# PharmacoLearn

**MRA104T Regulations and Legislation in India and IPR, M.Pharm Semester 1**

## Unit 2: Regulatory Requirements and Approval Procedures

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### 2.1 The two tier architecture of Indian drug regulation

India distributes drug regulation between the Union and the States, and almost every procedural question in this unit is answered by knowing which tier owns it. The **Centre** owns: standards and the pharmacopoeia; approval of new drugs and permission for clinical trials; import licensing and registration; the licensing of the sensitive biological and device categories described in Unit 1; bans and safety withdrawals; clinical trial ethics committee registration; and coordination of the state systems. The **States** own: licensing of manufacture for established drugs and of sale and distribution within their territory; inspection and enforcement on the ground; drug testing through state laboratories; and prosecution of offences. The Central Drugs Standard Control Organization (CDSCO) is the Centre's operating machinery, headed by the Drugs Controller General (India), and the State Licensing Authorities are the States' counterparts. A dossier may therefore need both tiers in sequence: central permission to test and to market a new drug, then a state manufacturing licence to make it. The figure sets the architecture out; the sections that follow take each authority and then each product family in turn.

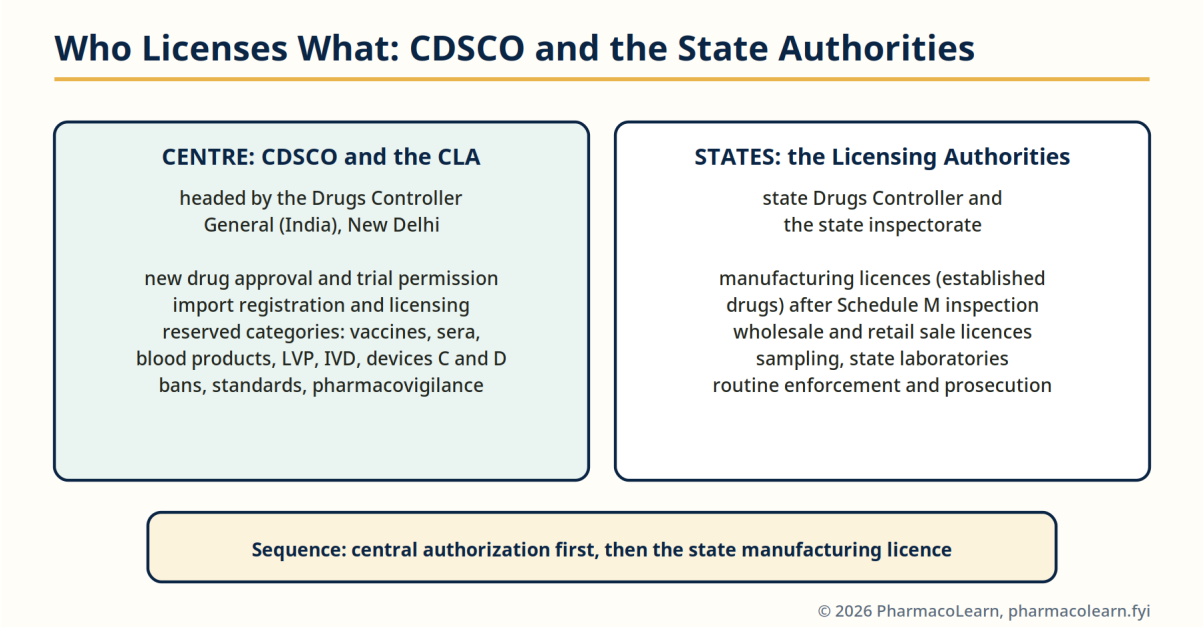


*Figure: Who licenses what in India: the central tier (CDSCO and the Central Licensing Authority) and the state tier (State Licensing Authorities), with the standards and price bodies beside them (Unit 2, section 2.1).*

