UNIT 8 MISCELLANEOUS ACTS AND RULES

Structure

8.1 INTRODUCTION

In Unit 8 we have studied about the drug and cosmetic acts and rules. We know the objective of the act is to regulate the import, export, manufacture, distribution and sale of drugs and clinical research in India.

In this unit we will study other acts and rules which control the industry in different segments like narcotic and psychotropic act, which is meant to control the drugs which can be dangerous and can be misused for addiction purposes. Poison act is meant to regulate importation possession and sale of poisons. Drugs and Magic Remedies Act to control the advertisement of drugs and

certain cases to prohibit advertisement for certain purpose of remedies alleged to possess magic qualities and to provide matters connected therewith.

MTP Act provides for the termination of certain pregnancies by registered medical practitioners. It was passed by parliament on 10 Aug, 1971.

Drugs Price Control Order (DPCO) is power to fix the maximum sale price of bulk drugs specified in the first schedule. Calculation of retail price of formulation and power to fix retail price of scheduled formulation.

There are other acts, like Pharmacy Act 1948. The aim of this law is to regulate the profession of pharmacy in India and the industries (Development and Regulation Act 1951).

In this unit we will discuss these acts in detail so that you can have some idea about the basic features of various acts and rules applicable in the pharmaceutical industries.

Objectives

After studying this unit, you should be able to:

- understand what are the different acts and rules that control this industry?;
- understand the Narcotic and Psychotropic Drugs Act;
- understand the Drugs and Magic Remedies Act. what is Poison Act, how to control its distribution and sales?;
- explain Medicine and Toilet Preparation Act?;
- explain Medical Termination of Pregnancy Act, 1971 to safeguard the abortion legally; and
- understand Drugs Price Control Order (DPCO) 1995 to make available essential drugs to consumer at a reasonable price.

8.2 NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES (NDPS) ACT

The Narcotic Drugs and Psychotropic Substances (NDPS) Act 1985 sets out the statutory framework for drug law enforcement in India. The basic features of the act are as follows:

a) The cultivation, production, manufacture, possession, sale, purchase, transportation, ware housing, consumption, inter-state movement, trans-shipment and import and export of narcotic drugs and psychotropic substances is prohibited, except for medical or scientific purposes. This is in accordance with the terms and conditions of any license, permit or authorization given by the government.

b) The central government is empowered to regulate the cultivation, production, manufacture, import, export, sale, consumption, use etc of narcotic drugs and psychotropic substances.

c) State governments are empowered to permit and regulate possession and inter-state movement of opium, poppy straw, the manufacture of medicinal opium and cultivation of *cannabis* excluding *hashish*.

d) All persons in India are prohibited from engaging in or controlling any trade where by narcotic drugs and psychotropic substances are obtained outside India. They cannot supply these substances to any person outside India except with the authorization of the central government and subject to such condition as may be imposed by the central government.

e) The central government is empowered to declare any substance, based on an assessment of its likely use in the manufacture of narcotic drugs and psychotropic substances as a control substance.

f) Assets derived from drugs trafficking are liable to penalty.

g) Both the central government and state governments are empowered to appoint officers for the purposes of the act.

Cannabis has long been used for fibre (hemp), for medicinal purposes, and as a psychoactive

The NDPS act is in effect a comprehensive code not only for the control and regulation of narcotic drugs and psychotropic substances; but also for the control of selected chemicals-commonly known as precursors. These can be used in the illicit manufacture of narcotic drugs and psychotropic substances, as well as for the investigation and forfeiture of drug related assets.

8.2.1 Enforcement of NDPS Act

Given India's size and the federal nature of our polity, a number of agencies both at the centre and in the states have been empowered to enforce the provisions of the act. These agencies include the following at central level.

- Department of Customs and Central Excise
- The Directorate of Revenue Intelligence
- The Central Bureau of Narcotics
- The Central Bureau of Investigation

At State level the following are included

- State police
- Excise departments

The union ministries of Social Justice and Empowerments and health are responsible for the demand reduction aspects of drug law enforcement, which broadly covers health-care, de-addiction, rehabilitation and social reintegration of addicts.

In 1986 the Narcotics Control Bureau (NCB) was set by government to coordinate drug law enforcement at national level. The NCB basically functions as the national coordinator, international nodal point for the collection and for dissemination of intelligence. This system assures coordinated implementation within the parameters of a broad national strategy.

