

Unit 1: Acts and Rules

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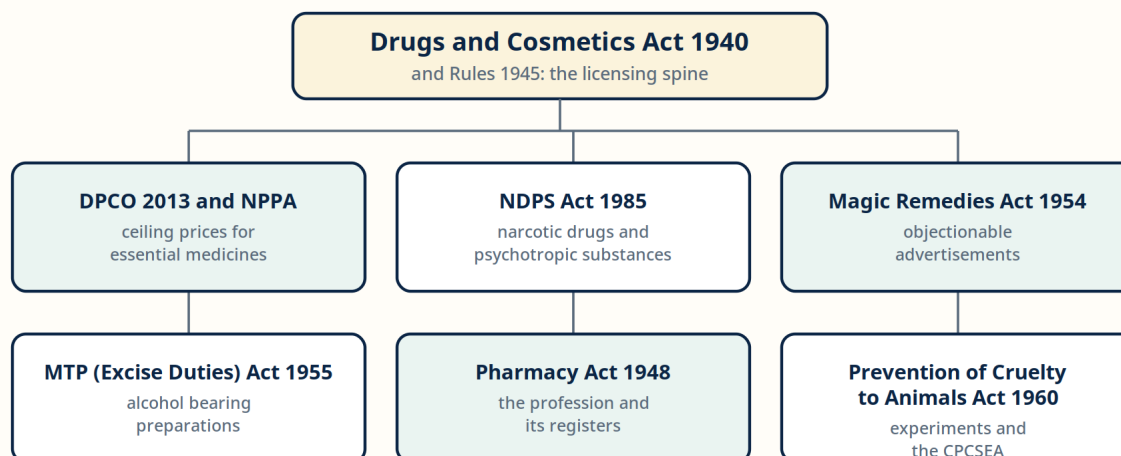
Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights, subject code MRA104T, is the fourth core subject of M.Pharm Regulatory Affairs, Semester 1. It carries 4 credits and 60 hours of theory, taught at 4 hours per week, for 100 marks. The three subjects before it built the working skills of the branch: MRA101T taught the good practices, MRA102T the documents, and MRA103T the regulation of clinical research across India, the United States and the European Union. This subject turns homeward. It is the Indian statute book of the pharmaceutical world, taken in one sweep: the Acts and Rules under which every drug, cosmetic, medical device, biological, herbal product and food sold in India is licensed, the authorities that run that system, the standards against which quality is judged, the bioequivalence and ethics framework that supports approval, and, closing the semester, the intellectual property rights that decide who may make a product at all and for how long. The course is designed to impart fundamental knowledge on regulations and legislation in India with respect to the five product families, and to prepare the student for the basic regulatory requirements of manufacture, import and registration, export, sale, marketing authorization, clinical trials and intellectual property rights. Its objectives are two: to know the different Acts and guidelines that regulate these industries in India, and to understand the approval process and regulatory requirements for each family. The units follow that design. Unit 1 reads the statute book itself, headed by the Drugs and Cosmetics Act 1940 and its Rules of 1945, with price control and the five companion Acts. Unit 2 walks the approval machinery: the Central Drugs Standard Control Organization and the State Licensing Authorities, and the procedure for each product family, ending with the dossier and with clinical investigations. Unit 3 is about standards, the Indian Pharmacopoeia, BIS and ISO. Unit 4 covers bioavailability and bioequivalence data, the BCS classification, stability, animal testing and its ethics, and the stem cell guidelines. Unit 5 is intellectual property: patent, trademark, copyright, industrial designs and geographical indications, the Indian patent scenario, and the working interface between IPR and regulatory affairs.

