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# Diploma in Pharmacy 2nd Year
# Pharmacy Law & Ethics
# Chapter 13 : Good Regulatory Practices

# Chapter 13
# Good Regulatory Practices

- → Good Regulatory Practices (GRP) is processes, systems, tools, and methods for improving the quality of regulations that are internationally recognised.
- → Before government initiatives are implemented, GRP systematically implements public consultation and stakeholder involvement, as well as impact analysis of government proposals to ensure they are fit for purpose and will achieve the goals set out.

## Good Regulatory Practice in Community and Hospital Pharmacy ( Retail and Whole sale )

## Documentation

- → Constitution of the entity, Memorandum of Association (MOA), Articles of Association (AOA) for a company, partnership deed, LLP agreement in case of partnership and LLP.
    - ID proof of partner/director/proprietor.
    - Documents related to premises – Copy of ownership documents of property or rental agreement and NOC (No Objection Certificate) from the owner of the rented premises as the case may be.
    - Site plan and key plan of the premises.
    - Copy of Board resolution permitting obtaining of a license.
    - Proof of availability of storage space as cold storage, refrigerator, etc.
    - Copy of challan as proof of depositing fee.
    - Affidavit regarding non-conviction of proprietor/partner/director and the firm.
    - The affidavit from the registered pharmacist/competent person.
    - Cover letter with name and designation of the applicant.
    - Declaration form in a prescribed format.
    - Applicant's qualification certificate.

## For a pharmacist at a retail sale

- Proof of qualification
- Registration of local pharmacy council
- Appointment letter

## For a pharmacist at a wholesale sale:

- Proof of qualification
- Experience certificate
- Appointment letter

# Prerequisites for Obtaining a License

- Pharmacist/ Competent Individual: The pharmacist must be qualified in the case of a retail business. In the case of a wholesale business, the individual must be a graduate with 1-year experience or an undergraduate with 4 years of experience.
- Space Requirement: The other important requirement is space, that is the area of the pharmacy/unit. For both wholesale and retail licenses the area of the pharmacy/unit should be 15 square meters. In the case of a retail and medical shop, it should be 10 square meters. The clear height of the sales premises shall be as per the guidelines laid down under the National Building Code of India, 2005.
- Storage Facility: The other important requirement is storage facility since some drugs require to be stored in low temperatures, refrigerators and air conditioners are a must.
- Technical Staff: The retail pharmacy staff must be experienced with in-depth knowledge. The staff of the wholesale pharmacy must be a graduate with a minimum of 1-year experience or an undergraduate having four years of experience

# Types of Drug License

- **Manufacturing License** : License issued to a business that manufactures drugs inclusive of allopathic/homoeopathy medicines.
- **Sale License :** License issued for the sale of drugs. It has the following bifurcations: – Wholesale Drug License – Retail Drug License
    - **Wholesale License :** A drug wholesaler must obtain a wholesale licence. Wholesale means the sale of the drug to a person/retailer to further sell it.
    - **Retail License :** A retail license is required for the retail sale of drugs. A retail sale means the sale of drugs or cosmetics for the consumption of the end consumer. Retailers can sell it to a dispensary, hospital, educational, medical, or research institute. Retailers engaged in pharmaceuticals, cosmetics, stand-alone pharmacists, ayurvedic shops, etc need this license.
- **Loan License :** License issued to a business that does not own the manufacturing unit but uses the manufacturing facilities of another licensee.
- **Import License :** License is issued to any dealer importing the products for the manufacturing of drugs or is engaged in the business of importing drugs in India.
- **Multi-Drug License :** License issued to businesses that own pharmacies in multiple states with the same name.

# Renewal of Drug Sales License

- Renewal of Sale license should be made on the application form same as the form submitted during the grant of the new license along with the necessary fee. The Fee for the renewal of the license is same as the grant of license. The late fee for the renewal of the license is as follows that is applicable up to six months.

### Late fee for Renewal Per month

- Rs. 500+500= Rs. 1000.00
- Rs. 500+500= Rs. 1000.00
- Rs. 250+250= Rs 500..00
- Rs. 250.00
- Rs. 250.00

# Documents Required for Renewal

- Copy of last renewal.
- Affidavit of Pharmacist and current rent agreement.
- Address proof of the authorised proprietor/applicant.
- Affidavit of the liable person for day-to-day working and for any violation of drug laws.

