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REGULATORY REQUIREMENTS OF OVER THE COUNTER (OTC)DRUGS IN INDIA AS PER CDSCO IN COMPARISION WITH UNITED STATES OF AMERICA

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ABSTRACT

The article outlines the principal distinctions in the regulatory regimes in the US and India for the production, importation, and export of over-the-counter (OTC) drugs. The Drugs and Cosmetics Act of 1940 governs OTC drug regulation in India, and the Central Drugs Standard Control Organization (CDSCO) is in charge of its enforcement. Regulating, however, is not always followed, especially in rural areas. On the other hand, the FDA in the United States has a strong regulatory framework that consists of production standards, import limitations, and severe export laws. Safe over-the-counter medications can be approved by the FDA more quickly thanks to the monograph system, but innovative formulations must pass stringent testing before being approved as NDAs. The study also examines post-market surveillance systems. The FDA actively monitors adverse drug reactions to ensure ongoing safety, whereas India's post-market surveillance is hindered by resource limitations. Ultimately, the comparative analysis emphasizes the need for India to enhance its enforcement mechanisms and establish clearer regulations, particularly in manufacturing and rural distribution. By aligning more closely with U.S. standards, India can improve the safety and efficacy of OTC medications, thereby enhancing public health outcomes and ensuring higher quality within the pharmaceutical sector.

KEYWORDS: OTC Drugs, CDSCO, FDA, Regulatory framework.

INTRODUCTION

'OTC Drugs' means drugs legally allowed to be sold 'Over-the-counter', i.e. without the prescription of a Registered Medical Practitioner.[1] Over-the-Counter (OTC) drugs are mostly used as an initial or first line treatment for a variety of mild and self-limiting diseases, such as allergies, musculoskeletal discomfort, headaches and common cold.[2] Over the counter products are regularly available to consumers without the requirement of a doctor's prescription. Most OTC Drugs are approved by the regulatory body and contain ingredients that are safe and effective when used without the guidance of a medical professional. Common disorders such as frequent headaches, allergies, the common cold, constipation, backache, acidity, and chronic fatigue can be treated without observation of physician in everyday life. In 1860s the preparations of remedies at home were replaced by purchasing of medicines. 1905s the market of the patent drugs was at its peak. 1920s due to intense economic and political struggle changed preferences care, resulted in decline in public demand and use of patient medicines. The Food, Drug, and Cosmetic Act (FD&C) of 1938 granted the FDA some regulatory authority, but it did not specify which medications could only be purchased with a prescription and which could be purchased without one. In 1951, FD&C Act was amended to explain the distinction between Over the counter and Rx drugs and to address drug concerns about safety. The Drug Consultative Committee of India declared in November 2016 that it was setting up a drug definition that could be dispensed without a prescription. It was widely assumed that any drug that did not fit into a prescription schedule could be acquired without a prescription.[3]

Regulatory body of india

Central drugs standard control organization (CDSCO)

Figure 1: CDSCO logo.

The Central Drugs Standard Control Organisation (CDSCO)

Under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country. The Drugs & Cosmetics Act, 1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics. It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and well-being of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.[4]

Organization of CDSCO

The Central Drugs Standard Control Organization (CDSCO) serves as the principal drug authority, executing tasks delegated to the Central Government under the Drugs and Cosmetics Act. CDSCO oversees multiple offices and laboratories.

