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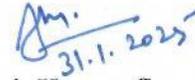
Government of India  
Ministry of Commerce and Industry  
Department of Commerce  
Directorate General of Foreign Trade

Public Notice No. 44/2024-25  
New Delhi, Dated 31<sup>st</sup> January, 2025

**Subject: Withdrawal of Para 2.76 of Handbook of Procedure - 2023 regarding Track and Trace system for export of drug formulations -reg**

S.O(E) : In exercise of the powers conferred under Paragraphs 1.03 and 2.04 of the Foreign Trade Policy 2023, as amended from time to time, the Director General of Foreign Trade hereby withdraws Para 2.76 of the Handbook of Procedures 2023 (previously Para 2.90A of HBP 2015-2020), which outlined the procedure for implementing the Track and Trace system for export consignments of drug formulations.

**Effect of this Public Notice:** Para 2.76 of the Handbook of Procedures 2023, concerning the Track and Trace system for the export of drug formulations, is hereby withdrawn with immediate effect. The implementation of the authentication system for drug formulations being exported shall be undertaken by Ministry of Health and Family Welfare in line with the provisions under Drug Rules 1945.

  
31.1.2025

(Santosh Kumar Sarangi)  
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& Ex-officio Additional Secretary, Government of India  
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## Press Note

### **Subject: Streamlining Export Compliance – Alignment with MoH&FW Regulations on Track and Trace System**

The Directorate General of Foreign Trade (DGFT) has decided to streamline export regulations by aligning with the evolving regulatory framework of the Ministry of Health & Family Welfare (MoH&FW). Accordingly, the provisions related to the Track and Trace System for pharmaceutical exports under the Foreign Trade Policy (FTP) are being withdrawn.

The Track and Trace System, introduced via Public Notice dated 10th January 2011, mandated barcoding at various packaging levels. While tertiary and secondary packaging requirements were successfully implemented in 2011 and 2013, primary-level barcoding and parent-child data uploading faced operational challenges and were repeatedly deferred, with the last extension valid until 1st February 2025.

The decision to withdraw these provisions is based on the following key considerations:

- MoH&FW has already implemented barcode/QR code requirements for 300 drug brands under the *Drugs Rules, 1945*, effective 1st August 2023, with plans for further expansion.
- Most export destinations have their own serialization requirements, ensuring product traceability without additional domestic regulations.
- MoH&FW, as the primary regulatory authority, provides a unified framework through the Central Drugs Standard Control Organization (CDSCO), ensuring consistency and eliminating duplication.

With this step, DGFT is enhancing ease of doing business for pharmaceutical exporters while ensuring regulatory coherence. Accordingly, the provisions under Para 2.76 of the Handbook of Procedures (HBP) 2023 has been withdrawn.

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