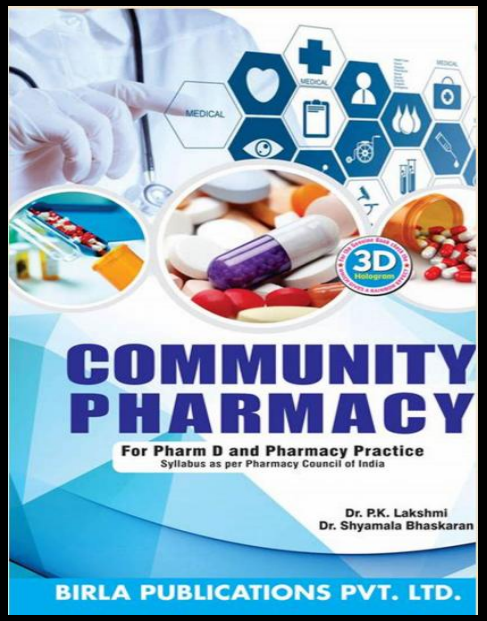
Best Regulatory Practices for community Pharmacies (Tamil)



BY,
DR.SELVARAJ,
B.Pharm.,M.B.A.,B.L.,M.L.,D.Tax.Law.,Ph.D
DIRECTOR OF DRUG CONTROL (Retd)
Tamilnadu

Various Regulatory Authorities in India

- **DCGI- Drugs Controller General of India**

  www.cdsco.nic.in

  Authority to approve the clinical trials of all drugs in India and approval of Drug manufacturing Licences and approval of drugs, Cosmetics and their formulation including medical devices in India.

- **DBT – Department of Biotechnology.**

  www.dbtindia.nic.in

  Authority to approve the clinical trails involving the use of recombinant biotech drugs.

- **MoEF – Ministry of Environment and Forests**

  www.envfor.nic.in

  Authority to approve the environment clearance and clearance under Biodiversity Act- Mainly for the herbal products.

Regulatory Authorities in India

- **CBN- Central Bureau of Narcotics**

  http://cbn.nic.in

  Authority to grant licences for Narcotic drugs .

- **NPPA- Nataional Pharmaceutical Pricing Authority**

  www.nppaindia.nic.in

  Authority to control the Prices of the drugs and Medical devices

- **State Regulatory Authorities**

  Authority to grant licences for Sales concerns and depots in the concerned State

- **State/Zone Excise Agencies**

  Local authority to grant transport permit and oversee the destruction of Narcotics.

LAWS CONNECTED TO DRUGS

- **THESE ARE SPECIAL LAWS**

1. DRUGS AND COSMETICS ACT 1940 AND RULES THEREUNDER, (The Drugs Act)

2. DRUGS PRICE CONTROL ORDER 2013

3.DRUGS AND MAGIC REMEDIES (OA) ACT

4. NARCOTIC DRUGS AND PSYCHOTROPHIC SUBSTANCES ACT.

GENERAL LAW

- 1. CODE OF CRIMINAL PROCEDURE, 1973 (The Bharatiya Nagarik Suraksha Sanhita (BNSS) 2023
- 2. THE INDIAN EVIDENCE ACT 1872 The Bharatiya Sakshya Adhiniyam, 2023 (BSA)
- 3. Indian Penal Code …(Bharatiya Nyaya Sanhita, 2023" (BNS)
- 4. FACTORY ACT 1948…. FOR THE PURPOSE SCHEDULE M Part

6. BIO-MEDICAL WASTE (MANAGEMENT AND HANDLING) RULES 1996

7. The Minimum wages Act 1948Minimum Wages ACtages Act, 1948

8. Bio Diversity Act 2002 – For Herbal products

9.Patents Law and Trades Mark registration Acts --- Patent registration under Intellectual property protection and trade name registration

Introduction of the Drugs and Cosmetics Act

- Drugs and Cosmetics Act 1940 and rules framed in 1945.

- Preamble of the Act.

"An Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics"

Objectives of the Act

Object of the Act is to ensure the availability of safe and quality medicines to public.

The Act amended now and then to meet out various issues in maintaining high standards of drugs. Recently amended in 2008 and called "Drugs and Cosmetics Act 2008".

