Regulatory Guidelines for Import and Export of Drugs, Cosmetics, Biologicals and Medical Devices in India: A Comprehensive Review

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***Abstract*—India is both a leading exporter of medicines and a large importer of active pharmaceutical ingredients, biological products, cosmetics and medical devices, so the rules governing cross-border movement of these products matter to manufacturers, importers, regulators and students. This review aims to describe, compare and critically evaluate the regulatory requirements for the import and export of drugs, cosmetics, biological products and medical devices in India.**

A narrative review was carried out using primary legal texts, guidance documents of the Central Drugs Standard Control Organisation (CDSCO), notifications of the Directorate General of Foreign Trade (DGFT), official trade data and peer-reviewed literature published up to November 2026. The review reveals that import control in India is product specific and based on licence, involving site and product registration (Form 40/41 and COS-1/COS-2) and clearance at the port and post-import quality checks (Lot release of vaccines). The primary tools to manage export control are domestic manufacturing licences, Good Manufacturing Practice certification of the manufacturers, export No Objection Certificates for unapproved or forbidden drugs and product specific measures like mandatory testing of cough syrups. Delays are being cut by recent reforms such as online filing, acceptance of European Union approval for medical devices and streamlined test licensing. But there are still challenges – such as the disjointed nature of the laws, the central/state divide, reliance on imports and disparities in compliance from small manufacturers. A single, converged, and harmonized framework will enhance patient safety and India's trade standing.

***Index Terms*—Drug import/ export regulation; Central Drugs Standard and control organisation; Medical drugs/cosmetics; Cosmetics act. Devices Rules; Cosmetics Rules; Biologicals**

I. INTRODUCTION

1.1. Background

Medicines, vaccines, cosmetics and medical devices directly affect human health, so their movement between countries is controlled by special laws in addition to general customs and trade rules. In India, these controls are exercised mainly through the Drugs and Cosmetics Act, 1940 and the rules made under it, with the Central Drugs Standard Control Organisation (CDSCO), headed by the Drugs Controller General of India (DCGI), acting as the national regulatory authority (Central Drugs Standard Control Organisation [CDSCO], 2025a; Government of India, 1940). The importance of such controls is shown by the World Health Organization's estimate that about 1 in 10 medical products circulating in low- and middle-income countries is substandard or falsified (World Health Organization [WHO], 2017). Because medicines move through long international supply chains, the import and export controls of a major producer such as India influence medicine quality far beyond its borders (WHO, 2017, 2021a). Substandard and falsified products fail to treat disease, waste the resources of patients and health systems and can cause serious illness or death, so regulation of cross-border trade is an important public health function rather than only an administrative matter (WHO, 2017).

1.2. India's Position in Global Health Product Trade

India's pharmaceutical exports reached USD 30.5 billion in 2024–25, nearly sixteen times the 2000–01 level, and the country ranked eleventh globally in pharmaceutical exports by value, supplying 191 countries; medical device exports grew from USD 2.5 billion in 2020–21 to USD 4.1 billion in 2024–25

(Press Information Bureau [PIB], 2026). Horner (2014) explained this growth as a selective and short-term "strategic decoupling" from the production networks of multinational firms, followed by "recoupling" with global markets. Rault-Chodankar and Kale (2023) also demonstrated how Indian companies with title "manufacturers without factories" contributed to India becoming a major supplier of medicines in the Global South. Findings from both studies reveal that regulatory capacity to secure approvals as well as certificates to enter into foreign markets has been a key to India's exporting success (Horner, 2014; Rault-Chodankar & Kale, 2023). This implies that the regulatory framework should not only control the large outflows of finished products but also the large inflows of critical inputs, which in fact, provides the outline of the import and export measures in India.

India has a significant reliance on imports for various active pharmaceutical ingredients (APIs), high technology medical devices and novel biologicals. Cherian et al. (2021) reported that although India ranks third in the world by volume of medicines produced, it relies heavily on imported raw materials, with implications for secure access to essential medicines, and recommended short-, medium- and long-term policy, fiscal and technological measures to build domestic API capacity. Bjerke (2022) similarly found that India is one of the largest exporters of antibiotic medicines but depends increasingly on China for antibiotic ingredients. For medical devices, the government informed Parliament in August 2025 that import dependence continued to be about 70% (Department of Pharmaceuticals, 2025).

1.3. Need for Regulation and Scope of the Review

Import regulation prevents the entry of substandard, spurious, adulterated or misbranded products and ensures that foreign manufacturing sites follow acceptable Good Manufacturing Practices (GMP) (CDSCO, 2007; Government of India, 1940). Export regulation protects patients abroad, India's reputation as the "pharmacy of the world" and its access to important markets, and it ensures that drugs banned or not approved in India are manufactured for export only under strict supervision (CDSCO, 2025d). Bastani et al. (2023) described a cluster of acute kidney injury among children in The Gambia in 2022 that was likely associated with diethylene glycol-contaminated syrup medicines imported from a single Indian manufacturer, with case fatality rates above 80%. Chopra et al. (2023) discussed the same tragedy and the WHO medical product alert of October 2022, and the event was followed by stricter pre-export testing of cough syrups in India (Directorate General of Foreign Trade [DGFT], 2023).