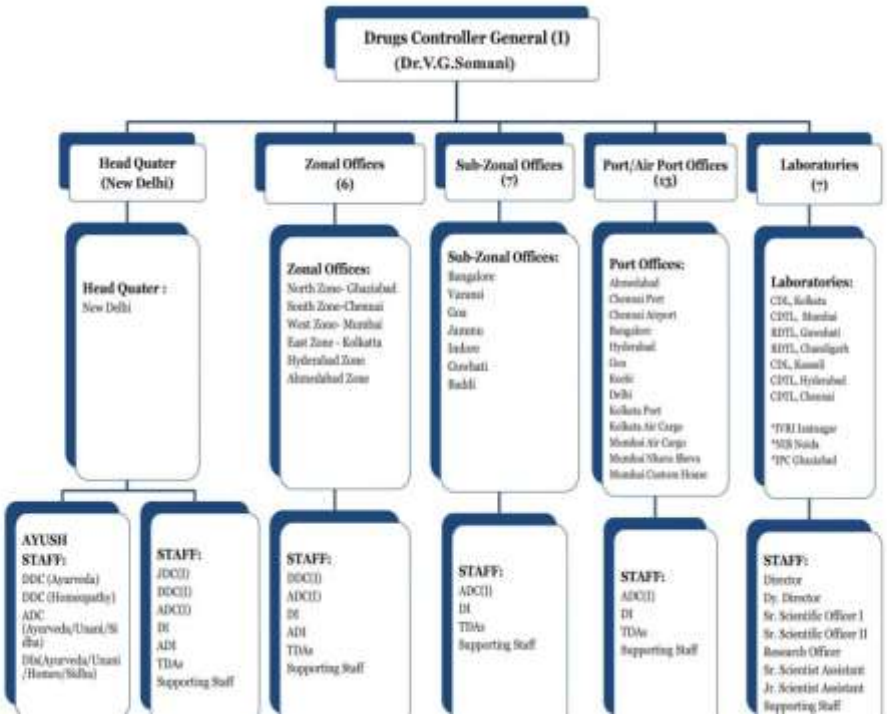

Figure 2: Organization Of CDSCO.

Functions of CDSCO

Regulatory oversight: CDSCO oversees the import of pharmaceuticals and monitors the adverse drug reactions (ADRs).

Approval: The CDSCO issues licenses for specific drug classes and authorizes clinical trials and new medications.

Standards: CDSCO establishes guidelines for medications, cosmetics, gadgets, and diagnostics.

Manufacturing of OTC drugs

Manufacturing overthecounter (OTC) drugs in India involves adhering to a range of regulatory requirements set forth by the Central Drugs Standard Control Organization (CDSCO) and other relevant authorities.

Indian Pharmaceutical industry is one of the world's largest and most developed, ranking fourth in terms of volume and thirteenth in terms of value. The country accounts for an estimated 10% of global production and 2% of world markets in pharmaceuticals.[5]

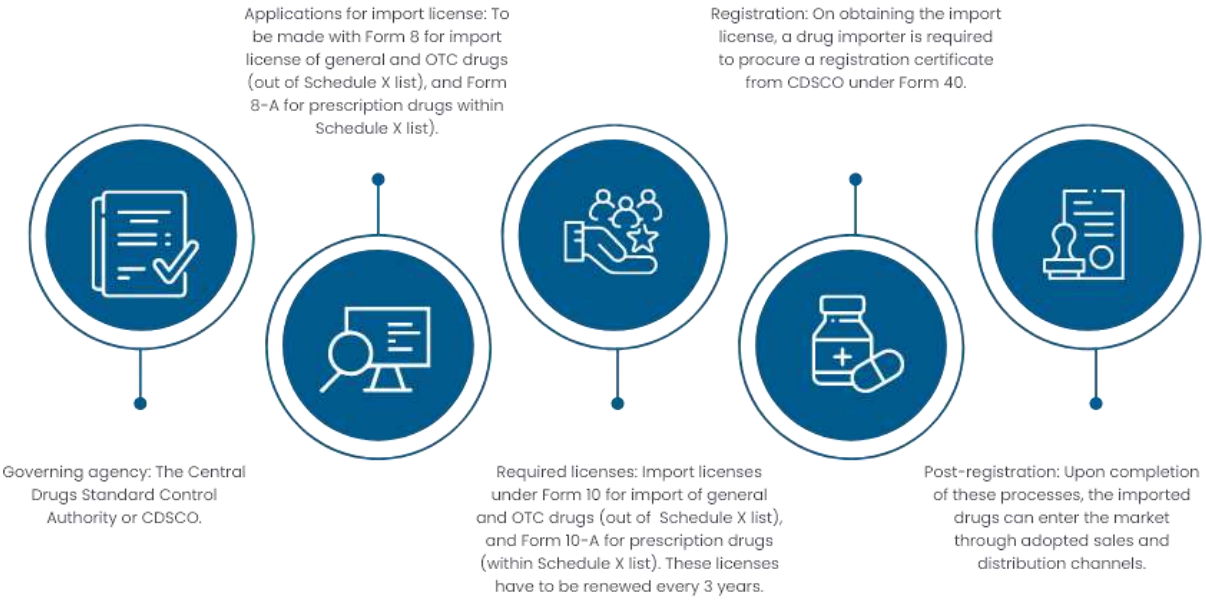

Figure 3: Manufacturing and Drug approval process.

