

DoP to take up issue of non-tariff barriers by EU with commerce ministry for further actions

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The Department of Pharmaceuticals (DoP) will take up the issue of non-tariff barriers related to regulatory requirements from European Union with the Ministry of Commerce for further actions along with Ministry of Health and Family Welfare and Pharmexcil.

Looking to frame a joint strategy between the concerned departments, the DoP would press for counter measures if required against companies exporting to India from Europe, sources said. The reported move by the EU to charge 15000 Euros for issuance of EDQM certificate per bulk drug would also be taken up for further steps.

According to the inputs gathered by the DoP, the bulk drug and formulation exporting units in the small scale sector were facing several types of non-tariff barriers related to regulatory requirements. Firstly the Indian units exporting to EU have to ensure compliance to EDQIM and have to obtain their certificates for every drug in addition to the standards of them for the importing country.

In the case of bulk drugs, third party audits are being insisted upon as a result the companies are forced divulge their intellectual property infringing on the right to protect the data. And in the case of formulations, EU is insisting on verification of pedigree of active pharmaceutical ingredients. The DoP would urge the Commerce Department to take up these matters urgently with EU authorities, sources said.

The DoP had already launched an exercise to assess the current status of regulatory matters regarding the exports, including issues like IPR, TRIPS, patent linkage, free trade agreements and data exclusivity, with purpose of getting a comprehensive view about the problems.

It had asked the 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.