8.2.2 Investigative Procedures

NDPS act sets out the powers as well as the procedures for the investigation of offences under the act. This empowers officers to issue warrants, to enter and search premises, to stop and search vehicles to seize Narcotic drugs. They are also authorized to take statements and to arrest persons. The investigative procedures in case of opium are given in Box for information as an example.

Opium Production

India is largest producer of opium in the world, which is both exported as well as used by the domestic pharmaceutical industries. The cultivation of opium in India is regulated and controlled by the Narcotics Commissioner of India. The central government announces an opium policy each year. This sets out the terms and conditions subject to which licenses for the cultivation of opium are given.

The key elements of the licit opium control regime in India are as follows:

i) Opium can be cultivated only on fields specifically licensed for the purpose.

ii) The entire crop must be tendered to the central government at prices fixed by the government.

iii) Failure to tender the minimum-qualifying yield can disentitle the cultivator to a license in the following crop season.

These policy controls are backed by strict enforcement on the ground, which includes the measurement of fields, surveys and physical checks to prevent diversion. Failure to tender the entire yield to the government is treated as a serious offence and any cultivator who embezzles or otherwise illegally disposes of the opium produced by him, is in terms of section 19 of the act, punishable with rigorous imprisonment for a term of between 10 to 20 years and a fine between Rs. 100,000/- to Rs. 200,000/-.

8.2.3 Offences and Penalties

Act sets out the penalties for offences. These offences are essentially related to violations of the various prohibitions imposed under the Act on the cultivation, production, manufacture, distribution, sale, import and export etc. of Narcotic drugs and psychotropic substances. All these offences are triable by special courts and the punishments prescribed range from imprisonment from 10 to 20 years for first offences to 15 to 30 years for any subsequent offences together with monetary fines. In addition to persons directly involved in trafficking Narcotic drugs and psychotropic substances, any person who finances trafficking or harbours a person involved in trafficking, or abets, or is a party to a criminal conspiracy, including a criminal conspiracy to commit an offence outside India, is also liable to the same scale of punishments. The act was

amended in May 1989 to mandate the death penalty for second offences relating to contraventions involving more than certain quantities of specified Narcotic drugs and psychotropic substances. The act however, makes a distinction between possession for personal consumption and trafficking and the punishment for the former being limited to between six months to one year only. To put it in other words:

i) The quantity of the drug involved in the offence should be a small quantity as specified by the central government.

ii) The onus is on the accused to establish that the drug in question was meant for personal consumption and not for sale, distribution etc.

8.2.4 Precursor Control

The 1988 UN convention against illicit traffic in Narcotic Drugs and psychotropic substances to which India is a signatory, requires parties to impose controls on the manufacture, internal distribution and import and export of chemicals which can be used in the illicit manufacture of Narcotic Drugs and psychotropic substances. In order to implement India's obligations under this Convention, the NDPS act was amended in 1993 in order to empower the central government to declare any substance as a controlled substance and to regulate its manufacture, import and export etc.

Methaqualone is a sedative drug that is similar in effect to barbiturates, a general CNS depressant.

Ephedrine is commonly used as a stimulant.

Amphetamine is a drug that acts by increasing levels of norepinephrine, serotonin, and dopamine in the brain.

In exercise of its power under the Act, the central government has so far notified acetic anhydride, which is used in the processing of opium into heroin, N-Acetylanthranilic acid which is used in the illicit manufacture of **methaqualone, ephedrine** and pseudoephedrine, which are used in the illicit manufacture of **amphetamine** type stimulants, as controlled substances.

SAQ 1

a) What is the full form of NDPS?

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b) What are precursor chemicals, defined under NDPS Act?

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c) Which agencies are empowered to enforce the Act?

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8.3 THE DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT, 1954

An Act was introduced in 1954 against objectionable advertisement that made false claims about certain drugs that produced magical cures.

This act is applicable in all over India except the state of Jammu and Kashmir. This act will apply to those people of Jammu and Kashmir who domiciled in other part of India.

8.3.1 Prohibition of Advertisement of Certain Drugs for Treatment of Certain Diseases and Disorders

Under this Act, no person shall be involved in the publication of any advertisement about any drug that promotes:

a) miscarriage in women or prevention of conception in women,

b) maintenance or improvement of the capacity of human beings for sexual pleasure,

c) correction of menstrual disorder in women,

d) diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule (Section 8.3.5) or any other disease, disorder or condition (by whatsoever name called) which may be specified in the rules made under this Act,

e) In respect of any disease, disorder or condition, which requires timely treatment in consultation with a registered medical practitioner or for which there are normally no accepted remedies.

