PHARMACEUTICAL JURISPRUDENCE

UNIT 1 NOTES

DRUGS & COSMETICS ACT

- SOME DEFINITIONS
- IMPORT OF DRUGS
- MANIFACTURE OF DRUGS

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DRUGS & COSMETICS ACT

- The Drugs & Cosmetics Act, 1940 and its rules 1945 are foundational legal frameworks in India that regulate the manufacture, sale and distribution of drugs & cosmetics to ensure their safety, efficacy and quality.
- The act verifies that the drug & cosmetics should be manufactured, distributed and sold only by qualified persons having a license for this purpose.

OBJECTIVES

- It ensures that drugs sold and used are of good quality & free from contamination.
- It protect consumers from harmful & ineffective medicines & cosmetics.
- Regulate the sale of prescription drugs to avoid misuse or abuse.
- Ensure that drugs & cosmetics are produced under hygienic conditions.
- Control false claims made about efficacy or safety of drugs.

KEY FEATURES OF THIS ACT

- Regulation of Drugs & cosmetics
- Licensing
- Quality Control
- Classification of Drugs in various schedules.
- Cosmetics Regulation
- Penalties

SOME DEFINITIONS

- The Drugs & Cosmetics Act, 1940 provides several legal definitions to ensure clarity in the regulation of drugs & cosmetics.
- Here are some key definitions as per the act :

DRUG

- It includes all medicines for internal or external use of Human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
- It also includes substances intended to affect the structure or function of body, including disinfectants, surgical dressings, medical devices & substances for destruction of insects.

COSMETIC

Any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or otherwise applied to human body or any part for cleansing, beautifying or promoting attractiveness or altering the appearance, including hair dyes, skin creams, lotions & perfumes.

MISBRANDED DRUGS

- Any drug is called misbranded drugs if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appears of better or greater therapeutic value.
- If it is not labelled in the prescribed manner.
- If its label or container or anything accompanying the drug bears any statement, design which makes any ~~cla~~ false claim for the drug.

ADULTERATED DRUGS

- Any drug is called adulterated if :
- If it consists, in whole or in part, of any filthy, putrid or decomposed substance.
- If it has been prepared, packed or stored under insanitary
- conditions whereby it may have been rendered injurious to health.
- If its container is composed of any poisonous or harmful substance which may render the contents injurious to health.
- If it bears or containers for purposes of colouring only, a colour other than one which is prescribed.
- If it contains any harmful or toxic substance which may render it injurious to health.
- If it contains any substance that reduce its quality or strength.

SPURIOUS DRUG

- A drug is considered spurious :
- If the drug is sold or distributed under the name of another drug.
- The drug is falsely represented as being manufactured by a company other than actual manufacturer.
- If it is presented in a way that makes it look like another reputable product.
- The drug either does not contain the ingredients it claims or has been substituted with different substances.
- The drug is manufactured or packed in a way that could deceive consumers into thinking it is a genuine, approved products.

PATENT OR PROPRIETARY MEDICINE

A drug that is marketed under a brand name or trade name rather than its generic name, with a formula that is not disclosed to public is called patent medicine.

MANUFACTURE

It includes any process or part of process for making, altering, finishing, packing, labelling or repacking a drug or cosmetic.

SCHEDULES TO THE ACT

Schedule to the act 1940 includes :

① **First Schedule** : It includes the name of books under Ayurvedic, Siddha, Unani & Tibb systems.

② **Second Schedule** : This includes standard to be compiled by drugs imported & manufactured for sale, stocked or distribution.

The following appendices are also included.

① **Appendix I** : Data to be submitted along with the application for permission to market a new drug.

② **Appendix II** : Format for submission of clinical trials.

③ **Appendix III** : Requirments for animal clinical trials & marketing a new drug.

④ **Appendix IV** : Number of animals for long term toxicity study.

⑤ **Appendix II** : Patient consent form for participation in Phase I clinical trials.

⑥ **Appendix III** : Four group of fixed dose combinations & their data requirments.

