

Press Release
For immediate release

22nd March 2010

**AYURVEDIC HERBAL MEDICINES ENDANGERED BY EU LEGISLATION:
International Workshop in Budapest**

An EU regulation on traditional herbal medicines is due to come fully into force in April 2011 and may then lead to a loss of the accustomed natural therapy of many patients. The Ayurvedic healing system, a treatment method exclusively based on natural ingredients, is especially endangered.

Last Saturday, a two-day meeting of European and Indian Ayurvedic experts took place in Budapest (March 19-20, 2010). This international workshop was organized by the Indian Embassy in association with the European Ayurveda Association (EUAA) with the support of the Indian Department AYUSH (Ministry of Health and Family Welfare, Government of India).

“We are finally seeing a broad cross-section of interests coming to together to help protect one of the world’s most long-lived and well established approaches to healthcare”, said MD Dr Harsha Gramminger, president of the EUAA and long-time practitioner of Ayurvedic medicine. Modern healthcare systems are afflicted by the burden of chronic diseases and the multi-faceted and holistic nature of Ayurveda holds so many answers. Unfortunately the EU directive has not been developed to suit traditional medicine cultures like Ayurveda. With this regulation the EU has considerably raised the standards for product registration of herbal preparations, with the effect that the registrations becomes economically unaffordable for many small enterprises in the EU market. Says Dr Gramminger: “A modification of the regulation is required to prevent discriminatory effects.”

Ms S. Jalaja, the Secretary of AYUSH set the scene by explaining the difficulties that were being encountered by manufacturers of Ayurvedic products in meeting the highly onerous pharmaceutical standards set by the European Directive. Although the EU directive was passed in 2004, and despite its 7 year transition phase, not a single traditional herbal Ayurvedic medicine has been registered under the so-called simplified licensing regime provided by the EU directive 2004/26.

Speakers at the meeting included Edit Herczog and Erika Mann (Members of the European Parliament), Dr Werner Knoess (responsible for registrations of herbal medicines in the German regulatory agency BfArM, Federal Institute for Drugs & Medical Devices). Brussels-based lawyer Paolo Vergano discussed the potential of bringing resolution to the problems caused by the EU directive via the World Trade Organization, while Dr Robert Verkerk, executive director of Alliance for Natural Health International, spoke about the potential for an EU legal challenge to the directive. Dr. Mathias Schmidt (Regulatory Affairs Director EUAA) explained the pre-conditions for product registration and pointed to the gaps in the present regulation.

Problems and potential solutions were discussed by the experts in specific working groups with emphasis on scientific, legal and political challenges. A close cooperation between European and Indian governmental and non-governmental bodies was achieved. A core group under the leadership of Erika Mann is working on solutions to

reach conditions for the registration of traditional herbal medicinal products which should allow preserving the patient's choice of Ayurvedic medicinal treatments. This core group has already started its coordination of activities on the level of the EU, the national regulatory authorities and the Indian government.

CONTACTS

For more information, please contact Dr Harsha Gramminger, EUAA by Tel +49 2652 527756 or info@euroayurveda.com.