



## *Newsletter No 2- 08*

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Dear CAM – supporters,

drug safety or *simply* “Pharmaceutical co-vigilance” will be the watchword of the year 2008. As part of the authority on “Economy and Finance” under the jurisdiction of the EU, the General Directorate (DG-Enterprise), concerns itself with the realization of the current system, and the change of its legal framework, in order to come up with a suggestion for a new directive. In this process, national authorities are working together with EU institutions in a cooperative manner.

We are already beginning to feel the results of these efforts in regards to herbal medicine. Dr. Anderson of the British department of admissions (MHRA), speaks of the imperative creation of effective regulation in Great Britain as the majority of herbal products can be sold there without a license.

Throughout the EU, the admissions process is proceeding very slowly. By October 2007, only 27 applications for traditional registration (in German technical jargon: “Transition of old registration according to §109a, to traditional registration according to §39a-d”), had been made in seven EU countries.

A good example for where the present debate concerning the topic “Safety of herbal medication” stands, lies in the chain of arguments made by Dr. Sievers (PhytoLab-MB-Holding Co.). From 1998-2007, his research dealt with the “suspicion of interaction” of 80 plants. At BfArM he found 52 cases (29 of which involved Rose of Sharon), 26 cases found in literature, and 6 cases that were reported to the WHO.

Dr. Sievers does not come to the conclusion that herbal medications are well-tolerated and safe. Instead he demands stricter and more exact requirements and tests, thereby supporting BfArM, which already considers testing and clinical trials necessary for well-known herbal preparations, according to its “grounds for possible **pharmacokinetic Interaction**”.

What does this mean for patients, therapists and manufacturers? With the exception of approximately 10 plants, all other herbal medications will most likely be classified as dietetic or nutritional supplements. With this, the scientific work of many great researchers involving **plant monographs** seems a bizarre and expensive spectacle. The path following the so-called “scientific proof of efficacy” leads nowhere... and the patient pays the price!

Best wishes from Schoeneck

Nora Laubstein

### **Association of Natural Medicine in Europe e.V.**

Waldstr. 21 D-61137 Schöneck Tel. 0049(0) 6187- 9928121 Fax: 0049(0) 6187-9928074  
e-mail: [info@anme.info](mailto:info@anme.info) home: [www.anme.info](http://www.anme.info)

Konto-Nr.: 4201780301 BLZ: 501 900 00 Frankfurter Volksbank e.V.  
IBAN: DE 52 501 900 00 420 1780 301 BIC:FFVBDEFF