In this review, there are four product groups under the umbrella of the same parent Act but reviewed using distinct rules and Regulations: Drugs - Drugs Rules, 1945 and the New Drugs and Clinical Trials (NDCT) Rules, 2019; Cosmetics - Cosmetics Rules, 2020; Biological products - Drugs Rules with additional guidance for Biological products; and Medical Devices and In-Vitro Diagnostics (IVDs) - Medical Devices Rules (MDR), 2017 (Government of India, 1945; Ministry of Health and Family Welfare [MoHFW], 2017a, 2019, 2020a). These aims are to provide an overview of the legal and institutional infrastructure for imports and exports, to provide details on the licensing process for each import and export, to outline any changes in regulation from 2023-2026, to highlight some of the differences in selected requirements between international practice and the country's requirements, and to identify challenges and gaps to be addressed and directions for reform.

II. METHODOLOGY

The article is designed in a narrative way with structured document analysis. The primary sources of law including Drugs and Cosmetics Act, 1940; Drugs Rules, 1945; Medical Devices Rules, 2017; NDCT Rules, 2019; Cosmetics Rules, 2019; and the Promotional Claims Rules, 2011 were reviewed first. Rules, 2020; the Narcotic Drugs and Psychotropic Substances (NDPS) Act and Rules, 1985; and the Foreign Trade Policy (FTP), 2023 (Government of India, 1940, 1945, 1985; MoHFW, 2017a, 2019, 2020a). Other secondary sources of regulation were guidelines by CDSCO, DGFT, public notice and gazette notification by Central Bureau of Narcotics and Press information bureau.

Peer-reviewed literature was identified through PubMed Central, Google Scholar and journal websites using combinations of the terms "India", "CDSCO", "import", "export", "regulation", "medical devices", "cosmetics", "biosimilars", "vaccine", "GMP" and

"warning letters". Articles were included if they covered or commented on Indian regulatory requirements or Indian pharmaceutical trade or quality issues as issues relevant to the movement of health products across borders. International standards were based on reports from the World Health Organization and documents published up to November 2026 inclusive were included.

Findings were presented in categories based on the type of product and direction of the trade and presented in tabular and pictorial form following the list of references as per the journal norms. The review is based on publicly available documents and therefore the analysis expresses the formal legal situation; in practice the timetables and enforcement considerations can vary from one port to another and from one state to another, as explained in section 12.

III. REGULATORY FRAMEWORK AND AUTHORITIES

3.1. Legislation

The Drugs and Cosmetics Act, 1940 is the parent law for all four product groups. Section 10 prohibits the import of drugs or cosmetics that are not of standard quality, misbranded, adulterated or spurious, Section 10A empowers the government to prohibit the import of any drug or cosmetic in the public interest, and Section 12 empowers it to make rules for import (Government of India, 1940). Medical devices are notified as "drugs" under Section 3(b)(iv) and are therefore also covered (Gomez et al., 2020). Detailed procedures are laid down in Part IV of the Drugs Rules, 1945 for drug imports; in the NDCT Rules, 2019, which replaced Part XA and Schedule Y for new drugs and clinical trials; in the MDR, 2017 for devices; and in the Cosmetics Rules, 2020 for cosmetics (CDSCO, 2007; Dubey et al., 2019; MoHFW, 2017a, 2020a).

3.2. CDSCO and the Division of Responsibilities

CDSCO, under the Ministry of Health and Family Welfare (MoHFW), is the Central Licensing Authority for all imports. Its headquarters grants registration certificates and import licences, while its zonal and port offices verify licences and inspect consignments. State Licensing Authorities (SLAs) license the manufacture of most drugs and of Class A and B devices, and therefore play an important role in export (CDSCO, 2024a). Applications are filed online through the SUGAM portal and the medical device portal, and the Central Drugs Laboratory (CDL), Kasauli serves as the national control laboratory for vaccines and sera (CDSCO, n.d.-a, 2025a).

Chowdhury et al. (2015) found that the division of powers between CDSCO and the state authorities "may create the risk of fragmentation", because there is no hierarchy between them, the Drugs Consultative Committee has not functioned as a credible mechanism for uniformity and the centre rarely uses its power to issue directions under Section 33P. They also reported persistent staff shortages, noting that the Mashelkar Committee's recommendation of one drug inspector for every 50 manufacturing units had largely not been implemented. This matters for export because certificates demanded by importing countries, such as WHO-GMP certificates, are issued after joint central and state inspections (CDSCO, 2024e).

3.3. Other Agencies

The Directorate General of Foreign Trade (DGFT) frames export–import policy, issues the Importer–Exporter Code (IEC) and notifies product-specific export conditions (DGFT, 2023). Customs clears import and export consignments under the Customs Act, 1962. The Narcotics Commissioner issues import certificates and export authorisations for narcotic and psychotropic substances (Department of Revenue, n.d.), and the Review Committee on Genetic Manipulation and the Genetic Engineering Appraisal Committee oversee recombinant biologics and genetically engineered organisms (CDSCO & Department of Biotechnology, 2016). Export promotion councils such as the Pharmaceuticals Export Promotion Council of India issue the Registration-cum-Membership Certificate needed for export benefits under the FTP, and central drug testing laboratories test samples drawn at ports and in the market (CDSCO, n.d.-a). The overall import pathway is illustrated in Figure 1.

