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India regulators need to inspect Chinese production facilities before imports: Dr G.G Nair

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Indian regulatory authorities should insist on inspection of Chinese manufacturing premises for GMP/GLC standards as they do in the case of Indian drug manufacturers, said Dr Gopakumar G Nair, Patent Attorney & Advisor-Pharmexcil.

He was speaking in a seminar cum interactive session on "GLP-eCTD and Patent Awareness Programme' organized by Pharmexcil in Ahmedabad last week. The programme was organized to give awareness to pharmaceutical units particularly to SMEs, about the regulatory issues, exports and intellectual property rights.

Later speaking on 'pharmaceutical industry in India v/s China', Dr Nair, opined that "quid pro quo" is the foundation of international trade regulations. India is currently registering a large number of Chinese pharmaceutical products without inspection of their manufacturing facilities.

Dr Nair said that India should insist on and pursue with China to register Indian pharmaceutical products including formulations on a reciprocal basis for importing into China. He further said that organizations like Pharmexcil and IDMA should represent to the concerned ministries to take urgent steps for reviving the Indian bulk drug industry with adequate incentives, so that Indian exports are not over dependent on Chinese APIs.

H G Khoshia, Commissioner, Food & Drugs Control Administration, Gujarat while delivering on the pharmaceutical industry status of the state, said his state contributes 42 per cent to the total turnover of India's pharmaceutical industry. Gujarat has a history of 103 years of pharmaceutical production and one of the oldest company, Alembic, is still operating in the state. He added that 22 per cent of the total pharma exports are also from Gujarat, which is exporting to more than 150 countries. The pharma companies alone provide job opportunities to more than 55,000 people, Khoshia said.

Presentation on Role of SME's was delivered by Nipun Jain, chairman SME Panel-Pharmexcil. A N Mishra, Joint DGFT, Ahmadabad, spoke on the schemes available for exports, presentation on GLP & Requirements of Premises & Equipment as per Schedule L-1 was delivered by Dr A Ramkishan, Asst Drugs Controller (I), CDSCO, Ahmadabad, and Ashuthosh Gupta, COA member, Pharmexcil spoke on Brand India & its challenges.

Over 150 participants from drug regulatory system, DGFT, and executives from pharmaceutical industry participated the event.

Several issues relating to exports, intellectual property rights and Anti-Counterfeiting Trade Agreement issues were discussed during the question and answer session. Pharmexcil has organized the program with the coordination and help of IDMA, Gujarat state.

Pharmexcil has also conducted a seminar on the subject in Bangalore last week. In the Bangalore seminar, Dr G G Nair clarified to the Drugs Controller of Karnataka that Drug Inspectors or Senior Officers of the Drug Administration have no locus-standi under the Drugs & Cosmetics Act, 1940 or any other Act to consider or enquire about the patent status or non-infringement of a drug in the country. The patent related aspects of a pharmaceutical product are within the ambit of Patent Office and the Controller General of Patents. Drugs Administrations are concerned with quality of the product and the premises along with GMP, GLC etc.

However, in view of the International trade restrictions on "passing off" through ACTA & other treaties, care should be taken to ensure that Trademark infringement are best avoided, he said.