# GRP in Pharma Manufacturing

1. **Document related to licensing authorities :**
    - Copies of all documents are submitted for grant of licence.
    - Copies of licence related to manufacture of drugs like premises licence , Licences of manufacturing of schedule X schedule C and C1 etc.
    - Inspections record : copies of all inspections done by licensing authorities.
    - NOC ( No Objection Certificate ) from pollution control board.
2. **Registration and qualification records of chemist**
    - Qualification record
    - Registration certificate
    - Address proof
    - In case of change of chemist and other trained staff the copies of all document of new registered chemist and staffs .
3. **Analytical laboratory records**
    - All approval letters copies of analytical laboratories.
    - Educational and experience certificate of analyst.
    - Approval letter of analytical chemist by State drug controller.

4. **Equipment Cleaning and Use Record**
5. **Records of Raw Materials, (Intermediates, API Labelling and Packaging Materials )**
    - All transaction records related to raw material used.
    - Signature of person in charge cash memo or credit memo.
6. **Records of production including**
    - Drug Name and batch number.
    - The manufacturing date.
    - Quantity of raw material used.
    - Quantity of finished product.
7. **Laboratory Control Records**
8. **Batch Production Record Review**

## Licenses For Drugs Manufacturing

| Type of Manufacturing License | Application Form to be Submitted |
|---|---|
| For drugs other than those mentioned in Schedules C , C (1) and X | Form 24 |
| For Homeopathic Medicines | Form 24C |
| For drugs mentioned in Schedule X and not specified in Schedules C & C(1) | Form 24F |
| For drugs mentioned in Schedules C and C (1) excluding those specified in Schedule X | Form 27 |
| For loan license for drugs mentioned in Schedules C and C (1) excluding those specified in Schedule X | Form 27A |
| For drugs mentioned in Schedules C, C(1) and X | Form 27B |
| For the manufacture of drugs for the purposes of examination, test or analysis | Form 30 |
| For approval for carrying out tests on drugs/cosmetics or raw materials used in the manufacture on behalf of licensees for manufacture for sale of drugs/cosmetics | Form 36 |

## Renewal of Manufacturing Licenses

→ Licenses are valid for 5 years Renewal of license should be made on the application form same as the form submitted during the grant of the new license along with the necessary fee. The Fee for the renewal of the license is same as the grant of license.

# Import / Export of Drugs and Medical Devices

## Documents

- Copies of Documents submitted for grant of registration certificate for import or export of drug.
- Registration certificate.
- Copies of document submitted while application for import license.
- License.
- Challan evidence.
- Registration and IEC No.
- records of drugs and cosmetics imported and distributed.
- list of products are approved.
- list of countries from where products exported.

## Renewal of License

➢ License for drugs and medical devices are valid for 3 years and application for renewal should be made before 9 months of expiry . IEC is valid for life time.

## Inspection

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

## Functions

→ Inspection Of Premises licensed for the Sale of Drugs to confirm whether the Condition are being followed or not . and he can investigate

1) **Records related to Licensing Authority :**
    - License Retention Fees records , Records of Premises , record of Change in premises if any , Record of Suspension if Any,
    - Copies of all documents submitted while grant of license , Copies of retail sale or Whole sale license.
    - Copies of all inspections done by licensing authority.
2) **Registered pharmacist**
    - Record of Certificate of qualification , pharmacist registration certificate , address proof, in case of change registered pharmacist the copies of all document regarding change of registered pharmacist.

3) **Purchase record of drugs**
    - The date of Purchase.
    - The name , address and the number of license of the person from whom purchased.
    - The name of the drug , quantity and batch number.
    - The name of manufacturer.
    - All the purchases invoice ,payment record including purchase bill with cash or credit memo and transactions record of drugs for tow 2 years.
4) **Sale record of drug**
5) **Prescription feeling records :** The record of the drugs has been sold on prescription should be maintain with ( this is only for retail sale )
    - Serial number of entry
    - Date of supply
    - Name and address of prescriber
    - The name and address of patient
    - Name of drug and strength
6) **Expiry drug Records**

# Inspection of Pharmacies of Manufacturing Drug

→ Inspectors are appointed by Central government or by State government as much required Inspection Of Premises licensed for the Manufacture of drugs to confirm whether the Condition are being followed or not , and he can investigate

## E- Governance In Good Regulatory Practice

- Electronic governance or e-governance is the application(Use) of information technology for delivering government services, exchange of information, communication transactions, between government to citizen (G2C), government-to-business (G2B), government-to-government .
- Government of India wants to replace the traditional paper system with Information and Communication Technology (ITC ) for good regulatory practices . and ICT is better than paper system.

## Some benefits

- It takes less time than paper system.
- It provide transparency.
- It reduce cost.
- It is easy.
- Increase the satisfaction of public on government services.
- It reduce chances of Commission , unnecessary charges by greedy authorities.

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