### 2.2 CDSCO: organization and responsibilities

CDSCO is the national regulatory authority for pharmaceuticals and medical devices, functioning under the Directorate General of Health Services of the Ministry of Health and Family Welfare, with its headquarters in New Delhi. It is headed by the **Drugs Controller General (India) (DCGI)**, who is also the Central Licensing Authority for the categories the Rules reserve to the centre. The organization reaches the field through zonal and sub zonal offices (the zonal offices at Mumbai, Kolkata, Chennai, Ghaziabad, Hyderabad and Ahmedabad among them), offices at ports of entry where imports are cleared, and the central drug testing laboratories, with the Central Drugs Laboratory at Kolkata serving as the statutory appellate laboratory whose report is conclusive in disputed analyses. Its responsibilities, read as a list, are the syllabus's own:

laying down standards for drugs, cosmetics, diagnostics and devices; market authorization of new drugs and clinical trial oversight; import registration and licensing; approval of licences for the specified biologicals, devices and diagnostics; oversight of ethics committees and of bioavailability and bioequivalence centres; regulatory advice to and coordination with the state authorities, including joint inspections; safety surveillance with the Pharmacovigilance Programme of India; and the power, exercised through government, to prohibit drugs of unacceptable risk. Since 2013 most applications to CDSCO are filed online through the **SUGAM** portal, which MRA102T covers as a submission system; the filing formats beneath SUGAM are the subject of section 2.9.

## 2.3 The State Licensing Authorities: organization and responsibilities

Each state and union territory runs a drug control administration, typically a Food and Drug Administration or a Drugs Control Department, headed by a state Drugs Controller who acts as the State Licensing Authority. Its field force is the drug inspectorate, and its analytical arm the state drug testing laboratory. Its responsibilities are the mirror image of the centre's: grant and renewal of manufacturing licences for established drugs (after premises inspection against Schedule M or Schedule T), grant of wholesale and retail sale licences, inspection of factories, pharmacies and distributors, drawing of samples for test and analysis, investigation of complaints and of not of standard quality reports, and prosecution of offences under the Act before the courts. The state authority is also a joint actor in central categories: the licences for blood banks and for Schedule C and C1 products are issued with central approval, so a state file and a central file can both exist for one premises. The practical lesson for a regulatory professional is that timelines, inspection culture and documentation expectations are state specific for state licences, while the legal text is national; compliance is planned nationally and executed state by state.

| Question | Central tier (CDSCO / CLA) | State tier (SLA) |
|---|---|---|
| New drug approval | Yes, marketing authorization and trial permission | No |
| Clinical trial permission and EC registration | Yes | No (state ECs register centrally) |
| Import licence and site registration | Yes | No |
| Manufacturing licence, established drugs | Only for reserved categories (vaccines, sera, blood products, LVP, IVDs, higher device classes) | Yes, the general rule |
| Manufacturing licence, new drugs | Authorization first; licence then issued by the state | Yes, after central authorization |
| Sale and distribution licences | No | Yes |
| Standards and pharmacopoeia | Yes (with the Indian Pharmacopoeia Commission) | Adopts and enforces |
| Routine inspection and prosecution | Joint inspections; appellate laboratory | Yes, the primary enforcement |

## 2.4 Approval procedures for drugs

The approval of a **new drug**, as the New Drugs and Clinical Trials Rules 2019 define the term, covering a drug not previously approved in India, a new indication, dosage form, route or strength of an approved drug, and fixed dose combinations not previously approved, runs through the Central Licensing Authority in the following order: the preclinical and pharmaceutical data are assembled; permission is sought to conduct clinical trials in India, with the data of foreign trials considered under the Rules' bridging logic; trials proceed through their phases under registered ethics committees; and the application for marketing authorization is then reviewed, ordinarily with the advice of a Subject Expert Committee, before the licence to import or

manufacture the new drug is granted. For a drug already approved and marketed, the work shifts to the state: the manufacturer obtains the state manufacturing licence and product permissions for the formulation. Import follows the registration and licence route for the site and product. The generic applicant's obligations are deliberately lighter on clinical data and heavier on pharmaceutical equivalence and bioequivalence (Unit 4), which is the balance the whole system strikes between access and evidence.