IV. IMPORT OF DRUGS

4.1. Registration Certificate and Import Licence

No drug manufactured outside India can be imported till both manufacturing site and drug at the manufacturing site is registered at CDSCO. The Indian

agent / subsidiary of foreign manufacturer is to make an application in Form 40 and the Registration Certificate will be granted in Form 41 as per Rule 27A of the Drugs Rules (Government of India, 2001). CDSCO's guidance provides a standard format for submissions, comprising of the Site Master File and product information in Common Technical Document (CTD) format alongside the manufacturing licence, free sale certificate, GMP certificate and Certificate of Pharmaceutical Product (COPP) from the country of origin (CDSCO, n.d.-i, 2007). The COPP is in line with the WHO Certification Scheme, where the regulator of the exporting country certifies the authorisation status of the product and compliance of its manufacturer with the GMP (WHO, 2021b).

Registration does not give permission to import! A wholesaler or manufacturer is required to obtain an import licence in form 10 from the importer after issuing the application in form 8 and a copy of certificate in form 41; Schedule X drugs need to be imported using an application in form 8A and an import licence in form 10A (Government of India, 2001). During crisis situations, the licensing authority, with permission from the Central Government, can waive off the requirement of the registration certificate and instead issue an import licence for the item (Government of India, 2001). This two-step process distributes the responsibility of regulating the foreign manufacturer from granting permission to an Indian entity responsible for the quality of drugs imported and their storage and distribution (CDSCO, 2007). The published process flow for applications includes that the applications are technically processed by drugs inspectors and then given for approval to senior officers in the Import and Registration Division, and that foreign sites can be inspected post-regulation or pre-regulation (CDSCO, 2007).

4.2. New Drugs and Test Licences

Under the NDCT Rules, 2019, permission to import a new drug for sale is sought in Form CT-18 and granted in Form CT-19 for an API or Form CT-20 for a formulation, normally within 90 working days; the importer must then obtain the Form 41 registration and Form 10 licence (MoHFW, 2019). Dubey et al. (2019) noted that the Rules aimed to make new drug regulation predictable, reduced clinical trial approval timelines to 30 days for domestic and 90 days for global trials, and allow waiver of local trials for drugs already approved in specified countries where there is no evidence of significant ethnic differences. The NDCT Rules also allow government hospitals and medical institutions to import small quantities of an unapproved new drug for patients with life-threatening diseases (MoHFW, 2019), which balances access to medicines unavailable in India against the need to keep commercial imports within the licensing system. Drugs for research, testing or clinical trials are imported under a test licence in Form 11 (application in Form 12) or under Forms CT-16 and CT-17 (CDSCO, 2025a). Test-licence requirements under the NDCT Rules were changed in January 2026 (MoHFW, 2026a), and a June 2026 draft proposed replacing Form 11 with an acknowledged online intimation for most analytical imports, excluding sex hormones, cytotoxic drugs, beta-lactams, live biologics and NDPS drugs (MoHFW, 2026b). Rule 36 separately allows patients to import small quantities of drugs for personal use, with larger quantities requiring a permit in Form 12B (Government of India, 1945).

4.3. Ports of Entry and Quality Surveillance

Under Rule 43A, drugs may be imported only through notified ports where CDSCO maintains port offices. Navi Mumbai International Airport was added in July 2026, and an October 2026 draft proposed adding inland container depots, ports and Special Economic Zones (MoHFW, 2026e, 2026g). On 26 May 2026, new guidelines, replacing those of February 2024, were released by the CDSCO on sampling of drugs, cosmetics and medical devices by central and state drugs inspectors, which include verification of the licence, certificate of analysis, labelling and shelf life, prior to issuing a No Objection Certificate (NOC) at the port. Concentrating imports at notified ports restricts expertise, but is also working to prevent congestion, a problem the extensive plans for additional entry points in 2026 are aimed at solving; restrictions are also needed on some products with special safety or diversion considerations, and this is what the draft test-licence for 2026 is addressing (MoHFW, 2026b, 2026g).

The checks are needed as the market surveillance demonstrates. The National Drug Survey 2014-16 sampled 47,012 samples of 224 molecules; in case of imported drugs, a separate sampling procedure was followed as it enters the market in different channels (MoHFW, 2017b). These results indicate that, while

there are relatively few spurious drugs, there are some quality failures which do occur but are measurable and thus warrant ongoing sampling at ports and in the market.

4.4. Narcotic Drugs and Psychotropic Substances

Import of substances in Schedule I of the NDPS Rules is prohibited, and every other import of a narcotic drug or psychotropic substance requires a consignment-specific import certificate from the Narcotics Commissioner in Form 4 or 4A (Department of Revenue, n.d.; Government of India, 1985). Applications are filed online through the SWIFT module of the Customs portal (Central Bureau of Narcotics, n.d.). This consignment-by-consignment control implements India's obligations under the international drug control conventions and prevents diversion of controlled substances into illicit channels (Department of Revenue, n.d.).

V. IMPORT OF COSMETICS

Since December 2020, cosmetics have been regulated under the separate Cosmetics Rules, 2020. A cosmetic manufactured abroad must be registered before import: the manufacturer, its Indian subsidiary or its authorised agent applies online in Form COS-1, and CDSCO grants an Import Registration Certificate in Form COS-2 (CDSCO, n.d.-e; MoHFW, 2020a). The application includes the manufacturer's authorisation, ingredient list with percentages, proposed labels, specifications and test methods, manufacturing licence, free sale certificate, a non-animal testing undertaking, and the importer's IEC and GST details (CDSCO, n.d.-h). The certificate remains valid in perpetuity provided that a retention fee is paid every five years (MoHFW, 2020a).

