BDMAI BULK DRUG MANUFACTURERS ASSOCIATION OF INDIA

Date: 31.03.2025

Dr. Rajeev Singh Raghuvanshi
Drugs Control General of India
Central Drugs Standard Control Organization
Directorate General of Health Services
Government of India, New Delhi

Dear Sir

Sub: Public Notice No. IMP/70/2024 dt. 7.3.2025 – Revised Guidelines for Export NoC for Unapproved / Approved New Drugs.

We refer to the above Public Notice and subsequent virtual interactive meeting with the stake holders on 29th March 2025.

On behalf of the members of BDMAI who are mostly manufacturers and exporters of Bulk API's, we express our sincere thanks for your pro-active approach to listen to the issues faced by the exporters in view of new export Guidelines for Export NoC issued on 7th March 2025. As discussed in the meeting, we bring the following issues with specific reference to export NOC for API's & suggested solutions for your perusal:

1.Requirement of status of Approval:

As per Clause 5 of Step II of the Guidelines, applicant is required to submit the Approval Status of the Drug in the importing country or in India for obtaining Export NoC for Unapproved / Approved New Drugs. Also it is stated that Validity of export NOC shall be 1 year.

As explained in the meeting, NoC for export of API's fall in different categories. In some cases the NoC is required on a regular basis as API's which are registered in certain countries and have published monograph in Major Pharmacopeia (EP/USP/JP), but are not approved drugs in India. There are instances where NoC is being taken for more than a decade on a regular basis.

In another case, New Chemical Entities (not known as drug at that stage) or patented drugs which are under clinical trials are being exported to various countries for the purposes of manufacturing exhibit batches and also for manufacture of formulations for filing DMF/ ANDAs in US and other regulated markets. Approval status for such APIs will be known only after the approval of DMFs/ ANDAs by the importing countries.

You may kindly appreciate that considering India's capabilities to manufacture quality APIs, our exporters are able to obtain orders from these regulated markets. If there is any delay or break in supply chain, Indian exporters are bound to lose their business to other competitors particularly from China. The value of these APIs exports may be a small fraction

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of the total India's exports now, but once their APIs are approved, the value of exports become very significant in India's future pharma exports. Due to confidentiality issues, our members are not able to share the product / value details of their pending applications for Export NoCs. As the whole data is available with Zonal offices, value of the APIs pending for Export NoCs may be ascertained.

Similarly, Indian exporters export unapproved / approved new finished formulations, particularly to semi-regulated markets, where registration certifications are available to the exporters at a very later date after product registration and in some countries, registration certifications are not issued. For SMEs, these markets are very important and any delays in getting Export NoCs, would severely hamper their business opportunities.

In view of the above, we suggest the following solutions:

In case of APIs:

i) API's are not consumed directly by any consumer and are supplied to registered Formulators of the importing countries who are in turn regulated by the regulatory Authorities of the importing country. So any Pharmacopial API appearing in USP/EP/JP compendium shall be treated as an approved drug for the purpose of export NOC & the existing system of issuing NoC till the validity of regular drug license may be continued (instead of 1 year validity). It is requested that Export NoC procedures for an API may be set differently than that for a Formulated drug product as the issues and risks are totally different.

ii) The existing system of issuing Quantity based Export NoCs based on Purchase Orders received from overseas Customers may be continued as in both cases it poses no risk of any misuse. As an additional precautionary measure, the applicant may be asked to provide an undertaking clearly mentioning the purpose of export in case.

iii) In order to simplify procedure and avoid workload on both sides, we request you to create a category of un- approved drugs for which NoC has been issued multiple times and have published monograph available in USP/JP/EP. Such drugs shall be permitted to obtain manufacturing Licenses without need for NoC.

iv) If the API intended to be exported is likely to fall under NDPS category, Zonal office may ask for any additional information and clear the Export NoC.

In case of Formulations:

i) In addition to status of approval in importing countries or in India, a third option may be given, where the applicant can submit a self-declaration along with purchase order from the importer, or any proof that the product is available in the markets of importing country, or any proof that the applicant has submitted applications for product registration in the importing country.

ii) If the product intended to be exported is likely to fall under NDPS category, the applicant may be asked to provide a letter from Registration Authority of Importing country that the application for production registration by the exporter is under its active consideration.

2. Export of APIs held at Ports:

We have also brought to your kind notice that export of APIs (Tapentadol) is held up at Hyderabad Airport, for want of clearance from ADC. It is understood that it held up as Tapentadol in combination of Caresoprodol has been recently banned by DCGI and there is no clarity whether Tapentadol as API can be exported or not. We request you to kindly issue necessary clarifications to ADCs at ports, so that such products are exported without any delays.

3. Procedure to be followed for release of consignments by CDSCO at ports :

We also request you to remove this procedure completely as your good office has earlier removed this procedure for USA, Japan, EU, Canada and Australia vide Notice No. DCGI/Misc/2025(199) dt. 11.12.2015 and further removed this procedure for all other countries vide Notice No. CGI/Misc/2025(199) dt. 21.3.2018, in line with Government's 'Ease of Doing Business' initiative. The reintroduction of procedures that were previously removed lacks a clear rationale and contradicts the spirit of simplifying business processes.

Thanking you and looking forward to your urgent positive action to ensure smooth Pharma exports.

Yours sincerely,
For Bulk Drug Manufacturers Association (I)

R K Agrawal
National President