Meeting report 21 October 2009 in Strasbourg on invitation of MEP Dr. Thomas Ulmer

An appropriate legal and regulatory environment for homeopathic and anthroposophic medicinal products

---

The MEP (Member of the European Parliament) and Doctor Thomas Ulmer organised a meeting on 21 October in Strasbourg during the plenary session of the Parliament, to discuss better regulation for homeopathic and anthroposophic medicines in the European Union. The MEPs Frieda Brepoels, Dr. Peter Liese, Michèle Rivasi, Anja Weisgerber as well as the assistant of Justas Vincas Paleckis all participated in the meeting. Dr. Ulmer had asked ECHAMP as well as the German Pharmaceutical Industry association (BPI) to present the industry sector and to outline the current regulatory obstacles.

Dr. Ulmer opened the meeting by stating the importance of this growing field of complementary medicine for Europe's citizens and added that unfortunately, it remained largely ignored by the Commission and certain Member States. He therefore saw an urgent need to ensure a better legal and regulatory environment for homeopathic and anthroposophic medicines with a strong role for the Parliament to step up the process.

Max Daege, Chair of the ECHAMP Membership Assembly, presented the basic principles of homeopathic and anthroposophic medicinal products, and of the specific therapeutic approaches. He gave a definition of both medicines, explained how these products were made, notably complying with the same production quality criteria as all pharmaceuticals. He gave a patients' perspective on the use of these products, outlined the market access requirements and finally some facts and figures on the sector.

Dr. Gesine Klein, Chair of the pharmaregulatory affairs working party of ECHAMP, presented a more detailed explanation on the fabrication and therapeutic use of the medicinal products, illustrated by a short video of a production site, showing the very high quality standards of the companies.

Nand De Herdt, President of ECHAMP, stressed the six main facts concerning the industry:
1/ It is an EU based industry with most of the know-how in Europe and with great growth potential. However this "pool-position" is in serious danger because of the current legislative set-up.
2/ The industry complies with the highest quality and safety standards, following not only GMPs (Good Manufacturing Principles) but also GACPs (Good Agricultural and Collecting Principles for medicinal plants.)
3/ Like any other pharmaceutical company, these companies need resources for research and development, whereas currently an important part of the investment is focused on dealing with the disproportionate regulatory burden.
4/ The industry employs directly 8000 people in Europe, and indirectly about another 8000 people in the supply chain. Not to mention the doctors and pharmacists in this branch, as well as the more than 100 million consumers – an estimation made by the European Commission itself.

ECHAMP European Coalition on Homeopathic and Anthroposophic Medicinal Products E.E.I.G.
Rue Gray 100 – 1040 Brussels – Belgium - Tel: +32-2-649.94.40 - Fax: +32-2-649.41.77
office@echamp.eu – www.echamp.eu – VAT BE 0467 826 644 RPR Brussels

5/ In terms of EU legislation on homeopathy, the key provisions for a more favourable legislative environment should have been voted in 2003 during the revision of the Directive 2001/83, but were rejected for unrelated political reasons, in spite of a very strong support within the European Parliament and an almost unanimous vote in the ENVI committee.
6/ Beyond legislation, the regulatory reality is very difficult in many EU Member States, with a few notable exceptions such as Germany and France.
Nand De Herdt briefly explained the main existing procedures and concluded by stressing that, without the right legislation and sufficient regulatory infrastructure within the next five years, the worldwide leadership position of this European industry could be lost.

Professor Dr. Barbara Sickmüller, Deputy Director-General of BPI introduced the position of the homeopathic and anthroposophic pharma industry on the EU Pharmaceutical package. She shared the general concern that all the measures should be efficient and proportionate, and based on the reduction of the administrative burden for the industry. She then detailed critical points regarding two out of the three parts of the package, which are of major importance for the sector, namely, pharmacovigilance and counterfeit products. Proposed amendments on the Commission proposals will be presented for being tabled as soon as the discussion will start in the ENVI Committee.

The presentations were followed by a discussion with MEPs who were interested to first of all understand better our sector and specificity, but also to receive from us more precise advice on the way towards a better legal environment. One of the rapporteurs on pharmacovigilance, Michèle Rivasi, indicated that she was keen to work with us and receive detailed input and proposals for amendments. ECHAMP and BPI committed to prepare a position paper including proposals for amendments as a follow-up to this meeting. Dr. Ulmer shared his experience as a doctor whereby he saw the great value of these products for the well-being of his patients, and stressed that the legislator could not go on ignoring more than 100 million users and the many doctors prescribing these products. He concluded by saying that simplification of rules and the right for a good legislative environment for the homeopathic and anthroposophic industry was therefore of crucial importance.

Valérie Golden
29.10.2009