Definition of "Drugs"

DRUG" INCLUDES :—

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of 6[vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette

Definition of " Drugs"

"DRUG" INCLUDES :—

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board"

Definititon of Cosmetics

- Sec3 (aaa) "Cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic

Medical devices rules 2017

- " Medical Devices rules " are notified w.e.f January 2018.
- Medical devices rules for the manufacture, quality control, import etc of Medical devices

- Rules for Cosmetics "Cosmetics rules 1945."
- "**Online Pharmacy"** draft rules published but not final notification is issued.

- 3 *(f)* —"**manufacture**" in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but *does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business;* and —to manufacture shall be construed accordingly

- 2[*(h)*] —**patent or proprietary medicine**—
- ***(i)*** **in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause *(a)*;**
- ***(ii)*** **in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5**

Definitions under the D & C rules 1945

- *2(ee)* "Registered medical practitioner" means a person—
- *(i)* holding a qualification granted by an authority specified or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or
- *(ii)* registered or eligible for registration in a medical register of a State meant for the registration of persons practising the modern scientific system of medicine excluding the Homoeopathic system of medicine; or

- *iii)* registered in a medical register, other than a register for the registration of Homoeopathic practitioner, of a State, who although not falling within sub-clause (i) or sub-clause (ii) is declared by a general or special order made by the State Government in this behalf as a person practising the modern scientific system of medicine for the purposes of this Act; or
- *(iv)* registered or eligible for registration in the register of dentists for a State under the Dentists Act, 1948 (16 of 1948; or
- *(v)* who is engaged in the practice of veterinary medicine and who possesses qualifications approved by the State Government;

- *2(f)* **"retail sale"** means a sale whether to a hospital, or dispensary, or a medical, educational or research institute or to any other person other than a sale by way of wholesale dealing;

- *2(g)* **"sale by way of wholesale dealing"** means sale to a person for the purpose of selling again and includes sale to a hospital, dispensary, medical, educational or research institution;

Quality of Drugs:

Section.16. Standards of quality.— (1) For the purposes of this Chapter, the expression "standard quality" means—

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed. (BIS)

If the Drug does not complies to the standards prescribed as above then it will be called as **"NOT OF STANDARD QUALITY"**

Various types of drugs which are prohibited for manufacturing, sale, distribution etc.

Misbranded Drugs

Adulterated Drugs

Spurious Drugs.

Not of standard quality drugs

QUALITY CONTROL IN MANUFACTURING OF DRUGS

(as per the Drugs and Cosmetics Act and rules..)

To achieve the standard quality drugs the act emphasis the following guidelines in manufacturing.

1.Good Manufacturing Practice (GMP) as per Schedule M

2.Good Laboratory Practice (GLP) as per Schedule L1.

3.Good Distribution Practice (GDP)-Guidelines.

(At present only for Biological Products)

GOOD MANUFACTURING PRACTICE

History of GMP

- 1961 - Requirements for equipment and Premises
- 1986 - First amendment based on 1975 WHO guidelines.
- 2001 - Second Amendment based on 1992 WHO GMP guidelines

  Effective from 11/12/2001 for New Units

  Effectve from 01/01/2001 for Existing Units

  Extended to another one year

- To achieve the Good Standard quality of drugs now
- **“Revised GMP** “ is amended wef. 05 Jan 2024.

Compliance with Legal Requirements

License Process

01

The registration process entails submitting necessary documents and fees to the relevant authorities, ensuring all operational standards and legal prerequisites are met.

Renewal of Licenses

02

Renewal of licenses requires periodic reviews to confirm ongoing compliance with regulations, often necessitating updated documentation and potential audits by licensing bodies.

VARIOUS TYPES OF SALES LICENCES

FORM 20- Retail Sales Licence for non biologicals

FORM 21- Retail Sales Licence for biologicals

FORM 20B-- Wholesale Sales Licence for non biologicals

FORM 21B- Wholesale Sales Licence for biologicals

FORM 20C- Retail Sales Licence for Homeopathic drugs

FORM 20D Wholesale Sales Licence for Homeopathic drugs

FORM 20F- Retail Sale licence for Schedule X

FORM 20G-- Wholesale Sale licence for Schedule X

FORM 20A – Restricted licences for household remedies

Condititons before licencing

- **Pre conditions for granting Licences.**

❖ Area of the premises

❖ Competent person/Registered Pharmacists

❖ Storage conditions to store drugs less than 10 * C and less than 25* C. (Refrigerator and Air conditions)

❖ Constitution of the concern

❖ Ownership of the premises or legal tenancy.

