



Naturopathy endangered by EU Regulatory?

The Budapest-Symposium shows Loopholes in European Legislation

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Only 350 days left: On March 31st, 2011 European citizens will have to dismiss a lot of well established nature remedies so the will of the EU commission. So far unperceived from the population European registration regulatories for traditionally used herbal remedies will be fully implemented from that day on. With it the transition period agreed on in 2004 ends. Until its end, herbal products of health either feature an officially approved statement by the European Food Safety Authority (EFSA) for its value in terms health, or are registered as a traditional herbal remedy. Sounding easy but showing lots of perniciousness on the practical side.

Many herbal preparations including the ayurvedian medicine system have been traded as dietary supplements. In the future this will not be possible anymore: The so called “Health Claim Directive” of the EU determines that statements related to healthiness of food by the EFSA have to be approved in the future. However practical experience shows that products with herbal ingredients evidently have no chance to such approvement. The last few months more and more explicitly demonstrated that statements according to healthiness of herbal preparations apply extremely savagely high demands by the EFSA. **Requirements according to the position of experts are totally exaggerated and not seldom higher then they are for essential approval of standard remedies.**

That’s why the European authorities claim certain forms of approvals of efficacy especially doubleblind-research on healthy patients, which are only in theory accomplishable. Possibly this has political reasons in order to force dietary supplements into the market of standard remedies – with the link to the possibility raised in 2004 giving herbal products with long tradition and approved application security under conditions of “easier registration” the status of standard school medicine remedies.

Theoretically looking like a considerable concession to the producers, it turns out to be a “present” to the pharmaceutical industry, of which small producers of naturopathic preparations hardly profit. This in particular affects the ayurvedian medicine preparation -

ayurvedian healing methods are solely based on natural remedies and an integral approach. Preparation from medical plants, natural products and minerals thereby play a major role. Ayurvedian therapists generally use individual tailor-made combinations – Preparations if produced as finished packages will be mandatory to run through registration in future.

This now clearly shows a very grave flaw of EU Regulation in traditional preparations: **According to the European Law only herbal preparations can be registered, yet combinations with non herbal preparations can't be.** From EU's side it's indeed indicated, that minerals and vitamins explicitly are approved as supplementary additives in small amounts – this however doesn't apply if minerals according to their amount are counted towards active ingredients. On details perspective it is even worse. Additional minerals do not come into consideration for many ayurvedian formulations, e.g. common salt or calcium from seashells. Natural products e.g. menthol and products based on animal origin like butter, honey or propolis are fully excluded.

Therewith the possibility to legally merchandise ayurvedian preparation in the EU will be omitted to a major extend – even though there are no questions about the application security of the major amount of preparations. After all a minimum of 30 years of experience as a qualification of a 5000 years long tradition out of India stand against the EU claims.

Complications in registrating traditional herbal preparations came along through a loophole in European jurisdiction. This is why according to today's interpretation children and women of childbearing potential are more or less completely excluded from such treatments. Due to the requirements that only information of self-medication (meaning without any monitoring by therapists) are allowed to be printed on the cover, the authorized areas of application are generally so diluted, that the products can hardly be used in a traditional manner. In addition to that there is **the claim for toxicological research, which hasn't been provided for in the EU-law at all** – all this increases the price of registry and reduces the practical utilisation for therapists, producers, and last but not least the consumers. One can investigate a shifting in supply into the totally uncontrolled internet merchandise already today – an area in which constrictions of merchandising statements and regulations for quality control at the expense of the costumer/patient are mostly irrelevant.

The problems with the current legal situation became present and discussed in Budapest during a meeting of the European and Indian government agency representatives, specialists for the EU- and WTO-Law, members of the EU-Parliament, associations as well as producers of ayurvedian preparations, organised by the European Ayurveda Association on March 19th and 20th. Thereby next to the already discussed restrictions the high costs for creating requested documents were pointed out. The extreme high requirements for quality demonstrating records are the major concerns. This doesn't mean, that basic and naturally accepted requirements for herbal remedies like standards for heavy metal, mildew, bacteria and pesticides are adhered and that mix-ups with herbal materials are to be excluded. In fact

it all comes down to the requirements for analysing methods, which in particular are practically not accomplishable for combined products. For reasonable cases the regulations give exceptions. The proof for technical impossibility can easily dispatch a 5 digit euro range. Pure technical-analytical expenses for quality control can even exceed 250.000 € with a combination of only 3 plants. – Money that has to be invested in hundreds of similar preparations. For most of the medium- and small-sized producers the term of “easier registration” is a legal deception.

Whether preparations in the future can hit the market even without a statement of health as a dietary supplement is doubtful at least for herbal preparations. Without a statement of the intended usage the economical basis for producers of corresponding preparations would largely not exist. Due to the intended implementation of the new rules/ regulations, most therapists working with ayurvedian healing methods will be sharply interfered with their work. The exception to this is the usage of self-made composition, which would have to be tailor-made for each patient in pharmacies. The majority of the presently standardized produced ayurvedian preparations would then not be available for therapies anymore.

During the meeting in Budapest it became apparent, that a sustainable solution has to be aimed for on European level urgently. A modification of the legitimate basis only then has chances of success, if the decision makers of the EU register the problem. This lies in the hands of the costumers, who should emphasise their wish for freedom in choosing therapies regarding naturopathic methods to the EU-representatives of their constituency. Even the associations of naturopathy e.g. EUAA, who make a great effort for political solutions, need the support of the population – otherwise the imminent danger of no longer having a major part of commonly used and well established remedies available for the patient, in particular for ayurvedian methods of therapies will appear with the transition period ending on march 31st, 2011.

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