Regulatory Aspects of QUM in India

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Definition

- Regulatory aspects of Quality Use of Medicines (QUM) refer to the laws, rules, policies, and guidelines that ensure medicines are used safely, effectively, and appropriately.
- These regulations help protect public health and promote rational use of medicines.
- In India, medicine regulation is mainly governed by the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.

Objectives

- To ensure the safety, quality, and efficacy of medicines.
- To promote rational prescribing and medicine use.
- To prevent misuse and abuse of medicines.
- To protect patients from unsafe or ineffective products.
- To ensure proper distribution and sale of medicines.

Regulation Including Scheduling

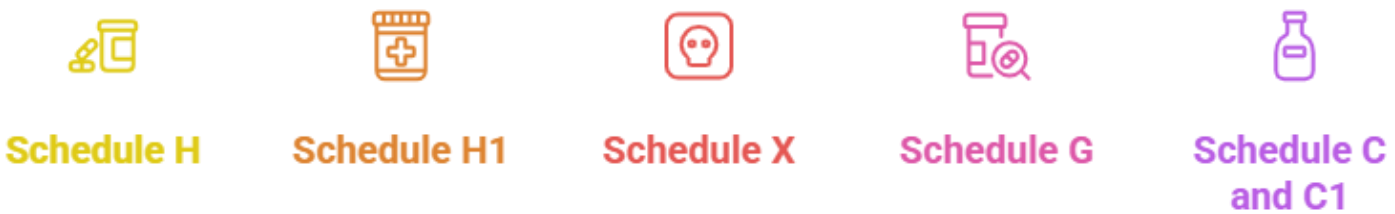
Definition

- Scheduling refers to the classification of medicines into different schedules under the Drugs and Cosmetics Rules.
- Medicines are categorized according to their safety, use, storage, labeling, and dispensing requirements.

Importance of Scheduling

- Scheduling helps control the sale and use of medicines.
- It ensures that certain medicines are used only under medical supervision.
- It helps prevent misuse and self-medication.

Important Drug Schedules



A. Schedule H

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- Schedule H medicines can only be sold with a valid prescription from a registered medical practitioner.
- These medicines are not allowed for over-the-counter sale.
- Antibiotics and many prescription medicines belong to this schedule.

B. Schedule H1

- Schedule H1 medicines require stricter control than Schedule H medicines.
- The pharmacist must maintain records of their sale.
- These medicines include certain antibiotics and anti-tuberculosis drugs.

C. Schedule X

- Schedule X medicines have a high potential for misuse and abuse.
- Special storage, record keeping, and prescription requirements are necessary.
- These medicines are supplied only under strict regulatory control.

D. Schedule G

- Schedule G medicines must be used under medical supervision.
- Their labels carry a warning indicating that they should be taken under medical advice.

E. Schedule C and C1

- These schedules include biological and special products such as vaccines and sera.
- They require special storage and handling conditions.

First Hope

Benefits of Drug Scheduling

- It improves medicine safety.
- It promotes rational medicine use.
- It helps prevent medicine abuse and misuse.
- It protects public health.

Regulation of Complementary Medicines

Definition

- Complementary medicines are products used in addition to conventional medical treatment.
- These include herbal medicines, Ayurvedic medicines, homeopathic medicines, Unani medicines, Siddha medicines, and other traditional therapies.

Need for Regulation

- Regulation ensures that complementary medicines are safe and of acceptable quality.

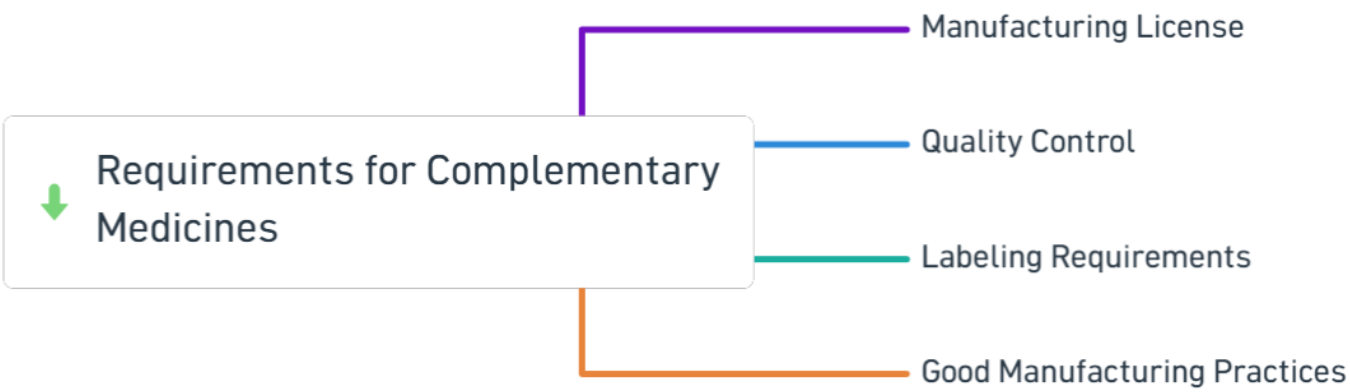
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- It helps prevent the sale of adulterated and misleading products.
- It protects consumers from unsafe products and false claims.

