

## TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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### REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

**1. What are the principal statutes, regulations, and competent authorities that govern the import, wholesale distribution, retail sale, and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?**

#### Principal statutes and regulations

The trade and distribution of therapeutic products in India is principally governed by the Drugs and Cosmetics Act, 1940 (Drugs Act). Under the Drugs Act, a ‘drug’ is defined to include medicines for external and internal use, components of drugs (including excipients) as well as medical devices, that are separately regulated under the Medical Device Rules, 2017 notified under the Drugs Act.

The Drugs Act regulates and prescribes necessary compliance requirements for the import, manufacture, distribution and sale of drugs, as well as the applicable penalties in cases of non-compliance. The drugs being manufactured and imported into India should be of standard quality, not be misbranded or spurious, and hold valid approvals according to the rules issued under the Drugs Act.

Additionally, the Drugs Rules, 1945, notified pursuant to the Drugs Act (Drugs Rules) regulate the import, manufacture, distribution, stocking and sale of drugs by imposing requirements pertaining to licensing and registration, product standard, packaging, labelling and other related processes upon entities seeking to carry out such activities. The licences are subject to conditions which need to be complied with in order to continue holding a valid licence.

The Drugs Rules classify drugs into various schedules based on their differing nature, and impose varying conditions in relation to their manufacture, import, and sale. For instance, drugs classified under Schedule D pertain to substances not intended for medicinal use, drugs imported for manufacture and export by units situated in special economic zones, and other substances used both as articles of food and drugs, and they are partly or wholly exempt from importing regulations under the Drugs Act.

Similarly, Schedule H1 primarily comprises certain third and fourth generation drugs and some anti-tuberculosis medication for which a separate register is to be maintained, and additional dispensing and labelling requirements are prescribed.

In addition, Schedule X enlists some highly potent drugs that are prone to abuse, and such drugs are required to be stored under lock and key or in a segregated area of the premises, and must

carry prescribed warnings. The New Drugs and Clinical Trials Rules, 2019 regulate new drugs and clinical investigations.

### **Competent authorities**

The Drug Controller General of India, acting through the Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health and Family Welfare, administers and approves the manufacturing, importing or marketing of medicinal products and medical devices in India. The CDSCO sets national standards, issues central licences for import, manufacture and marketing, and oversees new drug and device approvals, while State Drug Controllers licence and inspect sales, stocking and distribution establishments and enforce retail/wholesale compliance at the state level.

Additionally, three agencies have been constituted under the Drugs Act for assisting and advising the central and state governments. These are:

- Drugs Technical Advisory Board, which advises the government on technical matters arising out of drug control administration;
- Drugs Consultative Committee, which advises the government and the Drugs Technical Advisory Board on matters tending to secure uniformity in drug control administration throughout the country; and
- Central Drugs Laboratory, which functions as the central drug testing laboratory for CDSCO.

### **Other key regulations**

The Legal Metrology Act, 2009 and Legal Metrology (Packaged Commodities) Rules, 2011 regulate price and quantity declarations on packaging.

Moreover, the Drugs (Prices Control) Order, 2013 administered by the National Pharmaceutical Pricing Authority (NPPA) sets ceiling prices and monitors overcharging, and the Narcotic Drugs and Psychotropic Substances Act, 1985 governs controlled substances with overlapping CDSCO and state controls. Customs enforcement at the border is undertaken by the Central Board of Indirect Taxes and Customs in coordination with CDSCO.

**2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use, risk classes for devices, etc.) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?**

### **Drugs**

The schedules to the Drugs Rules classify medicines as ‘prescription-only’ or ‘over-the-counter’ (OTC), along with relevant dispensing restrictions, record-keeping and advertising constraints.

Products listed under Schedule H to the Drugs Rules are prescription-only medicines. The sale of these drugs to end users can only be undertaken by licensed retailers against a valid prescription issued by a registered medical practitioner. Packaging must bear mandatory prescription legends and warnings, and retail sales must be supervised by a registered pharmacist.

Schedule H1 to the Drugs Rules imposes enhanced obligations on a subset of medicines, notably critical antimicrobials and certain controlled substances. Retailers must maintain a detailed prescription register capturing the prescriber's particulars, patient details, product and quantity supplied, and must retain records for a prescribed period.

