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Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Important Questions
Chapter 3 : Drugs and cosmetic act 1940 and Rules 1945 and New Amendments

Chapter 3
Drugs and cosmetic act 1940 and Rules 1945 and New Amendments
IMPORTANT Questions

Q1. Write a note on Drugs and Cosmetics Act 1940 & Rules 1945.

Ans.

- → The main aim of The Drugs and Cosmetics Act, 1940 and Rules 1945 is to maintain the import, manufacture, distribution, and sale of drugs and cosmetics.
- → Continuous use of cosmetics in luxury items prove to be harmful as they may contain harmful ingredients. Therefore, there is a need to control the cosmetics.
- → This Act verifies that the drugs and cosmetics should be manufactured, distributed, and sold only by qualified persons having a licence for this purpose.
- → The Central and State Drugs Control authorities are also recognised to control these actions. To this Act and Rules, timely amendments are made.
- → The major amendment was made in 1982, in which Schedules E, I, and L were eliminated, Schedules G and H were revised and expanded, and Schedule X was added. Previously there were Schedule C and C, drugs, and drugs other than those specified in these schedules.
- → At the present time, there are :
    1) Drugs not specified in Schedule C, C_1, and X,
    2) Schedule C and C_1 drugs, excluding Schedule X drugs, and
    3) Schedule X drugs.

Objectives

- ❖ For Preventing sub standard (Low quality) in drugs , ant for promoting high medical standards.
- ❖ For controlling the import , manufacturing , distribution and sale of drug and cosmetics by licensing.
- ❖ Ensuring that manufacturing , distribution, in sale of drugs and cosmetic is done by qualified persons only.
- ❖ For establishing Drug Technical Advisory Board(DTAB) in Drug consulting Committees (DCC) for allopathic drugs and cosmetics.

Q2. Write a note on loan license.

Ans.

- → This type of license is issued to the person who used other's Premises to manufacture the drugs . Except those drugs are specified in Schedule X can be manufactured under this license.
- → The licensee and premises should comply all the conditions and requirements are necessary for manufacture of drugs.
- → He Should submit the consent document of owner of the premises to the Licensing authority along with the Application for grant of Loan License.
- → The licensee is required to test each batch of raw material and finished goods and should maintain the record of test for at least 5 years from the date of manufacture (2 years in the case of expiry of drug).

Q3. Write a note on Repacking license.

Ans.

Repacking License

- → **Repacking :** It is a process in which someone take the products from manufacturing unit and packs on his brand name and Market the products . This type of license is required for repacking the other than drugs are specified in Schedule C and C1

Conditions are related to repacking :

1) For repacking operations sufficient space and equipment should be provided and should be carried out under hygienic conditions and under the supervision of a penon approved by the Licensing Authority as a Competent Person
    a) Who passed intermediate with chemistry. or
    b) passed diploma in pharmacy. or
    c) A registered pharmacist. or
    d) A person have 4 year experience in manufacturing , dispensing , or repacking of drugs.
2) The licensee should have sufficient arrangements for analysis and testing of each batch of raw materials and repacked drugs or should get them analysed and tested by an approved institution. He should also maintain reconds of such tests for 3 years from the date of manufacture and in case of drugs with expiry date at least for 3 months from such date.
3) The licensee should make suitable arrangements for storage of drugs and should allow an authorised Inspector to inspect the premises and take samples. The factory premises should meet the requir ements specified in Schedule M.
4) The licensee should mamtain proper records for repacking of drugs and should allow an inspector to check them.
5) The licence should be kept on the licenced premises and should be produced before an authorised Inspector on demand.
6) The drugs repacked should bear the number of the licence preceded by the words Rpg. Lic. (Repackaging Licence). No. , on their label.
7) The licensee should comply with the provisions of the Act and the Rules and other requirements, a notice for which has been given for not less than 4 months by the Licensing Authority

Q4. Describe a note on Sale of Drugs.

Ans.

Sale of drugs

- → The process of passing drugs from manufacturers to consumers is termed "sale".
- → Before 1940 , there was no restriction / prohibition for selling , compounding , and dispensing of drugs.
- → but after implementation of D& C Act 1940 , selling , compounding , dispending of drugs became a prohibited work , and only licensed persons can involve in these works.

Types of Sale

1) Wholesale of Drugs
2) Retail Sale of drugs

Wholesale of Drugs :

- → A wholesale licensee can directly contact to manufactures for supplying of drugs to retailers .

Conditions for wholesale of drugs :

- ◈ Separate licenses are required for the drugs of Schedule C and C1 and the drugs are other than Schedule C and C1.
- ◈ The Licensee must have adequate premises , and premises should not be less than 10 square meters.
- ◈ There should be facilities for storage of drugs that can preserve the potency of drugs.
- ◈ these drugs should not be sold to whom , who don't have preservation facilities.
- ◈ The wholesale Licensee sell the drugs to persons who have a license to retail them , and drugs also can be sold to hospital , educational and research institutes , but the records of the drugs should be maintained for 3 years with their names , quantity , batch no. ,date manufacturer name and cash memo (bill)
- ◈ The license should be displayed in premises.

