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DoP takes steps to assess current status of regulatory matters relating to exports

Joseph Alexander, New Delhi
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The Department of Pharmaceuticals (DoP) has launched an exercise to assess the current status of regulatory matters regarding exports, such as IPR, TRIPS, patent linkage, free trade agreements and data exclusivity, with purpose of getting a comprehensive view about the problems and then take up the issues with concerned departments and agencies.

The DoP has asked the Pharmaceutical Export Promotion Council (Pharmexcil) to submit the current status report on all issues concerning the exports, especially exports to the European Union. The issues related to compliance with standards in other countries will also be covered. The DoP has set up a panel for taking up the studies and making the report.

Apart from Pharmexcil, the representatives of Department of Commerce and Department of Industrial Policy and Promotion will be also members of the panel. Besides, the DoP would also fund Indian Pharmaceutical Association (IPA) and Bulk Drug Manufacturers Association (BDMA) to conduct a study and prepare a report on export of Indian APIs/formulation drugs to EU and details of APIs being manufactured in these countries in four weeks time. The report will have also details of APIs production especially in Spain, Italy, Portugal and Eastern Europe. IDMA was asked to provide further details with regards to Paris meet of WIPO, sources said.

The DoP has plans to fund IPA to set up a cell to deal with all issues related to IPR, regulatory issues and other trade barriers. The IPA has been asked to submit a proposal in this regard. The cell would help the industry players to get updates and clear their doubts concerning the export related regulatory issues.

The department is also planning to hold regular and periodic meetings with other concerned departments like health, commerce and stakeholders to get feedback on the regulatory issues concerning the exports and try to solve.