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Licence Issuing Authority and Their Maintenance

*1 Ramling Raghunath Gojarte(B.Pharm), 2 Mr.L.R.Bagwan(M.Pharm), 3 L.D.Hingane(Ph.D Scholar)

***1** *At,Post.shirol(wa) Tq.nilanga Dist.Latur. maharastra,India 413530*
2 Aditya Pharmacy College,Beed
3 Aditya Pharmacy College,Beed

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I. INTRODUCTION

The Pharmacy education and profession in India upto graduate level is regulated by the PCI, a statutory body governed by the provisions of the Pharmacy Act, 1948 passed by the Parliament.

- The Pharmacy Act 1948 was enacted on 4.3.48 with the following preamble- "An Act to regulate the profession of pharmacy. Whereas it is expedient to make better provision for the regulation of the profession and practice of pharmacy and for that purpose to constitute Pharmacy Councils".
- The PCI was constituted on 9.8.49 under section 3 of the Pharmacy Act.

II. OBJECTIVES

- Regulation of the Pharmacy Education in the Country for the purpose of registration as a pharmacist under the Pharmacy Act.
- Regulation of Profession and Practice of Pharmacy.
- To regulate the import, manufacture, distribution and sale of drugs & cosmetics through licensing.
- Manufacture, distribution and sale of drugs and cosmetics by qualified persons only.
- To prevent substandard in drugs.
- To regulate the manufacture and sale of Ayurvedic, Siddha and Unani drugs
- To establish Drugs Technical Advisory Board(DTAB) and Drugs Consultative Committees(DCC) for Allopathic and allied drugs and cosmetic.

III. FUNCTIONS AND DUTIES

- To prescribe minimum standard of education required for qualifying as a pharmacist. (Ref.: section 10 of the Pharmacy Act)
- Framing of Education Regulations prescribing the conditions to be fulfilled by the institutions seeking approval of the PCI forimparting education in pharmacy. (Ref.: section 10 of the Pharmacy Act)
- To ensure uniform implementation of the educational standards through out the country. (Ref. : section 10 of the Pharmacy Act)
- Inspection of Pharmacy Institutions seeking approval under the Pharmacy Act to verify availability of the prescribed norms. (Ref.: section 16 of the Pharmacy
- To approve the course of study and examination for pharmacists i.e. approval of the academic training institutions providing pharmacy courses. (Ref. : section 12 of the Pharmacy Act)
- To withdraw approval, if the approved course of study or an approved examination does not continue to be in conformity with the educational standards prescribed by the PCI. (Ref.: section 13 of the Pharmacy Act).To approve qualifications granted outside the territories to which the Pharmacy Act extends i.e. the approval of foreign qualification. (Ref. : section 14 of the Pharmacy Act). To maintain Central Register of Pharmacists. (Ref. : section 15 A of the Pharmacy Act)

Drug and Cosmetic Act 1940.

Drugs Enquiry Committee appointed by Government in 1931 under the chairmanship of Colonel R.N.Copra to have a control on the import, manufacture and sale of drugs. But it not have strict rule. thus Finally, to control the import, manufacture, distribution and sale of drugs and cosmetics, Drugs and Cosmetics Act was passed on10th April 1940 by the Indian Legislature.

Schedules to the Act-(List of drug and equipment)

Schedule A: It prescribes different forms required under Drugs and Cosmetic Act, for making the application to grant or issue of licences, sending memorandum, etc.

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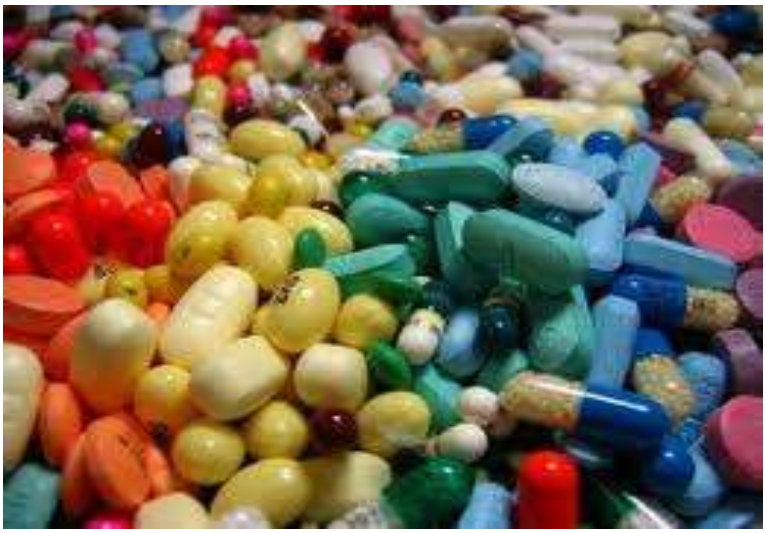
Schedule B: It prescribes the fees to be charged for test or analysis of samples of drugs by Central Drugs Laboratory and Government Analyst.
Schedule C& C(i): It prescribes the list of the biological and other special products.
Schedule E(i): It prescribes list of Ayurvedic, Siddha and Unani poisonous substances.
Schedule F: It prescribes provisions applicable to the blood bank requirements and licensingto process the blood components.
Schedule G: It prescribes list of drugs which are required to be taken only under the supervision of a Registered Medical Practitioner. It is labelled with direction: 'Schedule G Drug'
Caution "It is dangerous to take this preparation except under the supervision of Registered Medical Practitioner".
Schedule H: It prescribes list of drugs which are to be sold by retail only on the prescriptionof Registered Medical Practitioner. Schedule H drugs are labelled with direction-
Warning - "To be sold by retail only on the prescription of Registered Medical Practitioner."
Schedule J: It prescribes the list of ailments or diseases for which drugs may not claim to prevent or cure.
Schedule L: It prescribes list of drugs to be sold on prescription only- omitted
Schedule M: It prescribes the good manufacturing practices (GMP) and the requirements of factory premises, plant, equipments, etc for manufacture of drugs.
Schedule P: It prescribes life period of drugs
Schedule R:It prescribes the standards for condoms made of rubber latex intended for single use.
Schedule S: It prescribes standards for cosmetic
Schedule T: It prescribes the requirements of factory premises, plant, equipments and hygienic conditions for manufacture of Ayurvedic, Siddha, and Unani
Schedule X: It prescribes list of habit-forming Narcotic drugs and Psychotropic substances for the import, manufacture, distribution and sale of which requires a licence (NRx).