❖ Cleanness of the

Conditions in the Licences

- Licences should be displayed in prominent place of the premises open to Public
- Licencee should comply with the provisions of the Drugs and Cosmetics Act
- If there is any change of qualified person/competent person should be reported to the licencing authority within one month of change.
- No Drug shall be sold unless it was purchased under cash/credit memo.
- If there is any change of constitution of the firm, it should be informed to the Licencing authority within three months.

change in the constitution of a licencee

- "change in the constitution of a licencee"
- (i) a firm means change from proprietorship to partnership including Limited Liability Partnership or *vice versa*;
- **(ii)a company means-**

❖ (A) its conversion from a private to a public company, or from a public to a private company; or

❖(B) any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate within the meaning of this clause;

Condititons Under The Provisisons of the Drugs act and rules.

Rule 65 of the Drugs Rules

1. If it the drugs are being compounded or made in the premises, it should be direct and personal supervisison of the regd.Pharmacist.

2. Supply of drugs other than wholesale (ie retail) on any prescription shall be effected only by or under the personal supervision of regd Pharmacist.

3. Supply of a drug on a prescription of a RMP shall be recorded at the time of supply in prescription register.

Provided option to maintain cash memo/credit memo book may be obtained from the licencing Authoriry.

Condititons Under The Provisisons of the Drugs act and rules

Supply by retail otherwise than on a prescription of a drug shall be recorded at the time of supply in a register and cash/credit memo should be maintained.

4. Records of the purchase of drugs meant for retail sales should be maintained in a chronological order.

5. Supply of drugs by a wholesaler should be made on cash/credit memo with their licence number , and purchaser details qty, B,No , signature of Competent person under whose supervisison the sale was effected etc

Condititons Under The Provisisons of the Drugs act and rules

- 6. The licencee shall produce for the inspection all registers and records maintained by them.
- 7. All registers and records should be maintained for the period not less than two years from the last entry.
- 8. The records as per these rules only required not any other records.
- 9. Drugs Of Sch H, H1 and X should be sold by retail only on the prescription of RMP. If it is for the hospitals, institutions, etc it should be supplied only on the written signed order, and it should be maintained for two years,

Condititons Under The Provisisons of the Drugs act and rules

- 10. The prescription as per clause 9, should be with original signature and date.name and address of the patient, and total qty of medicine with dose to be taken.
- 11. Sch H and H1 drugs should be supplied once unless it is mentioned in the prescription for dispense more than once. In the prescription above the signature of the prescriber, the name, address of the seller and date on which the drug is dispensed.
- 12. The drugs of Sch X kept in rack under lock and key, and separated from other drugs.

Condititons Under The Provisisons of the Drugs act and rules

- 13 &14----- Deleted
- 15 a. **"Drug Store** "–Who don't require service of regd Pharmacist.

b. **"Chemists and druggist"** employ Pharmacist but no services of Compounding.

c. **"Pharmacy-**" employed Pharmacist and maintaining Pharmacy, compounding against preparations.

16. Licencee must maintain the inspection book in form 35 issued by the licencing authority, in which the inspectiong authority record the impression and defects noted.

Condititons Under The Provisisons of the Drugs act and rules

- 17. No drug should be sold or stocked after the expiry of the drugs by the licencess .

If it is kept for reimbursement or return it cane be stored separatly from the tradable stocks, with the marking **“ NOT FOR SALE”**

18. No drug intended for distribution for RMP as free sample , or ESI sample , Govt drugs etc cannot be sold or stocked .

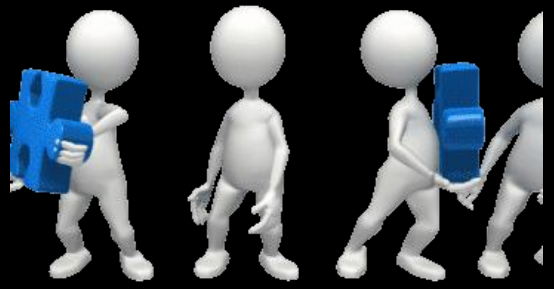
If they are approved agent for ESI, or Govt, appointed in writing , or the C&F depots for storing free samples under the written authority of the mfr is permitted.