A "new cosmetic", containing an ingredient not previously used or recognised for cosmetic use, requires prior permission in Form COS-3 supported by safety and effectiveness data (CDSCO, n.d.-e; MoHFW, 2020a). The Rules prohibit import of animal-tested cosmetics, of cosmetics not permitted in their country of origin, and of products with a "use before" date less than six months from import (MoHFW, 2020a). Imported cosmetics must also carry the importer's name and address, the registration certificate number, batch number and use-before date, and must comply with Bureau of Indian Standards specifications (MoHFW, 2020a). CDSCO regularly cancels products from registration certificates and has published common deficiencies in COS-1 applications, such as unsigned non-animal testing declarations and labels without batch number or expiry date (CDSCO, n.d.-c, n.d.-d).

Rampal and Kanti (2020) compared the Indian cosmetics regulation with the cosmetics regulation of USA and concluded that within the USA cosmetics are mainly controlled after the production, while in India, the imported cosmetics need to be registered before the production. The Indian route provides direct control by the regulator to imported products; but imposes a greater documentary burden upon the importers, while the animal-testing ban is closer to the EU route. These differences mean that the requirements of each foreign market would have to be fulfilled separately by the exporters and for importers, information about the foreign products would have to be adapted to fit the Indian variants (CDSCO, n.d.-e; Rampal & Kanti, 2020).

VI. IMPORT OF BIOLOGICAL PRODUCTS

Biological products, including vaccines, sera, blood products, monoclonal antibodies and r-DNA-derived proteins, are legally "drugs", so their import requires Form 40/41 registration, a Form 8/10 licence and, for new products, permission under the NDCT Rules (CDSCO, 2021, 2024c). CDSCO's Guidance for Industry specifies quality, non-clinical and clinical data, including characterisation, viral safety, stability and comparability studies (CDSCO, 2024c). Applications for r-DNA-derived drugs are filed through SUGAM, and clearance from the biotechnology committees may also be needed (CDSCO, 2018; CDSCO & Department of Biotechnology, 2016).

Similar biologics are governed by the 2016 guidelines issued jointly by CDSCO and the Department of Biotechnology, which require a stepwise demonstration of similarity to a reference product in quality, non-clinical and clinical studies (CDSCO & Department of Biotechnology, 2016). Jois et al. (2020) noted that the guidelines aimed to provide a pathway at par with international regulation, while unresolved issues remained around interchangeability, nomenclature and labelling; CDSCO released draft revised guidelines in 2025 (CDSCO, 2025b). Because

India both imports innovator biologics and exports similar biologics, clear and internationally aligned similarity requirements matter for both directions of trade: they determine which foreign reference products may be relied upon and how readily Indian biosimilars are accepted abroad (CDSCO & Department of Biotechnology, 2016; Jois et al., 2020).
A distinctive feature of biological regulation is Lot release. Each batch of a vaccine or antiserum, imported or domestic, may be sold only after CDL, Kasauli has reviewed the summary lot protocol and, where required, tested samples (CDSCO, n.d.-a, n.d.-j). The national vaccine policy document sets out requirements for marketing approval, export and lot release (CDSCO, 2021), and in June 2026 post-approval change applications for vaccine registration certificates and import licences were moved onto SUGAM (CDSCO, 2026e). In September 2024, a re-benchmarking exercise conducted by WHO determined that India's vaccine regulatory system was in operation at Maturity Level 3 according to the WHO Global Benchmarking Tool, ensuring vaccine confidence across the globe for vaccines regulated in India (PIB, 2024; World Health Organization India, 2024). Further, cold-chain integrity is important: Das et al. (2020) reported vaccines were at temperatures outside recommended limits for an average of 6.6% of the time in storage in three states in India, with the highest being at district stores, and port officers could refuse to let vaccines be loaded if excursion of temperature during transit cannot be justified through stability data. Under similar principles, veterinary biologicals are regulated by a separate veterinary division of CDSCO (CDSCO, n.d.-f).

VII. IMPORT OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS

7.1. Classification and Licensing

Before 2017, only a limited list of "notified" devices was regulated, under the Drugs Rules. Gomez et al. (2020) concluded that the MDR, 2017 overhauled this framework and brought it closer to international norms, and D. Sharma and Chandra (2020) described its classification of devices into four risk classes: A (low), B (low–moderate), C (moderate–high) and D (high), with IVDs classified in a similar way (CDSCO, n.d.-g). Licensing was extended to all Class A and B devices from 1 October 2022 and to Class C and D devices from 1 October 2023 under the phased scheme notified in 2020, with non-sterile, non-measuring Class A devices placed under online registration instead (MoHFW, 2020b, 2022b). Online risk classification applications became available from 27 November 2025 for devices and 18 February 2026 for IVDs (CDSCO, 2025c).
Unlike drugs, devices need only a single import licence: the application is made in Form MD-14 and the licence issued in Form MD-15 by CDSCO for all classes (CDSCO, n.d.-k). The dossier includes Device and Plant Master Files, a free sale certificate from the country of origin, quality management certification and labels, and the licence remains valid subject to a retention fee every five years (CDSCO, n.d.-b, 2024a). Other routes cover test licences (MD-16/MD-17), import of investigational devices by government hospitals (MD-18/MD-19) and personal import (MD-20/MD-21) (MoHFW, 2017a). Used or refurbished equipment is additionally controlled under the Hazardous and Other Wastes Rules, 2016 (Ministry of Environment, Forest and Climate Change, 2016).
Rule 63 allows waiver of local clinical investigation for devices without a predicate that have been approved and marketed for at least two years in specified countries. The Medical Devices (Third Amendment) Rules, 2026 added European Union countries to this list and required self-certification of quality management systems for non-sterile, non-measuring Class A devices (MoHFW, 2026f). A June 2026 draft further proposed shorter timelines for audits, inspections and licence decisions (MoHFW, 2026d), and in March 2026 CDSCO clarified the licensing of devices used in assisted reproductive technology (CDSCO, 2026b). These changes show that device regulation in India is still developing rapidly.