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New drug approval in India (NDCT Rules 2019 route)
Discovery and preclinical data (Unit 4)
        |
        v
Application to CLA (CDSCO) in SUGAM, CTD format dossier (2.9)
        |
        v
Permission for clinical trials -> EC approval -> CTRI registration
        |
        v
Phase I to III data generated (MRA103T); SEC review
        |
        v
Marketing authorization by CLA
        |
        v
Manufacturing licence from the State Licensing Authority
        |
        v
Market, under DPCO pricing (1.7) and pharmacovigilance
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## 2.5 Approval procedures for cosmetics

Cosmetics were separated into their own code by the **Cosmetics Rules 2020**, replacing the cosmetic provisions scattered through the 1945 Rules. Imported cosmetics must be **registered** with the Central Licensing Authority before import, with a licence to import following the registration; no imported cosmetic may be sold unregistered. Manufacture within India is licensed by the State Licensing Authority, with factory premises expected to meet the good manufacturing practice expectations the Rules prescribe. Registration and licensing both work through product categories and positive and negative lists: ingredients prohibited in cosmetics in India, and colourants and other ingredients permitted only within stated limits, are scheduled in the Rules and read with the standards of the Bureau of Indian Standards that the Rules adopt for finished products. Two Indian policy choices stand out. India has **prohibited the import of cosmetics tested on animals abroad** and the manufacture of cosmetics tested on animals at home, aligning the cosmetic code with the welfare statute of Unit 1. And misleading cosmetic claims are policed through the Drugs and Magic Remedies Act and the consumer protection framework together, so the label and the advertisement are reviewed as one communication.

## 2.6 Approval procedures for medical devices

Devices entered the Drugs and Cosmetics Act through the definition of drug, by notification; from 2020 the notification covers **all medical devices**, and the **Medical Devices Rules 2017** supply the code. The Rules classify devices into four classes by risk: **Class A** (low risk, such as non sterile examination gloves and surgical dressings), **Class B** (low to moderate risk, such as sterile gloves, suction equipment and many in vitro diagnostic reagents), **Class C** (moderate to high risk, such as ventilators, bone fixation plates and dialysis equipment) and **Class D** (high risk, such as implantable defibrillators, heart valves and drug eluting stents). The licensing authority follows the class: the State Licensing Authority licenses manufacture of Class A and Class B (Class B being preceded by audit by a notified body registered with CDSCO), while the Central Licensing Authority licenses Class C and Class D manufacture and all imports. Every class carries a quality management system obligation keyed to the Rules' Schedule V; clinical investigation of

devices in India follows the Rules' own provisions, conceptually parallel to the ISO 14155 standard for device trials; adverse events are reported into the Materiovigilance Programme of India; and registration of the manufacturer and product precedes the licence for imports. The device industry thus works under the drug statute but with a risk grammar of its own, which is exactly why the syllabus names it a separate family.

