

Overview of the Laws Applicable to sale of Drugs

Presented By:

Goni Fakkirappa
ADC (Retd)

HOST:AIDCOC



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o • BEST REGULATORY PRACTICES
FOR COMMUNITY
PHARMACIES
HOST:AIDCOC

Presented by Goni Fakkirappa
Asst. Drugs Controller (Retd)
Govt of Karnataka



Types of Drugs

Ayurveda

Unani

Siddha and tibb

Allopathic

Homeopathic

Types of licences Sales

1. Form 20 and 21
2. Form 20B and 21B
3. Form 20A and 21A
4. Form 20G and 20F
5. Form MD-42
6. Form 20C
7. Form 20D
8. Form 21BB

Laws related to sale licence

Drug and cosmetic Act 1940 and Rules there under 1945

Drugs (price control) order 2013

DMR 1955

Pharmacy Act 1948

Medical devices rules 2017


Cosmetics rules 2020

The Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985



Package commodity act and Rules

Poison Act 1919

FSSAI



Introduction to Drugs and Cosmetics Rules, 1945



- Established to regulate the import, manufacture, distribution, and sale of drugs and cosmetics.



- Ensures safety, efficacy, and quality of medicines.

What is Rule 65?

- Specifies conditions for selling drugs under a license.

- Includes storage, record-keeping, prescription requirements, and compliance.

General Conditions for Sale of Drugs

- **Display the Original License**
Only licensed dealers can sell drugs.
- **Certain drugs require prescriptions.**
- **Proper records must be maintained.**



Requirements for Retailers

- A valid drug license is mandatory.
- License must be displayed prominently.
- Sales should be supervised by a registered pharmacist.



Storage and Handling of Drugs

- Maintain prescribed temperature conditions.

- Separate storage for prescription and non-prescription drugs.

Store Veterinary Drugs and Expired Drugs Separately

- Proper stock rotation to prevent expired drugs.



Prescription Drugs (Schedule H, H1, X)

- Schedule H/H1 drugs require a prescription.
- Schedule X drugs have stricter regulations.
- Sale records must be maintained.

Issue of sale Bills compulsory and maintenance of Duplicate Bills



Record-Keeping for Prescription Drugs

- Maintain prescription copies for Sch-X Drugs
- Record patient details for Schedule H1 drugs

Maintain Purchase invoices in Chronological order.

Put Dispensed seal on Prescription.

Do not Substitute.

- Proper documentation helps in audits.



Check the Labeling and Packaging Regulations



- Drugs must have proper labels.



Explain to the Patients about Label Restrictions



- Labels must include composition, expiry, batch number.



- Tamper-proof packaging for certain drugs like thyroxine Tablets and Pre-Filled Syringes.

Sale of Over-the-Counter (OTC) Drugs

- Can be sold without a prescription.
- Retailers should educate customers on proper usage.
- Avoid over-promoting self-medication.

Do not sold Sch -Drugs without Proper Prescription.

Banned and Restricted Drugs

- Selling banned drugs is illegal. Information is Notified by CDSCO under Section 26A by Gazette
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- Always check the updated banned drug list.
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Latest Notification by Govt of India Dated:20-2-2025 regarding Prohibition of Mnuufacture and sale of “Nimesulide and it’s formulations” for Veterinary Use

Dispensing of Narcotic and Psychotropic Substances

- Requires special permission from authorities for sale of Drugs like Morphine ,Pentenyyl
 - Strict record-keeping is necessary.
 - Non-compliance leads to severe legal action.
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Sch-X Required prescription in Duplicate

Inspection and Compliance

- Drug inspectors conduct routine checks.

Maintain Form-35

- Maintain proper records and licenses.
- Any violations can lead to penalties or license cancellation.
- If Drugs sold Less than the MRP there is no Violations.

Penalties for Non- Compliance

- Violation of Section 18 and Rule 65
Offence Under Section 27

Heavy fines and imprisonment for violations.

- License suspension or cancellation.
- Always follow legal regulations to avoid issues.

Recent amendments Provide provision for compounding of Offences (Vide notification 10-7-2024)

Patient Safety and Ethical Practices

- Dispense drugs as per prescription.
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- Educate patients on dosage and side effects.
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Patient counselling

- Avoid selling habit-forming medicines without proper prescriptions.
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Don't Dispense in absence of Pharmacist.

Recent Amendments and Updates

- New rules to be introduced on electronic prescriptions.
 - Stricter regulations on Schedule H1 drugs.
 - Stay updated with regulatory changes.
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Update your knowledge by visiting

CDSCO website and State Drugs Control Dept

NPPA

Role of Digital Prescription and Online Sales

- E-pharmacy trends are increasing.

- Online drug sales require special Regulation.

- Compliance with digital record-keeping is mandatory.

Best Practices for Retail Chemists

- Keep valid prescriptions and records.

- Follow proper storage conditions.

- Educate customers about drug safety.

Case Studies and Common Violations



- Examples of pharmacies penalized for violations.



- Lessons learned from past cases.



- Importance of following rules strictly.

Conclusion and Q&A

- Summary of key points discussed.
- Adherence to Rule 65 is essential.
- Open floor for questions and discussion.





THANK YOU