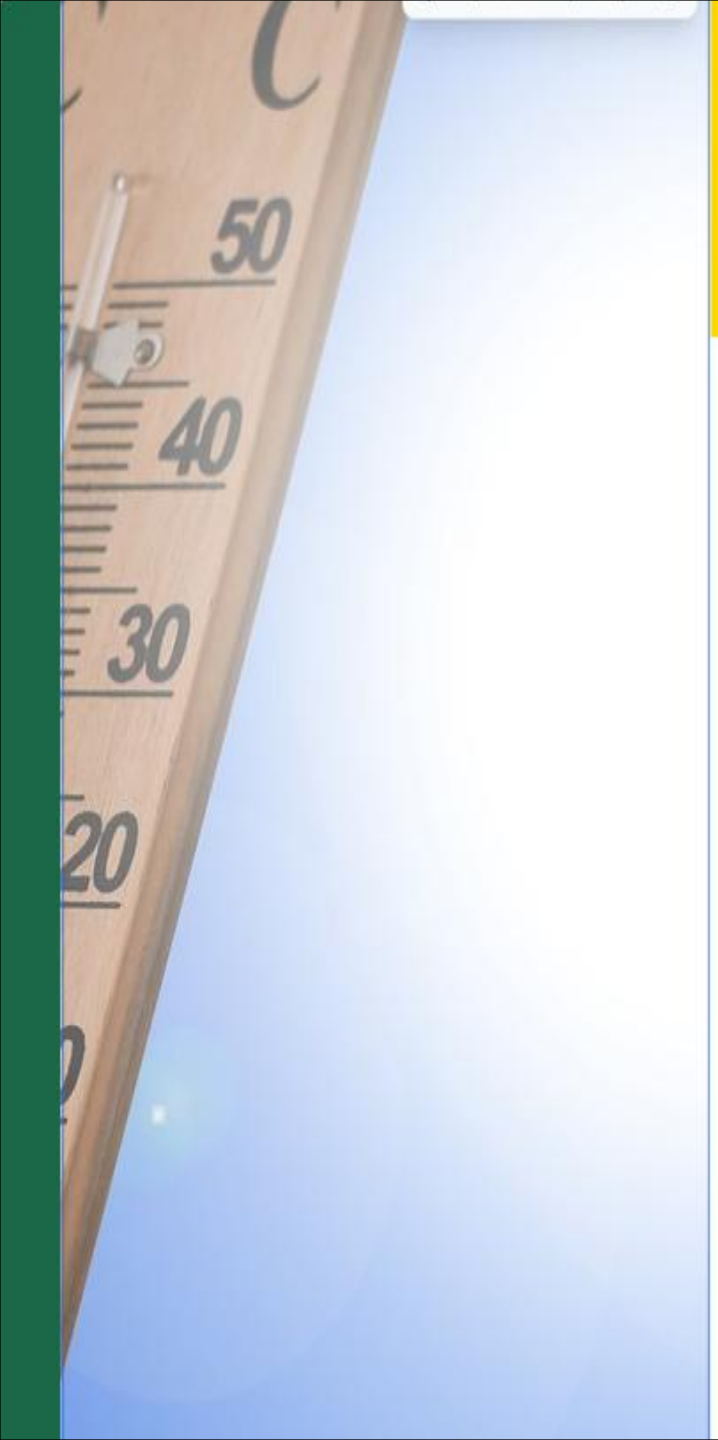
Condititons Under The Provisisons of the Drugs act and rules

- 19. If the drugs sold in a container other than the one in which the mfr supplied , only by regd pharmacist in retail in an envelope with name of the drug, qty, name of the dealer.
- 20. The Drugs meant for the Vertinary purposes , labelled as " Not for human use- for treatment of animal only. It should be stored separtly, not easily accessable by customers.
- 21. Supply of drugs of Sch X should be recorded in a register specially maintained register.

Plea for the sellers

- 19(3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves—
- *(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;*
- *(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and*
- *(c) that the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it.*
- (G.S.R. 101 (E) dt 11.02.2020 effective from 01/03/2021---- Marketer is also liable for the quality and others)





மருந்து சேமிப்பு முறைகள்

01

வெப்பநிலை கட்டுப்பாடு

மருந்துகளை 20°C - 25°C இடத்தில் சேமிக்க வேண்டும்.

இது மருந்துகளின் தரத்தை பாதுகாக்கும்.

அதிக வெப்பம் செயல்திறனை குறைக்கும்.

