Pharmaceuticals Working Group

Output Recommendations

Dr Oliver Werner & Vd J Pandey

Chair & Co Chair

Focus Areas

- Good Manufacturing Practices
- Pharmacopoeia Standards
- Issues related to establishing contact / dialogue with countries and trade blocks

Market Access & Opportunity

Markets for which discussion took place :

a. SAARC (South Asian Association for Regional Cooperation)
b. ASEAN (Association of South East Asian Nations)
c. Russia and erstwhile CIS republics
d. USA
e. EU

Action Points – SAARC

South Asian Association for Regional Cooperation:

- Common heritage of Ayurveda – Afghanistan, Pakistan, India, Nepal, Bhutan, Bangladesh & Sri Lanka
- Initiate discussion on adoption of Ayurvedic Pharmacopoeia of India standards and Schedule T GMP
- Important to have '**one voice**' emerging from custodians of ancient common heritage

Action Points - ASEAN

Association of South East Asian Nations

- Bangkok Declaration for ASEAN cooperation on mainstreaming of Traditional Medicine
- Important for India to find pronouncement and acceptance for Ayurveda in working group and ASEAN nations
- Dept of AYUSH to initiate a dialogue with Min of Ext Affairs and Min of Com to determine approach
- API and Sch T GMP is once again a core discussion proposal

Action Points – Russia & CIS

ALERT :

Russia has proposed a new regulatory regime applicable from next year for all medicinal products

Indian exports to Russia and CIS block is Rs 1670 million, is 30 % of total exports for ASU – AT RISK

It is believed that 70% of their domestic industry would stand affected !!

Urgent need to initiate a

better understanding and dialogue

Protect 30% of Indian ASU exports

Action Points - USA

- To take US FDA – New Delhi office offer to install Sch T GMP as an equivalent std to DSHEA GMP → for Dietary Supplements

  (Dietary Supplement & Health Edu Act)
- Therefore, **AYUSH Standard Mark** can mean compliance under DSHEA GMP
- It may mean pre-shipment inspection for export consignments but a better compliance regime

Action Points - EU

- EU does not differentiate GMP norms for botanicals and modern pharma
- India has large infrastructure of EU compliant GMP units – allopathic sector
- Government should allow “for exports” allowance to such units for ASU (ASU = Ayurveda / Siddha / Unani) formulations – allowing for a savings in investment for mkt access
- ASU Industry requires intensive training on Dossier preparation strategy – documentation & validation criteria and presentation
- ASU Industry requires a panel of experts at hand to undertake the attempt to register

Basic Common Points

- Ayurvedic Pharmacopoeia Committee (APC) to consider inclusion of suitable assay methods for herbal inputs – additional criteria not mandatory in India but a boost for API's global acceptance
- A repository of "marker" standards and herbal reference material → to be made available to ASU industry at a deep subsidised cost

Basic Common Points

- Important to activate existing MoU between AYUSH and National Center for Natural Product Research and deliver validated science for ASU botanicals.
- Important to consider similar MoUs with centres in EU to hasten scientific validation.
- Establish AYUSH cell in PHARMEXCIL (Pharmaceutical Export Promotion Council)
- Establish Focus Mkt Wise Task Task Forces to achieve fruition on agenda.

Suggestions of 2009 needing attention …

- International cooperation of Ayurveda Pharmacopoeia Committee to set standards which are internationally accepted. These do not have to be mandatory within India.
- Dept. of AYUSH to initiate with renewed vigor the interface & dialogue with EU HMPC / MHRA for securing the trade for ASU formulations

Members of Group

- Dr. Oliver Werner – werner@ayurveda.nl
- Dr. Janardan Pandey - djpv2002in@gmail.com
- Mr. Ranjit Puranik- rap@sdlindia.com
- Dr. Nagesh Sandu- sanherbs@gmail.com
- Dr. Ashish C. Suthar- ashish.suthar@piramal.com
- Dr. Bansh Deep Sharma Kharad- kbamsdeep@gmail.com
- Dr. Gaurav Sharma- sharmadrgaurav@gmail.com
- Dr. Shruti Khanduri- drshruti_ayurveda@hotmail.com