Schedule X covers narcotic and psychotropic medicines, which in addition to the prescription-only constraints, require secure storage and stringent inventory control. Entities intending to sell drugs covered under Schedule X must hold a specific Schedule X endorsement, maintain purchase and sale registers, ensure longer retention of records, and comply with restrictive dispensing rules. Packaging must also include prominent cautionary legends.

For products outside the prescription schedules, supply without prescription is generally permissible, subject to standard quality, labelling, and advertising controls. India does not maintain a comprehensive positive list of OTC medicines; market practice and regulator guidance determine whether a particular non-scheduled product can be sold in general retail. Certain centrally approved products may be designated 'for hospital/institutional use only' as a condition of approval, limiting trade to licensed hospitals or institutions and excluding open retail channels.

The New Drugs and Clinical Trials Rules, 2019 require 'new drugs' to obtain pre-market permission prior to manufacture for sale or import. The definition of a 'new drug' inter alia includes:

- new drugs which have not previously been used to a significant extent in India and not approved as safe and efficacious;
- newly modified or sustained release forms of previously-approved drugs;
- new fixed-dose combinations;
- new indications; and
- new routes of administration.

For drugs that are not 'new' in India, while state-level manufacturing and sale licences remain necessary, and imports require central import licences, formal central 'new drug' approval is not required.

### **Medical devices**

The classification of medical devices is based on the risks they pose to patients, the intended use, and the duration of contact with the body. Higher-risk categories of medical devices require conformity assessment and central registration/licensing, and all classes are subject to quality control, labelling, and post-market obligations once notified as 'drugs'. The four classes, ie, Class A, Class B, Class C, and Class D, represent an increasing order of risk. Each class has distinct regulatory implications and requirements.

These classifications determine who may supply which products, the need for prescriptions, documentation and pharmacovigilance, and whether distance selling is permitted under state pharmacy and CDSCO guidance.

For Classes A and B, manufacture and sale generally proceed on the basis of state-level licensing and registration, supported by conformity assessment and quality management systems aligned to ISO 13485. For Classes C and D, central licensing by CDSCO is mandatory.

Across all classes, only licensed entities may manufacture, import, stock, exhibit, or offer devices for sale. Distributors must hold appropriate licences and comply with storage, handling, and installation or servicing requirements when applicable. Post-market vigilance, adverse event reporting, and recall procedures are mandatory and scale with risk classification.

All regulated products must obtain pre-market licences appropriate to their classification.

## LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

### 3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

#### Licence and eligibility criteria

A licence is required to sell, stock, exhibit or offer for sale or distribute by wholesale:

- drugs not specified in Schedules C, C(1) and X) in Form 20-B of the Drug Rules;
- drugs specified in Schedules C and C(1) in Form 21-B of the Drug Rules; and
- drugs specified in Schedule X of the Drugs in Form 20-G of the Drug Rules.

A separate licence is required to be obtained for each place where the drugs are sold or stocked for sale. Unless suspended or cancelled by the licensing authority, once a licence is obtained in Form 20-B, Form 21-B and Form 20-G, as applicable, the licence is valid in perpetuity. This is subject to the payment of a licence retention fee every five years from the date of issue of licence.

A wholesale licence may only be granted if the competent authority is satisfied that the premises are suitable, have proper storage facilities to preserve the properties of the drugs covered by the licence, and are supervised by a person whom the authority considers competent to oversee the sale, distribution and preservation of drugs.

In deciding whether to grant a licence, the authority must consider the average number of licences granted in the preceding three years and the occupation, trade or business ordinarily carried on by the applicant in that period. The authority may refuse a licence if the applicant or licensee has been convicted of an offence under the Drugs Act or the Drugs Rules, or has had a licence previously cancelled or suspended, and is therefore not a fit person to hold a licence.

For applications for a wholesale licence in Form 20-B or 21-B of the Drugs Rules, the authority must be satisfied that the relevant premises where the drugs are proposed to be sold or stocked for sale:

- have an area of not less than ten square meters; and
- are under the charge of a competent person who is either –
  - a registered pharmacist; or

- has passed the matriculation (or equivalent) examination with four years' experience in the sale of drugs; or
- holds a recognised university degree with one year's experience in dealing with drugs.

