OPEN LETTER TO COMMISSIONER DALLI

Commissioner John Dalli
European Commission
Directorate-General Health & Consumers
B-1049 Brussels
Belgium

24th June 2011

Dear Commissioner

RE: NON-EUROPEAN TRADITIONAL HERBAL SECTOR IN CRISIS

I was one of four experts attending a forum in the European Parliament on 21st June 2011 considering challenges posed by the Traditional Herbal Medicinal Products Directive (THMPD) (Directive 2004/24/EC). These challenges are particularly acute for genuine, long-standing traditional systems of medicine, and especially those that are of non-European origin. The forum was hosted by Michèle Rivasi, Bart Staes, Carl Schlyter, Satu Hassi and Heide Rühle of the Greens/ EFA group.

We have reported on the event on our website and the organisers ensured the event was video recorded, streamed live and archived.

As you will be able to see from the record of proceedings, the forum was very usefully organised, primarily in Question & Answer format. Questions were asked by a wide range of interests, ranging from non-governmental organisations (NGOs), such as ourselves, to herbalists, practitioners associations, suppliers, scientists and MEPs.

Lack of clarity in European Commission answers

What became astoundingly obvious to the concerned parties present at the forum was the inadequacy of the answers provided by the European Commission representatives, Dr Andrzej Rys, Ms Figuerola Santos and Mr Francesco Carlucci. We are well aware that these representatives were "just doing their jobs". But when it came to considering the implications of the Directive and its disproportionate impact on long-standing traditions of holistic healthcare, such as those embodied by southern and eastern Asian traditions, their answers were either non-existent or meagre. Even more worrying was the lack of any apparent interest by Ms Figuerola Santos in addressing possible solutions.

The urgent need for clarification

I personally asked three questions during the Greens/EFA forum, and felt that the responses were neither illuminating nor helpful. I had been asked by the hosts to prepare queries, and had actually compiled 17 questions, which were submitted to the organisers a few days before the event. These and other questions are now in the hands of MEPs and will be formulated as formal questions to be asked in the Committee of Environment, Public Health and Food Safety (ENVI).

I write this open letter to you in the spirit of transparency, in the hope—given the severity of issues facing the non-European traditional medicine sector in the EU—that you or members of your staff will comment on the concerns I raise in this letter with a view, on the basis that the problems are acknowledged, to considering possible solutions.

Among my questions raised in the forum, I referred to two of the points that you had made in a response to Giles Chichester MEP on 13th April 2011 (Appendix). In the first point, you indicate that all herbal medicinal products sold in the EU now need to be authorised for sale. You will understand that, given the very broad definition of a medicine (as given in Article 1.2 of amending Directive 2004/27/EC), many manufacturers and suppliers are deeply concerned that Member State competent authorities will now regard their products as unregistered medicines. Since most of these products are presently sold predominantly as food supplements, they are at grave risk of being made illegal by default.

In the second point, you claim there are no additional barriers to the registration of Ayurvedic and traditional Chinese medicine (TCM) products, as compared with products from European traditions. These include products associated with the comparatively recent European, and especially German, phytopharmaceutical 'tradition'. You may have appreciated, from the report on the uptake of the traditional use registration (TUR) scheme by the European Medicines Agency (EMA) in June 2011, that it is primarily products associated with this European phytopharmaceutical system that are successfully gaining registrations. By contrast, not a single product authentic to the Ayurvedic, Unani, TCM, Tibetan, Thai, southern African or Amazonian—or, indeed, any other non-European—system has yet been registered.

Reasons for lack of uptake of TUR registrations among non-European traditions

Following is a brief crystallisation of the reasons why uptake among the non-European traditions has been non-existent until now:

1. *Eligibility limitations.* Four key obstacles to eligibility include:
    a. The traditional use requirement (which requires at least 15 years' usage within the EU) for individual products locks out many products that may been used for decades, or even centuries or millennia, outside the EU. It also locks out any modification to a formula that might be appropriate given scientific advances or to meet the needs of a particular target population;
    b. Indications for the TUR scheme are limited to minor, self-limiting conditions, yet the Asian traditions cover the entire scope of health conditions;
    c. Many authentic poly-ingredient herbal products deal with multiple body systems, by virtue of their complex biochemical and bio-energetic actions. Such actions are not recognised in the existing model of pharmaceutical legislation, and there appears to have been no adjustment made to cater for the different indications and mechanisms of action of products associated with long-standing traditions;

d. Products containing significant mineral or animal ingredients are excluded from the TUR scheme, which is currently limited to herbal ingredients only.