02

ஈரப்பதம் கட்டுப்பாடு

மருந்துகளை 30% - 50% ஈரப்பதத்தில் சேமிக்க வேண்டும்.

அதிக ஈரப்பதம் மருந்துகளை பாதிக்கக்கூடியது.

ஈரப்பதியை கட்டுப்படுத்துவது முக்கியம்.

SCHEDULE P

COLD PLACE----Place having temp not exceeding 8*C

COOL PLACE --- Place having temp less than 10*C ---25*C

CAPSULES- - Should be kept in well closed containers at the temp not exceeding 30*C.

OTHER DRUGS—To be stored in normal room temperature

நோயாளி பாதுகாப்பு நடவடிக்கைகள்

நோயாளர் அடையாளம்

நோயாளியின் அடையாளம் உறுதிப்படுத்த வேண்டும்.

தவறான தகவல்களை தவிர்க்க இது உதவுகிறது.

தகவல் பரிமாற்றம்

நோயாளியின் தகவல்களை மருத்துவ குழுவுடன் பகிர வேண்டும்.

இது நோயாளியின் பாதுகாப்புக்கு முக்கியம்.

பாதுகாப்பு பரிசோதனை

பாதுகாப்பு பரிசோதனைகள் முறையாக நடத்த வேண்டும்.

இது மருத்துவ செயல்முறைகளை பாதுகாக்கிறது.

அறிக்கைகள்

நிலைகள் பற்றிய தகவல்களை பதிவு செய்ய வேண்டும்.

இது மருத்துவர்களுக்கு தேவையான தகவல்களை வழங்குகிறது.

செயல்முறை வழிமுறைகள்

பாதுகாப்பு நடவடிக்கைகளை பின்பற்ற வேண்டும்.

இது நோயாளியின் பாதுகாப்பை மேம்படுத்துகிறது.

சமூக மருந்தகங்களில் சிறந்த ஒழுங்குமுறை நடைமுறைகள்

ஒழுங்குமுறை விதிகள்

ஒழுங்குமுறை விதிகள் மருந்தகங்களில் அடிப்படையாக உள்ளன.

இவை மருந்துகளை பாதுகாப்பாக கையாள்வதற்கான வழிமுறைகளை வழங்குகின்றன.

மருந்து பாதுகாப்பு

மருந்துகளை பாதுகாப்பாக சேமிக்க வேண்டும்.

மருந்துகளின் காலாவதியான தேதிகளை கவனிக்க வேண்டும்.

தரநிலை பராமரிப்பு

தரநிலைகளை பராமரிக்க சோதனை மற்றும் மதிப்பீடுகள் அவசியம்.

தரநிலைகளை மேம்படுத்த பயிற்சிகள் வழங்கப்பட வேண்டும்.

நோயாளி பாதுகாப்பு

நோயாளிகளின் பாதுகாப்பு முதன்மை முக்கியத்துவம் வாய்ந்தது.

மருந்துகளை வழங்கும் போது, நோயாளியின் தகவல்களை சரியாக பதிவு செய்ய வேண்டும்.

தரவுகள் பராமரிப்பு

தரவை சரியான முறையில் பதிவு செய்து பராமரிக்க வேண்டும்.

தரவுகளை அடிக்கடி புதுப்பிக்க வேண்டும்.

மருந்து பாதுகாப்பு நடவடிக்கைகள்

மருந்து சேமிப்பு

மருந்துகளை வெப்பம் மற்றும் ஈரப்பதம் இல்லாத இடத்தில் சேமிக்க வேண்டும்.

சேமிப்பதற்கான இடம் சுத்தமாகவும், ஒழுங்காகவும் இருக்க வேண்டும்.

மருந்து விநியோகம்

மருந்துகளை தேவையான அளவுக்கு மட்டுமே விநியோகிக்க வேண்டும்.

விநியோகிக்கும் போது, மருந்தின் காலாவதியாகும் தேதி மற்றும் உபயோகிக்கும் முறையை கவனிக்க வேண்டும்.

மருந்து கையாளுதல்

மருந்துகளை கையாளும் போது, கை கழுவுதல் மற்றும் சுத்தமான கருவிகளை பயன்படுத்துதல் முக்கியம்.

மருந்துகளை எடுத்துக்கொள்ளும் போது, மருத்துவரின் ஆலோசனைகளை பின்பற்ற வேண்டும்.