### **Key conditions**

A licensee must comply with the following conditions of a wholesale licence:

- the licence must be displayed conspicuously in a public area of the premises;
- the licensee must comply with the Drugs Act and the Drugs Rules;
- the licensee must not sell any drug unless it was bought with a cash or credit memo from a duly licensed dealer or manufacturer;
- the licensee must not sell any drug to a person who does not hold the required licence to sell, stock, exhibit for sale, or distribute that drug. This restriction does not apply to sales made to – (i) a government officer or authority purchasing on behalf of the government; (ii) a hospital, medical, educational or research institution, or a registered medical practitioner for supply to patients; and (iii) a manufacturer of beverages, confectionery, biscuits, or other non-medicinal products where the drugs are needed for processing those products; and
- the licensee must notify the competent authority in writing if the licensee's constitution changes. After such a change, the existing licence remains valid for up to three months from the date of change, unless a new licence in the name of the reconstituted firm is obtained earlier.

#### **4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies, or other retailers), and what key conditions attach to them?**

Businesses that provide therapeutic products directly to consumers must hold a licence to sell, stock, exhibit or offer for sale, or distribute drugs:

- drugs other than those in Schedules C, C(1) and X under Form 20 (or Form 20-A as a restricted licence where no qualified person is engaged);
- drugs in Schedules C and C(1) under Form 21 (or Form 21-A as a restricted licence where no qualified person is engaged); and
- Schedule X drugs under Form 20-F, which may be granted only to a pharmacy, and where no pharmacy operates, to a chemist and druggist.

A separate licence is required for each premises where drugs are sold or stocked, except for itinerant vendors who may be licensed for a defined area.

Licences issued in the above forms remain valid in perpetuity, subject to payment of a retention fee every five years, unless suspended or cancelled. Compliance with licence conditions, the Drugs Act and the Drugs Rules will be assessed at least once every three years, or more frequently on a risk basis.

A restricted licence may be issued only if the relevant premises are adequate and provide sufficient storage to preserve the properties of the drugs. While deciding whether to grant any licence, the authority considers, among other factors, prior licences in the locality, the applicant's

occupation or business, and any convictions or prior suspensions/cancellations under the Drugs Act or Drugs Rules. A licence may not be granted to an applicant found not to be fit to hold a licence.

Other retail licences in Forms 20, 20-F and 21 require suitable premises with proper storage and supervision by a competent person acceptable to the authority. For retail licences in Forms 20 or 21, the premises, equipment, record-keeping and operational requirements in Schedule N apply. The minimum area is ten square meters, or fifteen square meters where both retail (Forms 20/21) and wholesale (Forms 20-B/21-B) activities are conducted from the same premises.

### **Key conditions**

A licensee must comply with the following conditions of a retail licence:

- the licence must be clearly displayed in a public area of the premises;
- the licensee must comply with the Drugs Act and the Drugs Rules;
- the licensee must not sell any drug unless it was bought with a cash or credit memo from a duly licensed dealer or manufacturer;
- the licensee must supply prescription drugs only under the personal supervision of a registered pharmacist; and
- the licensee must notify the competent authority in writing if the licensee's constitution changes – after such a change, the existing licence remains valid for up to three months from the date of change, unless a new licence in the name of the reconstituted firm is obtained earlier.

## **5. What rules govern the sale of therapeutic products to consumers over the internet (including social-media and marketplace platforms)?**

As highlighted above, a licence is inter alia required under the Drugs Act to sell, stock, or exhibit or offer for sale, or to distribute any drugs or cosmetic. However, the sale of drugs through an online platform is not specifically covered under the Drugs Act. Consequently, there is ambiguity on the applicability of the Drugs Act to a marketplace selling pharmaceutical products online.

In this regard, the Ministry of Health and Family Welfare has released draft amendments to the Drugs Rules on 28 August 2018 (Draft Rules), which prescribe that any distribution, sale, stocking, exhibiting or offering of drugs for sale through an e-pharmacy portal can only be undertaken after obtaining registration under the Drugs Act.

In addition, the Draft Rules provide for inspection of e-pharmacies at regular intervals and set out an obligation to maintain confidentiality of customer information. The term 'e-pharmacy' is defined under the Draft Rules as the 'business of distribution or sale, stock, exhibit or offer for sale of drugs through web portal or any other electronic mode'. However, the Draft Rules are yet to be notified.