2. *Technical limitations.* The greatest technical hurdle for most authentic traditional herbal medicinal products, which are often whole-herb or aqueous extractions, are the pharmaceutical and stability standards as set out in EMA guidelines. These are considerably more straightforward for single-herb products or limited combinations, where the herb has been well studied in the West, and for which biomarkers have been identified and included in the Committee on Herbal Medicinal Products (HMPC) monograph listing. The HMPC monographs are strongly Euro-centric in terms of their consideration of herbal species: there appears to have been no effort to balance the monographs being produced with ones for herbs that are used more or less exclusively in the major (or minor) non-European traditions. Since many traditions utilise whole-plant material or aqueous extracts, they experience considerably more difficulty in meeting the EMA guidelines for pharmaceutical standards relative to solvent-extracted, European herbal products that are stabilised in a pharmaceutical base that includes synthetic polymers/preservatives (as is the case for the majority of products that have been registered to date).

3. *Excessive cost burden*. There are great variations in registration fees being charged by Member State competent authorities, varying from around €2,000 to over €50,000 per product. In addition to this are the often much more substantial costs of meeting the pharmaceutical standards, especially stability and genotoxicity testing. You will be aware that a typical total cost for registration of a single product may range from €100,000 to upwards of €250,000. This is not an obstacle for most European phytopharmaceutical manufacturers or suppliers, where typically a narrow range of products sell in high volumes. However, it is a very significant barrier to the long-standing, non-European traditions—and especially the Asian traditions—as their suppliers are often required to carry a range of 100 to 300 distinct products, each selling at relatively low volumes. If the annual revenue for an individual product line is expected to be, say, €5,000, based on an up-front registration cost of €200,000, it would take 40 years to repay the cost of registration. For a supplier that sold a relatively small line of, say, 100 traditional herbal medicines, the total cost of registration, assuming the same total cost of registration, would amount to €20 million. These amounts are unquestionably out of reach of the small-to-medium sized enterprises (SMEs) supplying products associated with non-European traditional systems.

4. *Lack of incentive*. There are two major factors that create a major disincentive for manufacturers of non-European traditional products to prepare and submit applications for registrations under the TUR scheme. These are:
    a. The fact that any SME in the non-European traditional sector, assuming the major technical and eligibility hurdles facing complex, multi-ingredient, non-European products had been overcome, would still only be able to register a handful of products in their full range, owing to the very high fixed costs involved;
    b. There is a very real concern, given the broad EU definition of a medicine, that products receiving medicinal licenses under the TUR scheme will set a precedent that will cause Member State regulators to classify equivalent products also as medicines. This is already happening in some Member States, such as Belgium and the UK. So, if a company were to apply for one or two licenses, it may effectively contribute to a situation where all or many of its other products would be rendered illegal. An understandable position from the standpoint of many suppliers, particularly while the borderline between medicinal and food products remains so diffuse, is to continue selling as many herbal products as possible as a category of

food (e.g. functional foods or food supplements). In effect, risking a huge amount of money that SMEs in the non-European traditional sector do not have, on a registration scheme which has been built around European phytopharmaceuticals —and not non-European, long-standing traditions—is not generally regarded as a viable business option for these SMEs. Nor is investing in registration under the TUR scheme a viable option for those whose passion or interest is to ensure continued supply of products associated with these non-European traditions to consumers and non-medically qualified practitioners in the EU.

If you consider the legislative history of the THMPD, it is apparent that the Directive was intended to provide an appropriate regulatory regime for products associated with all the major herbal traditions, where these products are sold directly to the consumer. This obviously includes products used in Ayurveda and TCM. Experience so far shows that the THMPD has not achieved its original objective, and some of the most important reasons for lack of uptake of TURs are laid out in the above four points.

While it might be convenient for your Directorate General to blame any problems facing products associated with non-European traditions on the autonomous actions of Member State medicines regulators, the reality is that these national authorities are culling back these traditions using tools provided them by Brussels. The two key death-knells for products that have been selling as food supplements in the various Member States are increasingly:

a. The excessively broad definition of a medicine, and in particular its functional limb (Article 1.2(b), Directive 2004/27/EC) that technically turns all effective natural health products into medicines, and;
b. Any product containing one or more ingredients that have not had demonstrable significant use in the EU prior to May 1997, under the terms of the Novel Food Regulation (No 258/1997).

Accordingly, it is inappropriate for the European Commission to lay exclusive blame at the door of the Member States.

Citizens demand action by European and national regulators

It is apparent that the European Commission and the EMA must look urgently at resolving the situation for these systems of healthcare that are used by many millions of Europeans, and which are indigenous to well over one-third of the world's population. The response from concurrent French, German and English petitions with over 1.1 million signatories between them, and from over 850,000 signatories to the Avaaz petition on herbal medicines, confirms a highly significant measure of citizen concern. Unfortunately, the European Commission's lacklustre performance at Tuesday's forum in the European Parliament has done nothing to suggest that the Commission is keen to resolve the unfolding crisis.

