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Strengthening of Export Regulations concerning Drugs in India

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Introduction

During Covid, India emerged as the largest exporter of vaccines to the world. The Indian pharmaceutical industry was and remains one of the largest exporters of pharmaceutical products in the world. In fact, in recent bilateral trade engagements of India, pharma products have become 'up front and center" agenda items for market access.

With a view to enhance the quality of the export of Indian pharmaceutical products, In response to recent events, India is seen tightening its regulations to improve the drug safety and quality. One such measure is centralizing the issuance of "No Objection Certificates" (**NOCs**) for the manufacture of unapproved, banned, or new drugs for exports. Such certification and quality control was previously managed by the State and Union Territory licensing authorities. In furtherance to the same, the Indian Central Drugs Standard Control Organisation (**CDSCO**) issued a guidance to the industry outlining the new procedures for obtaining NOCs.

CDSCO Guidance

With effect from May 15, 2024, the central government has taken over export licensing from state level authorities. [1]

On July 3, 2024, the CDSCO issued a guidance document detailing the new procedures for obtaining such NOCs (**Guidance**).[2]

The key elements of the Guidance are the following:

Application: The application should be filed on the company letterhead duly signed and stamped by an authorized signatory. The application must include *inter alia* details of the list of products to be exported, composition and strength, dosage forms, manufacturing sites, the countries to which the drugs will be exported and details of past exports. Copies of valid purchase order or export order or proforma invoice must also be enclosed.

Legal Undertaking: A "legal undertaking" in a prescribed format must be submitted on a non-judicial stamp paper – notably, this is the first time that the regulator has required drug manufacturing companies to provide legal undertaking on a stamp paper. While separate formats are prescribed for a bulk drug manufacturer and formulation manufacturer, some of the common clauses in the undertaking formats are *inter alia* the following:

- **Country of export:** The manufacturer must provide the name of the country of export.
- **Quality control:** The manufacturer must ensure that the batch shall undergo quality control testing as per the specification of the importing country as well as comply with the importing countries quality standards.
- **Record Keeping and Inspection:** The manufacturer must undertake to maintain books and records of transactions for which NOC will be granted as well as allow the inspection of such books and records.
- **Export Purpose Only:** The manufacturer must ensure that the quantity subject to NOC shall not be diverted for sales in India or used for any other purpose in India other than export purpose only.

[1] Directorate General of Health Services Central Drugs Standard Control Organization, IMP-12/1/2024-eoffice, April 30, 2024, available at URL: cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTExNDQ=

[2] Guidance for Export NOC for Manufacture of Unapproved / Banned / New Drugs along with Annexures, July 3, 2024, available at URL: https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Guidance-documents/; See also, Drug firms' CEOs to file legal undertaking for exports NOC, July 13, 2024, available at URL: Drug firms' CEOs to file legal undertaking for exports NOC | Mint (livemint.com)

- **Physical Destruction:** If the export order is cancelled, whereby the export does not materialize, the manufacturer shall ensure physical destruction of the stocks.

Reportedly, the industry has requested for a relaxation of the above measures, particularly concerning the destruction of drugs which were not exported as implementing such measures will lead to significant financial losses to the manufacturer concerned.[3]

The centralization of the NOC process is a crucial step towards improving drug safety and quality in India. Notably, the detailed documentation requirements and the emphasis on quality control testing reflects India's commitment to ensuring that manufacturers are adhering to international standards.

Moreover, by implementing a standardized process across the country, the Indian government aims to streamline and centralize the approval process, ensure that NOC applications are subject to uniform standards and scrutiny, and enhances regulatory oversight. This will in turn enhance confidence in Indian pharmaceuticals.

We trust you will find this an interesting read. For any queries or comments on this update, please feel free to contact us at insights@elp-in.com or write to our authors:

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[3] CDSCO centralises powers to issue NOC for unapproved, banned & new drugs solely for exports, May 3, 2024, available at URL: https://www.pharmabiz.com/NewsDetails.aspx?aid=170150&sid=1 (Accessed on July 15, 2024)