8.3.2 Prohibition of Misleading Advertisements Relating to Drugs

Subject to the provisions of this Act, no person shall take part in the publication of any advertisement relating to a drug if the advertisement contains any matter which -

a) Directly or indirectly gives a false impression regarding the true character of the drug; or

b) Makes a false claim for the drug; or

c) Is otherwise false or misleading in any material particular.

8.3.3 Prohibition of Advertisement of Magic Remedies for Treatment of Certain Diseases and Disorders

No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purpose specified.

8.3.4 Penalty

Whoever contravenes any of the provisions of this Act 1(or the rules made thereunder) shall, on conviction, be punishable-

a) In the case of a first conviction, with imprisonment which may extend to six months or with fine, or with both;

b) In the case of a subsequent conviction, with imprisonment which may extend to one year, or with fine, or with both.

8.3.5 The Schedule

Name of the Disease, Disorder or condition, which come under drugs and magic Remedies Act are given below:

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1. Appendicitis
2. Arteriosclerosis
3. Blindness
4. Blood poisoning
5. Bright’s disease
6. Cancer
7. Cataract
8. Deafness
9. Diabetes
10. Diseases and disorders of the brain
11. Diseases and disorders of optical system
12. Diseases and disorders of uterus
13. Disorders of menstrual flow
14. Disorders of the nervous system
15. Disorders of the prostatic gland
16. Dropsy
17. Epilepsy
18. Female disease (in general)
19. Fevers (in general)

20. Fits
21. Form and structure of the female bust
22. Gallstones, kidney stones and bladder stones
23. Gangrene
24. Glaucoma
25. Goiter
26. Heart diseases
27. High or low blood pressure
28. Hydrocele
29. Hysteria
30. Infantile paralysis
31. Insanity
32. Leprosy
33. Leucoderma
34. Lockjaw
35. Locomotor ataxia
36. Lupus
37. Nervous debility
38. Obesity
39. Paralysis
40. Plague
41. Pleurisy
42. Pneumonia
43. Rheumatism
44. Ruptures
45. Sexual impotence
46. Smallpox
47. Stature of Persons
48. Sterility in women
49. Trachoma
50. Tuberculosis (TB)
51. Tumors
52. Typhoid fever
53. Ulcers of the gastro-intestinal tract
54. Venereal diseases, including syphilis, gonorrhea, soft chancre
55. Venereal granuloma and lympho granuloma.

SAQ 2

a) Name the state where this Act is not applicable?

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b) What is the penalty for violation of Drugs and Magic Remedies act?

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c) Treatment for the following diseases or order can be advertised Blindness, Epilepsy, Fits, female diseases, and cataract.

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8.4 THE POISONS ACT, 1919

The poison at of 1919 to consolidates and amends the law which regulates the importation, possession and sale of poisons. This act is applicable to the whole of India.

Provided that it shall not apply to the state of Jammu and Kashmir except to the extent to which the provisions of this Act relate to the importation into India of any specified poison.

8.4.1 Power of the State Government for Sale of Poisons

Power of the state Government to regulate possession for sale and sale of any poison is as follows:

a) to grant license to possess any specified poison for sale, (wholesale or retail,) and the fixing of the fee (if any) to be charged for such licenses;

b) to classify persons to whom alone such licenses may be granted;

c) to classify of persons to whom alone any such poison may be sold;

d) to determine the maximum quantity of any such poison which may be sold to any one person;

According to poison Act of 1919: Any substance specified as a poison in a rule made or notification issued under this Act shall be deemed to be poison for the purposes of this Act.

e) to ensure the maintenance of record by vendors of any such poison in registers or sales. Details or particulars to be entered in registers, to be available for inspection;

f) to ensure safe custody of such poisons and the labelling of the vessels, packages of coverings in which poison is sold or possessed for sale; and

g) to ensure inspection and examination of any such poison when possessed for sale by vendor.

