December 16th, 2010

Minutes of the meeting the EP CAM INTEREST GROUP
European Parliament, Brussels November 18th, 2010, 12.30 – 14.00 pm

List of Participants: See below

Mrs Marian Harkin MEP hosted the meeting.

Mrs Elena Oana Antonescu MEP chaired the meeting.

Topic: EU Directives are not working for products used in Complementary and Alternative Medicine (CAM)

Introduction:
Mrs Antonescu welcomed her colleagues, the speakers and other participants and expressed her gratitude for the large turnout.

Commission's position
The first presentation was given by Mr Nils Behrndt PhD, Deputy Head of Cabinet of the Directorate General for Health & Consumer Policy (DG SANCO), also the most senior European Commission official responsible for pharmaceuticals. Mr Behrndt outlined the EC's specific framework for handling herbal, homeopathic and anthroposophic medicines. Many products associated with traditional systems of healthcare have been sold as botanical food supplements in certain Member States, including the Netherlands, Belgium, Sweden, the UK and Ireland. This is despite the fact that medicines legislation, rather than food law, would normally cover such products.

Mr Behrndt's presentation focused on the Commission's role in implementing harmonised measures for these groups of products, and, usefully, recognised the importance of wide consumer choice of CAM products. He also made clear that the Commission would intervene to improve the frameworks in the event of sufficient pressure from the European Parliament and the Council of Ministers. However, his comment in relation to herbal medicines and the THMPD that "the framework is level and the system is working quite well" was heard with some surprise by the CAM representatives present. Maximum permitted levels (MPLs) of vitamins and minerals in food supplements are being mandated under the terms of Directive 2002/46/EC on food supplements and Regulation (EC) No 1925/2006 on fortified foods. On this topic, Mr Behrndt reported that "MPLs will be imposed under the old comitology procedures" – meaning that MPLs may be imposed at short notice and with only 3 weeks' scrutiny by the European Parliament allowed. On the other hand, the procedure now gives the European Parliament (EP) the power to veto such specific measures passed by the EC. No timeline has been decided for imposing MPLs, said Mr Behrndt.

Regarding health claims legislation under the Nutrition and Health Claims Regulation (No. 1924/2006), Mr Behrndt clarified the role of the European Food Safety Authority (EFSA) in the process. "Step One was to have EFSA evaluate non-botanicals, and Step Two was [to evaluate] botanicals, the delay being to get full coherence between the food supplement, food and medicine regimes." Thus, claims made for any natural product, whether in the areas of efficacy, safety, taste, nutritive benefits or anything else, will be subject to similar oversight.

Mr Behrndt referred to a paragraph from a Commission report published in September 2008[1],

[1] COM(2008) 584 final: Communication from the Commission to the Council and the European Parliament concerning the Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products

which reads as follows: 'Medical traditions such as those mentioned above are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is not appropriate for a global regulation of such medical practices. The regulation of such traditions would demand a different approach from that introduced by Directive 2004/24/EC. Therefore, the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such. Nevertheless, independently of this report, the suitability of a separate legal framework for products of certain traditions should be assessed'. Which means that there surely is an opening for establishing a separate legal framework for certain CAM products.

In his presentation built on the questions 'where do we stand and where do we go' Mr Behrndt referred to the various current registration procedures for homeopathic medicinal products, focussing mainly on the simplified registration procedure and the option to use the mutual recognition procedure. He stated he was well aware of the difficulties for the industry as well as the slow progress made over recent years. He was also aware of the very divergent situations in the various Member States as regards the national marketing authorisation process for the homeopathic medicinal products with indications. The main reason for the different approaches is related to the fact that these medicinal products are not only characterised by the substance/product itself but also by the therapeutic system that is behind them. This makes it difficult for Member States where there is no knowledge about a specific therapeutic system or where it is not well accepted. On the question 'where do we go' he mentioned the future ECHAMP regulatory status and impact assessment report and he expressed the necessity for targeted work with the Member States. For anthroposophic medicinal products he was of the opinion that a different approach will be needed.