7.2. Critical Assessment

Manu and Anand (2022) have noted some of the disparities between the rules in India and the European Union regulation, including inconsistent provisions between the clinical investigation and post-market evaluation requirements, inadequate pre-market clinical data requirements, missing of EUDAMED, which is a public adverse-event database, and limited post-market obligations. The gaps are important as India is highly dependent on high technology devices imports, a Parliamentary Committee report in March

2026 showed that India imports USD 8.8 billion of such devices while exporting approximately USD 4 billion during 2024–25 (R. Sharma, 2026). Manu and Anand (2022) also pointed out that there is a lack of uniformity in the rules with some products still subject to the drug rules and others to the rules for devices. The reliance on approvals of fast-track countries such as EU (under a schedule for implementation in 2026) helps facilitate access to imported devices, while also making India's own post-marketing surveillance of such devices even more critical (Manu & Anand, 2022; MoHFW, 2026f). A comparison of import requirements among the four categories is provided in Table 1.

VIII. EXPORT OF DRUGS, COSMETICS, BIOLOGICALS AND MEDICAL DEVICES

8.1. General Framework and Certificates

Under the FTP, 2023, most drugs, cosmetics and devices are "free" for export unless DGFT notifies a restriction. Exporters need an IEC, a shipping bill and a valid Indian manufacturing licence, so quality is controlled mainly at the stage of manufacture (Chitte et al., 2026). Chitte et al. (2026) identified procedural complexity, staffing constraints and varying international requirements as the main challenges for exporters, and Pateriya et al. (2011) earlier showed that destination-specific registration requirements are essential knowledge for Indian exporters to emerging markets.

Importing countries commonly require a WHO-GMP certificate and COPP issued after joint CDSCO–state inspection, free sale, market standing and non-conviction certificates, and, for APIs exported to the European Union, a Written Confirmation of GMP equivalence, which CDSCO streamlined on SUGAM in March 2026 (CDSCO, 2019, 2024b, 2024e, 2026d; WHO, 2021b). Rule 94 allows export labelling according to the importing country's requirements (CDSCO, 2025d). WHO guidelines on the Certification Scheme set out how an exporting regulator should attest to a product's authorisation status and the GMP status of its manufacturing site (WHO, 2021b), so the reliability of Indian COPPs depends directly on the quality of GMP inspections discussed in Section 9. The export pathway is shown in Figure 2 and summarised in Table 2.

8.2. Unapproved, New and Banned Drugs

Products approved abroad but not in India, or banned in India, may be manufactured for export only under an export NOC. By an office order dated 30 April 2024, CDSCO withdrew, with effect from 15 May 2024, the delegation under which state and union territory licensing authorities issued these NOCs, and required manufacturers to obtain them from CDSCO zonal offices through the SUGAM portal before the state manufacturing licence is granted (CDSCO, 2024d). The revised guidance of May 2025 prescribes registration with the zonal office followed by verification of the NOC, purchase order and quantity at the port, with order-specific NOCs for NDPS and banned drugs (CDSCO, 2025d). Since January 2026, bioequivalence studies of unapproved drugs for export need only an online intimation (MoHFW, 2026c). Centralisation reduces the risk of diversion to the domestic market that existed under the earlier state-based system (CDSCO, 2024d; Chowdhury et al., 2015).

8.3. Pre-Export Testing of Cough Syrups

The export of cough syrups was made subject to testing of export samples and a certificate of analysis from the list of government laboratories (DGFT, 2023) from 1 June 2023, with NABL-accredited private laboratories approved later in 2023 (CDSCO, 2023). The measure will tackle the risk identified by Bastani et al. (2023), which is contamination of syrup medicines with diethylene glycol and testing the finished product will be done at the point at which contaminated products described by Bastani et al. (2023) and Chopra et al. (2023) reached patients abroad. Pre-export testing is the most apparent example in India of a product-specific export control, which was introduced for the benefit of patients in other countries, and how a single quality failure can lead to the enlarging of export control for an entire class of products (Chopra et al., 2023; DGFT, 2023).

8.4. Narcotics, Biologicals, Cosmetics and Devices

Narcotic and psychotropic drugs require a consignment-specific export authorisation in Form 5 from the Narcotics Commissioner, and exports of some psychotropic substances to particular countries are prohibited (Department of Revenue, n.d.; Government of India, 1985). For vaccines, India has 36 major manufacturing facilities, supplies about 150

countries and provides vaccines to UNICEF, WHO and the Pan American Health Organization (PIB, 2024); export requires GMP-compliant manufacture and, where the purchaser requires it, CDL lot release (CDSCO, 2021). Retention of Maturity Level 3 in the 2024 WHO benchmarking is therefore not only a domestic achievement but also a condition for continued international confidence in Indian vaccines (World Health Organization India, 2024). Cosmetics made under a valid licence can be exported freely with free sale and GMP certificates (MoHFW, 2020a), while device manufacturers obtain free sale certificates from CDSCO for Class C and D devices or from the SLA for Class A and B devices (CDSCO, 2024b).