8.4.2 Unlawful Action Importation of Poison

Any poison in respect of which an offence has been committed under this Act, together with the vessels, packages or coverings in which the same is found, shall be liable to confiscation. People who are involved in the following activities while importing poison can be punished under the poison act:

a) Commit a breach of any rule made under the act

b) Import any poison without a license whose importation is restricted for the time being.

c) Breaks any condition of the license granted to him for the importation of the poison

Imposition of Penalty

i) On a first conviction, imprisonment will be upto three months, or fine may be upto five hundred rupees, or both,

ii) On a second or subsequent conviction, imprisonment a term, which may extend to six months, or with fine, may be upto one thousand rupees, or both.

8.4.3 Power to Issue Search Warrant

i) The District Magistrate, the Sub-Divisional Magistrate and in a presidency-town, the commissioner of police, may issue a warrant for the search of any

place in which he has reason to believe or to suspect that any poison is possessed or sold in contravention of the poison Act or any rule there under. All of these people may also issue a warrant regarding any poison liable to confiscation under this Act is kept or concealed.

ii) The warrant permits entry and search and is governed by the Code of Criminal Procedure, 1898 relating to search warrants.

SAQ 3

a) What is poisons Act?

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b) Who as per the act has power to issue search warrant?

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c) Can a person import any poison without a license into India?

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8.5 THE MEDICAL TERMINATION OF PREGNANCY (MTP) ACT, 1971

The Medical Termination of Pregnancy MTP Act provide for the termination of certain pregnancies by registered medical practitioners and for matters connected to it or incidental to it. This Act (Act No. 34) of 1971 was passed on 10th August, 1971. This is a Central Act applicable to the whole of India. In the state of Jammu and Kashmir, it was adopted in 1980.

The purpose of this act was to define the situations and circumstances in which safe abortion could be legally performed and to empower medical practitioners and institutions delivering this service. All practice of induced abortion medical or surgical has to be conducted within the MTP Act.

8.5.1 The MTP Act – A Protective Umbrella

Even today, voluntarily ‘causing miscarriage’ to a woman with child – other than in ‘good faith for the purpose of saving her life’ is a crime under Section

312 of the Indian Penal Code, punishable by simple or rigorous imprisonment and/or fine. Consequent sections (IPC Sections 313 – 316) relating to causing miscarriage without a pregnant woman's consent or causing maternal death due to the procedure are stricter, with punishments ranging up to 10 years imprisonment, and extending up to life imprisonment.

The MTP Act is an empowering legislation, which allows clinicians to offer legal safe abortion services within well-defined limits. The use of medical methods for early abortion is also completely covered by the MTP Act.

When Pregnancies may be Terminated

A registered medical practitioner (RMP) is protected under law if a pregnancy is terminated in accordance with opinion formed in good faith (Section 3 of the MTP Act).

Duration of Pregnancy

Pregnancies not exceeding 12 weeks may be terminated based on a single clinical opinion formed in good faith. Since the use of medical methods governed by clear guidelines issued by Drug Controller is presently up to 49 days, the single clinical opinion is necessary and sufficient.

Reasons for MTP

The pregnancies can be terminated if:

i) the pregnancy would involve a risk to the pregnant woman or cause grave injury to her physical and mental health.

ii) there were a substantial risk if the child to be born, would suffer physical or mental abnormalities so as to be seriously handicapped.

iii) pregnancy alleged by the pregnant woman to have been caused by rape.

iv) pregnancy resulting from a failure of any device used by any married woman or her husband for the purpose for limiting children.

It is important to note that the MTP Act does not permit abortions on demand. The responsibility rests with the medical practitioner to opine in good faith regarding the presence of a valid legal indication. These indications are also mandatory with medical methods.

Valid legal consent

A valid legal consent is essential under the MTP Act.

In case of termination of pregnancy in minors (under 18 years age) or lunatics consent of guardian is essential. While termination of pregnancy in adult woman over 18 years age is permissible with her consent.

The consent of the patient must be recorded for MTP. This is also a requirement every time a medical method is used for early abortion. An adult woman requires no other person's consent except her own.

Approved Venue for Conducting MTP

Pregnancies may only be terminated in the following settings.

i) A hospital established or maintained by the Government.
ii) A place approved for the purpose of the Act by the Government.

The MTP Act protects the registered medical practitioner from suits or other legal proceedings for any damage caused or likely to be caused by anything done in good faith under the act.

Section 52 of the IPC defines good faith as adequate and due care.

Drugs Inducing MTP

The Federation of Obstetric and Gynaecological Societies of India (FOGSI) recognizes the universal evidence on the effectiveness and safety of mifepristone – misoprostol administered for inducing medical termination of pregnancy up to 49 days from the Local Medical Practitioner (LMP) as approved by the drug controller in India.