1.1 One statute book for five product families

Indian pharmaceutical law is not a single code but a shelf of statutes, most of them old, each written for the problem of its decade, and the regulatory affairs professional works across the whole shelf at once. One product can sit under several Acts simultaneously: a cough preparation containing alcohol and a psychotropic ingredient touches the Drugs and Cosmetics Act for its licence, the price control order for its ceiling price, the excise Act for its alcohol content and the narcotics Act for its controlled ingredient. The Drugs and Cosmetics Act 1940 is the spine of the shelf: it defines what a drug and a cosmetic are, sets the quality offences, creates the licensing system and names the standards a product must meet. Around it stand the companion statutes of this unit: the Drugs (Prices Control) Order and the National Pharmaceutical Pricing Authority for price, the Narcotic Drugs and Psychotropic Substances Act 1985 for controlled substances, the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 for advertising claims, the Medicinal and Toilet Preparations (Excise Duties) Act 1955 for alcohol bearing preparations, the Pharmacy Act 1948 for the profession itself, and the Prevention of Cruelty to Animals Act 1960 for the animals on whom products are first tested. Two reading rules apply to everything in this unit. First, the Acts state principles and create powers, while the Rules made under them carry the operative detail, so the pair must always be read together. Second, the framework is alive: the clinical trial provisions once carried in the Rules now sit in the New Drugs and Clinical Trials Rules 2019, medical devices have their own Medical

Devices Rules 2017, and cosmetics their own Cosmetics Rules 2020, each noted where it belongs below.

The Indian Pharmaceutical Statute Family



One product can sit under several Acts at once; the D and C Act is read with all of them

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Figure: The statute family of Unit 1: the Drugs and Cosmetics Act 1940 at the centre, with the price, narcotics, advertising, excise, pharmacy and animal welfare statutes around it (Unit 1, section 1.1).

1.2 The Drugs and Cosmetics Act 1940: origin and architecture

The Act grew out of the Drugs Enquiry Committee of 1930-31, chaired by Colonel R. N. Chopra, which documented a market flooded with adulterated and substandard drugs, much of it imported, and recommended central legislation. The result was the Drugs Act 1940, initially concerned with imports; manufacture and sale were brought in by later amendment, and cosmetics were added to its reach and its title in 1962, giving the Drugs and Cosmetics Act in its modern form. Its architecture is simple and durable. The opening chapters define the territory and build the institutions: the Drugs Technical Advisory Board (DTAB), the expert body that advises the Central Government on technical matters; the Drugs Consultative Committee, through which the Centre and the States coordinate; the Central Drugs Laboratory; and the government analyst and drug inspector machinery through which quality is actually policed. The operative chapters then regulate, in turn, the import of drugs and cosmetics, their manufacture, and their sale, stocking, exhibition and distribution, with separate treatment for Ayurvedic, Siddha and Unani drugs (Chapter IVA, added in 1964) and a chapter of offences and penalties. Two features of the design matter for regulatory practice. The Act works through **licensing**: no one may import, manufacture or sell a drug or cosmetic except under a licence granted under the Rules, and the licence, not the product registration, is the basic permission for most established categories. And the Act creates the **quality offences** in a careful ladder of definitions, examined in section 1.4, so that the seriousness of a prosecution follows the seriousness of the defect.

1.3 The Drugs and Cosmetics Rules 1945: the schedules are the machinery

The Rules of 1945, framed under the Act, are where the system is actually operated, and their organising device is the **schedule**: lettered annexures that attach a special regime to a class of products, premises or activities. A regulatory professional reads the Rules by their schedules. Schedule M prescribes the good manufacturing practices and premises requirements with which a manufacturing licence must comply (its device and other parts extend the same approach beyond drugs). Schedule Y once carried the requirements and guidelines for permission to import or manufacture new drugs and to conduct clinical

trials; its clinical trial substance has since been re-enacted in the New Drugs and Clinical Trials Rules 2019, as MRA103T describes, and the schedule is now read in that light. Schedules C and C1 list the biological and special products, sera, vaccines, insulin and their class, whose manufacture and import attract central oversight. Schedule F and its parts set standards for particular preparations. The prescription and caution schedules govern how medicines may be sold: Schedule G drugs must carry the caution that it is dangerous to take the preparation except under medical supervision; Schedule H drugs are prescription drugs, labelled with the Rx symbol and the prescription warning; Schedule H1, introduced in 2013 for specified antibiotics, anti-tuberculosis drugs and habit forming medicines, adds a separate record of sale, with name and address of the prescriber and patient, retained for three years, a direct legislative answer to antimicrobial resistance and self medication; Schedule X covers the narcotic and psychotropic substances that demand a special licence and duplicate prescriptions. Schedule J lists diseases and conditions for which no drug may claim a cure, the statutory backstop to the advertising Act of section 1.9, and Schedule T prescribes good manufacturing practices for Ayurvedic, Siddha and Unani drugs. The lesson of the schedules is procedural humility: in Indian drug law the answer to almost any working question (may I sell it, who may prescribe it, what must the label say, what records must exist) is found not in the Act's chapters but in a schedule and the licence conditions that point to it.