DGFT's track-and-trace barcoding requirement for pharmaceutical exports, repeatedly deferred since 2011, was withdrawn in January 2025 (PIB, 2025b). Exporters now follow destination-market traceability rules, such as the Drug Supply Chain Security Act in the United States and the Falsified Medicines Directive in the European Union, but India lost a national mechanism that could have supported investigation of falsified products of claimed Indian origin, a problem of global relevance (WHO, 2017).

IX. GOOD MANUFACTURING PRACTICES AND FOREIGN INSPECTION EVIDENCE

GMP underpins both import and export regulation. The revised Schedule M, notified on 28 December 2023, added requirements for a pharmaceutical quality system, quality risk management, product quality review, validation and computerised systems; manufacturers with turnover of ₹250 crore or less were conditionally given until 31 December 2025 to comply (PIB, 2025a). Reports at the end of 2025 indicated that only about a quarter of an estimated 6,500 small manufacturers had submitted upgrade plans (Koul, 2025). Because only compliant units can obtain WHO-GMP certificates and COPPs, revised Schedule M will directly affect which manufacturers can export.

Foreign inspections provide independent evidence. Bablani and Janodia (2020) observed the significant rise in US Food and Drug Administration (US FDA) warning letters issued to Indian pharma and device companies from 2005 to 2018, wherein 85.87% of the wrongdoings were with respect to the current GMP; and 80.72% of warning letters did not have a close out letter. Rathore et al. (2023) found that the main GMP violations in FDA warning letters from 2010 to 2020 concerned process validation (26%), documentation and data integrity (21%) and quality control (15%). Since these are the areas that were also covered by the revised Schedule M, enhanced domestic enforcement can minimize the risk of import alerts and loss of access to foreign markets and also make the Indian medicines market better.

Furthermore, the low close out rate reported by Bablani and Janodia (2020) confirm that corrective action in the aftermath of a foreign inspection is many times delayed, with the need for ongoing domestic inspection rather than dependence on foreign inspectors to find problems.

X. COMPARATIVE PERSPECTIVE AND REGULATORY RELIANCE

WHO defines regulatory reliance as taking into account the work of another trusted regulator while focusing national resources on activities others cannot perform, such as vigilance, market surveillance and oversight of local manufacturing (WHO, 2021a). The use of COPPs and free sale certificates already exists for imports, waiver of local trial for new drugs are already approved in specified countries and the recognition of European Union device approvals has been done since 2026 (CDSCO, 2007; Dubey et al., 2019; MoHFW, 2026f).

Meanwhile, literature indicates that India is missing on certain post-market and transparency tools in the European Union and has a more stringent approach towards pre-market registration of cosmetics when compared to the United States (Manu & Anand, 2022; Rampal & Kanti, 2020).

The literature highlights that India is lacking in inspection of domestic exporters and surveillance of imported products as the areas of greatest weakness, and a more explicit reliance policy, outlining which foreign decisions India will accept for which purposes, could help in this direction.

Reliance would not remove national responsibility: WHO makes clear that the regulator relying on conformity assessment remains responsible for its decisions and must still maintain capacity for vigilance and market surveillance (WHO, 2021a).

XI. RECENT REGULATORY DEVELOPMENTS (2023–2026)

Between 2023 and 2026, there have been two parallel development trends (Table 3). The first is better quality control, including universal device licensing (October 2023), mandatory testing of cough syrup, revised schedule M, centralisation of export NOCs and draft proposals for an authorised person for batch release and the definition of all antimicrobials as 'new drugs' (CDSCO, 2024d, 2026a; DGFT, 2023; PIB, 2025a). The following measures are directly related to the quality shortcomings mentioned above, especially the contamination of exports in 2022 and the GMP shortcomings in foreign inspections (Bastani et al., 2023; Rathore et al., 2023). The latter one is procedural facilitation: online filing and risk categorization, simplified test license, more ports, elimination of export track and trace requirements and acceptance of European Union device approvals (CDSCO, 2025c; MoHFW, 2026b, 2026e, 2026f; PIB, 2025b). At the level of the parent law, the Ministry of Health and Family Welfare released the draft New Drugs, Medical Devices and Cosmetics Bill, 2022 on 8 July 2022, inviting public comments within 45 days; the Bill, which would replace the 1940 Act and regulate medical devices separately from drugs, has not been enacted (MoHFW, 2022a). The challenge for the regulator is to ensure that facilitation does not weaken safety and that stricter controls do not create unnecessary barriers to legitimate trade (WHO, 2021a).

XII. CHALLENGES AND DISCUSSION

The results indicate that India has a well-defined country-level framework for regulating import & export of health products, which has been significantly enhanced since 2023. Read together with the literature, however, they also reveal recurring structural weaknesses across product categories (Chowdhury et al., 2015; Manu & Anand, 2022).

Fragmented legislation and divided authority.
An Act more than eighty years old, several sets of rules, NDPS, biosafety, trade and customs laws each impose separate forms and portals, which is particularly confusing for combination and borderline products (Manu & Anand, 2022). Central and state split (Chowdhury et al., 2015) provides for the variation in the licensing and inspection capacity.
Procedural burden. However, applicants still have to deal with multiple queries and submit apostiled foreign documents, and the port sampling process causes delays for temperature-sensitive biologicals (CDSCO, n.d.-d; Chitte et al., 2026). Chitte et al. (2026) reported that inadequate staffing contributes to administrative strain, delays in preparation, and impacts are the greatest on small exporters.