Retail Sale of drugs

Conditions For retail sale of drugs :

1) Facility according to Schedule N.
2) Purchase only from Licensed wholesalers.
3) Separate license for Schedule C and C 1 drugs , Schedule X and for the drugs other than schedule C and C 1 and X.
4) Schedule H and X drugs will not be sold without valid prescription.
5) All the registers and records should be maintained for at least 2 years from the date of the last entry.
6) The licensee should allow the inspectors for inspection of premises , registers and records.

Q5. Give the Offences and Penalties regarding sale of drugs.

Ans.

Offenses and penalties regarding Sale of Drugs

Offences	Penalties
Sale , stocking , exhibition , or offer for sale of drugs which may cause death or serious hurt.	Imprisonment from 5 years to life and fine of not less than 10,000 rupees
Sale , stocking , exhibition , or offer for sale of spurious drugs	Imprisonment of 1-3 years and fine of up to 5,000 rupees on first conviction , and for 2-6 years Imprisonment and fine 10,000 rupees on next conviction.
Sale , stocking , exhibition , or offer for sale in Contravention of any other provisions.	Imprisonment of 1-2 years and for subsequent offence 2-4 years , or 5000 fine.
Failure to keep records or disclose required Information	Imprisonment for 1 year or fine up to 1000
False warranty to purchase	Imprisonment for 1 year or fine up to 5,000 on first conviction , and imprisonment for up to 2 years or fine or both on subsequent convictions

Q6. Write a note on Drugs Technical Advisory Board (DTAB)
Drug Consultative Committee (DCC)
Central Drug Laboratory.

Ans.

Drug Technical Advisory Board (DTAB)

→ DTAB is constituted the Central Government to advise the Central and State Governments on technical matters arising out of the administration of this Act.

→ It consists of 18 members, of whom are ex-officio, 5 nominated and 5 elected members, as follows:

I. Ex- officio members :

1. Director General of Health Services (chairman)
2. Drug Controller of India.
3. Director, Central Drug laboratory, Kolkata
4. Director, Central Research Institute, Kasauli
5. Director, Indian Veterinary Research Institute, Izatnagar
6. President, Pharmacy Council of India g. President, medical Council of India
7. Director, Central Drug Research Institute, Lucknow

II. Nominated members

- Two Persons nominated by the Central Government from amongst persons who are incharge of drugs Control in states.
- One person from the Pharmaceutical industry, nominated by the Central Government
- Two Government analyst, nominated by the Central Government.

III. Elected members

- A teacher in Pharmacy or Pharmaceutical Chemistry or Pharmacognosy on the staff of an Indian University or an affiliated - College, elected by the Executive Committee of the Pharmacy Council of India.
- A teacher in medicine or therapeutic on the staff of an Indian University or an affiliated college, elected by the Executive Committee of the medical Council of India.
- One Pharmacologist elected by the Governing body of the Indian Council of medical Research.
- One Person elected by the Council of the central medical Association.
- One Person to be elected the Council of the Indian Pharmaceutical Association.

Drug Consultative Committee (DCC)

→ The drugs Consultative Committee is constituted by the Central Government. It is an advisory committee for the Central and State governments and the DTAB

→ It Consists of two representatives nominated by the central Government and one nominee of each of state Governments.

→ The Committee meets when required by Central Government to do so and is empowered to regulate its own procedure.

Central Drug Laboratory

- The Act provides for the establishment of a Central Drug Laboratory under the Control of a director appointed by Central Government. This laboratory established in Kolkata has been entrusted with the following functions.
- To analyse or test samples of drugs or Cosmetics send to it by the Customs Collectors or Courts.
- To carry out such other duties as entrusted to it by the Central Government or with its permission by the State Government after Consultation with the DTAB.
- The functions of the laboratory in respect of sera, Solutions of serum proteins for injection, vaccines, toxins antigens, antitoxins, sterilised surgical ligature and sutures and bacteriophages are carried out at the Central Research Institute Kasauli.

Q7. Give the note on Drugs Inspector.

Ans.

Drugs Inspectors

→ Drug Inspectors are appointed by Central government or by State government as much required,

Functions

- Inspection Of Premises licensed for the Sale of Drugs.
- Inspection Of Premises licensed for the Manufacture of drugs.

Qualification

- Degree in Pharmacy , Pharmaceutical science or medicine with specialization in clinical Pharmacology or microbiology.
- He should have Associated ship diploma of the Institution of Chemists (India) after passing examination with analysis of drugs and pharmaceuticals.

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