Mifepristone is used to facilitate MTP in first two months of pregnancy, and in smaller doses as an emergency contraceptive

It needs to be stressed that, under existing laws; these methods can only be administered by gynaecologists and Registered Medical Practitioners (RMP) recognized for performing MTPS by the MTP Act of 1971.

FOGSI recommends close monitoring of distribution and use of these drugs by medical profession as well as pharmaceutical industry.

Misoprostol is a drug for the prevention of non-steroidal anti-inflammatory drug induced gastric ulcers. It is also used to induce labor and as MTP.

SAQ 4

a) When was MTP act passed?

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b) As per law pregnancy above 12 weeks can be terminated?

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c) Where pregnancies may be terminated?

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8.6 THE MEDICAL AND TOILET PREPARATION (EXCISE DUTIES) ACT, 1995

An Act to provide for the levy and collection of excise duty on medicinal and toilet preparations containing alcohol, opium, Indian hemp or other Narcotic drugs was passed in 1995, under this Act. The main points of the Act are:

i) There shall be levied duties of excise, at the rates specified in the schedule, on all dutiable goods containing alcohol opinion Indian hemp or narcotics manufactured in India.

ii) Excise shall be leviable:

   a) Where the dutiable goods are manufactured in bond, in the state in which such goods are released form a bonded warehouse for home consumption, whether such state is the State of manufacture or not;

   b) Where the dutiable goods are not manufactured in bond, in the state in which such goods are manufactured.

iii) Subject to the other provisions contained in this Act, the duties aforesaid shall collect in such manner as may be prescribed.

Explanation – Dutiable goods are said to be manufactured in bond if they are allowed to be manufactured without payment of any excise duty or levy under any law for the time being in force. For example, in case of alcohol, opium, Indian hemp or other narcotic, used as an ingredient in the manufacture of certain drugs.

Offences and Penalties

A person would have committed an offence if she/he:

a) Contravenes any of the provisions of a notification issued by Govt. or
b) Evades the payment of any excise duty or.
c) Fails to supply any information, which he is, required to supply under rules: or supplies false information or
d) Attempts to commit or abets any offence.

Each of these offences is punishable with imprisonment for upto, six months, or with a fine, upto two thousand rupees or with both.

Permissible rebate of duty on alcohol, etc., supplied for manufacture of dutiable goods.

Consider a situation in which alcohol, opium, Indian hemp or other narcotic drugs have been supplied to a manufacturer of any goods for use as an ingredient of such goods, e.g., manufacturing a medicine. Also suppose that the final product (the medicine) is dutiable by, or under the authority of, the collecting Government, and the duty of the excise on the goods so supplied (i.e. the medicine) had already been recovered by the Government under the law. Then the Government shall, on an application being made to it in this regard, grant a rebate in the duty of excise leviable under this law to the manufacturer. The quantum of the rebate would be the excess, if any, of the duty so recovered over the duty leviable under the law.

8.6.1 The Schedule of Dutiable Goods

The Schedule for dutiable goods are given in Table 8.1.

Table 8.1: The Schedule of dutiable goods

Item No.	Description of dutiable goods	Rate of duty
	Medicinal preparations	
1.	***Allopathic Medicinal Preparations:***	
	i) Medicinal preparations containing alcohol which are not capable of being consumed as ordinary alcoholic beverages:	
	a) Patent or proprietary medicines	Ten percent ad valorem or rupee one and ten paise per liter of the strength of London proof spirit, whichever is higher.
	b) Other	Rupee one and ten paise per liter of the strength of London proof spirit.
	ii) Medicinal preparations containing alcohol which are capable of beings consumed as ordinary alcoholic beverages:	

