

Medicines Legislation, Regulation and International Policy

**2nd Interactive Meeting for Global
Propagation of Ayurveda
Delhi, May 3/4 2010**

Dr. Harsha Gramminger

Chairs

Dr. Harsha Gramminger (President EUAA)

Dr. Mathias Schmidt (Medicines Director EUAA)

Anup Kalra (Ayurved. Ltd.)

Participants

17 Participants from

- India (11)
- Korea (1)
- Russia (1)
- Nepal (1)
- Indonesia (1)
- Germany (2)

Topics

- Specific problems with THMP registration in Europe
- Apparently no problems with exports to US
- Exports to Australia require approval by TGA
- Plant material with organic certification require more documentation
- Raw materials (e.g., flavours) can be imported to India, but re-exportation in finished products may be difficult in some cases.

THMP registration: Proposed Action plan

1. Pilot project: Registration of two products in Europe as support of the AYUSH for the Indian industry

Costs: Estimated 850,000 €*

* Worst case estimation assuming that all details will have to be newly developed

THMP registration: Proposed Action plan

2. Indian manufacturers will follow in GMP (EU) approved production units (raising standards in the next 18 months)

Costs: Depend on the situation encountered in the individual company and the amount of preparational work already achieved. Case-by-case estimation

THMP registration: Proposed Action plan

3. Lobby group to start informing MEP's , meetings with President of EU Council. Organized by former MEP Erika Mann (June 2010)

Costs: Still needs to be evaluated (external costs)

THMP registration: Proposed Action plan

4. Indian Government to work along side with other Governments who face the same difficulties about exporting their traditional herbal preparations to EU countries like
Brazil, South Africa, Mexico, China (June 2010)

Costs: Cannot be evaluated by the working group

THMP registration: Proposed Action plan

5. Manufacturers to create a budget to support work of Lobby group in Brussels (Parliament, Council and EC Commission) and PR work. Coordinated by Mr. Anup Kalra as contact person of Indian manufacturers (May). Distribution of funding by interested parties to be agreed on. It would be good to have many manufacturers supporting the goal.

Costs: Approximately 100,000 €/year

THMP registration: Proposed Action plan

6. Government of India should start project with coordinated action between Indian government, Indian WTO experts and Brussels based lawyers specialized in WTO legislation, e.g. Paolo Vergano (FratiniVergano Brussels lawyers) aimed on WTO dispute settlement (May)

Costs: Estimated 350,000 €

THMP registration: Proposed Action plan

7. AYUSH to support legal challenge group with the aim of creating an Annex to the THMPD in order to include non-herbal constituents, e.g., minerals or constituents of animal origin (May)

THMP registration: Proposed Action plan

8. AYUSH to support legal challenge group in working towards a change in THMPD regarding a simplification of requirements of analytical testing in multiherb formulations. Allow for a broader range of indications of THMP, especially with indications where the patient does not require a medical re-confirmation of his/her health condition

Costs: (Items 7+8) Estimated 200,000 €