Regulatory Framework in India

- Ayurvedic, Siddha, and Unani medicines are regulated under the Drugs and Cosmetics Act.
- Homeopathic medicines are also regulated under specific provisions of the Act.
- Manufacturers must comply with quality standards and licensing requirements.

Requirements for Complementary Medicines



A. Manufacturing License

- Manufacturers must obtain a valid license before producing complementary medicines.

B. Quality Control

- Raw materials and finished products should meet established quality standards.

C. Labeling Requirements

- Labels should provide accurate information about the product and its ingredients.

D. Good Manufacturing Practices

- Manufacturers should follow Good Manufacturing Practices to ensure product quality.

Challenges in Regulation

- Standardization of herbal ingredients may be difficult.
- Variations in raw materials may affect product quality.
- Monitoring safety and efficacy may be challenging for some traditional medicines.

Regulation of OTC Medicines

Definition

- OTC (Over-the-Counter) medicines are medicines that can be purchased without a prescription from a doctor.

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- These medicines are generally used for minor illnesses and common health conditions.

Importance of OTC Regulation

- Proper regulation ensures safe use of OTC medicines.
- It helps prevent misuse and inappropriate self-medication.
- It protects consumers from potential health risks.

Characteristics of OTC Medicines

- They have a wide margin of safety when used according to instructions.
- They are intended for short-term treatment of minor conditions.
- Consumers can use them without direct medical supervision.

Examples of OTC Medicines

A. Pain Relievers

- Certain mild pain-relieving medicines are available as OTC products.

B. Antacids

- Antacids are used to relieve acidity and indigestion.

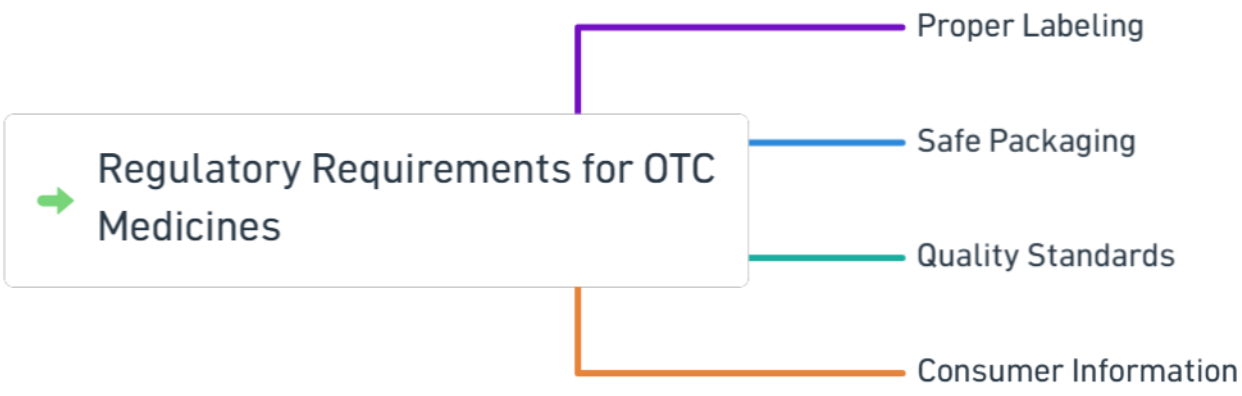
C. Cough and Cold Preparations

- Some cough syrups and cold remedies are available without prescription.

D. Vitamin Preparations

- Many vitamin and nutritional supplements are sold as OTC products.

Regulatory Requirements for OTC Medicines



1. Proper Labeling

- Labels should provide clear instructions for use.
- Labels should include warnings and precautions.

2. Safe Packaging

- Packaging should protect the medicine from contamination and damage.

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