CDSCO revises Export NOC guidelines, keeps importing country approval norm

While the drug regulator has retained the requirement for firms to submit approval from the importing country's National Regulatory Authority (NRA), the revised guidance has dropped the earlier provision allowing exports of unapproved finished formulations of NDPS category and drugs banned in India.

New Delhi: The Central Drugs Standard Control Organisation (CDSCO) has issued the revised guidelines for obtaining No Objection Certificate to export approved and unapproved new drugs from the country.

Under the revised guidance, the apex drug regulator has retained the requirement for firms to submit approval from the importing country's National Regulatory Authority (NRA).

"The applicant needs to submit a document of the applied drugs as issued by the NRA of the importing country and in case NRA approval of the importing country is not available, the applicant has to submit certain other specified documents" the notified guidelines states.

Fearing export disruption and risk of losing market share to competitors from other countries, small drugmakers– those with an annual turnover of less than or of ₹250 crore—have expressed strong reservations and have called for its withdrawal.

Last week ETPharma reported that, in a meeting with Niti Aayog member DK VK Paul and the Drugs Controller General of India (DCGI), small drugmaker lobby groups including Laghu Udyog Bharati, CIPI, FOPE, and several others had urged to "revoke the provision."

“Export NOC-related objections were endorsed, as it's the responsibility of the importing country to evaluate products but if India stops any formulation export, it doesn't mean that such country procurement will be put on hold and as per global practices and trends we need to revoke Export NOC-like restrictions”, the representatives had said.

Similarly, earlier in a letter to the Union Minister of Chemicals and Fertilizers, RSS affiliated Laghu Udyog Bharati (LUB) had concerned that, “it will be difficult for a MSME unit to meet the conditions of New Export N.O.C Procedure and due to this N.O.C hurdle neighboring country will capture the export market.”

Besides this, reportedly a government-backed export promotions body Pharmexcil had also written a letter to the country apex drug controller the DCGI, concerning that, “the amendment will significantly strain India's pharmaceutical export sector and sought a review of the then new rule."

While the regulator has diluted the initial provision by granting certain relaxations through two rounds of revisions, small drugmakers have maintained their objections.

Under the latest notified guidelines, for approved product both active pharmaceutical ingredient (API) and Finished Formulation (FF) a CDSCO approval can be substituted in case NRA approval of the importing country is not available, whereas for unapproved product, approval status of a SRA country—US, EU, Canada, Japan, Australia, and Switzerland— can be submitted in place of the importing country NRA approval.

However in case of an unapproved API of NDPS category or a banned ingredient in India an approval from the importing country NRA has been made mandatory under the guidelines.

The revised guidance has dropped the earlier provision for exporting unapproved finished formulations of NDPS category and drugs banned in India.

A key relaxation introduced in the previous revision—allowing consideration of approvals granted to other firms—has been retained in the notified guidance document.

"In case the product API or formulation has been registered and approved by the NRA of the destination country for a specific firm, such approval may be considered applicable for other applicants," the document reads.

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