

India, China to appeal against EU regulation on API

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Bangalore: Following a change in rules for importing active substances into the European Union for medicinal products for human use, India and China are contemplating to take up the matter with the World Trade Organization (WTO).

The amended rules on bulk drugs, to be effective from July 2013, is likely to affect exports of active pharmaceutical ingredients (APIs) from the two countries to Europe.

EU's new regulation makes it mandatory to have current good manufacturing practices certificate from the local authority for all bulk drugs exports. Reports said the commerce ministry of India has already taken up the matter with the EU authorities.

India can raise the issue at the WTO forum. Reports suggest India will possibly make a joint statement with China at the next WTO meeting. China Chamber of Commerce has already reportedly written to Pharmaceutical Export Promotion Council of India (Pharmexcil) on the possibility of a joint statement. The ministry has also reportedly sought the opinion of Bulk Drug Manufacturers Association on the issue.