SCHEDULES TO THE RULES

Following are schedules to the rules :

① **Schedule A** : It specifies list forms and applications for licenses, permits & certificates related to the sale, manufacture, import & testing of drugs and cosmetics.

② **Schedule B** : It specifies / contains the fees payable for testing or analysis of drugs & cosmetics.

③ **Schedule C** : It contains list of biological & special products whose import, sale, distribution and manufacture are governed by specific provision.

④ **Schedule C1** : It contains list of other special & biological products whose import, sale, distribution & manufactured are governed by specific provision (other than parentral)

⑤ **Schedule D** : It contains list of drugs exempted from provision of import of drugs.

⑥ **Schedule E1** : It contains a list of poisonous substances under Ayurvedic & Unani system of medicines that require careful regulation.

⑦ **Schedule F** :
- It specifies space, equipment and supplies required for a blood bank.
- Minimum requirments for grant of license to produce blood components from human blood.

Schedule F1 : Part I : Provisions applicable to the production of bacterial & viral vaccines.
Part II : Provisions applicable to the the production of serum from living animals.
Part III : Provisions applicable to the manufacture and standardisation of diagnostic agents.

Schedule F2 : Standards for surgical dressings.

Schedule F3 : Standards for sterilised umbilical tapes.

Standard Ff : Standards for opthalmic preparations.

Schedule G : It consist of list of drugs that must be taken under medical supervision. labels for these drugs should carry the warning 'Caution'.

Schedule H : It contains list of prescription drugs that are to be sold only on the prescription of a registered medical practitioner.

Schedule H1 : It added to schedule H, with strict monitoring for certain antibiotics, anti TB drugs etc.

Schedule J : It specifies list of diseases and conditions for which no drug is allowed to claim a cure or treatment (e.g. AIDS, Cancer, Diabetes etc.)

Schedule K : Provide exemptions to certain drugs for manufacturing from specific provisions of the act.

Schedule M : It specifies GMP (Good Manufacturing Practices) for pharmaceuticals, including infrastructure, personnel quality control etc.

Schedule M_1 : GMP for Homeopathic Medicines.

Schedule M_2 : GMP for Cosmetics

Schedule M_3 : GMP for Medical Devices.

Schedule N : It lists the minimum equipment required for efficient running of pharmacy.

Schedule O : Standards for disinfectant fluids.

Schedule P : Life Period of Drugs

Schedule P_1 : Pack Sizes of Drugs

Schedule Q : List of Permitted colours & pigments in drugs and cosmetics.

Schedule R : Standards for contraceptives such as condoms and other mechanical contraceptives.

Schedule R_1 : Standards for medical devices

Schedule S : Standards for cosmetics

Schedule T : GMP for ayurvedic, siddha & unani medicines

Schedule U : Specifies the records to be maintained by manufacturers for drugs.

Schedule U1 : Specifies the records to be maintained by manufacturers for cosmetics.

Schedule V : Standards for Potent or Pooprietary medicines.

Schedule W : List of drugs to be marketed under generic names only.

Schedule X : Lists narcotic and psychotropic substances that are strictly regulated & require a special license to manufacture, distribute or sell.

Schedule Y : Regulates the clinical trials of new drugs, requiring a detailed information on protocols, ethics, responsibilities.

IMPORT OF DRUGS

- The import of drugs refers to the process of bringing drugs into a country from abroad for the purpose of distribution, sale or use.
- The import of drugs in India is controlled & regulated by Drugs & Cosmetics Act, 1940.
- The act regulates the import of drugs to ensure that only safe, effective and high quality products enter the Indian Market.

KEY POINTS ABOUT IMPORT OF DRUGS

- Import Licensing
- Standards of Quality
- Prohibited Drugs
- Labelling & Packaging
- Inspection & Testing

CLASSES OF DRUGS & COSMETICS PROHIBITED FROM IMPORT

- Any drug or cosmetic which is not of standard quality.
- Any adulterated, spurious or misbranded drug, expired drug.
- Drugs that are banned by central government.
- Any patent or proprietary medicine, which not displayed true formula.
- Any drug which claims to cure or prevent any disease specified in Schedule J.
- Any cosmetic or drug containing any ingredient, which is unsafe/harmful.
- Drugs not labelled in the prescribed manner
- Drugs without import license, for which license is required/necessary.