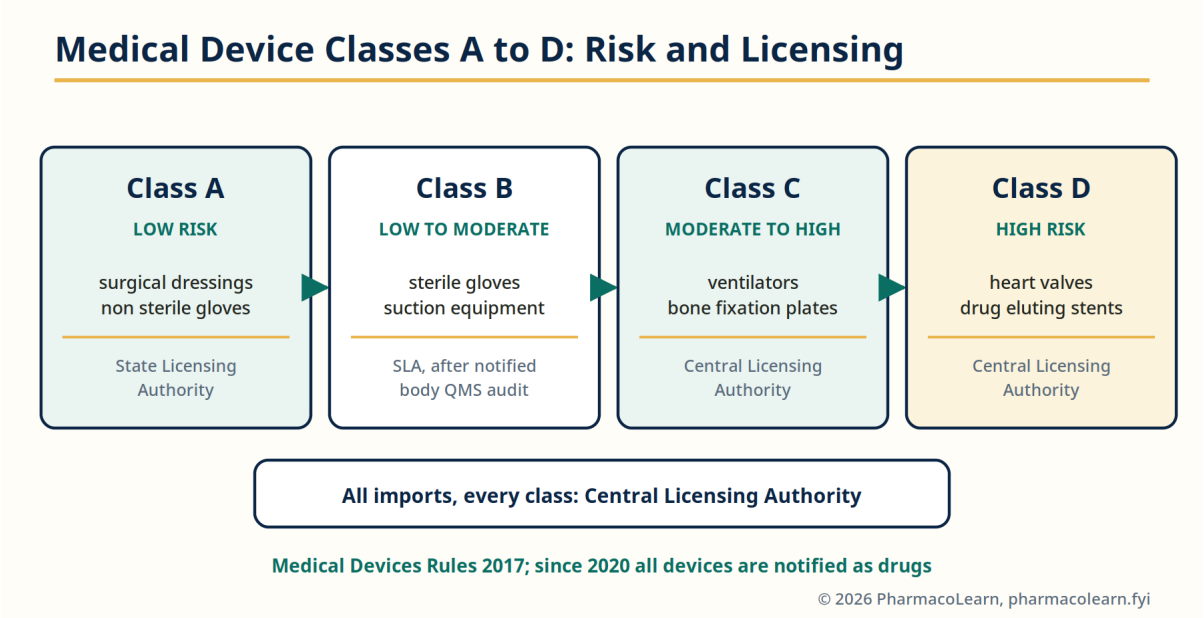


*Figure: The four device classes under the Medical Devices Rules 2017, rising risk from A to D, with the licensing authority split between the State Licensing Authority (A, B) and the Central Licensing Authority (C, D and all imports) (Unit 2, section 2.6).*

## 2.7 Approval procedures for biologicals and herbals

**Biologicals** occupy the Act's most supervised shelf. Vaccines, sera, blood and blood products, recombinant products and other Schedule C and C1 items require central approval of the licence, batch by batch diligence in manufacture, and characterisation data that chemical drugs do not generate: cell banks, viral safety, potency assays against reference standards (Unit 3). Whole human blood and its components are licensed as drugs with the blood bank as a licensed premises, a system built after the transfusion safety failures of the 1990s. Where genetic engineering is involved, an additional statutory layer precedes the drug licence: the **Review Committee on Genetic Manipulation (RCGM)** of the Department of Biotechnology oversees research and development of recombinant products under the Environment (Protection) Act machinery, before CDSCO's market authorization is sought. **Herbals** run on two tracks. The classical track is the Ayurvedic, Siddha and Unani (ASU) system of Chapter IVA of the Act: proprietary and classical ASU medicines are licensed by the state ASU licensing authority, with manufacture under Schedule T good manufacturing practices, and with a markedly lighter evidence regime for classical formulations, though safety and efficacy evidence is required for new proprietary claims. The modern track is the **phytopharmaceutical** category created by amendment in 2015: a purified and standardised fraction of a medicinal plant, presented with data on quality, safety and efficacy on the pattern of a new drug, regulated by CDSCO as a drug in the modern sense. The professional skill in this family is classification: the same plant can be a classical ASU medicine, a phytopharmaceutical drug, or a food ingredient, and the route chosen fixes the evidence, the licence and the claims.

## 2.8 Approval procedures for food and nutraceuticals

Food left the pharmacy statutes behind in 2006: the **Food Safety and Standards Act 2006** consolidated the old food laws (including the Prevention of Food Adulteration Act) and created the **Food Safety and Standards Authority of India (FSSAI)**, under the Ministry of Health and Family Welfare, as the standard

setting and licensing authority, with State Commissioners of Food Safety as the enforcement tier. Every food business operator must hold an FSSAI licence or registration, in three tiers by scale: petty food businesses register; medium scale businesses take a state licence; and the largest businesses, importers, exporters and the categories the regulations reserve (which include manufacturers of nutraceuticals and health supplements) take a **central licence**. The product law for the syllabus's family is the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, first issued in 2016 and revised in 2022, which list the permitted ingredients, their forms and daily limits for the nutraceutical and supplement categories, and import a discipline of permitted claims: a supplement may carry the structure and function claims the regulations allow and must carry the statutory advisory that it is **not for medicinal use**, and no food may claim to cure or treat disease. The drug and food boundary is policed from both sides: a product that makes disease claims, or exceeds the vitamin and mineral limits the drug rules set for food style presentations, is treated as a drug and needs a drug licence. Regulatory affairs in this family is therefore boundary work: ingredients, dose, format and claim wording are checked against both statute books before a launch is advised.

