Removal of Syrups from Schedule K: Strengthening Drug Regulation and Public Health Safety in India

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Recent Developments:

- The **Union Ministry of Health and Family Welfare** has amended the **Drugs Rules, 1945** by removing the term **"Syrups"** from **Schedule K**, thereby ending the exemption previously available to syrup-based medicines.
- As a result, cough syrups and other medicinal syrups can now be sold only through licensed pharmacies under stricter regulatory oversight, particularly in rural areas where exemptions earlier existed.
- The decision follows international concerns regarding contaminated cough syrups linked to child fatalities in several countries since 2022, which intensified scrutiny of India's pharmaceutical regulatory framework.
- The measure is intended to improve traceability, accountability, quality control and responsible dispensing of medicines while reducing unsafe self-medication practices.

Background of the Issue:

Why was the Amendment Necessary?

- Several incidents involving cough syrups contaminated with toxic industrial solvents such as **Diethylene Glycol (DEG)** and **Ethylene Glycol (EG)** resulted in deaths of children in multiple countries, raising serious concerns regarding pharmaceutical quality assurance.
- The incidents attracted global attention because India is one of the world's largest suppliers of generic medicines and pharmaceutical products.
- The controversy highlighted weaknesses in manufacturing oversight, supply-chain monitoring and regulatory enforcement mechanisms.
- The amendment seeks to strengthen public confidence in Indian pharmaceutical products and protect India's reputation as a major global medicine supplier.

India's Pharmaceutical Sector:

Global Importance of the Sector:

- India is widely referred to as the **"Pharmacy of the World"** because of its ability to supply affordable and quality-assured medicines to numerous countries.
- India possesses the largest number of **United States Food and Drug Administration (USFDA)** approved pharmaceutical manufacturing facilities outside the United States.
- The country plays a critical role in global health security by supplying vaccines, generic medicines and essential pharmaceutical products.
- India accounts for nearly **20% of the global supply of generic medicines by volume** and is among the leading vaccine producers globally.
- The pharmaceutical industry contributes significantly to exports, employment generation and healthcare accessibility.

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Active Pharmaceutical Ingredient (API) Ecosystem:

- India hosts nearly **500 Active Pharmaceutical Ingredient (API)** manufacturers.
- The country contributes approximately **8% of global API production**.
- APIs constitute the biologically active component responsible for the therapeutic effect of medicines.
- Strengthening domestic API manufacturing has become a strategic priority under initiatives such as **Production Linked Incentive (PLI) Scheme** and **Bulk Drug Parks Scheme**.

Schedule K under Drugs Rules, 1945:

Meaning and Purpose:

- **Schedule K** contains a list of drugs exempted from certain provisions of the **Drugs and Cosmetics Act, 1940** and the **Drugs Rules, 1945**, subject to specified conditions.
- The schedule was designed to facilitate easier access to selected medicines where strict licensing requirements were considered unnecessary.
- Certain medicines under Schedule K could be sold through specified channels under relaxed regulatory conditions.
- The exemption was particularly useful in remote and sparsely populated areas lacking adequate pharmacy infrastructure.

Implications of Removing Syrups from Schedule K:

- Syrup formulations are no longer eligible for Schedule K exemptions.
- Their sale, storage and dispensing now fall under stricter regulatory requirements.
- Distribution of cough syrups in villages and smaller settlements must occur through licensed pharmacies.
- The amendment enhances accountability throughout the supply chain and improves regulatory oversight.

Regulatory Framework Governing Drugs in India:

Central Drugs Standard Control Organization (CDSCO):

- **CDSCO** is India's national regulatory authority responsible for ensuring the safety, efficacy and quality of drugs.
- It functions under the Ministry of Health and Family Welfare.
- The organization is headed by the **Drugs Controller General of India (DCGI)**.
- CDSCO regulates approval of new drugs, clinical trials, imports and central licensing activities.

Drugs and Cosmetics Act, 1940 and Related Rules:

- The **Drugs and Cosmetics Act, 1940** forms the foundation of pharmaceutical regulation in India.
- It regulates the import, manufacture, sale and distribution of drugs and cosmetics.
- Important subordinate regulations include:
- **Drugs Rules, 1945**.
- **Medical Devices Rules, 2017**.
- **New Drugs and Clinical Trials Rules, 2019**.
- **Cosmetics Rules, 2020**.