Import Under License Or Permit

- Drugs specified in Schedule C & C1 excluding those specified in schedule X
- Drugs specified in schedule X
- Small quantities of drugs imported for examination, test, analysis.
- Drugs for personal use prescribed by a Registered Medical Practioner
- Any new drug.

Import Of Drugs Specified in Schedule C & C1

The key conditions for importing drugs under schedule C & C1 are as follows:

- Licensee must have appropriate storage conditions for the import of drugs under schedule C & C1
- Licensee must maintain the records for import of drugs.
- Licensee must allow an ispector to inspect premises and check the records.
- Licensee shall supply sample of drugs for examination / test or analysis.
- Imported drugs must comply with labelling & packaging requirments as specified in the act.
- Licensee must comply with the undertaking given in form 9.

Import Of Drugs Specified In Schedule X

- Licensee must have adequate storage facility for storage.
- Applicant must be reputable in the occupation, trade or business.
- Licensing authority may refuse to grant the license if:
  - Previously granted license was cancelled or suspended.
  - The applicant failed to comply with any provision of act.

Drugs Imported For Examination, Test or Analysis

- Drugs under this can be imported only under a license in Form 11.
- Licensee must use imported drug only for the purpose for which they are imported.
- Licensee must comply with the conditions as specified.
- The drugs imported must be examined, test or analysed in the specific place authorised by licensing authority.
- Must allow an inspector to inspect the premises & check the records.
- Licensee must keep record of samples imported under license along with their quantities, date of importation & name of manufacturer.

Import Of Drugs for Personal Use

- To import the drugs for personal use, following guidelines must be followed.
- The drug should be a part of passenger's luggage. ~~and~~
- Daug must be for personal use only.
- The quantity of drug must not exceed hundred average doses.
- For more than 100 doses, apply on form no 12-A, 12B

Import of New Drugs

- Written permission of licensing authority.
- An application for an import license for small quantities of a new drug in rule 122-E for the purpose of treatment of patient.
- The drug should have purity, quality, strength & safety.

OFFENCES & PENALTIES

	PENALTIES	
OFFENCES	First Conviction	Subsequent Conviction
• Import of adulterated or spurious drugs, cosmetics or any cosmetics containing harmful ingredient	Imprisonment upto 3 years & fine upto ₹ 5000	Imprisonment upto 5 years & fine upto ₹ 10,000
• Import of drugs or cosmetics other than those reffered whose import is prohibited.	Imprisonment upto 6 months & fine upto ₹ 500	Imprisonment upto 1 year & fine upto ₹ 1000
• Import of any drugs / cosmetics in contravention of any notification issued under section 10A	Imprisonment upto 3 years & fine upto 5,000	Imprisonment upto 5 years & fine upto 10,000

MANUFACTURE OF DRUGS

- The manufacture of drugs also known as pharmaceutical manufacturing involves the process of designing, synthesizing, formulating and producing pharmaceutical products such as medications, vaccines and dietary supplement on a large scale
- The manufacture of drugs in India is regulated under the Drugs & Cosmetics Act 1940 which establishes the framework for ensuring that drugs produced within country meet quality, safety & efficacy standards.

PROHIBITION OF MANUFACTURE & SALE OF CERTAIN DRUGS

- Any drug which is not of standard quality.
- Any misbranded, adulterated or spurious drugs
- Any patent or proprietary medicine whose formula is not disclosed on label or container.
- Any drug that claims to cure, prevent disease specified in schedule J.
- Any cosmetic containing any ingredient which make it unsafe or harmful for use.
- Any drug or cosmetic which is against of the act & rules.

