find more details in the chapter: Drug Price Control order.

Then the new policy 'Pharmaceutical Policy 2002' was announced but could not be implemented because of protests from several corners and high court judgement. This policy further proposed price deregulation to bring down the number of drugs under DPCO is just to 35 from 74. The rationale behind this liberalization was that completion stabilises price of consumer products where consumers have a direct choice. But the medicines are different commodities where real consumers have no choice.

The new draft policy was then released in 2006 "National Pharmaceutical Policy 2006". The Sandhu Committee and Pronab Sen Committee's report on access and affordability of medicines to the vulnerable and poorer segments of the population were the part of the draft policy. This too could not be materialised.

Thus the policy of 1994 is in existence.

The Government of India, instead of concentrating on Pharmaceutical Policy, has notified National Pharmaceutical Pricing Policy 2012 (NPPP 2012) on July 2012. The NPPP is the extension of Drugs Policy of 1994. The objective of the policy is to place a regulatory framework for pricing of drugs to ensure availability of required medicines—"essential medicines"—at reasonable prices and at the same time providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well-being for all. The outcome of NPPP is the DPCO 2013 which currently regulates the prices of all medicines listed in NLEM 2015.

In September 2014, the Indian Government launched the "Make in India" campaign, with the objective of making India a global manufacturing hub; thus, bringing foreign technology and capital into the country. In 2017, the draft pharmaceutical policy is announced inviting stakeholders' comments before finalizing the long pending holistic pharmaceutical policy.

Infrastructure and Administration

The Government of India established a separate 'Department of Pharmaceuticals' under the Ministry of Chemicals and Fertilisers to look after the following divisions: Pharmaceutical Industries, Public Sector Pharmaceutical Industries, National Institute of Pharmaceutical Education and Research (NIPER), Research and Development and National Pharmaceutical Pricing Authority (NPPA). The department is headed by a secretary and assisted by two joint secretaries, one economic adviser, and one Deputy Director General.

The Central Drugs Standard Control Organization (CDSCO) has shifted its operation from the Nirman Bhawan to a newly build palatial FDA Bhawan. The then newly appointed Drugs Controller General India (DCGI) initiated several steps such as improving the manpower through recruiting drugs inspectors and other staff, promoting the present staff to various levels and promising e-governance like online submission of all forms and applications, digitalised interactive portals, online approvals with digital signature, nearly paperless office, etc. The CDSCO has been strengthened over the years with more number of employment of regulatory officers.

Over the years, CDSCO has changed its role too. Initially, it was perceived just as regulator. Its website now projects its vision "To Protect and Promote Public Health in India" and mission as "To safeguard and enhance the public health by assuring safety, efficacy and quality of drugs, cosmetics and medical devices".

Schedule M is made mandatory for all manufacturing companies with effect from 1st July 2005 which further ensures that India produces quality medicines. The Government now proposes to upgrade the Schedule M to be on par with WHO GMP. The Schedule M (III) for Medical Devices too made mandatory.

Against the backdrop of campaign that India has a significant spurious drugs market, the Government of India constituted an expert committee under the chairmanship of Dr R A Mashelkar, Director General of

Chapter

2

Drugs and Cosmetics Act

"The *National Human Rights Commission* (NHRC) has described the manufacture, distribution and sale of unsafe drugs and medical devices as a violation of human rights."

— www.drugscontrol.org

After reading this chapter, you should be able to understand and appreciate:

- Need of drugs control mechanism
- Regulation relating to import and export, manufacture, labelling and packaging, sale of medicine of allopathic, homeopathic and Ayurvedic, siddha and unani systems and cosmetics.
- Regulation relating to medical device.
- Regulation relating to quality of medicines and cosmetics
- Administrative procedure for implementing the regulations
- Regulatory Authorities of other countries.

Drugs or medicines (often used interchangeably) are part of our lives. They not only save lives and promote health, but also prevent epidemics and diseases. They have been recognised as the greatest weapon of mankind to fight diseases and deaths. But they need to be safe, effective, and of good quality and used appropriately. This in turn requires that their development, production, importation, exportation and subsequent distribution must be regulated to ensure that they meet the prescribed standard. With advancement of science and technology, many new and sophisticated medicinal products have been introduced into the market for the patient care. But at the same time, circulation of toxic, substandard, and counterfeit drugs on the national and international market has increased. The use of toxic, substandard and counterfeit medicines is not only a waste of money, but may also threaten the health and lives of those who take them. The issue of safety, efficacy, and quality can be effectively controlled or redressed through effective drug regulation.

Legal structures form the foundation of drug regulation. The drug laws provide basis for drug regulation. Throughout the world the drug legislation exists. Drug regulation comprises all measures: Legal, administrative and technical—which the government takes to ensure the safety, efficacy and quality of medicines or similar products, besides ensuring appropriate product information.