IV. SORT DEFINITION

Drug

It includes all medicines intended for internal or external use for or in diagnosis, treatment, prevention, mitigation or cure of diseases in human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative(standard) books of Ayurvedic, Siddha and Unani systems of medicines specified in First Schedule.



Cosmetic

Cosmetic means any article intended to be rubbed, sprayed, poured, sprinkled on or introduced into or otherwise applied to the human body thereof, for cleansing, beautifying or promoting the attractiveness oraltering the appearance and also includes any article intended to be used as a component of cosmetic but does not include soa soap.
• it contains or bears for the purpose of colouring only, a color other than **Loan Licence [Rule 69A]**
It means a licence granted to a person who do not have his own arrangements of manufacture but who intends to avail himself of the manufacturing facilities owned by another manufacturer.

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Adernal Drug

• A drug shall be deemed to be adulterated if-
• it contains in whole or in parts of filthy, putrid or decomposed substances; or
• it is prepared, packed or stored under unsanitary conditions whereby it may have been contaminated with filth or which may render the contents injurious to the health, or
• its container is composed in whole or in parts of poisonous deleterious
substance which may render the contents injurious to the health; or
thoseprescribed or it contains harmful or toxic substances which may render it injurious to health; or
• any substance has been mixed therewith so as to reduce its quality or strength.

Manufacture : Manufacture in relation to any drug or cosmetic includes any process or part of process for making, altering, ornamenting, finishing, packing, labelling, treating or adopting any drug or cosmetic with a view to its sale or distribution but does notinclude compounding or dispensing of drugs in the ordinary course or the course of retail business.

Drug Technical Advisory Board (DTAB):

Drugs Technical Advisory Board is constituted by Central Government and its work to advise the Central Government and State Government on the technical matters(Advise technical bases).

Ex- officio:

(i) Director General of Health Services (Chairman)
(ii) Drugs Controller, India
(iii) Director of the Central Drugs Laboratory, Calcutta
(iv) Director of the Central Research Institute, Kasauli
(v) Director of Indian Veterinary Research Institute, Izatnagar
(vi) President of Medical Council of India
(vii) President of the Pharmacy Council of India
(viii) Director of Central Drug Research Institute,Lucknow

Nominated:

1) Two persons by the Central Government
2) One person by the Central Government from the pharmaceutical industry
3)Two persons holding the appointment of Government Analyst under this Act,

Elected

1) one person, to be elected by the Executive Committee of the Pharmacy Council of India,
2) one person, to be elected by the Executive Committee of the Medical Council of India,
3) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;
4) one person to be elected by the Central Council of the Indian Medical Association;
5) one person to be elected by the Council of the Indian Pharmaceutical Association

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Functions:
To advise the Central Government and the State Governments on technical matters.
To carry out the other functions assigned to it by this Act.

Drug Consultative Committee (DCC)
1) It is also an advisory body constituted by central government.
2) Constitution:
a. Two representatives of the Central Government
b. One representative of each State Government

Functions
1) To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act.
2) The Drugs Consultative Committee shall meet when required
3) Has power to regulate its own procedure.

Central Drug laboratory (CDL)
- Established in Calcutta, under the control of a director appointed by the Central Government.

Functions:
- Analysis or test of samples of drugs/cosmetics sent by the custom collectors or courts.
- Analytical Q.C. of the imported samples.
- Collection, storage and distribution of internal standards.
- Preparation of reference standards and their maintenance.
- Maintenance of microbial cultures.
- Any other duties entrusted by Central Government.