CONDITIONS FOR GRANT OF LICENSE

- The manufacturing must be conducted under active direction and personal supervision of a qualified technical stuff.
- The licensee & factory premises should comply with conditions and requirments prescribed under Schedule M respectively.
- The applicant must provide adequate space, plant & equipment as per schedule M.
- The applicant must provide separate testing unit or quality control section for test & standardization of drugs & raw materials.
- The applicant should make adequate arrangements for storage of drugs, manufactured.
- For patent & proprietary medicines, the applicant must convey the documents and data related to claims, safety, stability, therapeutic justifications etc as per the rules.

TYPES OF LICENSES FOR MANUFACTURE OF DRUGS

Following licenses are provided for manufacture of drugs under Drugs & Cosmetics Act.

- Drugs specified in schedule C & C1
- Drugs specified in schedule X
- Drugs other than those specified in schedule C, C1 & X.
- Drugs for the purpose of examination, test or analysis.
- Loan License
- Repacking license

License For Manufacture Of Drugs Specified in C.G

- Licensee should comply with schedule M
- Licensee should have adequate facility for testing, separate from manufacturing
- Should have adequate storage facility
- Records maintained for at least 2 years from date of Exp.
- Should provide sample to authority
- Maintain the inspection book.
- Maintain reference sample from each batch.
- Form of application no 27 filled.

License for Manufacture of Drugs Specified in Schedule X

- For obtaining a license regarding manufacturing of drugs specified in schedule X, form 24-F is filled.
- Accounts of all transactions regarding manufacturing should be maintained serially.
- Have to sent invoice of sale to licensing authority every 3 months.
- Store drugs in direct custody of responsible person.
- Preparation must be labelled with XRx
- Drug should not be supplied in sample.

Manufacture Of Drugs Other Than Those Specified in C, C+ & X

- Form of Application - 24-A.
- Must maintain an inspection book.
- Should have adequate storage area.
- License is valid for a period of 5 years one from the date on which ih is issued.
- License shall deemed to have expired if the application for its renewal is not made within 6 months of its expiry.

Manufacture of Drugs for Examination / Test / Analysis

- License should obtain in Form 29.
- Drug should be used exclusively for the purpose for which they are manufactured.
- Licensee allow inspector to inspect the premises & satisfy himself that only examination, test or analysis is being conducted.
- Licensee should maintain inspection book.
- Licensee must comply with all the rules mentioned in act.
- License remains valid for a period of 1 year time.

LOAN LICENSE

- A loan license means a license which a licensing authority may issue to a applicant who not have his own arrangements for manufacture but want to manufactures drugs at the premises of manufacturing facilities owned by another licensee.
- Drugs other than those specified in schedule X can be manufactured under the grant of loan license.
- Application for license is made in Form 24-A & the license is issued in form 25-A
- Before grant of license, the LA shall get the premises inspected by one or more inspectors.
- Inspector shall check into all the positions of plant & shall also inquire qualification of technical staff employees.

Repacking License

- Repacking refers to the process of transferring a drug from its original bulk packaging into smaller packages or different containers, without altering drug composition.
- This license ensures that repacked drugs maintained their quality, safety & efficacy.
- It is applied under form 24-B
- Repacking of drugs should be conducted under hygienic conditions under personal supervision of a well qualified person.
- Should allow inspect the premises & take sample of repacked drugs.
- Records must be maintained for 5 years from date of manufacturing.
- Shall maintain the reference sample from each batch of repacked drugs.
- License valid for a period of 5 years.

Penalties Related To Manufacture

OFFENCES	PENALTIES
• Manufacture of any spurious drugs	1-3 years imprisonment, 5,000 fine 2-6 years imprisonment, 1000 fine on subsequent conviction
• Manufacture of Adulterated Drugs	1 year imprisonment, 2000 fine 2 year imprisonment, 2000 fine on subsequent conviction.
• Manufacture of Drugs in contravention of the provisions	Imprisonment upto 3 months, 500 fine. Imprisonment upto 6 months, 1000 fine on subsequent Conviction

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