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# IAF to challenge legality of THMPD in UK court

Suja Nair Shirodkar, Mumbai

With an intend to show displeasure over the ban of all ayurvedic products in the European Union through the Traditional Herbal Medicinal Products Directive (THMPD), the International Ayurveda Foundation (IAF) will soon initiate legal proceedings under Article 234 EC in the Courts of the United Kingdom challenging the legality of the THMPD.

The IAF has prepared a 200 pages report based on three arguments. First, it will challenge the legality of how the directive became a law since it is in contravention with lots of existing laws in EU. The second will be focusing on how EU is violating the European human rights legislation, and the third argument will be focused on how EU is violating the existing protocol of WTO treaty through this directive.

According to Praful Patel, general secretary, IAF they will be fighting either both of the first three suites together or one by one separately. However, he informed that only the Indian government is legally authorised to challenge in the third case since its a WTO matter. As of now the IAF is in talks with the barristers from the EU on these matter so that they can take this issue ahead, whereas, they are subsequently planning to have meeting with its advisors on Ayurveda soon.

Patel informs, "It is necessary to challenge the EU directive because if it remains unchallenged there is a good chance that even other countries like US, Australia, Canada may follow suit and ban the traditional medicines in their respective countries as well. If this happens, it will be a disaster for the five billion worth Indian ayurvedic industry."

He said that it is a shame that the Indian government did not take any steps in this matter till now and that it does not have the political will to highlight the Indian issue at an international level. ◆

# Ayush hopes EU will ease restrictions on Ayur drugs

Joseph Alexander, New Delhi

The Department of Ayush, with the help of the Commerce Ministry, is in talks with the European Union to ease the restrictions on Ayurveda drugs recently imposed by the EU authorities, according to the Department authorities.

The EU guidelines, following the Traditional Herbal Medicine Products Directive (THMPD) 2004, were too 'strict' and would affect the export of India's traditional drugs, Ayush secretary Anil Kumar told newsmen here last evening.

According to the ban came into force from May 1, a company needs to demonstrate its efficacy and safety through traditional use for at least 30 years of which 15 years should be within EU. The new guideline mandates registration of a herbal medicine.

"This is very strict. We along with the Department of Commerce have taken up the issue with them (the EU) and they said they will look into it. We feel the compulsory period of usage should be reduced," Anil Kumar said.

The THMPD had granted seven-year transitional period to all unlicensed herbal medicines to comply with the requirements and it ended on April 30 this year. This may have an impact on export of ayurvedic medicines though. Kumar said the word 'ban' would not be proper in this respect.

He said a unit is also being set up to monitor adverse news reports about Indian medicinal systems which will prepare and send immediate and detailed responses to the media organisations concerned. Kumar also said manufacturers will have to ensure good quality of products.

The secretary also disclosed that guidelines to run Ayurveda, Homoeo, Siddha and Unani colleges in the country. One of the guidelines is to have at least 32 teachers in a college. Those colleges which can admit 50 students should have minimum 10 teachers in the capacity of professors and readers. Besides, the inspections of these colleges have also been made stricter. ◆

# ALTERNATIVE MEDICINE

## Centre's inaction, poor coordination with Ayush failed to convince EU to stall TMP directive

**Nandita Vijay, Bangalore**

Centre's inaction and misdirected effort by the government of India together with the lack of co-ordination amongst Ayush industry stake holders has left the Indian traditional medicine sector in the lurch with the imposition of the European Union's Directive on Traditional Medicine Product Directive (TMP).

"The government and the industry have not been able to propagate the credibility of the ayurveda. The big issue is that the government, despite several efforts, was unable to bring the industry stake holders to carry out a meaningful exercise in adhering to the required EU requirements," Ranjit Puranik, chairman, Pharmaceutical Export Promotion Council for Ayush and managing director, Dhoot Pappeswar told Pharmabiz.

"Just like the information technology industry which ran into a crisis in the US market a few months ago, we saw a consensus across associations and the industry that helped the government of India to take a stand to solve the issue. In the case of Ayush industry, the attempt was mired in arguments instead of being able to arrive at a consensus. Now that EU has defined parameters, Ayush industry needs to look at ways to find pathways to market the products in the region, adhering to the stringent norms of the EU TMP directive," they said.