Drug control laboratories in state
In gujarat three laboratories established which collect, analysed and report the various sample of the drugs and food.
1) Baroda: Established in 1959.
2) Bhuj: Established in 1979.
3) Rajkot: Established in 1983
The laboratory has the following devision:-
- Pharmaceutical Chemistry Division
- Immunology Division
- Pharmacology Division
- Pharmacognocy Division
- Food Division
- Ayurvedic Division

Function:
- testing of drug sample
- Analysis of food sample
- Analysis of exicse sample

Government Analyst
1) These officers are appointed by the central or state government and perform the duties.
a. Qualification of government analysist
2) Persons having qualification for appointment as government as govermental Analysis for allopathic drugs ;
3) having a degree in medicine, ayurved, sidha or unani system and not less than three year post graduate experience in the analysis of drugs in a laboratory under control of a government analyst.

Duties:
1) The Government Analyst shall cause to be analysed or tested such samples or drugs and cosmetics as may be sent to him by Inspectors.
2) A Government Analyst shall from time to time forward reports to the Government giving the result of analytical work and research with a view to their publication.

V. LICENSING AUTHORITY

The Central Government may appoint an authority called as "Licensing Authority" to issue license for the import of drugs. Each State Government may appoint "Licensing Authority" to issue license for manufacture, distribution and sale of drugs.These authorities have power to grant the license or refuse the license depending onthe Conditions of the applicant. These authorities may also suspend the license ifthe licensee has committed any offence in the contravention of the provisions of this Act.

Qualification:
(i) Graduate in Pharmacy on Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a University established in India by law; and
(ii)Experience in the manufacture or testing of drugs a minimum period of five years, Provided that the requirements as to the academic qualification shall not apply to those inspectors .

Duties:
1) to inspect all establishments licensed for the sale of drugs within the area assigned to him;
2) to satisfy himself that the conditions of the licences are being observed;

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3) to procure and send for test or analysis, if necessary, imported packages.
4) to maintain a record of all inspections made and action taken by him in the performance of his dupackage
5) to make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention to the Act;

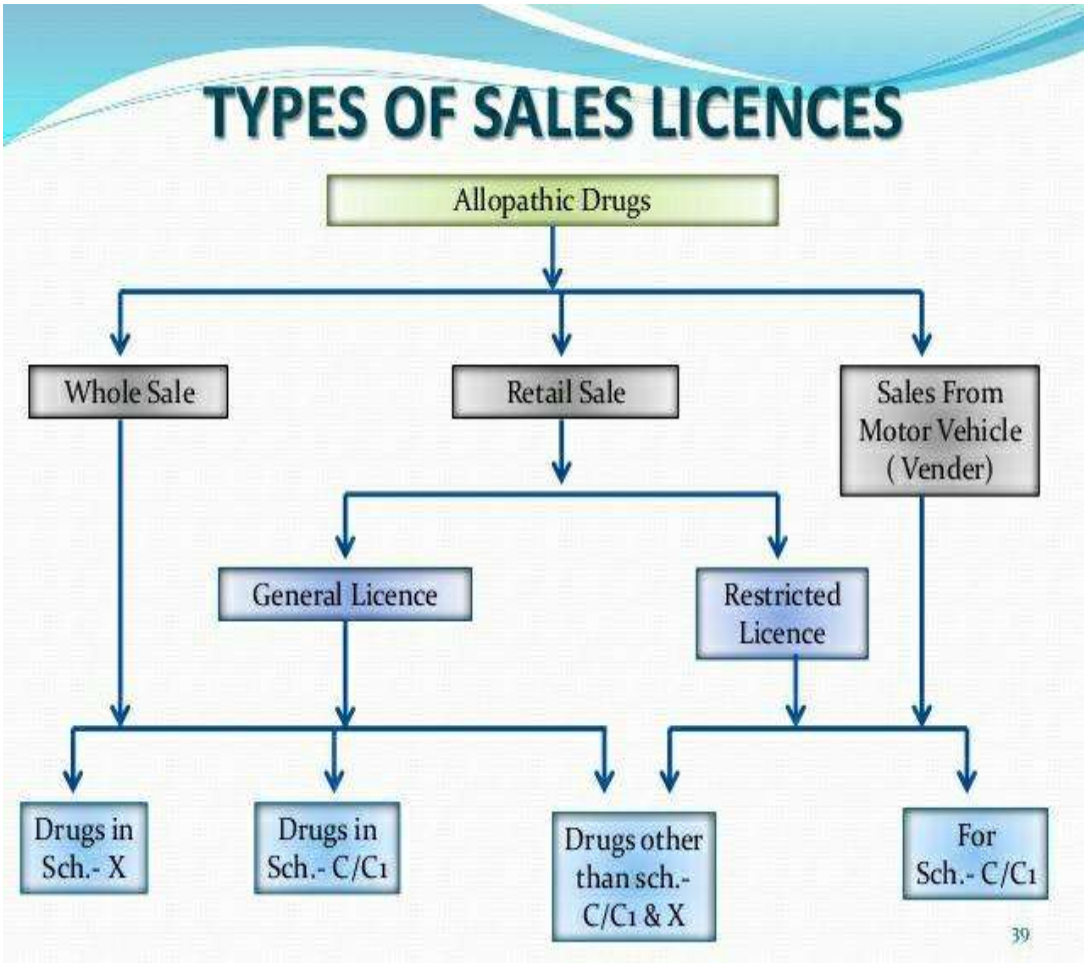
Controlling Authority
DRUG INSPECTOR
Qualification:
1) graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in clinical Pharmacology or microbiology from a University established in India by law and
2) experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years:

Power: Duties of Drug Inspector

a) **Inspect, --**
(i) any premises where in any drug or cosmetic is being manufactured.
(ii) any premises where in any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed ;

(b) Take samples of any drug or cosmetic,-
(i) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;
(ii) from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee.