National Pharmaceutical Pricing Authority (NPPA):

- **NPPA** regulates prices of essential medicines under the **Drugs (Prices Control) Order, 2013**.
- It ensures affordability and availability of essential medicines.
- It monitors compliance with government pricing policies.

Indian Pharmacopoeia Commission (IPC):

- **IPC** publishes the **Indian Pharmacopoeia**, which serves as the official compendium of drug standards in India.
- The Pharmacopoeia prescribes standards relating to identity, purity, quality and strength of medicines.
- Compliance with Pharmacopoeial standards is essential for ensuring drug quality and safety.

State Licensing Authorities (SLAs):

- Manufacturing, sale and distribution of drugs are regulated through a licensing system administered by State Licensing Authorities.
- State drug regulators conduct inspections, licensing and enforcement activities within their respective jurisdictions.
- The Indian regulatory structure follows a dual model involving both Union and State governments.

Concerns Regarding India's Pharmaceutical Regulatory Ecosystem:

Manufacturing Quality Challenges:

- Cases of contamination, substandard medicines and manufacturing lapses indicate weaknesses in compliance with **Good Manufacturing Practices (GMP)**.
- Inadequate quality assurance systems can undermine patient safety and international confidence.

Fragmented Regulatory Oversight:

- Different enforcement capacities across States create variations in regulatory effectiveness.
- Uneven implementation of standards may result in regulatory gaps.

Over-the-Counter Drug Culture:

- Self-medication remains widespread across India.
- Unsupervised consumption of medicines can lead to adverse effects, antimicrobial resistance and irrational drug use.
- Easy availability of medicines often discourages professional medical consultation.

Capacity Constraints in State Drug Regulation:

- Several State drug control departments face shortages of inspectors, laboratories and technical experts.
- Limited infrastructure reduces the frequency and effectiveness of inspections.
- Rapid growth of the pharmaceutical sector has increased the burden on regulatory agencies.

Recent Reforms and Regulatory Strengthening Measures:

State Health Regulatory Excellence Index (SHRESTH):

- **SHRESTH** is a national initiative designed to benchmark and strengthen State-level drug regulatory systems.
- The framework promotes transparency, accountability and evidence-based performance assessment.
- The initiative encourages States to improve regulatory infrastructure and governance standards.

Enhanced Manufacturing Surveillance:

- Following contamination incidents, regulatory authorities increased inspections of pharmaceutical manufacturing facilities.

- Greater emphasis has been placed on compliance with quality standards and corrective action mechanisms.
- Risk-based inspections are increasingly being adopted to improve regulatory efficiency.

Way Forward:

Strengthening Pharmaceutical Governance:

- Quality assurance systems should be integrated throughout the manufacturing lifecycle rather than relying solely on final product testing.
- Regulatory agencies should adopt risk-based inspections, digital monitoring and continuous quality surveillance.
- Public disclosure of inspection findings and enforcement actions can improve transparency and accountability.
- Harmonisation of regulatory standards across States is necessary for uniform enforcement.

Leveraging Technology for Drug Regulation:

- **Artificial Intelligence (AI)** and advanced data analytics can improve detection of quality risks.
- Digital supply-chain tracking systems can enhance traceability and recall mechanisms.
- Real-time monitoring platforms can strengthen regulatory responsiveness.
- Integrated databases can facilitate coordination among central and state regulatory authorities.

Value Addition for UPSC:

Important Terms:

- **Schedule K:** List of drugs exempted from specific provisions of the Drugs Rules, 1945 under prescribed conditions.
- **CDSCO:** National regulatory authority responsible for drug approval and quality regulation.
- **DCGI:** Head of CDSCO and India's chief drug regulatory authority.
- **API:** Active component responsible for the therapeutic action of a medicine.
- **NPPA:** Authority responsible for regulation of drug prices.
- **IPC:** Institution responsible for publishing standards for medicines marketed in India.
- **Good Manufacturing Practices (GMP):** Quality assurance standards governing pharmaceutical manufacturing.
- **SHRESTH:** National framework for evaluating and strengthening State drug regulatory systems