	a) Medicinal preparations which contain known active ingredients in therapeutic quantities.	Ten percent ad volorem or rupees three and eighty-five paise per liter of the strength of London proof whichever is higher
	b) Others	Rupees fifteen and fifty paise per liter of the strength of London proof spirit.
	iii) Medicinal preparations not containing alcohol but containing opium, Indian hemp, or other narcotic drug.	Ten percent ad valorem.
2.	***Medicinal preparations in ayurvedic, unani or other indigenous systems of medicine:***	
	i) Medicinal preparations containing self-generated alcohol which are not capable of being consumed as ordinary alcoholic beverages:	Nil
	ii) Medicinal preparations containing self-generated alcohol which are capable of being consumed as ordinary alcoholic beverages.	Thirty eight paise per liter of the strength of London proof spirit.
	iii) All others containing alcohol which is prepared by distillation or to which alcohol has been added.	Rupees fifty and fifteen paise per liter of the strength of London proof spirit.
	iv) Medicinal preparations not containing alcohol but containing opium, Indian hemp, or other Narcotic drug or Narcotic.	The percent ad valorem.
3.	***Homeopathic preparations alcohol.***	Rupees three and eighty five paise per liter of the strength of London proof spirit.
	Toilet preparations	
4.	***Toiletries (Toilet preparations) containing alcohol, or opium, Indian hemp, or other narcotic drug or narcotic.***	Twenty five percent ad valorem or rupees three and eighty five paise per liter of the strength of London proof spirit, whichever is higher.

LONDON PROOF SPIRIT: Mixture of ethyl alcohol and distilled water which at 51 degree Fahrenheit weights exactly 12/13 parts of an equal measure of distilled water at the same temp.

SAQ 5

a) What is medicinal and toilet preparation Act?

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b) What is the rate of duty of patent and proprietary medicines?

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c) What is London Proof spirit?

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8.7 DRUGS PRICES CONTROL ORDER

To regulate the prices of the drugs, Government of India introduced the Drugs Prices Control Order (DPCO) in 1995. The order inter *alia* provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Govt., penalties for contravention of provisions etc. For the purpose of implementing provisions of DPCO, powers of Government have been vested in National Pharmaceutical Pricing Authority (NPPA) under Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India.

Drugs are essential for health of the society and so have been declared as essential and accordingly put under the essential commodities Act, 1955.

There are only 74 out of about 500 commonly used bulk drugs that are kept under statutory price control. All formulations (drug) containing these bulks either in a single or combination form, fall under price-controlled category.

However, the prices of other drugs in case of public interest can also be regulated.

As per the provisions of DPCO, NPPA fixes two types of prices viz. Ceiling prices and Non-ceiling prices for medicines in the controlled category.

Ceiling Prices

Ceiling price refers to a single maximum fixed selling for each bulk drug, which is under price control price. This ceiling price is applicable throughout the country.

Non-ceiling prices are fixed by NPPA under DPCO, 1995 are specific to a particular pack size of scheduled formulation of a particular company. Hence they are formulation specific and company specific. The prices fixed for non-ceiling packs are communicated to the respective firms by issuing office orders. In such order, usually excise duty element is shown separately. However, local taxes are not included in the non-ceiling prices.

The manufacturer of non-scheduled drugs (drugs not under direct price control) is not required to take price approvals from NPPA. However, NPPA is required to monitor the prices of such drugs and take corrective measures where they have required, authority to fix and regulate such prices.

"A manufacturer, distributor or wholesaler shall sell a formulation (drug) to retailer, unless otherwise permitted under the provisions of this order or any order made there under, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen percent there of in the case of Scheduled drugs".

"Notwithstanding anything contained in sub-paragraph, the Government may by a general or special order fix, in public interest, the price of formulations sold to the wholesaler or retailer in respect of any formulation the price of which has been fixed or revised under this order". For non-scheduled formulations the companies are at liberty to decide the margin. However, it is reported by the industry that the prevailing normal trade margin, in respect of some decontrolled formulations is 20% for retailers and 10% for wholesalers.

8.7.1 Punishment for Violation

Contravention of any of the provisions of DPCO is punishable in accordance with the provision of the Essential Commodities Act, 1955. As per section 7 of Essential Commodities Act, the penalty for contravention of DPCO is from three months to seven years and the violator is also liable to a fine.

If a manufacturer sells a medicine at a price higher than the price approved / fixed for the product the manufacturer is liable for prosecution under Essential Commodities Act and also liable to deposit with the government the amount accrued due to charging of prices higher than those fixed or notified by the government.

The National Pharmaceutical Pricing Authority, the Food and Drug Authority (FDA) Drugs Controller of the State and Drugs Inspector of the district are the enforcing authorities at national, state and district levels respectively.

SAQ 6

a) The government issues DPCO under which act?

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b) How many drugs are at the moment under price control?

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c) What are non-scheduled drugs?

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8.8 SUMMARY

Let us summaries what all we discussed in this unit.