The EMA's Action Plan for Herbal Medicines 2010–2011 addresses a small number of issues of concern, ignores many others, and has yet to implement a significant proportion of its stated actions.

Trying to put a square peg in a round hole

The THMPD was enacted in 2004 and fully implemented on 1st May this year. You say that 7 years should have been sufficient time for products to have been registered. But your Directorate-General failed to acknowledge that the registration scheme had been biased toward European phytopharmaceuticals during the entire 7-year transition phase, and against the much more widely adopted non-European traditions, such as the great Asian traditions of Ayurveda and TCM.

These Asian traditions long preceded your regulatory framework. However, Dr Konstantin Keller, first head of the HMPC, and others within the HMPC did very little during the transition phase to facilitate the registration of non-European products. Conversely, Dr Keller had an intimate knowledge of German phytopharmaceuticals, for which he oversaw registration under German national medicines law while he was responsible in his role in the German regulatory authority, BfArM. Experience now demonstrates that the registration scheme is not favourable to products of non-European traditions. Worse than this, the European pharmaceutical regulatory model is increasingly alienating holistic traditions, such as Ayurveda, TCM and anthroposophical medicine, something that is acknowledged in the final paragraph of your predecessor's experience report of 2008.

It seems that the criticism you now face from some quarters is down to the creation by the EU of what is effectively a European protectionist tool; one that favours certain products of the European phytopharmaceutical system, and discriminates against those of non-European traditional systems of medicine. What the EU has attempted to do is akin to trying to put a square peg in a round hole. So, rather than trying to force non-European products into a European phytopharmaceutical model, would it not have been better to build a regulatory system around the great, long-standing, non-European traditions? But we understand neither the European Commission nor the EMA was ever serious about getting the necessary technical support from China, India or elsewhere, so perhaps we should not be surprised.

The first step: Acknowledging the problem for non-European traditions

Over the years of discussion between the Member States and your predecessors in DG Enterprise, it has been apparent there has been a very low level of willingness to deal with, or even recognise, the type of problems I raise in this letter.

Creating an efficient, fair and non-discriminatory system of regulation would be neither technically nor legally difficult. Together with our colleagues, other scientists, lawyers and stakeholders across Europe, we have many ideas of how the situation could be remedied.

However, I believe I would be wasting your time—as well as my own—if we were to now delve into the detail of our proposals for regulatory reform if you continue to be resistant to any significant change to the existing regulatory regimes facing herbal products in the EU.

In this light, I will end my letter with two requests:

1. Could I please ask for your comment and clarification on the concerns I have expressed in this letter, and in particular, on the four areas I have outlined (above) in which we claim there is a disproportionate obstacle in the way of products associated with long-standing, non-European—as compared with European—systems of medicine?

2. With respect to the European Commission's recognition of the inappropriate nature of the TUR scheme for holistic systems of medicine (as stated in its 2008 experience report), will your Directorate General now consider as a matter of urgency the feasibility of a new regulatory framework for the practice of such systems?

I greatly look forward to your written response to these two points. I would like to add that should members of your Directorate General be interested in a meeting of experts and stakeholders related to the non-European sector, to discuss both the challenges faced and possible solutions, I would be very happy to arrange this at a mutually convenient time and place.

Yours sincerely

Robert Verkerk PhD
Founder, executive and scientific director
Alliance for Natural Health International

cc.

European Commission

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APPENDIX

Response by Commissioner Dalli to Giles Chichester MEP

Dated 13th April 2011

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.

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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.

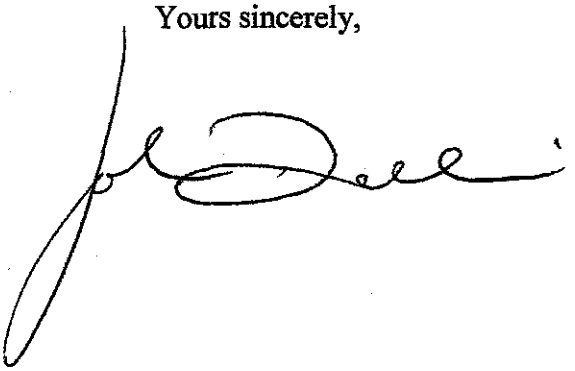
Vitamins and minerals are essential nutrients but in some cases excessive intakes can lead to adverse health effects. The maximum amounts are foreseen by Article 5 of the Directive and will be established on a safety basis taking into account scientific assessment carried out by the European Food Safety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



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[3] OJ L 183, 12.7.2002, p. 51–57

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

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