Import dependence. India is dependent on imports of API and devices which make it vulnerable in the event of supply disruption, as pointed out by Cherian et al. (2021) and Bjerke (2022) reliance is on Chinese pharmaceutical inputs, and imports are approximately USD 4.8 billion higher than exports (R. Sharma, 2026). Regulation should serve the purpose of protecting quality without hindering vital imports.
Uneven manufacturing compliance. Weakest manufacturers indicate India's export reputation with their high prevalence in contaminated exports, GMP violations in FDA warning letters and low adoption of Schedule M by small manufacturers (Bablani & Janodia, 2020; Bastani et al., 2023; Koul, 2025).
Low level of harmonisation and supervision. The absence of agreements for mutual recognition to facilitate different manufacturers to carry out repeated foreign examinations, and the lack of post-marketing systems, can lead to issues with imported medical devices being identified late (Manu & Anand, 2022; WHO, 2021a). Convergence can be achieved by closer alignment with international guidelines, and by implementing the EU recognition of device approvals in 2026, but these should be combined with enhanced national vigilance systems.

On the whole, India's greatest deficiency in terms of regulation is not the lack of regulation, but the even-handedness of regulation. The legal procedures in import registration, export certification and GMP are generally in accordance with international practices, but the level of enforcement varies by the manufacturer and the state (Bablani & Janodia, 2020; Bastani et al., 2023; MoHFW, 2017b). Reforms to increase the inspection capacity, transparency and coordination are therefore likely to yield greater benefits than further additions to the rule book (Chowdhury et al., 2015; WHO, 2021a).

XIII. FUTURE PERSPECTIVES

There are a number of steps that could be taken to make things more efficient and to protect public health. Having one modern legislation with specific chapters for drugs, cosmetics and devices would minimise the overlap (Manu & Anand, 2022; MoHFW, 2022a), and coordination with the states, along with power of the centre to issue directions, would minimise the variation in the enforcement of GMP. Investment in drug inspectors and testing laboratories, in line with the staffing norms recommended in earlier expert reviews, would support both domestic quality and the credibility of export certificates (Chowdhury et al., 2015). Linking SUGAM, the device portal, Customs, DGFT and the Central Bureau of Narcotics through a single window, and adopting risk-based port sampling, would allow a consignment to be cleared on a single electronic record and concentrate testing on high-risk products (CDSCO, 2025a, 2026c; MoHFW, 2026b).

Wider reliance on approvals and inspection reports from trusted regulators, as already begun for medical devices, would reduce duplication and free resources for inspection of domestic exporters and surveillance of imported products (MoHFW, 2026f; WHO, 2021a). Support for small manufacturers' Schedule M upgrades would protect export quality without mass closures (Koul, 2025), and continued promotion of domestic API and device manufacture would reduce supply vulnerability (Bjerke, 2022; Cherian et al., 2021). Last but not least, a national track and trace system and a public adverse-event database for devices would assist with the identification of falsified and unsafe devices (Manu & Anand, 2022; WHO, 2017).

XIV. CONCLUSION

The regulation of import and export of drugs, cosmetics, biological products and medical devices in India rests on the Drugs and Cosmetics Act, 1940 and a growing set of product-specific rules. Import control is strict and licence-based, requiring registration of foreign sites and products, licensed importers, notified ports and, for vaccines, lot release. Relying on the quality of domestic manufacture, in conjunction with the WHO-GMP certification, export NOCs for unapproved and banned drugs, NDPS authorisations and targeted measures like cough syrup testing are important elements of export control. Despite reforms that took place between 2023 and 2026, which strengthened quality requirements but simplified procedures, fragmented legislation, divided powers, dependence on imports and sporadic GMP compliance are significant areas of concern. India's position as a trusted global supplier of health products and protection of its patients at home and abroad can be improved with a single modern law, the law of integrated clearance, explicit regulatory reliance, and better post-marketing surveillance.

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TABLES

Table 1. Comparison of import requirements for the four product categories.

Product category	Pre-import approval	Import licence / permission	Special conditions
Drugs (APIs and formulations)	Registration certificate for site and product: Form 40 (application) → Form 41; new drug permission CT-18 → CT-19 (API) / CT-20 (formulation)	Form 8 → Form 10; Schedule X drugs Form 8A → Form 10A; test licence Form 12 → Form 11	Import only through ports notified under Rule 43A; NDPS import certificate where applicable; personal import under Rule 36
Cosmetics	New cosmetics: prior permission in Form COS-3	Import registration certificate: Form COS-1 → Form COS-2 (valid in perpetuity with retention fee every 5 years)	No animal-tested products; use-before date of at least 6 months at import; labelling and BIS standards
Biologicals (vaccines, sera, r-DNA products, blood products)	Form 40 → Form 41; new drug permission under NDCT Rules; RCGM/GEAC clearance for r-DNA/GE products where required	Form 8 → Form 10	Lot release by CDL, Kasauli for vaccines and sera; cold-chain evidence; biological guidance for industry
Medical devices and IVDs	Risk classification (Class A–D); no separate registration certificate	Single import licence: Form MD-14 → Form MD-15; test licence MD-16 → MD-17; hospital MD-18 → MD-19; personal MD-20 → MD-21	Free sale certificate from country of origin; ISO 13485; Rule 63 waiver of clinical data for devices approved in specified countries including EU (2026)

Source: Compiled from CDSCO (2007), MoHFW (2017a, 2019, 2020a), CDSCO (2021), CDSCO (n.d.-e, n.d.-k) and MoHFW (2026f).