The Schedules of the Drugs and Cosmetics Rules 1945

Schedule M GMP and premises for manufacture	Schedule Y trial requirements (read with NDCT 2019)	C and C1 biological and special products	Schedule F standards for particular preparations	Schedule G danger caution: medical supervision
Schedule H prescription only (Rx drugs)	Schedule H1 2013: antibiotics, TB drugs, 3 year records	Schedule X narcotic and psychotropic substances	Schedule J diseases no drug may claim to cure	Schedule T GMP for Ayurvedic, Siddha, Unani drugs

The working answers of Indian drug law (may I sell it, what must the label say) live in the schedules

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Figure: The schedules a regulatory professional reads first: quality and premises (M, C and C1), sale control (G, H, H1, X), trial requirements (Y, now read with the NDCT Rules 2019), claim limits (J) and ASU manufacture (T) (Unit 1, section 1.3).

1.4 Definitions that carry legal weight

Because prosecutions and licence refusals turn on them, the Act's quality definitions are worth learning as a graded set. A drug is **misbranded** if it is not labelled in the prescribed manner, if its label or accompanying claim is false or misleading, or, for a cosmetic and certain preparations, if it is coloured or presented in a way the definition captures: the defect is in the presentation. A drug is **adulterated** if it consists in whole or part of a filthy, putrid or decomposed substance, if it has been prepared or stored under insanitary conditions, if its container is poisonous or deleterious, if it carries a prohibited colour, or if its strength has been reduced or an admixture made injurious to health: the defect is in the substance or its keeping. A drug is **spurious** if it is manufactured under a name belonging to another drug, if it imitates or substitutes for another drug deceptively, or if it falsely claims to be the product of a manufacturer with whom it has no connection: the defect is in its identity, a counterfeit concept, and it carries the heaviest penalties. Standing slightly apart is the everyday quality verdict of **not of standard quality** (NSQ), applied when a sample fails the standards of the pharmacopoeia or of the Second Schedule to the Act; most government laboratory failures in India are NSQ findings rather than adulteration. The word **drug** itself is defined expansively,

covering medicines for internal and external use, diagnostic and preventive substances, and articles intended to affect the structure or function of the body, and it is through this definition, by notification, that medical devices were progressively brought inside the Act, until in 2020 all medical devices were notified as drugs for regulatory purposes, as section 2.6 describes. **Cosmetic** is defined by its intended use on the human body for cleansing, beautifying, promoting attractiveness or altering appearance, a boundary that keeps generating classification disputes with borderline products, as happens in every jurisdiction.

1.5 Licensing under the Act and Rules

The licensing map follows the Act's structure. **Import** of drugs is licensed centrally, with registration of the foreign manufacturing site and the product for the categories that require it. **Manufacture** is licensed by the State Licensing Authority of the state where the factory sits, on the licence forms prescribed in the Rules, after inspection of the premises for Schedule M compliance; a defined set of sensitive categories, including vaccines and sera, whole human blood and blood products, large volume parenterals and in vitro diagnostic products, is approved at the centre by the Central Licence Approving Authority acting with the state. Loan licences and repacking licences serve manufacturers who use another's premises or repack bulk product. **Sale, stock and distribution** licences, wholesale and retail, are also state licences, and the retail licence carries the condition that dispensing is done by or under a registered pharmacist, which is where the Pharmacy Act of section 1.11 bites on the system. Around the main licences sit the test licence for small quantities imported or manufactured for examination, test or analysis, and the special regimes for Schedule C and C1 products and for narcotic and psychotropic items under Schedule X. The Central Government holds the emergency and standards powers, including the power under Section 26A to prohibit the manufacture and sale of a drug in the public interest, the provision behind the fixed dose combination bans of recent years. Every licence is time bound, renewable, inspectable and revocable, and the licence conditions, not merely the licence itself, are the compliance document a company actually lives under.