மருந்து குப்பை அகற்றல்

மருந்துகளை குப்பையில் வீசுவதற்கு பதிலாக, அவற்றை பாதுகாப்பாக அகற்ற வேண்டும்.

காலாவதியான மருந்துகளை நன்கு மூடிய பாட்டில்களில் வைக்கவும், பின்னர் உள்ளூர் மருந்து அகற்றும் மையத்திற்கு கொண்டு செல்லவும்.

தரநிலை பராமரிப்பு முறைகள்

தரநிலை பரிசோதனை

தரநிலையை உறுதிப்படுத்துவதற்கான பரிசோதனைகள்.

மாதாந்திர சோதனைகள் மூலம் தரநிலையை மதிப்பீடு செய்யலாம்.

தரநிலை பராமரிப்பு

தரநிலையை நிலைநாட்டுவதற்கான நடவடிக்கைகள்.

வாராந்திர பராமரிப்பு மூலம் சிக்கல்களை தவிர்க்கலாம்.

தரநிலை மேம்பாடு

தரநிலையை மேம்படுத்துவதற்கான திட்டங்கள்.

புதிய தொழில்நுட்பங்களை அறிமுகப்படுத்துவதன் மூலம் தரநிலையை உயர்த்தலாம்.

மருந்து குப்பை அகற்றல் முறைகள்

சேமிப்பு

மருந்துகளை பாதுகாப்பாக சேமிக்க, அவற்றை குழந்தைகள் மற்றும் விலங்குகளுக்கு அணுக முடியாத இடங்களில் வைக்க வேண்டும்.

சேமிப்பதற்கான இடம் காய்ச்சல், ஈரப்பதம் மற்றும் நேரடி வெளிச்சத்திலிருந்து பாதுகாக்கப்பட வேண்டும்.

பரிசோதனை

மருந்துகளை அகற்றுவதற்கு முன், அவற்றின் காலாவதியான தேதி மற்றும் நிலைமை பரிசோதிக்க வேண்டும்.

காலாவதியான மருந்துகளை தனியாக பிரித்து, அவற்றை அகற்றுவதற்கான முறைகளை திட்டமிட வேண்டும்.

அகற்றல்

மருந்துகளை அகற்றுவதற்கான முறைகள் உள்ளன, அவற்றில் சில உள்ளூர் மருந்து கடைகளில் திருப்பி அளிக்கலாம்.

மருந்துகளை அகற்றுவதற்கான பாதுகாப்பான முறைகளை பின்பற்றுவது முக்கியம்.

மருந்து வகைகள்

மருந்துகள் பல வகைகளில் உள்ளன, அவற்றில் சில ஆபத்தானவை மற்றும் சில சாதாரணமாக அகற்றப்படலாம்.

ஆபத்தான மருந்துகளை தனியாக கையாள வேண்டும், அவற்றை உரிய முறையில் அகற்ற வேண்டும்.

சுற்றுச்சூழல் பாதிப்பு

மருந்து குப்பை தவறாக அகற்றப்படும்போது, சுற்றுச்சூழலுக்கு தீங்கு விளைவிக்கலாம்.

சுற்றுச்சூழலுக்கு பாதிப்பு ஏற்படாமல் இருக்க, மருந்துகளை சரியான முறையில் அகற்றுவது அவசியம்.

மருந்து [illegible] மற்றும் தரநிலைகள்

Inventory Control

Stock Management Systems

Implementing automated stock management systems can enhance efficiency through real-time tracking and reporting, ensuring optimal stock levels and minimizing wastage.

Expiration Date Monitoring

Regularly monitoring expiration dates of medications is vital to maintain patient safety and compliance, avoiding the dispensing of ineffective or harmful products.

