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India may even challenge EU's herbal medicines directive, if no changes are effected

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Joseph Alexander, New Delhi

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=56036§ionid=>

India may challenge EU's Traditional Herbal Medicine Product Directive (THMPD) which is planned to be implemented from April, 2011. Some of the leading international agencies are expected to support the country in this initiative and may win some relaxation, it is learnt.

The department of Ayush sources said the country is still continuing the dialogue process over the issue with the European Union and at the same time is resorting to all possible steps like working closely with some international agencies to legally challenge the directive with a view to ensure some helpful amendments. ANH Consultancy, the arm of Alliance for Health International based in Europe has already held meeting with the officials of the Ayush Department recently.

ANH-1 is also coordinating with China, another affected country of the THMPD, for putting pressure on the European Commission by legally challenging the directive if no amendment is made and is in touch with top EU lawyers, industry players both in India and China. ANH-I said the two firms – Cheney Goulding and 11KBW – had provided advice that showed a, “solid way forward” to challenging the directive, eventually in the European Court of Justice (ECJ), possibly via Germany and Hungary.

“A significant proportion of the world's population is concerned about what the EU is doing with herbal products, and it's high time European regulators took stock of what they are doing. If they don't do it of their own volition, forcing them via legal action to prevent discrimination and adapt the regulatory regime to make it more suitable to a wider diversity of cultures is the only option available,” according to ANH-1.

It is also learnt that India is planning to move World Trade Organisation (WTO) over the issue of creating trade barriers to Indian exports of herbal medicines to Europe. Commerce Ministry and health ministry have launched joint measures in this regard and the matter is likely to be finally taken up with the WTO at the earliest. Indian herbal industry will hit badly by the directive, as per industry observations.

The THMPD came into force in 2004, but has given a transition period till March 31, 2011. Under the directive, a company needs to demonstrate the safety and efficacy of the herbal medicine through traditional use within the EU for at least 30 years or 15 years within the EU and 30 years outside the EU.