C) Other Duties
1. Search in places, Persons, vechicles, etc
2. Verification of stock registers
3. Seizing of medical shops any offences under this act



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Retail Sale

For retail sale, two types of licenses are issued:

i) General licenses

ii) Restricted licenses

GENERAL LICENCE

General license are granted to person who have premises for the business and who engaged a service of qualify person to supervise the sale and do compounding and dispensing

VI. CONDITION OF GENERAL LICENCE

While granting such licence, the licensing authority should consider the following conditions

a) The average number of such licences granted during three years

immediately proceeding year.

b). The occupation, trade or business carried on by the applicant.

Where licence is granted for the wholesale (Form 20Bor 21B) and retail sale (Form 20 or of drugs in such premises should be under the control of competent person i.e. registered pharmacist and have an area of not less than square meters

Dispensing and compounding of drugs

Any drug shall, if compounded or made on the licensee's premises be compounded or made under the direct and personal supervision of a registered pharmacist.

The drugs other than the sale by the way of wholesale dealing, shall supplied only on the prescription of a Registered Medical Practitioner and shall be under personal supervision of a registered pharmacist.

The supply of any drug [other than those specified in Schedule X Narcotic & Psychotropic] on a prescription of a Registered Medical Practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of the entry in the register shall be entered on the prescription.

Following particulars enters in the register

- Serial number of the entry in
- The date ofsupply
- The name and address of theprescriber
- The name and address of the patient, or the name and addressof The owner of the animal if the drug supplied is for veterinaryuse
- The name of drug or preparation and the quantity or in case of a medicinemadeupbythe licensee,theingredientsandquantitiesthere of in the case of a drug specified in Schedule C or Schedule H the name of the manufacturer of the drug, its batch number and the date of expiry of potency, if any the signature of the registered pharmacist by or under whose supervision the medicine was made up or supplied.

Supply of Schedule C drugs

The supply of Schedule C drugs by retail shall be recorded in the register. The register should include the following details.

- Serial number ofentry
- Date ofexpiry
- Name and address ofpurchaser
- Name of the manufacturer, batch number and expiry date
- Sign of qualifiedperson
- Name and quantitie of drugs

Supply of otherdrugs

In case of drugs other than those specified in Schedule C is supplied by retail under cash or credit memo that should include the following particulars:

- ➢ Name, address and sale license number ofdealers
- ➢ Serial number of cash or creditmemo
- ➢ Name and quantity of drugsupplied
- ➢ Carbon copies of cash and credit memos shall be maintained by the licensee.
- ➢ The records shall be maintained and preserved for at least two years from the date of last entry

VII. RESTRICTED LICENSE

Granted to those dealers who do not engage the services of a qualified person and only deal with such classes of drugs whose sales can be effected without qualified person and vendors who do not have fixed premises.

CONDITION OF RESTRICTED LICENSE

1) He must have storage facility
2) He shall deal only drugs can which sold with supervision of experience person.
3) License should be displayed to public.
4) Drug should be sold in original container

The following particulars shall be entered in the register

- serial number of the entry
- the date of supply

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▪ the name and address of the prescriber
▪ the name and address of the patient, or the name and address of
the owner of the animal if the drug supplied is for veterinary use
▪ the name of drug or preparation and the quantity or in case of a
medicine made up bythe licensee, the ingredients and quantities thereof in the case of a drug specified in Schedule C or Schedule H the name of the manufacturer of the drug, its batch number and the date of expiry of potency, if any the signature of the registered pharmacist by or under whose supervision the medicine was made up or supplied.

Supply of Schedule C drugs
The supply of Schedule C drugs by retail shall be recorded in theregister. The register should include the following details.

- Serial number of entry
- Date of expiry
- Name and address of purchaser
- Name of the manufacturer, batch number and expiry date
- Sign of qualified person
- Name and quantities of drugs

Supply of other drugs
In case of drugs other than those specified in Schedule C is supplied by retail under cash or credit memo that should include the following particulars:

➢ Name, address and sale licence number of dealers

➢ Serial number of cash or credit memo

➢ Name and quantity of drug supplied

➢ Carbon copies of cash and credit memos shall be maintained by the licensee. The records shall be maintained and preserved for at least two years from the date of last entry.

Sale of Schedule H and X drugs
Schedule H and X drugs shall be sold by retail only on the prescription of Registered Medical Practitioner. The prescription should be in duplicate form one copy of this prescription should be preserved by the licensee for at least two years

➢ Sale of Schedule H and X drugs to Registered Medical Practitioners, hospital, dispensaries or nursing homes shall be made under the signed written prescription which shall be preserved by the licensee for at least two years.

