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Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Important Questions
Chapter 9 : National Pharmaceutical Pricing Authority (NPPA)

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Chapter 9
National Pharmaceutical Pricing Authority (NPPA)
IMPORTANT Questions

Q1. Write a note on Drug Price Control Order (DPCO) 2013.

Ans.

Drugs Price Control Order (DPCO) - 2013

- The Drugs Price Control Order (DPCO) 2013 is an order issued by the Government of India under the Essential Commodities Act, 1955, which regulates the prices of essential and life-saving drugs in the country.
- Under the DPCO 2013, the National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the prices of drugs under price control and monitoring the prices of decontrolled drugs.
- The order covers all formulations that are specified in the National List of Essential Medicines (NLEM), and the prices are revised periodically based on changes in the wholesale price index.
- The DPCO 2013 has helped in ensuring the availability and accessibility of essential medicines at affordable prices for the general public and reducing the burden of out-ofpocket expenditure on healthcare.
- It also promotes the growth of the domestic pharmaceutical industry by creating a fair and competitive market for bulk drugs and formulations.

Objective

- Fixing the maximum prices of essential and life-saving drugs and formulations to ensure affordability for the general public.
- Regulating the prices of bulk drugs and formulations that are specified in the National List of Essential Medicines (NLEM).
- Monitoring the prices of decontrolled drugs to prevent them from becoming too expensive.
- Encouraging the domestic pharmaceutical industry to promote growth and innovation while ensuring a fair and competitive market.
- Reducing the burden of out-of-pocket expenditure on healthcare for the general public.

Q2. Describe Brief note on National Pharmaceutical Pricing Authority (NPPA).

Ans.

National pharmaceutical Pricing Authority (NPPA)

- → National pharmaceutical Pricing Authority is a department of Ministry of Chemicals and Fertilisers , It was established in 1997.
- → It regulates the DPCO Rule , and fix the price cap for drugs are listed in National List of Essential medicines (NLEM) . all the powers of government of pricing , according to Essential Commodity Act Has been given to it.

Functions

- ✓ To implement and enforce the provisions of the DPCO.
- ✓ To appoint the officers and other staffs members of the authority.
- ✓ To deal with the legal matters arising against the decision of the authority.
- ✓ To collect data on production , export , import market share of individual companies and their profitability.
- ✓ To monitor the availability of essential drugs , and management in case of shortage.

Q3. Write a note on Retail Price of Formulation.

Ans.

Retail Price of Formulation

- → The retail price of formulations is the price that a consumer pays for a finished dosage form of a drug, such as a tablet, capsule, syrup, etc.
- → The retail price of formulations is influenced by various factors, including the cost of raw materials, production costs, marketing and distribution expenses, and government regulations
- → The following formula is used to calculate the retail price of formulation .

$$RP = \frac{(MC+CC+PM+PC) \times (1+MAPE) + ED)}{100}$$

Where :

RP= Retail Price.

MC= Material cost.

CC= Conversion Cost , the cost comes in converting raw material into final product e.g. labour cost , Manufacturing cost etc.

PM= Cost of packing material.

PC= Packing charge.

MAPE = Maximum allowable Post manufacturing Expenses (it includes ex factory cost , trade margin , and manufacturing margin , and it should not exceed 100%).

ED= excise duty . it is a local tax applied on domestically production of goods.

Q4. Write a note on National list of Essential Medicines (NLEM).

Ans.

National List of Essential medicines (NLEM)

- The National List of Essential Medicines (NLEM) is a list of essential medicines that are considered necessary for meeting the basic health needs of the population. It is a comprehensive list of drugs and medicines that are considered essential for public health, and is updated periodically to reflect the changing needs of the population.
- The NLEM is prepared and maintained by the Ministry of Health and Family Welfare, Government of India, and is based on the World Health Organization's (WHO) Model List of Essential Medicines. The list is reviewed and updated every two years to keep pace with the changing needs of the population and the advances in medical science.
- The NLEM includes a wide range of essential medicines, including those used for the treatment of common illnesses, life-threatening conditions, and chronic diseases. The list includes both generic and branded drugs and covers a wide range of therapeutic categories, such as anti-infective agents, cardiovascular drugs, and anti-cancer drugs, among others.
- The NLEM plays an important role in the regulation of drug prices in India and is used as a reference for fixing the maximum retail price of essential and life-saving medicines. The National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the maximum prices of drugs included in the NLEM, based on the manufacturing cost, market price trends, and wholesale price index.
- The NLEM is an important tool for ensuring the availability of essential medicines to the public, and helps in promoting access to quality healthcare and reducing the financial burden on patients and their families. The list helps in promoting rational use of medicines and ensures that the most essential and life-saving drugs are available and accessible to the public
- The first National list of essential medicines of India was prepared and released in 1996.
- This list was revised many times and last was in 2022.