## **IMPORT**

**6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?**

To import drugs into India, an import licence is required in Form 10 for all drugs other than those listed in Schedule X of the Drugs Rules, and in Form 10-A for drugs listed in Schedule X drugs of the Drugs Rules. Applications must be made to the licensing authority either by: the manufacturer holding a valid wholesale licence for sale or distribution under the Drugs Rules; or the manufacturer's Indian agent holding either a valid manufacturing licence for sale or a valid wholesale licence.

The application must be accompanied by the prescribed fee and an undertaking in Form 9 signed by or on behalf of the manufacturer. The foreign manufacturer must also obtain a registration certificate from the licensing authority.

A licence may be granted by the licensing authority if it is satisfied that the applicant's premises for storing imported substances are suitably equipped with proper storage facilities to preserve the properties of the relevant drugs and that the licence aligns with the occupation, trade, or business ordinarily carried on by the applicant.

An import licence is inter alia governed by the following conditions:

- the manufacturer must always comply with the undertaking provided by or on their behalf in Form 9;
- the licensee must permit any inspector authorised by the licensing authority for this purpose to enter (with or without prior notice) any premises where the imported substance is kept, to examine the testing arrangements (if any) and to take samples; and
- the licensee must provide the licensing authority on request with a sample from every batch of each substance (or from such batches as the authority may specify from time to time) in such quantity as the authority considers sufficient for any required examination. The licensee must also (if required) provide complete test protocols that have been applied (if any).

Imported drugs must conform to the standards specified in the Indian Pharmacopoeia or other recognised standards. Port offices of the CDSCO may sample and test consignments before clearance.

**7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?**

Consumers may import small quantities of any drug for personal use, subject to the following conditions:

- the drugs must form part of the passenger's bona fide baggage, be the property of the passenger, and be exclusively intended for the passenger's personal use;
- the drugs must be declared to the customs authorities if so directed; and

- the quantity of any single drug so imported must not exceed 100 average doses, provided that the licensing authority may, in an exceptional case, sanction the import of a larger quantity.

Any drug imported for personal use but not forming part of bona fide personal baggage may be allowed to be imported subject to the following conditions:

- the licensing authority, on an application made in Form 12-A of the Drugs Rules, is satisfied that the drug is for bona fide personal use;
- the quantity to be imported is, in the opinion of the licensing authority, reasonable and is covered by a prescription from a registered medical practitioner; and
- the licensing authority grants a permit in respect of the said drug in Form 12-B of the Drugs Rules, requiring the permit holder to provide details of the drugs imported and used on a yearly basis.

**8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification, or labelling obligations – if any – must they satisfy?**

Foreign suppliers cannot ship therapeutic products directly to consumers in India. Any import and retail sale must be routed through an Indian authorised agent or importer holding the requisite import/registration licences, with retail supply made by Indian-licensed entities complying with prescription, pharmacist and record-keeping controls.

**9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?**

Parallel importation is permitted under Indian law for certain products, but is subject to safety, labelling integrity, and intellectual-property considerations.

For medicines, simplified routes may be available only where the imported product is identical to an Indian-authorised reference, with secondary packaging fully compliant with Indian requirements and clear identification of both the foreign marketing authorisation holder and the Indian importer.

For medical devices, importers must verify conformity, apply Indian labelling (including user language requirements), ensure traceability, and comply with vigilance and recall duties irrespective of origin.

**EXPORT**

**10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?**

Export trade in India is primarily regulated by the Directorate General of Foreign Trade (DGFT), an agency under the Ministry of Commerce and Industry, responsible for formulating and implementing India's Foreign Trade Policy to promote exports. Exports are 'free' except when regulated by way of 'prohibition', 'restriction' or 'exclusive trading through State Trading Enterprises (STEs)' as laid down in Indian Trade Classification (Harmonised System) (ITC (HS)) of Exports and Imports. ITC(HS) is a compilation of codes for all merchandise/goods for export/import.

ITC-HS codes for pharmaceuticals fall primarily under Chapter 30 (Pharmaceutical Products), with major headings like 3004 (medicaments for therapeutic/prophylactic use), 3003 (mixed/unmixed medicaments not in 3002/3005/3006), and 3006 (pharmaceutical goods like surgical dressings, waste).

The DGFT may, through a notification, impose 'prohibition' or 'restriction' inter alia:

- on export of foodstuffs or other essential products for preventing or relieving critical shortages;
- for ensuring essential quantities for the domestic processing industry; and
- for protection of public morals or to maintain public order.