1.6 The living statute: successor rulebooks under the same Act

Three modern rulebooks now carry large parts of what was once inside the 1945 Rules, and the syllabus's phrase "with latest amendments" points at exactly this movement. The **New Drugs and Clinical Trials Rules 2019** took over the approval of new drugs, clinical trials, bioavailability and bioequivalence studies and ethics committee registration from Schedule Y and the old appendices, under the Central Licensing Authority; MRA103T treats them in full. The **Medical Devices Rules 2017**, in force from 2018, created a complete risk based code for devices within the Act: classification, notified bodies, licensing by class and the materiovigilance programme, taken up at section 2.6. The **Cosmetics Rules 2020** separated cosmetics into their own code, with central import registration and state manufacture licensing, at section 2.5. The pattern to note is that Parliament has not replaced the 1940 Act; successive governments have preferred to govern through fresh rules under it, so a professional cites the Act for power and the current rulebook for procedure, and checks which instrument governs the act in question before advising on any filing.

1.7 Price control: the DPCO and the NPPA

Drugs are the standing exception to market pricing in India, and the instrument is the Drugs (Prices Control) Order, issued not under the Drugs and Cosmetics Act but under the Essential Commodities Act 1955, which is why price work sits slightly apart in the statute family. A succession of price control orders runs from 1970 to the current **Drugs (Prices Control) Order 2013**. The 2013 Order controls the ceiling price of **scheduled formulations**: dosage forms and strengths of the medicines listed in the National List of Essential Medicines, which the Order adopts as its first schedule. For each scheduled formulation the ceiling price is calculated in a market based way, as the simple average price to retailer of the brands of that formulation holding at least one percent of market turnover, adjusted as the Order prescribes;

manufacturers may price at or below the ceiling, and prices are revised with the wholesale price index on the Order's cycle. Formulations outside the schedule are not price fixed, but their maximum retail prices may not rise by more than ten percent in a year, and the authority watches the trade margin debate and exceptional cases, having used its public interest powers for items such as coronary stents and knee implants. The **National Pharmaceutical Pricing Authority (NPPA)**, constituted in 1997 as an attached office of the Department of Pharmaceuticals, is the implementing body: it fixes and revises ceiling prices, monitors prices and availability, maintains the price database, enforces recovery of overcharged amounts with interest, and advises the government on the Order and on the national list. The regulatory lesson is that a marketing authorization is only half the commercial permission: the price label on the pack is itself a regulated statement, and a price filing error is a compliance breach in its own right.

1.8 The Narcotic Drugs and Psychotropic Substances Act 1985

The NDPS Act is India's consolidated law against narcotics, enacted to meet international convention obligations and to control the licit trade as firmly as the illicit. It prohibits the production, manufacture, possession, sale, transport and consumption of narcotic drugs and psychotropic substances except as licensed for medical and scientific purposes, and it builds a licensing lattice to keep the legitimate pharmaceutical trade inside the law: the Central Bureau of Narcotics administers the opium and alkaloid side and the international trade permits, state authorities license much of the domestic manufacture and possession, and the schedules of the NDPS Rules name the substances and the forms. For the pharmaceutical professional the Act intersects daily practice at three points. First, the psychotropic and narcotic ingredients of ordinary medicines pull those products into Schedule X of the Drugs and Cosmetics Rules and into duplicate prescription and record keeping discipline (section 1.3). Second, manufacture, export and import of controlled substances need the specific NDPS licences and quotas in addition to drug licences, so a controlled product carries two regulatory identities. Third, the Act's enforcement is penal and severe, with punishments graded by the quantity involved since the 2001 amendment, so documentation failures in this area are not clerical matters. The medical exception is written into the Act's own design: the object is control of abuse, not denial of therapy, and the recognised medical and scientific channel is the licence system itself.