"Meeting market requirements in terms of product quality and safety are crucial for Ayush industries to be successful in the future. Right now there is no approval mechanism in place to address the EU needs. While the EU insists on information categorized on a 'product' basis, Indian Ayush sector operates on a 'system' basis for its 2,000 formulations. Every product needs a safety clearance with labels certifying quality norms. There cannot be a compromise," stated Puranik.

According to Raghuvir Singh Rathore, Head - International Regulatory Affairs, The Himalaya Drug Company, the ban came into effect from May 1, 2011, seven years since the issuance of the directive. ◆

**Note from International Ayurveda Foundation:**

**We attach a Press Note issued by Department of AYUSH on page 3 & 4. The readers can make their own judgement.**

**5 July 2011**

***PRESS NOTE***

**Department of AYUSH initiatives on Traditional Herbal Medicinal Products Directive (THMPD) 2004/24/EC. :**

India exports various herbal ingredients to European Union (EU). In 2008 India exported 53.1 million US$ worth herbal ingredients to European Union (source: PHARMEXCIL).

The Traditional Herbal Medicinal Products Directive (THMPD) was established to provide a regulatory approval process for herbal medicines in the European Union (EU). Since 30 October 2005, herbal medicines in the EU are controlled under the EU regulation, 2004/24/EC (Traditional Herbal Medicines Product Directive). Under this regulation, a company needs to demonstrate the safety and efficacy of the herbal medicine through traditional use for at least 30 years out of which 15 years should be within the EU.

THMPD came into force in 2004 granting seven year transitional period to all unlicensed herbal medicines to comply with the requirements of the directive. The seven year transitional period ended on April 30th, 2011, now all ASU products have to comply with the requirements and get licensing under THMPD. Consequently, with effect from 1st May 2011 all unlicensed herbal products which were marketed in the EU now have to be either registered as traditional herbal medicinal product (THMP) or get marketing authorisation as regular medicinal product, or carry on as dietary supplements. Products sold as dietary supplements had never made any health or medicinal claims in any way but were always marketed under a very restrictive environment.

In the past Department of AYUSH, however, has been persistently impressing upon the officials of European Commission voicing its concerns on the THMPD against 15 years safe documented usage requirement for traditional use registration in a European country and suggested that it should be replaced with 30 years safe usage criteria anywhere in the world with supportive bibliographic evidence of safety

**Department of AYUSH initiatives :**

Department of AYUSH is taking all steps falling within its purview to deal with the 2004/24/EC directive. Officials of Dept. of AYUSH along with Dept. of Commerce have attended several meetings and negotiated the issue at various forums. Some of them are as follows :

- The 5th India-EU Summit held in The Hague on 8th November, 2004 resulted in Draft Joint Action Plan which included initiation of discussion on harmonization of registration procedures for Indian Pharmaceutical products

in the EU and also initiation of a dialogue in pharmaceuticals with special reference to alternative traditional medicines.

- As a result of India's concerted efforts market authorization of Ayurveda products was included as an Agenda Item in the India – EU Joint Working Group on Pharma & Bio-technology set up in 2006 under the aegis of India – EU Strategic Partnership.

- An Indian team of officials and experts made a presentation on Ayurveda to the European Medicine Evaluation Agency (EMEA) in London in May, 2006 on the Evidence Base of Ayurveda and quality control of Ayurveda medicines.

- A three member EU Commission team visited India in January, 2007 for talks with the Indian side. The Indian side comprising of official and experts from Deptt. of AYUSH, CSIR, ICMR and AYUSH drug industry held discussions with European Commission team and emphasized the need for review of the above Directive in view of the fact that the Directive is hindering rather than fast tracking of market authorization of Ayurveda and other traditional medicinal products. The European Commission team also visited R&D, health care and manufacturing facilities of Ayurveda in Delhi, Jammu and Kottakal and presented its report in the India – EU Joint Working Group meeting held in Delhi on 30th May – 1st June, 2007 in which it has acknowledged that there is a properly regulated vast infrastructure of Ayurveda in India in terms of qualified practitioners, hospitals, dispensaries and manufacturing facilities.

- On Jan. 19th 2011 a delegation from Dept. of AYUSH along with officials from Dept. of Commerce visited Brussels for negotiations with European Commission officials on 2004/24/EC directive. EC officials explained their stand on the Directive and agreed for further negotiations and inputs from India on Committee on Herbal Medicinal Products (HMPC) monographs.