1. We learned about other acts and rules, which are directly or indirectly connected with the pharmaceutical industry. We discussed about narcotic and psychotropic drugs Act. Which is meant to control the cultivation, production, manufacture, possession, sale, purchase, transportation, ware housing, consumption interstate movement, trans-shipment, import export of narcotic and psychotropic substances.

2. We also learned about drugs and magic remedies Act, which is an act to control the advertisement of drugs in certain cases to prohibit the advertisement for certain purpose of remedies alleged to possess magic qualities and to provide for matters connected there with.
3. Poisons act an act to consolidate and amend the law regulating the importation, possession and sale of poisons in the country.
4. We also learned about medicine and toilet preparation act, which is an act to provide for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp or other Narcotic drug or Narcotic.
5. We also learned MTP act, which was passed by parliament on Aug 10, 1971. The act provide for the termination of certain pregnancies by registered medical practitioners, in which safe abortion could be legally performed and to empower medical practitioners and institutions delivering the service.
6. Lastly we learned about DPCO (drug prices control order, 1995, which is an order issued by the Government of India under essential commodities Act 1955. The order provides the list of controlled drugs. Procedure for fixation of prices of drugs. And ensuring abundant availability at reasonable prices of essential and life saving drugs.

8.9 TERMINAL QUESTIONS

1. What are the salient features of NDPS Act 1985?
2. What are drugs and Magic Remedies Act 1954?
3. What are the salient features of Poison Act 1919?
4. What is the purpose of the MTP Act 1971?
5. Which preparations come under the Medicinal and Toilet Preparations Act 1995?
6. What are the salient features of DPCO 1995?

8.10 ANSWERS

Self Assessment Questions

1. a) It is Narcotic Drugs and Psychotropic Substances.
   b) There are selected chemicals, which can be used in the manufacture of Narcotic and Psychotropic Substances.
   c) Agencies include department of Custom and Central Excise. The directorate of Revenue intelligence and Central Bureau of Narcotic and Central Bureau of investigation, State Police and Excise department at state level.

2. a) Jammu and Kashmir.
   b) In case of first conviction, imprisonment up to six months or with fine, subsequent conviction imprisonment which may extend to one year or with fine.
   c) No

3. a) An act to consolidate and amend the law regulating the importation, possession and sale of poisons.
   b) The district magistrate, the sub-divisional magistrate and the commissioner of police.
   c) No, it will be unlawful.

4. a) The MTP act was passed by parliament on 10 Aug, 1971.
   b) No, not above 12 weeks.
   c) A hospital established or maintained by Govt. or a place approved for the purpose of the act by the government.

5. a) An act to provide for the levy and collection of duties of excise medicinal and toilet preparations containing alcohol, opium, Indian hemp or Narcotic substances.
   b) Patent or proprietary medicines rate of duty is rupee one and 10 paise per liter of London proof spirit.
   c) London proof spirit is mixture of ethyl alcohol and distilled water

6. a) The essential commodities act 1955.
   b) At the moment there are 74 bulk drugs under price control.
   c) Drugs, which are not under direct price control.

Terminal Questions

1. The NDPS act is to regulate the cultivation, production, manufacture, import, export, sale, consumption use etc of Narcotic and psychotropic substances.

2. This is an act to control the advertisement of drugs in certain cases to prohibit the advertisement for certain purpose of remedies alleged to possess magic qualities which directly or indirectly gives a false impression of the drug, or makes a false claim for the drug for treatment of certain diseases and disorders.

3. Poisons act 1919, is an act to consolidate and amend the law regulating the importation, possession and sale of poisons in India. Under the act the state Government are given the power to issue the licenses etc.

4. The purpose of this act was to define situations and circumstances in which safe abortion could be legally performed, and to empower medical

practitioner and in situations delivering this service. All the practice of induced abortion medical or surgical has to be conducted as per MTP act.

5. All medicinal and toilet preparations containing alcohol, opium, Indian hemp or other Narcotic drugs come under this act. The duties shall be levied on all such preparations as per the rate fixed by the government.

6. The Drugs prices control order 1995 is an order issued by the government to regulate the prices of drugs, procedures for fixation of prices of drugs, method of implementations of prices fixed by government penalties for violation of the order. For the purpose of implementing provisions of DPCO, power of government has been vested in NPPA. NPPA fixes two types of prices VIZ. ceiling prices and non-ceiling prices for medicines in controlled category. The NPPA, the FDA / Drugs controller of the states, drugs inspectors of the districts are the enforcing authorities at national / state / district level.