The genesis of drug control in India could be traced back to the preindependence era. The council of states adopted a resolution in 1927 to initiate immediate measures to control the indiscriminate use of drugs and to legislate for standardization of the preparations and for sale of such drugs. In

- Drug for which import license is prescribed, otherwise without a license.
- Patent and proprietary medicines whose true formula or list of ingredients with quantity is not displayed on the label or container.
- Drug which purports or claims to cure or mitigate any such disease or ailment specified Schedule J.
- Drugs whose manufacture, sale or distribution is prohibited in the country of origin. (But can be imported for examination, test or analysis.)
- Drugs not labelled and packed in the prescribed manner.
- Unapproved new drugs.
- Biological and other special products specified in Schedule C or C (1) whose potency is lost or acquired toxicity (after expiry date).
- Drug whose import is prohibited by the rule.

MANUFACTURE OF DRUGS

The following classes of drugs are prohibited to be manufactured:

- Substandard, misbranded, adulterated or spurious drugs;
- Patent or proprietary medicine unless true formula or list of ingredients including quantities used is displayed on the label;
- Drug which purports or claims to prevent, cure or mitigate any disease or ailment described in Schedule J.

However, prohibition is not applicable for manufacturing of small quantities of any drug for the purpose of examination, test or analysis.

Manufacturing of drugs can be undertaken only under a manufacturing license. The state Drugs Controller is the Licensing Authority. There are six different types of license for manufacture of drugs.

- License to manufacture drugs other than those specified in Schedule C, C(1) and X. These drugs are liquid orals, tablets and ointments, and are not psychotropic substances.
- License to manufacture Schedule X drugs. These are psychotropic drugs for oral administration.
- License to operate blood bank or process whole human blood for components or manufacture blood products.
- License to manufacture Large Volume Parenterals (LVP), sera or vaccines. The LVP means sterile solutions intended for

Schedule D (List of drugs exempted from the provisions of import drugs)

Class of drugs	*Extent and conditions of exemption*
Substances not intended for medical use.	Import permissible if imported in bulk and the importer certifies that the substance is for non-medical use. If not in bulk, then each container must indicate that it is not for medicinal use.
Substances included in Schedules C and C (1) required for manufacturing purposes but not intended for medical use in the form in which they are imported.	No license is necessary if the importer holds a license for manufacture of Schedule C and C (1) drugs.
Substances used as articles of food as well as drugs: Condensed or powdered milk whether pure, skimmed or malted, fortified with vitamins and minerals; farex, oats, lactose and all other cereal preparations fortified with vitamins (excepting those for parenteral use); virol, bovril, chicken essence and all other predigested foods; ginger, pepper, cumin, cinnamon and other similar spices and condiments if they are not labelled to have in conformity of official standards as prescribed under the Act and Rules.	No regulation.

Wholesale License

Like retail, there are three types of license.

- Space requirement: Not less than 10 sq m.
- Sale operation should be in charge of registered pharmacist/matriculation with four years of experience in dealing with drugs/recognized university degree with one year experience dealing with drugs.
- Maintains purchase records.
- Maintains sales records: The date of sale; the name and address of licensee to whom sold and his license number; the name and address of authority, institution, or registered medical practitioner if the medicines are sold to government, institution or registered medical practitioner; the name of the drug, quantity and the batch number; the name of the manufacturer; and the signature of the competent person under whose supervision the sale was effected. The carbon copy of the cash or credit memos need to be preserved for three years from the date of sale.
- Can sell to hospitals, medical institutions and registered medical practitioners and such records have to be maintained.

In the internet age and opportunities of home delivery of every commodities, the on-line business of or sale of medicines is not an exception. Though not legal, it has been in operation. The GoI now proposes to allow on-line pharmacy operation and brought a draft in June 2017 called "Drugs (Sale and Distribution Rules) 2017. It proposes to have legal operation of e-pharmacy. A strict enforcement of law is necessary to prevent illegal sale and to protect the public health.

SALE LICENCE CONDITIONS

[http://www.drugscontrol.tn.gov.in/guidelines_procedures_grant_renewal_retail_wholesale_licences_allopathic_drugs.html accessed on 22.10.2017]:

Licensing Authority

The Assistant Director of Drugs Control of Concerned zone

Documents to be Submitted

- Covering letter addressed to the Assistant Director of Drugs Control of **Concerned zone** along with Rs. 2/- court fee stamp for each licence.
- **Form 19** duly filled and signed by the applicant. **Form 19—**One number for each form of Licence, as applicable
- Authorization letter, in case of application signed by the authorized signatory in stamp paper/Board resolution.
- **Declaration form** duly filled and signed by the applicant and pharmacist/competent person.
- Fees of Rs. 1500/- for each form of licence.
- Premises details
  - Ownership document of the premises
  - Plan of the premises
  - Rental agreement of the premises, if applicable
- Pharmacist/competent person's details
  - Pharmacy council registration certificate/ Education qualification certificate
  - Experience certificate of competent person
  - Declaration of pharmacist/ competent person
- Applicant details
  - Document relating to constitution of concerned firm/Company/LLP and others
  - Passport size photos—3 of each and every applicant
  - Address/ID proof of the applicant
  - Legal tenancy affidavit
- Storage Accommodation details
  - Purchase bills of A/C and refrigerator along with working condition/ installation certificate

In case of change of premises and change in constitution.

Enclose Original Licence

Documents related to change in constitution like sale deed, Dissolution/Reconstitution deed, Amalgamation court order if it is Private Limited Company with board resolution and any other document.