

## Suggestions of the EUAA (and ANME) for changes to the THMPD

The THMPD has been created as a means of consumer protection by ensuring a proper product quality of herbal preparations with a traditional medicinal use.

**The EUAA is clearly supportive of the approach of improving product quality and consumer safety by registering the preparations as traditional medicinal products.**

This said, the EUAA also recognizes that the current rules of drug registration make a major part of Ayurvedic remedies ineligible for registration. At the same time the possibilities of marketing such products as food supplements are drawing towards an end due to the very strict conditions of health claim approvals, which may effectively close both approaches, the status as supplement and the status as a drug.

The EUAA therefore makes the following suggestions for cautious changes of the THMPD (Directive 2001/83/EC as amended), with the aim of keeping a high level of quality and thus consumer protection, and at the same time reduce the impossible economic burden on the mostly small enterprises in the registration process.

### **1. Extending the traditional registration to non-herbal traditional constituents**

Many products contain natural plant constituents such as thymol or menthol, or actives of animal origin such as honey or propolis. Ghee butter (clarified butter) or cowry (calcium carbonate from shells) are typical and essential constituents of Ayurvedic preparations, but the presence of such constituents would effectively close the door to registration.

As the rule of 30 years was created to ensure the safe use, the same safety would necessarily apply to non-herbal constituents used over the same period of time. There is no reason to believe that ghee butter or honey should be more dangerous than any herbal constituent.

The EUAA therefore suggests that the wording "traditional herbal medicinal product" be changed to "traditional medicinal product", which would effectively solve the problem without changing the overall safety situation.

### **2. Allowing more liberty in the choice of indications**

The supportive use in conditions which have once been diagnosed but do not require constant medical supervision should generally be allowed.

### **3. Reducing the economic burden of registration**

Even in the best of cases the development of the registration dossier a simple herbal mono-preparation (plant powder in single dose form) will cause costs of minimum 200,000 € - multiherb combinations would usually involve a multiple of this sum. Most of these costs are due to the development of analytical and manufacturing methods, their validation and product stability testing.

The EUAA suggests that the quality of herbal medicinal products be tested on the level of the herbal substance (absence of contaminants, if available tests and quantifications according to pharmacopeia monographs). On the level of the drug product, however, physical tests, the identification of the constituents (e.g., by TLC) and the assessment of a surrogate marker should be sufficient, and at the same time keep up a very high level of quality.