



## **EU-Review of the pharmaceutical legislation**

### **Substantial changes for homeopathic medicinal products are necessary**

When submitting a new model for a European legislation in the pharmaceutical field in Autumn 2001, the European Commission planned to fulfil several tasks. The “Review” should give an answer to the demands of new technological developments in pharmaceuticals and prepare the legal and regulatory framework to an enlarged European Union. At the same time the Directive on homeopathic and anthroposophic medicinal products of 1992 which was not satisfying neither for the regulatory public services nor for the respective industry should be revised.

The Commission report of 1997 demonstrated perfectly the weak points of the Directives 92/73 and 92/74. As homeopathic and anthroposophic medicinal products were still subject of strictly national systems it was recommended to consider **mutual recognition** systems instead of 15 national, differing solutions. The report further considered the **amplification of the scope** of the simplified registration procedure: other forms than just oral or external should be admitted. A considerable disadvantage for biological agriculture was the missing access to homeopathic **veterinary** medicinal products for food-producing animals to the simplified registration procedure.

National administrations like regulatory bodies as well as the producers of homeopathic medicinal products stated since long time the necessity of a substantial amendment of the relevant Directives. The process of the Review of the pharmaceutical legislation was expected with great interest in the Member States of the European Union.

In order to accompany this amendment process, 33 companies of 12 Member States have joined together to ECHAMP, the European Coalition of Homeopathic and Anthroposophic Medicinal Products. The European interest group has left national interest and competition affairs far behind and is speaking very effective on behalf of a harmonised European market for homeopathic and anthroposophic medicinal products. Working groups of ECHAMP are collecting data on socio-economic information on the branch and are studying, in co-operation with international university institutes, recent results of research on non-conventional medicinal products. Other ECHAMP members are working on a concrete model for a European Notice to Applicants.



ECHAMP states that the European Commission has undertaken a great step in the right direction. By opening the Mutual Recognition Procedure for homeopathic and anthroposophic medicinal products, those products are finally on the way to a harmonised Internal Market.

However, there are substantial gaps in the legislation proposal. While a solution for simplified registered products is going to be achieved, harmonised specific rules for market authorisation procedure are still missing.

Experts in homeopathic and anthroposophic medicinal products cannot understand, why the scope of the products which are included in the simplified registration procedure has not been enlarged to injectables. Therewith, an action of caution has blocked especially those medicinal products which have the lowest side effects of all. The same argument ruled the inflexible dilution rules. A comparison of official potency limits is compiled which will prove that a strict application of 1:10,000 rule has to be reconsidered.

It is common agreement that the disclaimer “homeopathic medicinal product without approved indication” must disappear from the labelling: Where an indication is not subject of an evaluation procedure, an approval could neither be awarded, nor refused.

ECHAMP would like to invite all concerned and interested persons to an open dialogue on this issue. Doctors’ and patients’ associations are substantially supporting the amendment process of the Directives, as their free access to pharmaceutical products of their choice is in acute danger.

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