

**Workshop on
'Development of Export of Pharmaceuticals to Europe'**

MUMBAI : NOVEMBER 24, 2006
HYDERABAD : NOVEMBER 27, 2006
AHMEDABAD : NOVEMBER 30, 2006

The series of workshops were conducted by the Eximius Centre in association with The Centre for Promotion of Imports from Developing Countries (CBI), The Netherlands. The objective of the workshops was to inform the SMEs in the pharmaceutical sector, about the Export Development Programme (EDP) developed by CBI to help SMEs to enter or enhance their exports to the European market.

Mr. Jan Ramakers, CBI Consultant, served as the faculty for the workshops. He began the workshops by providing a brief overview of the Pharma and Chemical Industry in Europe. Later, he spoke on the EDP for Pharmaceuticals to Europe followed by the role CBI plays in EDP.

Overview of Pharma & Chemical Industry in Europe

The value chain in pharmaceutical and chemical industry goes through commodity, intermediate, advanced intermediate, active ingredient to marketing. The European Union (EU) is a major market for chemicals and pharmaceuticals accounting for 28.6% of global chemical manufacturing and 27% & 53% of the pharmaceutical market and intermediates respectively. The value of the EU pharma market in 2005 was \$155 billion, registering a growth of 7%. Production and consumption of chemicals has increased by 3-4% per year since 2002. The EU has around 71,000 chemical companies and around 71% of chemical output is used within EU.

The pharma sector including the chemical sector in the EU is highly regulated. Key Regulatory requirements include: Mutual Recognition Procedure (MRP), under which the assessment and marketing authorization of one Member State should be "mutually recognised" by other "Concerned Member States"; Centralised Procedure (CP), which facilitates single approval for marketing authorisation for all markets in the EU. Registration of pharma is mandatory through the European Medicines Agency, London. Drugs that contain new Active Pharmaceutical Ingredients (API) need a full registration, which is expensive and time consuming. Ethical drugs are being replaced by

generics, which also need registration. Some countries grant incentives to encourage generics. Bioequivalence study is mandatory for each drug. Registration in one country is valid throughout the EU.

Fine chemicals have a significant market in the EU. The regulatory requirements for chemicals export to the EU includes safety and packaging requirements such as Responsible Care, Product Stewardship, ISO 9000/14000, REACH and packaging and transport. REACH is the new EU chemical system (Registration, Evaluation, Authorisation, Restriction of Chemicals).

EDP for Pharmaceuticals to Europe

The EU is one of the most profitable markets in the world. At the same time, it is also a complex, competitive and dynamic market. One of the essentials for success in the EU market is compliance with prevailing regulations and market standards, especially with regard to safety, quality and packaging. There are good opportunities for aspiring exporters, and the time is ripe for Indian SMEs to direct greater marketing thrust towards the EU, as rising production costs are forcing many European companies to look outside the EU, to more cost competitive countries for sourcing their requirements.

To help manufacturers and exporters in the pharmaceutical sector and to improve their export prospects in the EU, CBI has developed a programme viz., Export Development Programme (EDP). Selected participants, under the programme receive individual support over a number of years by means of on-site consultancy, training schemes, market information, trade fair participation and business-to-business activities. Depending on its specific needs, the participant company may also receive support in the field of product and production improvement, quality control; export marketing and EU market entry. The programme is accessible for companies that meet the following criteria:

- Employee strength between 25 and 500 employees;
- Local ownership of at least 51% (joint venture/part of a company from a country belonging to a UMIC or higher country is excluded);
- No licence agreements that would hinder export to the EU;
- Ability to communicate in English;
- Compliance or the willingness to comply with EU market requirements;
- Competitive prices and sufficient production capacity;

- Willingness and capacity to invest in adaptations of product assortment and production processes, as required by the European market.

The scope of the EDP for Pharmaceutical Products covers producers of basic and advanced intermediates used in the manufacture of pharmaceuticals; fine chemical intermediates manufactured under cGMP; Bulk Pharma Actives; API's; solid and liquid dosage form pharmaceutical drugs; injectables; sterile dosage forms; capsules; gel caps; excipients etc.

The CBI EDP operates on a step-by-step approach. It begins with an application process followed by a pre-selection, evaluation of factors critical to exports and export audit. The final stage of EDP comprise of a seminar organised by CBI for the selected participants at Rotterdam, the Netherlands. The seminar consists of lectures, discussions, case studies and practical assignments in the areas of export marketing, management, sector-specific topics, and visits to important European Trade Fairs and Buyer's Meet.