➢ The premises should be under the control of registered pharmacist to supervise the sale, distribution and preservation of drugs.

➢ The licence shall be displaced at the prominent place open to the public.

➢ The purchase of drugs should be carried out from duly licensed manufacturers or dealers.

➢ The drugs which are specified in schedule C and C(i) should be properly stored
before its sale.

➢ A licence in Form 20 F shall be granted to pharmacy in such area ato
pharmacy which is not operating Chemists /Druggists.

➢ The records / registers which are maintained shall be preserved for two years from the date of last entry therein.

➢ If there is a change in the premises, such change should be informed to licensing authority within one month.

Dispensing of Schedule H and X drugs
• The prescription shall not be dispensed more than once unless the prescriber
have stated that it may be dispensed for more than once.
• If the prescriptions contains directions, it may be dispensed for the stated number of times. It must be dispensed according to the directions.
• While dispensing Schedule H and X (Narcotic & Psychotropic) drugs, signature, names and address of the seller and date on which it is dispensed, shall be recorded
• While dispensing Schedule H and X drugs, it should not contain other
preparation or any other drugs.
Storage of Schedule X (Narcotic &Psychotics) DrugsIn retail shops, **Schedule X drugs shall be stored -**
• Under lock and key in a cupboard or in premises recorded for the storage of these substances.
• In a part of premises solely separated from the remainder of premises and qualified person is responsible to access (sell & Store).

Records of Purchase
Records of purchase of drugs for retail sale shall be maintained by licensee and such record shall contain following particulars

➢ Date of purchase

➢ Name and address of person from whom purchased and his licence number

➢ Name of drug, quantity and batch number

➢ Name of manufacturer

➢ Licensee shall serially number the purchase bills

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including cash or credit memos and maintain it in chronological order.

Wholesale supply of drug

Drugs for wholesale supplied under cash or credit memos should include the following particulars:

Name, address and sale licence number of licensee to whom such drugs are soldSerial number of cash or credit memo Name, quantity and batch number of drug suppliedName of manufacturerCarbon copies of cash and credit memos shall be maintained by the licensee. The records shall be maintained and preserved for at least two years from the date of last entry.

Records of Purchase

Records of purchase of drugs wholesale sale shall bemaintained by licensee and such record shall contain following particulars

• Date of purchase
• Name and address of person from whom purchased and his licence number
• Name of drug, quantity and batch number
• Name of manufacturer

Licensee shall serially number the purchase bills including cash or credit memos and maintain it in chronological order.

Licensee shall produce all registers and records for inspection on demand by inspector.

Description for premises

Drug store Licensee who do not require services of qualified person shall display
description, "Drug store".
ii) Chemists and Druggists

Licensee who employ the services of qualified person shall display description, "Chemists and Druggists" but where drugs are not compounded against prescription.

Pharmacy +

Licensee who employ the services of qualified person shall display description, "PHARMACY" and where drugs are compounded against prescription.

Storage of Veterinary (Animal) medicine

• Veterinary medicines are kept in retail shops or the premises reserved for this purpose shall be labelled with direction. "NOT FOR HUMAN USE" for the treatment of animals only.
• The veterinary medicines shall be stored under lock and key in a cupboard or in premises reserved for this purpose.
• Part of the premises separated from the remainder of the premises and the customers will not have to access veterinary medicines.

The licensee shall not sell or stock expired drug which is registered on label, container or wrapper. He shall keep such drugs in packages or cartons aside and label the top with the words, "Not for sale".

Classes of prohibited Drugs

The following classes of drugs are prohibited for its manufacture, sale, distribution, etc.

• Adulterated, spurious, misbranded drug or drug which are not of standard quality.
• Patent and proprietary medicine of which formula is not disclosed.
• Drug imported or manufactured in the contravention of the provisions of the Act.
• Drugs which may claim to cure any of the diseases specified in the Schedule J.
• Expired drugs.
• The drugs intended for its consumption by Employees State Insurance Scheme (E.S.I.S) or Government Institutions (only for govt suuply).
• Drugs intended for its distribution to the members of the medical profession as free
sample and bearing on the container the words "Physician sample, Not to be sold."
• Drugs not intended for sale.

Sale of CosmeticsThe cosmetic which are not in the contravention of the provisions of the Act and Rules
may be sold without licence. Dealer of cosmetic require a licence for the sale of cosmetic.

Conditions for grant of licence for manufacture of Cosmetics

Manufacturer of cosmetics shall satisfy the following conditions for the manufacture of cosmetics

• The manufacture of cosmetics should be conducted under the personal
supervision of a competent technical staff with the following qualifications-
• Diploma in pharmacy
• Registered pharmacist

Passed intermediate examination with Chemistry as one of the subject or any other examination approved by licensing authority.

• Manufacturing premises shall be separated from rooms for private use and shall be clean and maintain hygienic conditions during manufacturing.

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• The applicant shall provide adequate space, plant and equipments for the manufacture of cosmetics.