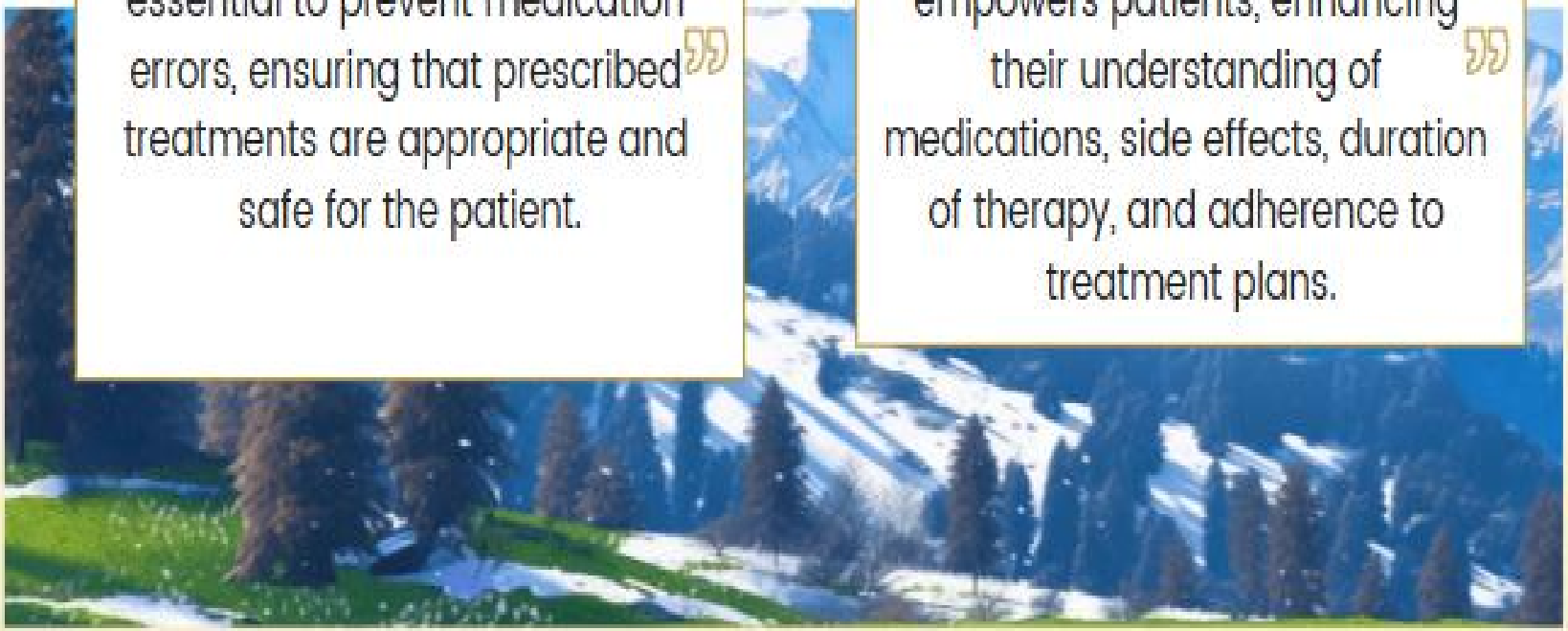
Patient Services

Prescription Verification

A comprehensive process for prescription verification is essential to prevent medication errors, ensuring that prescribed treatments are appropriate and safe for the patient.

Counseling and Education

Providing thorough counseling and educational resources empowers patients, enhancing their understanding of medications, side effects, duration of therapy, and adherence to treatment plans.



மருந்து விநியோக முறைகள்

மருந்து ஆர்டர்

மருந்து ஆர்டர் தேவைகளை அடையாளம் காணுங்கள்.

நிதி மற்றும் சப்ளையர்களை உறுதிப்படுத்துங்கள்.

மருந்து வரவு

ஆர்டர் செய்யப்பட்ட மருந்துகள் வரும்போது, அவற்றை சரிபார்க்கவும்.

மருந்துகளின் தரம் மற்றும் அளவை உறுதிப்படுத்துங்கள்.

மருந்து பரிசோதனை

வரவான மருந்துகளை பரிசோதிக்கவும்.

மருந்துகள் பாதுகாப்பானவையா என்பதை உறுதிப்படுத்துங்கள்.

மருந்து விநியோகம்

மருந்துகளை தேவையான இடங்களுக்கு விநியோகிக்கவும்.

விநியோகத்தின் போது, மருந்துகளின் பாதுகாப்பு மற்றும் தரத்தை கவனிக்கவும்.

மருந்து கையாளுதல் முறைகள்

மருந்து கையாளுதல்

மருந்துகளை சரியான முறையில் கையாளுதல் அவசியம்.

மருந்துகளை வகைப்படுத்தி சேமிக்கவும்.

மருந்து பரிசோதனை

மருந்துகள் பரிசோதனை மூலம் செயல்திறனை உறுதி செய்யலாம்.

பரிசோதனைகள் மருத்துவ நிபுணர்களால் மேற்கொள்ளப்பட வேண்டும்.