1.9 The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954

This short Act polices what may be claimed to the public. It prohibits advertisements of drugs that suggest use for the procurement of miscarriage or prevention of conception, for the correction of menstrual disorders, or for the diagnosis, cure, mitigation, treatment or prevention of the diseases and conditions listed in its Schedule; it prohibits advertisements of **magic remedies**, a defined term covering talismans, mantras, charms and similar articles claimed to possess miraculous powers; it prohibits taking part in the publication of such advertisements and controls the import and export of the offending material. Two connections make the Act examinable rather than antiquarian. Its Schedule of diseases overlaps with Schedule J of the Drugs and Cosmetics Rules (section 1.3), which forbids cure claims for the same class of conditions on labels and in promotion generally, so an advertisement can breach both instruments at once. And the Act is the ancestor of the modern Indian debate on drug promotion: direct to consumer advertising of prescription medicines remains outside lawful practice in India, and when advertisements for Ayurvedic and other products promise cures for scheduled diseases, it is still this 1954 Act that is invoked. One caution belongs in the record of this subject: some printed copies of the syllabus list this Act at 1955; the Act is of 1954, and those printings are in error (see the verification note for this package).

1.10 The Medicinal and Toilet Preparations (Excise Duties) Act 1955

A large class of medicines and toilet preparations (tinctures, extracts, syrups, hair oils, mouthwashes) is made with alcohol, and alcohol has always been a revenue and control subject in India. The Medicinal and Toilet Preparations (Excise Duties) Act 1955 imposes a duty of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp or other narcotic drugs, administered largely by the states, with licensed premises, bonded warehouses and the familiar machinery of duty paid and duty free (L-1 and kindred) licences for manufacture and for use of alcohol in manufacture. The Act matters to regulatory affairs for two reasons. It is a second licence system sitting on top of the drug licence for any alcohol bearing product, with its own inspections, registers and sampling. And it explains a permanent feature of Indian pharmaceutical geography: because alcohol duty and prohibition policy are state subjects in practice, the same preparation faces different fiscal conditions from state to state. The goods and services tax subsumed most excise duties from 2017, but alcoholic liquor for human consumption stayed outside the GST, so this excise framework continues to operate for the preparations within its charge.

1.11 The Pharmacy Act 1948

If the Drugs and Cosmetics Act regulates products and premises, the Pharmacy Act regulates people. It created the **Pharmacy Council of India** as the central council for pharmacy education and the profession, and the State Pharmacy Councils that maintain the registers of pharmacists. Its operative machinery is registration: a person whose name is entered in the state register, on the strength of an approved qualification (the Diploma in Pharmacy as the minimum for registration, with the Bachelor of Pharmacy above it), is the registered pharmacist whom the other statutes then rely upon. The Education Regulations framed under the Act set the minimum standards of the D.Pharm and B.Pharm courses, and council approval of institutions flows through those regulations. The Act connects to the rest of this subject at the dispensing point (section 1.5): retail sale of drugs must be effected by or under the personal supervision of a registered pharmacist, so the professional register is part of the drug control system, and the long Indian debate about enforcement of that requirement in community pharmacy is a debate about this Act.

1.12 The Prevention of Cruelty to Animals Act 1960

The last of the companion Acts looks away from the market to the laboratory. The Prevention of Cruelty to Animals Act 1960 is India's general animal welfare statute, and its Chapter IV, on experimentation on animals, provides that experiments may be performed only for the advancement of physiological knowledge or knowledge useful for saving or prolonging life or alleviating suffering, and creates the committee to control and supervise them: the **Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)**, a statutory body of the Government of India. CPCSEA registers establishments that breed animals for or perform experiments, and its guidelines govern facilities, housing, and the Institutional Animal Ethics Committees that approve protocols locally. Unit 4 returns to CPCSEA in its working detail; here the point is structural. Animal data are a legal precondition of drug approval, and this 1960 Act is the legal licence under which that precondition may be generated, which is why a welfare statute belongs in a regulatory affairs syllabus.

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