The status of herbal medicines in the EU.
Dr Robert Verkerk, UK, ANH-Intl Executive & Scientific Director, presented on behalf of three organisations, namely ANH-Intl itself, as well as the European Herbal & Traditional Medicine Practitioners Association (EHTPA) represented by Michael McIntyre, UK, and European Initiative for Traditional Asian Medicine (EITAM) represented by Dr Herbert Schwabl, Austria. His presentation gave an insight into the problems facing manufacturers and suppliers of traditional herbal medicinal products. These products have been largely left out in the cold by the very legislation originally enacted to create a 'safe haven' for them. Since the Traditional Herbal Medicinal Products Directive (THMPD) was implemented in 2004, not a single licence has yet to be granted to products from any non-European traditional medicinal cultures, such as traditional Chinese medicine (TCM), Ayurveda from the Indian subcontinent or Tibetan medicine.

While around 200 traditional herbal medicinal product licenses have been issued in all 27 EU Member States, they are all from the European herbal tradition. Many of them are single-herb products, rather than the polyherbal blends so commonly associated with the ancient, non-EU traditions. Together, they represent approx. 50 different plant species, a very small number compared to approx. 1,500 plant species used in TCM, Ayurveda and other Asian medical Traditions.
See attachment: proposed action points for MEPs regarding the Traditional Herbal Medicinal Products Directive

The status of homeopathic and anthroposophic medicines in the EU.
Mr Ferdinand De Herdt, Belgium, President of the European Coalition on Homeopathic and Anthroposophic Medicinal Products (ECHAMP) emphasised the need for consumer choice in healthcare, and presented evidence of how citizens' rights are being denied by the current framework. Recent data from the Netherlands and Switzerland show how overburdened health systems could make significant cost savings by using more CAM and cutting spending on drugs and orthodox medical procedures. In confirming this, he referred to a recent paper written by Peter Kooreman and Erik Baars, of Tilburg and Leiden Universities, respectively, the conclusions of which are best summed up by its title: Patients Whose GP Knows Complementary Medicine Have Lower Costs and Live Longer. It is no surprise, therefore,

that one of the eight major concerns of European citizens as regards their health, expressed in a very large European Citizens' Consultation in the 27 member states made and published in 2009 is the following: "The EU should encourage links between alternative and mainstream medicine. It should regulate research, transfer of good practices, and education in alternative medicine. Treatments in alternative medicines should also be fully reimbursed by health insurance providers." This is consistent with growing consumer demand for natural and preventative methods of healthcare, but the EC and Member States continue to drag their heels. Given the Commission's own estimates that adverse drug reactions are responsible for 197,000 deaths[2] annually, at a cost of €79 billion/year, the question must be asked: which model is more in need of safety legislation.

Discussion

Several attendees emphasised that in Europe the availability of CAM products, including homeopathic, anthroposophic and herbal medicinal products and food supplements, is increasingly being reduced by unnecessarily onerous requirements and restrictions that are leading to prohibitive costs for manufacturers. In contrast to usual prescription drugs, CAM products are generic, non-patentable substances. The decreasing availability thwarts the growing demand of European citizens for more natural, health enhancing, low-risk medicinal products and food supplements. The discussion centred on the plight of herbal medicines given the rapidly approaching end of the THMPD's transition phase. The significant financial implications of licensing could not be avoided, given that polyherbal products cost at least €150,000 each for companies to register. The business model of herbal product suppliers of non-EU traditional medical systems is also relevant here. Since they generally produce numerous products in small volumes, many of which consist of polyherbal mixtures, it is not financially viable for them to apply for multiple licenses.

The complex issue of where the borderline lies between foods and medicines remains one of the biggest challenges for the herbal sector, especially for those wishing to sell products associated with non-European herbal traditions in Europe.
In addition, it was underlined that there are 27 different approaches to implementing the legislation, with some Member States being considerably more liberal than others.

Dr Verkerk added: "European regulators are always needing to distinguish between what is a food and what is a medicine, whereas in Asian systems of herbal medicine, there are no such distinctions. In EU law, the legal borderlines between foods, novel foods, food supplements and medicines are so fuzzy and open to so many interpretations by regulators, that they are creating havoc for many companies. Coupled with the unsuitable pharmaceutical standards required by European medicine law, this is one of the main reasons why the new simplified medicinal licensing regime provided by the THMPD presents such a problem for the different non-European traditions".