VIII. REGISTRATION OF PHARMACISTS

Preparation and maintenance of register:-

(1) As soon as may be after this chapter has taken effect in any State, the State Government shall cause to be prepared in the manner hereinafter provided a register of pharmacists for the State.

(2) The State Council shall as soon as possible after it is constituted assume the duty of maintaining the register in accordance with the provisions of this Act.

(3) The register shall include the following particulars, namely:-

(a) the full name and residential address of the registered person;

(b) the date of his first admission to the register;

(c) his qualifications for registration;

(d) his professional address, and if he is employed by any person, the name of such person;

(e) such further particulars as may be prescribed.

Preparation of first register:-

(1) For the purpose of preparing the first register, the State Government shall by notification in the Official Gazette constitute a Registration Tribunal consisting of three persons, and shall also appoint a Registrar who shall act as Secretary of the Registration Tribunal.

(2) The State Government shall, by the same or a like notification, appoint a date on or before which applications for registration, which shall be accompanied by the prescribed fee, shall be made to the Registration Tribunal.

(3) The Registration Tribunal shall examine every application received on or before the appointed date, and if it is satisfied that the applicant is qualified for registration under section 31, shall direct the entry of the name of the applicant on the register.

(4) The first register so prepared shall thereafter be published in such manner as the State Government may direct, and any person aggrieved by a decision of the Registration Tribunal expressed or implied in the register as so published may, within sixty days from the date of such publication, appeal to an authority appointed by the State Government in this behalf by notification in the Official Gazette.

(5) The Registrar shall amend the register i accordance with the decisions of the authorit appointed under sub-section (4) and shall thereupo issue to every person whose name is entered in th register a certificate of registration in the prescribed form.

(6) Upon the constitution of the State Council, the register shall be given into its custody, and the State Government may direct that all or any specified part of the application fees for registration in the first register shall be paid to the credit of the State Council.

Qualifications for entry on first register

[1][A person who has attained the age of eighteen years shall be entitled] on payment of the prescribed fee to have his name entered in the first register if he resides, or carries on the business or profession of pharmacy, in the State and if he-

(a)holds a degree or diploma in pharmacy or pharmaceutical chemistry or a chemist and druggist diploma of an Indian University or a State Government, as the case may be, or a prescribed qualification granted by an authority outside [2][***] India,

or

(b)holds a degree of an Indian University other than a degree in pharmacy or pharmaceutical chemistry, and has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than three years,

or

(c)has passed an examination recognised as adequate by the State Government for compounders or dispensers, or

(d)has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than five years prior to the date notified under sub-section (2) of section 30.

Qualifications for subsequent registration. -

(1) After the date appointed under sub-section (2) of section 30 and before the Education Regulations have, by or under section 11, taken effect in the State, [3][a person who has attained the age of eighteen years shall on payment of the prescribed fee] be entitled to have his name entered in the register if he resides or carries on the business or profession of pharmacy in the State and if he-

(a) satisfies the conditions prescribed with the prior approval of the Central Council, or where no conditions have been prescribed, the conditions entitling a person to have his name entered on the first

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register as set out in section 31, or
(b) is a registered pharmacist in another State, or
(c) possesses a qualification approved under sectio 14:
Provided that no person shall be entitled 4[unde clause (a) of clause (c)] to have his name entere on the register unless he has passed a matriculatio examination or an examination prescribed as bein equivalent to a matriculation examination.
(2) After the Education Regulations have by o under section 11 taken effect in the State, a perso shall on payment of the prescribed fee be entitled t have his name entered on the register if he ha attained the age of 5[eighteen years], if he reside or carries on the business or profession o pharmacy, in the State and if he has passed a approved examination or possesses a qualificatio approved under section 14 6[or is a registere pharmacistin another state

A.Special provisions for registration o certain persons.
(1) Notwithstanding anything contained in sectio 32, a State Council may also permit to be entere on the register-
(a) the names of displaced persons who have been carrying on the business or profession of pharmacy as their principal means of livelihood from a date prior to the 4th day of March, 1948, and who satisfy the conditions for registration as set out in section 31;
(b) the names of citizens of India who have been carrying on the business or profession of pharmacy in any country outside India and who satisfy the conditions for registrations as set out in section 31;
(c) the names of persons who resided in an are which has subsequently becom a territory of India and who satisfy the condition for registration as set out in section 31;
(d) the names of persons who carry on the busines or profession of pharmacy in the State, and
(i) would have satisfied the conditions fo registration as set out in section 31, on the dat appointed under sub-section (2) ofsection 30, ha they applied for registration on or before that date or
(ii) have been engaged in the compounding o drugs in a hospital or dispensary or other place i which drugs are regularly dispensed o prescriptions of medical practitioners as defined i sub-clause (iii) of clause (f) of section 2 for a tota period of not less then five years prior to the dat appointed under sub-section (2) of section 30;(e the names of persons who were qualified to b entered in the register for a State as it existed immediately before the 1st day of November, 1956, but who, by reason of the area in which they resided or carried on their business or profession of pharmacy having become part of a State as formed on that date, are not qualified to be entered having in the register for the latter State only by reason of their not having passed either a matriculation examination or an examination prescribed as being equivalent to a matriculation examination or an approved examination or of their not possessing a qualification approved under section 14;(f) the names of persons–(i) who were included in the register for a State as it existed immediately before the 1st day of November, 1956; and(ii) who, by reason of the area in which they resided or carried on their business or profession of pharmacy having become part of a State as formed on that date, reside or carry on such business or profession in the latter State;(g) the names of persons who reside or carry on their business of profession or pharmacy in an area in which this Chapter takes effect after the commencement of the Pharmacy (Amendment) Act, 1959 (24 of 1959), and who satisfy the conditions for registration as set out in section 31.