Table 2. Key export requirements by product category.

Product category	Regulatory requirements	Certificates commonly issued for importing countries
All products	IEC from DGFT; shipping bill under Customs Act; RCMC from export promotion council for incentives; valid Indian manufacturing licence	—
Drugs	Export NOC from CDSCO zonal office for unapproved, new or banned drugs (order-specific for NDPS and banned drugs); NDPS export authorisation in Form 5; pre-export testing and certificate of analysis for cough syrups (from 1 June 2023); export labelling under Rule 94	WHO-GMP certificate; COPP; free sale certificate; Written Confirmation for APIs exported to the EU
Biologicals and vaccines	Manufacturing licence; GMP compliance; lot release by CDL where required by purchaser	COPP; lot release certificate; documents supporting WHO prequalification
Cosmetics	Manufacturing licence under Cosmetics Rules, 2020	Free sale certificate; GMP certificate
Medical devices	Manufacturing licence under MDR, 2017	Free sale certificate (CDSCO for Class C/D; SLA for Class A/B); market standing and non-conviction certificates

Source: Compiled from CDSCO (2019, 2021, 2024b, 2025d, 2026d), DGFT (2023), Government of India (1985) and Chitte et al. (2026).

Table 3. Major regulatory developments affecting import and export (2023–2026).

Year	Development	Effect on import/export
2023	Licensing of all Class C and D devices from 1 October; cough syrup pre-export testing (DGFT Notification 06/2023); revised Schedule M notified in December	Universal device import control; stricter export quality checks
2024	Export NOC for unapproved/new/banned drugs centralised with CDSCO zonal offices	Uniform national control of export-only manufacture
2024	WHO re-benchmarking confirms India's vaccine regulatory system functional at Maturity Level 3	Supports continued supply of Indian vaccines to United Nations procurement agencies
2025	Track-and-trace provisions for pharmaceutical exports withdrawn (January); revised export NOC guidance (May); MSME Schedule M deadline 31 December; online risk classification on SUGAM (November)	Lower export compliance cost; stronger GMP basis for export certificates
2026	Test licence changes under NDCT Rules (January); draft Form 11 simplification (June); NMIA added under Rule 43A (July); EU added to MDR Rule 63 (August); draft expansion of Rule 43A ports and other drafts (October–November)	Faster research imports; more entry points; easier licensing of EU-approved devices

Source: Compiled from MoHFW (2020b, 2026a, 2026b, 2026e, 2026f, 2026g), DGFT (2023), PIB (2025a, 2025b), WHO India (2024), CDSCO (2024d, 2025c, 2025d).

FIGURES

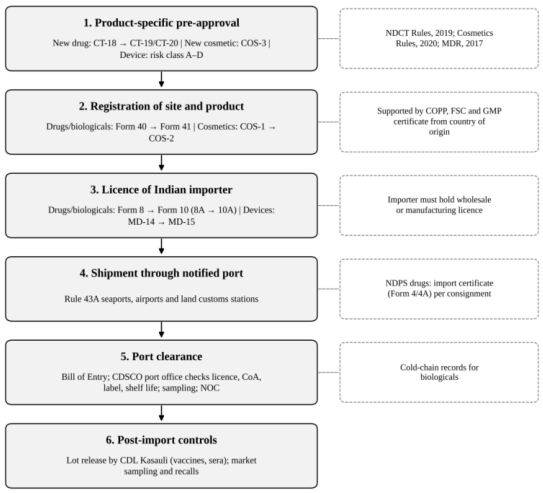


Figure 1. General pathway for the import of drugs, cosmetics, biologicals and medical devices into India. Main boxes show the sequence of regulatory steps; dashed boxes show related conditions. Not every step applies to every product category.

Source: Prepared by the authors from CDSCO (2007), MoHFW (2017a, 2019, 2020a), Government of India (1945, 1985) and CDSCO (n.d.-a).

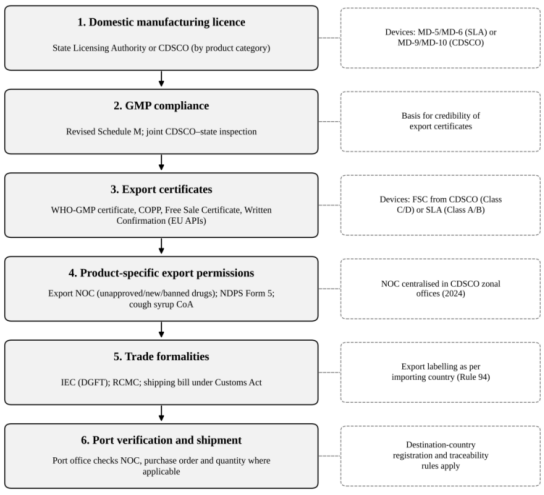


Figure 2. General pathway for the export of drugs, cosmetics, biologicals and medical devices from India. Product-specific permissions in step 4 apply only to the categories named.

Source: Prepared by the authors from CDSCO (2024b, 2024e, 2025d, 2026d), DGFT (2023), Government of India (1985), Chitte et al. (2026) and CDSCO (n.d.-k).