Several attendees referred to the suggestions in the 2008 Commission report, i.e that the 'suitability of a separate legal framework for products of certain traditions' should be assessed. This way a more appropriate legal framework could be developed that allows the continuing viability of CAM products. It was mentioned that the Parliament at that time did not follow up on the Commission report because, towards the end of the previous legislative period, there was no possibility for an "Initiative Report" left for the ENVI Committee, the only possible way the Parliament could have responded. Since the Commission needs a request from the Parliament before it will take action, it was emphasised that an initiative from the Parliament is now urgently needed.

At the end of the meeting the CAM experts in the audience offered their expertise to the Commission and Parliament to help advise them in their work.

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2 http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/782&format=HTML&aged=0&language=EN&guiLanguage=en

Conclusion
The meeting was summarised by the Chair, Ms Antonescu. She indicated that there is a growing number of her MEP colleagues with strong interests in the area. She said that the CAM Interest Group represents a vital forum to deal with problems caused by European legislation, and it is in the public interest, as well as that of the Parliament and the Commission, to resolve these problems.

Mrs Antonescu announced the next meeting of the Interest Group, which will be held in Spring 2011 and will address healthy ageing, long-term care and the role of Complementary and Alternative Medicine in these areas.

The meeting was closed at 14.00 hrs.

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ANNEX 1 - Proposed action points for MEPs regarding the Traditional Herbal Medicinal Products Directive

16th November 2010

Background

European Commission Directive 2004/24/EC, the Traditional Herbal Medicinal Products Directive (THMPD), was designed to implement a streamlined process for registration of traditional herbal medicinal products (THMPs) in the EU. Due to legislative weaknesses, only around 200 THMPs have been registered throughout the EU since the THMPD was enacted in 2004. The THMPD makes no provision for Asian traditional systems of medicine, such as Ayurveda (from the Indian subcontinent) or traditional Chinese medicine (TCM). Accordingly, very few if any products from either of these traditions have yet been registered. The THMPD should be reassessed urgently to ensure a workable regulatory framework for traditional herbal medicinal systems in the EU, and to discourage a black or grey market in herbal products.

Proposed Action Points

1. The European Parliament (EP) should urgently follow-up on issues raised by the European Commission (EC) in its experience report [COM(2008)584[1]] and the European Medicines Agency's (EMA) *Action Plan for Herbal Medicines* 2010–2011[2], with a view to extending the scope of Directive 2004/24/EC, the THMPD.
   In particular: [citations in brackets refer to COM(2008)584]
   a. The EP should urge the Herbal Medicinal Products Committee (HMPC) to rapidly increase its production of monographs, including those on herbs of non-European origin [page 3, section 1.2, paragraphs 6–7; page 4, section 2.4, paragraphs 2–4].
   b. Clarification is required from the EC and HMPC as to which remedies from Asian traditional systems of medicine "could qualify as THMPs" [page 5, section 3.1, paragraph 3] and how simplified registration can be extended to include other medical traditions [page 9, section 4, paragraph 4-5]
   c. The EP should urge amendment of the THMPD to allow inclusion of non-herbal ingredients in traditional medicines [page 7, section 3.2, paragraphs 3–5]
   d. To qualify for THMP registration at least 15 years' usage within the Community, out of a total of 30 years, is necessary to verify traditional usage. The EC should recognize that this requirement imposes a barrier on some THMPs from third countries [page 7, section 3.1, final paragraph].
   e. The EP should amend the 15-year usage restriction to admit satisfactory evidence of safe traditional usage outside the EU for the total 30-year period [page 8, section 3.2, paragraphs 8–9]
2. The EP may consider proposing reform of the duties of the HMPC under the terms of the THMPD, so as to more broadly interpret the technical requirements for products under the THMPD. This will also necessitate providing additional resources and budgeting to achieve substantially more registrations
   a. To date, only around 200 registrations have been issued among 27 MSs in nearly 7 years. The aim should be to register most herbal products that have been used traditionally for treatment of ailments as THMPs
   b. To consider an alternative framework for quality-control requirements to that currently offered by the EMA, which both guarantees product safety and substantially reduces cost.[3] At present, quality standards used for conventional pharmaceuticals are rigorously applied to herbal products with only minor allowances made for the special complex nature of herbal medicines or the ability of small to medium businesses to pay for the processes.
   c. The HMPC should widen its interpretation of what constitutes an herbal preparation. According to guidance by the HMPC even substances with clear botanical origin are considered not suitable for THMPs (e.g. natural camphor)