Moreover, the government may, under the Customs Act, 1962, prohibit the import or export of goods of any specified description. Such a ban may be either absolutely or subject to such conditions (to be fulfilled before or after clearance) as may be specified in the notification.

**11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling, or record-keeping obligations apply?**

A manufacturer in India holding a valid licence copy under the Drugs Rules can obtain a no objection certificate from zonal offices of the CDSCO for export purposes only for new drugs in India.

Labels on packages or containers of drugs for export must be adapted to meet the specific requirements of the law of the country to which the drug is to be exported, but the following particulars must appear in a conspicuous position on the innermost container in which the drug is packed and every other covering in which that container is packed:

- name of the drug;
- name and address of the manufacturer and the number of the licence under which the drug has been manufactured;
- batch or lot number; and
- expiry date, if any.

**LABELLING, TRACEABILITY, AND PRODUCT INFORMATION**

**12. What local language labelling, patient information, unique device identification, serialisation, anti-counterfeiting, or traceability requirements must be met before**

**imported therapeutic products may circulate domestically or before therapeutic products may be exported?**

India requires distinct labelling, patient information, identification and traceability measures for medicines/biologics and for medical devices, with different rules for products placed on the Indian market versus those exported.

For imported medicines placed on the Indian market, labels must be in English (additional languages, including Hindi, may be added) and must carry statutory particulars under the Drugs Act and Drugs Rules, including:

- the name of the product;
- dosage form and strength;
- active ingredients;
- batch/lot number;
- manufacturing and expiry dates;
- storage conditions;
- manufacturer details; and
- critically for imports, the name and address of the importer and the relevant import licence details.

Retail packs must also comply with the Legal Metrology regime by displaying the minimum retail price (MRP) in Indian currency (INR) (inclusive of taxes), month and year of manufacture or import, quantity, importer particulars, and consumer care details, in the prescribed format and size, in English or Hindi.

The approved package insert/prescribing information must accompany prescription medicines, while OTC products may include consumer leaflets. As to anti-counterfeiting and traceability, India has not mandated universal serialisation for all domestically sold medicines.

However, a QR code obligation applies to notified ‘top’ formulations capturing fields such as a unique identifier, product name, manufacturer, batch, and dates, and APIs are subject to QR codes on labels to strengthen upstream traceability.

Baseline batch/lot and expiry details remain essential, and special categories (eg, Schedule H/H1/X, narcotics, vaccines, blood products, cold-chain biologics) must carry the prescribed legends, colour boxes and storage/handling particulars.

**PRICING, REIMBURSEMENT, AND MARKET ACCESS**

**13. Are there any price-control, reimbursement, public procurement, or stock/supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?**

Price control under the Drugs (Prices Control) Order, 2013 caps prices of scheduled formulations on the National List of Essential Medicines and monitors non-scheduled products for excessive increases, directly influencing market viability and distribution strategies. The NPPA enforces

ceilings, mandates trade margin rationalisation in selected device/product categories, and orders refunds for overcharging.

Public procurement by central and state agencies, including pooled procurement and rate contracts, shapes channel dynamics and availability, while compulsory stockpiling directions for essential medicines can impose supply-obligation burdens on market authorisation holders and distributors. Marketing authorisations can be revoked or suspended for non-marketing beyond specified timelines, impacting supply continuity.

## **ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS**

### **14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?**

CDSCO and State Drug Controllers exercise inspection and market-surveillance powers, with administrative measures including product seizure, stop-sale, recall orders, and suspension/revocation of licences.

Criminal prosecutions and penalties may be pursued for serious violations such as manufacture or sale of substandard, spurious, or unlicensed products, and corporate liability may attach where organisational failures enable offences. Authorities routinely publicise alerts and safety warnings, and courts have upheld robust enforcement in cases affecting public health.

### **15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends, or anticipated reforms that may significantly alter the regulation of trade, distribution, or cross-border movement of therapeutic products in the future?**

India is tightening and modernising its therapeutic products regime, with an upgraded Schedule M to the Drugs Rules which sets out the good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products, full risk-based device licensing (including stricter import licence checks), expanding QR code/serialisation and track-and-trace requirements, and targeted pre-shipment testing for higher-risk exports that affect release timelines and customs clearance.

Regulators are also intensifying risk-based inspections, port scrutiny, recalls, and actions against misbranding and non-compliant e-pharmacy models while the legal status of online sales remains unsettled pending dedicated rules.