மருந்து பாதுகாப்பு

மருந்துகளை பாதுகாப்பாக சேமிக்க வேண்டும்.

பாதுகாப்பான இடங்களில் வைக்கவும்.

Safe Medication Practices

01.

Adverse Drug Reaction Reporting

Promptly documenting and reporting any adverse drug reactions helps in identifying safety concerns and contributes to broader pharmacovigilance efforts to improve patient care.

02.

Handling of Narcotics and Controlled Substances

Strict protocols for the storage, dispensing, and documentation of narcotics and controlled substances are essential to prevent misuse, ensure accountability, and comply with regulatory standards.

Drugs (Prices Control) Order, 2013

under Essential commodities Act 1955,

Now amended as Essential commodities Act 2020

MEDICAL DEVICES RULE 2017

Came into force with effect from 1st day of January, 2018.

- **“medical device”** means,-

- substances used for *in vitro* diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i),
- substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), notified in the Official Gazette under sub-clause (ii),
- devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Act;
- ***Explanation***: For the purpose of these rules, substances used for *in vitro* diagnosis shall be referred as *in vitro* diagnostic medical device

Classification of medical devices

- (1) Medical devices **other than *in vitro* diagnostic** medical devices shall be
- classified on the basis of parameters specified in Part I of the First Schedule, in the following classes, namely:—
- (i) low risk - Class A;
- (ii) low moderate risk- Class B;
- (iii) moderate high risk- Class C;
- (iv) high risk- Class D.

- (2) ***In vitro* diagnostic medical devices** shall be classified on the basis of parameters specified in Part II of the First Schedule, in the following classes, namely:—
- (i) low risk - Class A;
- (ii) low moderate risk- Class B;
- (iii) moderate high risk- Class C;
- (iv) high risk- Class D.

List of Notified Medical devices.

Disposable Hypodermic Syringes
Disposable Hypodermic Needles
Disposable Perfusion Sets
In vitro Diagnostic Devices for HIV, HbsAg and HCV
Cardiac Stents
Drug Eluting Stents
Catheters
Intra Ocular Lenses
I.V. Cannulae
Bone Cements
Heart Valves
Scalp Vein Set
Orthopaedic Implants
Internal Prosthetic Replacements

List of Notified Medical devices.

- Further, the following products are regulated as 'Drugs' under Drugs & Cosmetics Act & Rules there under: -
- 1. Blood Grouping Sera
- 2. Ligatures, Sutures and Staplers
- 3. Intra Uterine Devices (Cu-T)
- 4. Condoms
- 5. Tubal Rings
- 6. Surgical Dressings
- 7. Umbilical Tapes
- 8. Blood/Blood Component Bags

List of Notified Medical devices.

- The following devices intended for use in human beings as drugs with effect from the 1st day of April, 2020, namely:—
- (i) All implantable medical devices;
- (ii) CT scan Equipment;
- (iii) MRI Equipment;
- (iv) Defibrillators;
- (v) Dialysis Machine;
- (vi) PET Equipment;
- (vii) X-Ray Machine; and
- (viii) Bone marrow cell separator.
- (iX) Nebulizer ;
- (X) Blood Pressure Monitoring Devices ;
- (Xi) Digital Thermometer ; and
- (Xii) Glucometer

- **“Medical Device Officer”** means an officer appointed or designated by the Central Government or the State Government, as the case may be, under sub-rule (2) of rule 18;

- **“Medical devices testing laboratory”** means any institute, organisation registered under sub-rule (3) of rule 83 forcarrying out testing or evaluation of any medical device on behalf of a licencee for manufacture for sale;

- **“Medical Device Testing Officer”** means an officer appointed or designated by the Central Government under sub-rule (1) of rule 18;

SALE OF MEDICAL DEVICES (Chapter XI of Medical devices rules)

Subject to the provisions of these rules, Part VI relating to "Sale of Drugs Other than Homeopathic Medicines" of the Drugs and Cosmetics Rules, 1945, shall be applicable *"mutatis mutandis"* in respect of sale of medical devices.

A retail or wholesale, may, supply invasive medical devices to be implanted through surgical intervention to a hospital for its patient against a delivery challan:

Provided that in respect of supplies made against delivery challan of such medical devices, the licencee shall ensure that specified storage conditions are met

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THANK
YOU!