(2.) Any person who desires his name to be entered in the register in pursuance of sub-section (1) shall make an application in that behalf to the State Council, and such application shall be accompanied by the prescribed fee.
(3.) The provisions of this section shall remain in operation for a period of two years from the commencement of the Pharmacy (Amendment) Act, 1959 (24 of 1959).
Provided that the State Government may, by notification in the Official Gazette, extend the period of operation of clause (a), clause (b) or clause (c) of sub-section (1) by such further period or periods, not exceeding two years in the aggregate, as may be specified in the notification.
Explanation 1.-For the purpose of clause (a) of sub-section (1), "displaced person" means any person who on account of the setting up of the Dominions of India and Pakistan or on account of civil disturbances or the fear of such disturbances in any area now forming part of Pakistan, has on or after the 1st day of March, 1947, left or been displaced from his place of residence in such area and who has since then been residing in India.
Explanation 2.-For the purposes of clauses (b), (c) and (g) of sub-section (1), the period referred to in clause (d) of section 31 shall be computed with reference to the date of application.]

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B. Special provisions for registration of displaced persons, repatriates and other persons:-

(1) Notwithstanding anything contained in section 32 or section 32A, a State Council may permit to be entered on the register-

(a) the names of persons who posses the qualifications specified in clause (a) or clause (c) of section 31 and who were eligible for registration between the closing of the First Register and the date when the Education Regulations came into effect.

(b) the names of persons approved as "qualified persons" before the 31st December, 1969 for compounding or dispensing of medicines under the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder;

(c) the names of displaced person or repatriates who were carrying on business or profession of pharmacy as their principal means oflivelihood in any country outside India for a total period of not less than five years from a date prior to the date of application for registration.

Explanation.-In this sub-section,-

(i.) "displaced persons" means any persons who, on account of civil disturbances or the fear of such disturbances in any area now forming part of Bangla Desh, has, after the 14th day of April , 1957 but before the 25th day of March , 1971 , left , or has been displaced from , his place of residence in such area and who has since then been residing in India;

(ii.) "repatriate" means any person of Indian origin who , on account of civil disturbances or the fear of such disturbances in any area now forming part of Burma , Sri Lanka or Uganda, or any other country has after the 14th day of April , 1957 , left or has been displaced from , his place of residence in such area and who has since then been residing in India.

(2.) The provisions of clauses (a) and (b) of sub–section (1) shall remain in operation for a period of two years from the commencement of the Pharmacy (Amendment)Act , 1976.]

Scrutiny of applications for registration

After the dateappointed under sub-section (2) of section 30 , applications for registration shall be Addressed to the register

the State Council and shall be accompanied by the prescribed fee.

(2.) If upon such application the Registrar is of opinion that the applicant is entitled to have his name entered in the register under the provisions of this Act for the time being applicable , he shall enter the name of the applicant in the register:

Provided that no person whose name has under the provisions of this Act been removed from the register of any State shall be entitled to have his name entered in the register except with the approval of the State Council recorded at a meeting.

(3.) Any persons, whose application for registration is rejected by the Registrar, may within three months from the date of such rejection appeal to the State Council, and the decision of the State Council thereon shall be final.

(4.) Upon entry in the register of a name under section, the Registrar shall issue a certificate of registration in the prescribed form.[9]

Renewal fees:-

(1) The State Government may, by notification in the Official Gazette, direct that for the retention of a name on the register after the 31st day of December of the year following the year in which the name is first entered on the register , there shall be paid annually to the State Council such renewal fee as may be prescribed , and where such direction has been made, such renewal fee shall be due to be paid before the first day of April of the year to which it relates.

(2) Where a renewal fee is not paid by the due date, the Registrar shall remove the name of the defaulter from the register:

Provided that a name so removed may be restored to the register on such conditions as may be prescribed.3).On payment of the renewal fee, the Registrar shall [10][issue a receipt therefor and such receipt shall be proof of renewal of registration.]

Entry of additional qualifications

A registered pharmacist shall on payment of the prescribed fee be entitled to have entered in the register any further degrees or diplomas in pharmacy on pharmaceutical chemistry which he may obtain.

