

## European Union ban on Ayurvedic Medicines

Recently, I attended the 10th Oxford Conference on 'Science of Botanicals' organized by the National Center for Natural Products Research, University of Mississippi, and the United States (US) Food and Drug Administration. The conference was attended by scientists, regulators and academicians from the US, European Union (EU) and Asia. I particularly noted that EU Pharmacopoeia experts are working closely with Chinese counterparts, and that many new monographs on Traditional Chinese Medicine are being added. During one of the panel discussions, an interesting question concerning discrimination against Ayurveda was directed to the EU panel. The policy imposed a ban on all herbal medicines, which had been used for less than 15 years within the EU, and less than 30 years outside the EU, with effect from 1<sup>st</sup> May 2011. The EU's Traditional Herbal Medical Products Directive was passed in 2004, and the experts said that it seemed strange that there was no formal response from the Indian government as to the safety and efficacy of Ayurveda products.

I also noticed that, in western mind, especially in the EU, Ayurveda tends to be perceived as a system of wellness rather than a system of treatment. There is also a great concern that India still does not have formal 'Observer status' at the EU, without which Indian government and industry representatives will not be allowed in EU meetings relating to these controversial directives. The EU experts expressed their opinion that India must take this up as a priority. Although they appear to be keen to work on Ayurveda, they did not receive the appropriate authoritative information. In the opinion of many experts, documentation still remains weak because India has not adopted the correct methodologies to study and evaluate Ayurveda, and create an appropriate evidence base in its support as a system of medicine.

Indeed, Ayurveda has been practiced in European countries with close connections to India for over a century. The EU directive limited the sale of herbal medicines throughout Europe and has severely curtailed the practice of Ayurveda throughout the continent. This situation is certainly of

concern for India, from both scientific and commercial viewpoints. However, there seems to be inadequate recognition of the real problems. As a reaction to this situation, there is a huge emotional outcry by Ayurveda professionals. However, a systematic and strategic response to deal with the situation is clearly lacking. Is such a ban well justified? Should the EU include Ayurveda among other *complementary and alternative medicine* (CAM) practices? Is this more of a trade barrier than a scientifically justified demand? All these and many other relevant questions may have been raised, but have probably not reached the right authorities. Thus, there has been an undesirable consequence of banning most Ayurvedic medicines from EU countries with effect from 1st May 2011.

Those who understand Ayurveda know well, and also articles in this journal have made it clear, that Ayurveda's approach to understanding physiology is deeper than that of modern science, and on occasion enables it to achieve things impossible for modern medicine; for example, improving overall health far beyond the mere 'absence of disease', which also constitutes modern medicine's definition of health. Ayurveda's classification of persons based on the concept of "prakriti" has genetic connotations.<sup>[1]</sup> The personalized approach of Ayurveda offers hope of recovery to many patients regarded by modern medicine as incurable.<sup>[2,3]</sup>

There are many reasons for regarding the EU directive as inappropriate. The foremost one has already been the subject of an article in this journal,<sup>[4]</sup> and a meeting in the United Kingdom's House of Lords.<sup>[5]</sup> The choice of a preferred system of medicine should be recognized to be a fundamental human right, in the same way that all indigenous peoples are recognized to have the right to be treated by their indigenous system of medicine. All paying patients have a right to a placebo effect; none should suffer from its opposite, a nocebo, harmful influence. The resulting increased health costs alone make the EU's new health policies unjustifiable.<sup>[6]</sup>

There are more general reasons for considering Ayurvedic herbs in a different light from chemical drugs. First, Ayurveda itself identifies any herbs with toxic properties as toxic, and lays out well-defined procedures to decrease their toxicity. The principles and practices of Ayurveda have evolved through observation and experimentation. In ancient times, the patient was treated strictly as an individual and not as a national statistic. Ayurveda's potential to improve world health is increasingly recognized. The

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## Patwardhan: Editorial

Fourth World Ayurveda Congress proclaimed it. The health of both developing and developed worlds will benefit from international Ayurveda initiatives.

There should be no doubt that safety and quality of herbal drugs should be strictly monitored and regulated.<sup>[7]</sup> Consistent use of herbal drugs in the community certainly provides valuable safety and efficacy data. Therefore some of the EU's demands are not unreasonable. The Ayurveda, Siddha and Unani industry should have played a more effective role. Bodies like the Ayurvedic Drug Manufacturing Association can facilitate scientific research on herbs and thereby provide evidence for the safety of herbal medicine. It is also important to educate Vaidya pharmacists to improve documentation among Ayurveda professionals. However, it must be understood that the size and structure of the industry is challenging. There are no big players, and the general economic clout of the Ayurvedic industry has remained low. These challenges are further compounded by low ability to invest in research, and poor documentation. These are trade barriers and the Government needs to deal with them in a speedy and practical way. The Department of AYUSH should have constituted an expert committee with a nodal person to deal with such issues in a timely manner. In contrast, although the Traditional Chinese Medicine sector is also affected by this action, their Chinese counterparts are extremely organized and strategic in their approach.

As I come to the end of this Editorial, I learn that the American Medical Association is trying to cancel Continuing Medical Education credit for courses offering Ayurveda training for doctors, primarily due to inadequate

scientific evidence in favor of Ayurveda. We need to address this issue firmly by preparing a dossier consisting of research, evidence of safety and use and systematic documentation of Ayurveda practices. Efforts in India like AYUSOFT, RUDRA and so on, can help by providing electronic data in support therapeutic efficacy and safety of Ayurvedic medicines and processes. We need to be strategic and proactive. Our stand should be based on science, logic and evidence – not just reactive emotional outcry.

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