d. The HMPC should consider allowing the inclusion in formulations of a broader range of safe ingredients that are associated with traditional systems of medicine, including foodstuffs such as honey, ghee, propolis etc.
e. The HMPC should allow the ancillary use of minerals and other ingredients where these are used in traditional systems of medicine
f. The HMPC should broaden the scope of appropriate indications for herbal products, given that minor ailments that are also considered self-limiting excludes a very large number of products associated with traditional systems of medicine
g. The HMPC should be allowed to use all sources of relevant scientific evidence to support their monographs, including those derived from published texts, peer-reviewed journals and the respective *Materia Medica* and pharmacopoeias

3. The EP should request of the EC and EFSA much greater clarification on the borderline between traditional herbal medicines and botanicals in food supplements
4. Given the severe obstacles to THMPD registrations, can the EP gain an extension of the transition phase of the THMPD beyond the 30 April 2011 deadline?

Explanatory notes *[these notes refer directly to the numbered Action Points above]*

[1] The EP did not follow-up on the important EC report (COM(2008)584) on THMPs that that outlined many of the problems with the THMPD.

[1a & 2g] The HMPC has a limited budget and cannot include commonly available literature in their assessments/monographs, for reasons of copyright. This prevents it from developing monographs as required.

[1b] The THMPD is not currently formulated to appropriately regulate the full range of medicines of Asian and other traditional systems.

[1c & 2c] The HMPC narrowly interprets what constitutes an herbal preparation, e.g. natural camphor is of botanical origin but is not considered suitable for THMPs.

[1c & 2d] Common foodstuffs are not permitted in THMPs by the HMPC, even as excipients.

[1c & 2e] The HMPC does not allow common minerals, such as kaolin or sodium sulphate, in THMPs.

[1d & 1e] 15 years' safe usage within the EU, out of a total of 30 years of continuous safe usage, is required to verify traditional usage; many products from traditional systems of medicine do not qualify as they have no history of traditional use within the EU.

[2] Membership of the HMPC is exclusively drawn from the medicines agencies of the 27 Member States.[4] As a result, the HMPC has applied the Directive conservatively, focusing too heavily on risk, quality and safety rather than on the need to maintain a wide range of choice of herbal medicinal products. In effect, the HMPC has narrowed the scope of the THMPD, resulting in a limited number of registrations which will likely increase public demand for unregulated products with its consequent risks.

[2, 2a & 4] At the current rate of registration, a huge number of unregistered herbal medicinal products will become illegal after 30 April 2011, despite high public demand.

[2b] The quality control guidelines were originally devised to evaluate conventional medicines comprising a single chemical entity. The THMPD scheme should, however, take into account the specific characteristics of herbal products which contain a multiplicity of chemical constituents that makes their assay, especially when combined together, technically challenging. At present, quality standards used for conventional pharmaceuticals are rigorously applied to herbal products with only minor allowances made for the special

complex nature of herbal medicines or the ability of small to medium businesses to pay for the processes. This has evidently led to a lack of registration of multi-herb combinations often used in herbal medicine.

[2f] Both the HMPC and national authorities consider that traditional medicines are only indicated for treatment of minor, self-limiting conditions. This excludes the great majority of traditional uses of herbal products; for example, relief of osteoarthritis using devil's claw or ginger would be disallowed under current legislation.

[3] Furthermore, the THMPD makes no clear distinction between herbal medicinal products and herbal products in food supplements, leading to regulatory confusion.

[4] The number of THMP-registration started to pick up only in the last 2-3 years. The first 3-4 years of the 7 year transition period were mainly used to establish the guidelines within the HMPC. To our best knowledge, not a single THMP registration has been issued for Ayurvedic or TCM products. Absence of practical legislation for these products or practitioners will drive European consumers toward dubious Internet sources or bogus, backstreet traders, which is clearly not in the public interest.

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