Removel from Register

(1) Subject to the provisions of this section, the Executive Committee may order that the name of a registered pharmacist shall be removed from the register, where it is satisfied, after giving him a reasonable opportunity of being heard and after such further inquiry, if any, as it may think fit to make,-

(i) that his name has been entered into the register

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by error or on account of misrepresentation or suppression of a material fact, or
(ii) that he has been convicted of any offence or has been guilty of any infamous conduct in any professional respect which in the opinion of the Executive Committee, renders him unfit to be kept in the register, or
(iii) that a person employed by him for the purposes of his business of pharmacy [11][or employed to work under him in connection with any business of pharmacy] has been convicted of any such offence or has been guilty of any such infamous conduct as would, if such person were a registered pharmacist, render him liable to have his name removed from the register under clause (ii):
Provided that no such order shall be made under clause (iii) unless the Executive Committee is satisfied-
(a) that the offence or infamous conduct was instigated or connived at by the registered pharmacist, or
(b) that the registered pharmacist has at any time during the period or twelve months immediately preceding the date on which the offence or infamous conduct took place committed a similar offence or been guilty of similar infamous conduct, or
(c) that any person employed by the registered pharmacist for the purposes of his business of pharmacy [11][or employed to work under him in connection with any business of pharmacy] has at any time during the period of twelve months immediately preceding the date on which the offence or infamous conduct took place, committed a similar offence or been guilty of similar infamous conduct, and that the registered pharmacist had, or reasonably ought to have had, knowledge of such previous offence or infamous conduct , or
(d) that where the offence or infamous conduct continued over a period, the registered pharmacist had, or reasonably ought to have had, knowledge of the continuing offence or infamous conduct, or
(e) that where the offence is an offence under the [12][Drugs and Cosmetics Act, 1940 (23 of 1940)], the registered pharmacist has not used due diligence in enforcing compliance with the provisions of that Act in his place of business and by persons employed by him [11][or by persons under his control].

(2) An order under sub-section (1) may direct that the person whose name is ordered to be removed from the register shall be ineligible for registration in the State under this Act either permanently or for such period as may be specified.
(3) An order under sub-section (1) shall be subject to confirmation by the State Council and shall not take effect until the expiry of three month from the date of such confirmation.
(4) A person aggrieved by an order under sub-section (1) which has been confirmed by the State Council may, within thirty days from the communication to him of such confirmation, appeal to the State Government, and the order of the State Government upon such appeal shall be final.
(5) A person whose name has been removed from the register under this section or under sub-section (2) of section 34 shall forthwith surrender his certificate or registration to the Registrar, and the name so removed shall be published in the Official Gazettte

Restoration to Register

The State Council may at any time for reasons appearing to it sufficient order that upon payment of the prescribed fee the name of a person removed from the register shall be restored thereto:
Provided that where an appeal against such removal has been rejected by the State Government, an order under this section shall not take effect until it has been confirmed by the State Government.

Bar Other jurisdiction

No order refusing to enter a name on the register or removing a name from the register shall be called in question in any Court.

Issue of duplicate certificate of registration:-

Where it is shown to the satisfaction of the Registrar that a certificate of registration has been lost or destroyed, the Registrar may, on payment of the prescribed fee, issue a duplicate certificate in the prescribed form.

Printing of register and evidentiary value of entries therein:-

(1) As soon as may be after the 1st day of April subsequent to the commencement of the Pharmacy (Amendment) Act, 1959 (24 of 1959), the Registrar shall cause to be printed copies of the register as it stood on the said date.
(2) The Registrar shall thereafter cause to be printed as soon as may be after the 1st day of April in each year copies of the annual supplement to the register referred to in sub-section (1), showing all additions to and other amendments in, the said register.
(3) (a) the register shall be brought up-to-date

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three months before ordinary elections to the State Council are held and copies of this register shall be printed.
(b) The provisions of sub-section (2) shall apply to the register as so printed as they apply to the register referred to in sub-section(1).
(4) The copies referred to in sub-section (1) or sub-section (2) or sub-section (3) shall be made be available to persons applyingtherefor on payment of the prescribed charge and shall be evidence that on the date referred to in the register or annual supplement, as the case may be, the persons whose name are entered therein were registered pharmacists.]

IX. CONCLUSION

- The pharmacy act provided the profession of pharmacy im india with frame work
- It regulated and raised the status y of the profession of pharmacy in the country
- Education imparted to indiduals willing to enter this profession was standardised and made uniform
- It helped government achive a certain level of control of the professionals engaged in this field

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[6]. The words "the Provinces of" omitted by the A.O. 1950.
[7]. Subs. by Act 24 of 1959, sec. 10, for "a person shall on payment of the prescribed fee" (w.e.f. 1-5-1960).
[8]. Subs. by Act 24 of 1959, sec. 10, for "under this sub-section" (w.e.f. 1-5-1960).
[9]. Subs. by Act of 24 of 1959, sec 10, for "twenty-one years" (w.e.f. 1-5-1960).
[10]. 6 . Ins. by Act 24 of 1959, sec. 10 (w.e.f. 1-5-1960).
[11]. Ins. by Act 24 of 1959, sec. 11 (w.e.f. 1-5-1960).
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[13]. In its application to the State of Andhra Pradesh, section 33A has been inserted by the Andhra Adaptation of Laws (Second Amendment) Order, 1954.In its application to the State of Madras, section 33A has been inserted by the Adaptation of Laws Order, 1954 and latter subs. by the Madras (Added Territories) Adaptation of Laws Order, 1961.
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