operators and consumers of the setting of maximum amounts of vitamins and minerals in foods, including food supplements will be taken into account. Every effort will be made to ensure that the maximum amounts set will take into account the concerns expressed by all interested parties. Pending the setting of maximum amounts of vitamins and minerals at the EU level, Member States are allowed to maintain or set such rules at national level, in accordance with the rules of the Treaty on the Functioning of the European Union.

In conclusion, Directive 2002/46/EC on food supplements will not result in reduction of consumers' choice but will rather ensure that food supplements placed on the market are safe and thus will allow consumers to choose from a wide range of safe products.

I trust that this information will alleviate your constituent's concern.

Yours sincerely,



Mr Giles Chichester, MEP
European Parliament,
Email: giles.chichester@europarl.europa.eu

[3] OJ L 183, 12.7.2002, p. 51–57

[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178633962601.htm

c.c
Mr. Alan Santillo
Email: alan@santillo.me.uk

Ms. Tanya Phillips
Email: tatianna-rosanna@hotmqail.com

Mr Peter Jennings
Email: paejennings@onetel.com

Ms Lucy Latchmore
Email: lucylatchmore@hotmail.com

Mr Michel E.Ash
Email: michaelash@nutri-linkltd.co.uk

Ms Sue Try
10 Marcus Road
Exmouth, Devon, EX8 4DB

Dr W W Richardson
Stratford Sub Castle
Salisbury, SPI 3YP

Ms Celia Bain
62A Avonfield Avenue
Bradford on Avon, Wilts, BA15 1JF