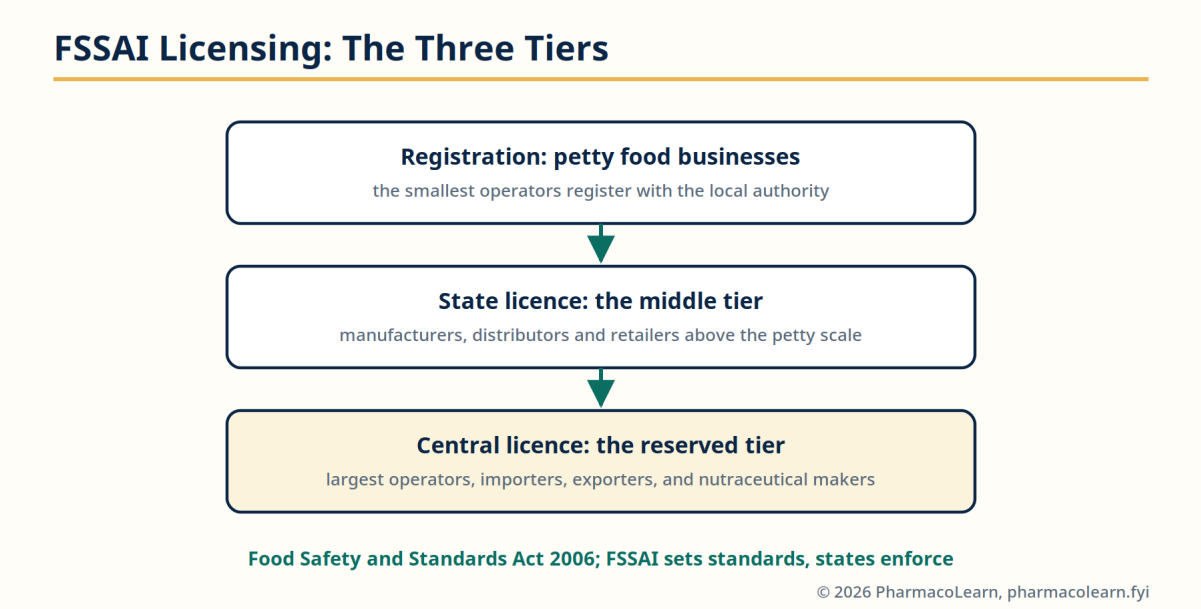


*Figure: FSSAI licensing by scale: registration for petty food businesses, state licence for the middle tier, and central licence for the largest operators, importers and nutraceutical manufacturers (Unit 2, section 2.8).*

## 2.9 Regulatory filing: format and contents of the dossier

The syllabus requires the format and contents of a regulatory dossier, and India asks for both a national layer and the international common format. The **Common Technical Document (CTD)** structure, the five module pyramid of ICH M4 that MRA101T introduces in its guidance survey, is the organising format CDSCO expects for new drug submissions: Module 1 carries the India specific administrative material (application forms, licences, labelling as proposed for India, and the certificates of the origin system), Module 2 the summaries and overviews, Module 3 the quality (chemical, pharmaceutical and biological) data, Module 4 the nonclinical reports and Module 5 the clinical study reports, with bioequivalence data of Unit 4 sitting in Module 5. Dossiers for other families adapt the same discipline to their codes: the device file follows the Rules' documentation and the quality system evidence; the cosmetic registration file the Rules' prescribed forms and ingredient declarations; the food licence and product approval files the FSSAI forms and standards. In every case the dossier is filed through the online systems (SUGAM for drugs and devices, the FSSAI licensing portal for food), and the regulatory professional's craft is completeness against the applicable checklist: a dossier is reviewed only as fast as it is complete, and deficiency letters are

almost always listable in advance by the person who assembled the file.

## 2.10 Clinical trial and investigations under this framework

Unit 2's closing item returns to trials, now from the Indian approval side. A clinical trial of a new drug in India requires the permission of the Central Licensing Authority under the NDCT Rules 2019, the approval of a registered ethics committee, and registration in the Clinical Trials Registry of India before the first participant is enrolled; investigations of medical devices follow the Medical Devices Rules' own clinical investigation provisions, and bioavailability and bioequivalence studies run through their dedicated registered centres (Unit 4). The global conduct of trials, including the Indian conduct standards, the United States and the European Union, is the province of MRA103T; the Indian statutory skeleton it hangs on is this unit's. What the student should carry forward is the sequence: preclinical justification (Unit 4), central permission, ethics oversight, registry transparency, and inspection readiness, because every later unit's data are generated inside this frame.

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