Regulatory requriments include

1. Introduction
2. Regulatory Framework

2.1 Central Drugs Standard Control Organization (CDSCO)
2.2 State Drug Standard Control Organization (SDSCO)

3. Licensing Requirements

3.1 Manufacturing License
3.2 Site Master File

4. Good Manufacturing Practices (GMP)

4.1 Compliance with GMP Standards
4.2 Quality Control

5. Product Registration and Approval

5.1 Drug Registration Process
5.2 Labeling Requirements

6. Quality Control and Testing

6.1 Quality Assurance
6.2 Stability Testing

7. Safety and Efficacy

7.1 Clinical Trials
7.2 PostMarketing Surveillance

8. Documentation and Record Keeping

8.1 Record Maintenance
8.2 Compliance Audits

9. Periodic Audits and Inspections

9.1 Regulatory Inspections
9.2 Addressing NonCompliance

10. Adverse Drug Reaction (ADR) Reporting

10.1 Pharmacovigilance System
10.2 Reporting Requirements

11. Regulatory Fees

11.1 Fee Structure
11.2 Payment Procedures

12. Intellectual Property Rights

12.1 Patents
12.2 Trademarks

License-Requriments

Companies need to have a Manufacturing License before they can start producing OTC medications. This entails submitting an application (generally Form 28) to the appropriate SDSCO or CDSCO, together with the necessary documentation, such as layout plans, personnel qualifications, equipment details, and verification of quality control methods, as well as proof of the production facility's address. The application is subjected to a review procedure that involves an examination to confirm adherence to GMPs, or good manufacturing practices. An approval for manufacturing is given after a successful review.

GMP

It is essential to adhere to GMP, specifically to Schedule M of the Drugs and Cosmetics Rules. This comprises maintaining up with appropriate staff training, sanitation, and facility design. To reduce the danger of contamination, clean rooms and strict sanitation procedures are helpful. However, staff members need to be properly trained and qualified.

Quality control

It is imperative to have strong quality control, which includes rigorous testing of raw materials, materials used in processing, and final products. To guarantee constant product quality, processes need to be validated and test documentation needs to be kept up to date.

Drug Registration and Approval

Drugs must be registered by submitting the necessary paperwork (such as Form 44) and a thorough file containing information on the manufacturing procedures, stability study data, quality control procedures, and formulation specifications. After completing a technical evaluation to make sure all regulations are followed, the CDSCO approves the application.

Labelling conditions
The drug's brand and generic names, active and inactive substances, dosing guidelines, cautions, manufacturer information, batch number, and expiration date must all be listed on the label. To ensure legibility and compliance with requirements, labels should be in either Hindi or English and have a clear font size and location.

Safety and Efficacy
To prove safety and efficacy, new medications may need to go through clinical trials. After they are on the market, pharmacovigilance is needed to track any negative drug responses.

In general, adherence to these standards guarantees the effectiveness and safety of pharmaceutical products in India.

Market dynamics
The India Over-the-counter Drugs Market size is estimated at USD 6.73 billion in 2024, and is expected to reach USD 8.76 billion by 2029, growing at a CAGR of 5.39% during the forecast period (2024-2029). The major factors driving the market's growth include a shift toward self-medication by consumers, product innovation, and the inclination of pharmaceutical companies toward OTC drugs compared to prescription drugs in the country. For instance, according to the report published by the Cureus Journal in January 2023, self-medication is rising at a significant rate in the country. The high prevalence of self-medication in the country, with 60% of individuals engaging in this practice, is significantly driving the growth of the OTC market in India. The predominant use of analgesics (66.25%) and antipyretics (59.16%) for common ailments like fever, body aches, and common colds. Additionally, according to a report published by the Sage Open Medical Journal in March 2024, the high prevalence of self-medication, particularly in urban areas, is driving the Indian OTC market's growth.[6]

As per the Economic Times, the Indian OTC market was estimated to be worth around $6.7 billion in 2020, with a projected compound annual growth rate (CAGR) of 9.6% from 2020 to 2025.[7] Furthermore, the COVID-19 pandemic has further accelerated the adoption of OTC healthcare products in India.

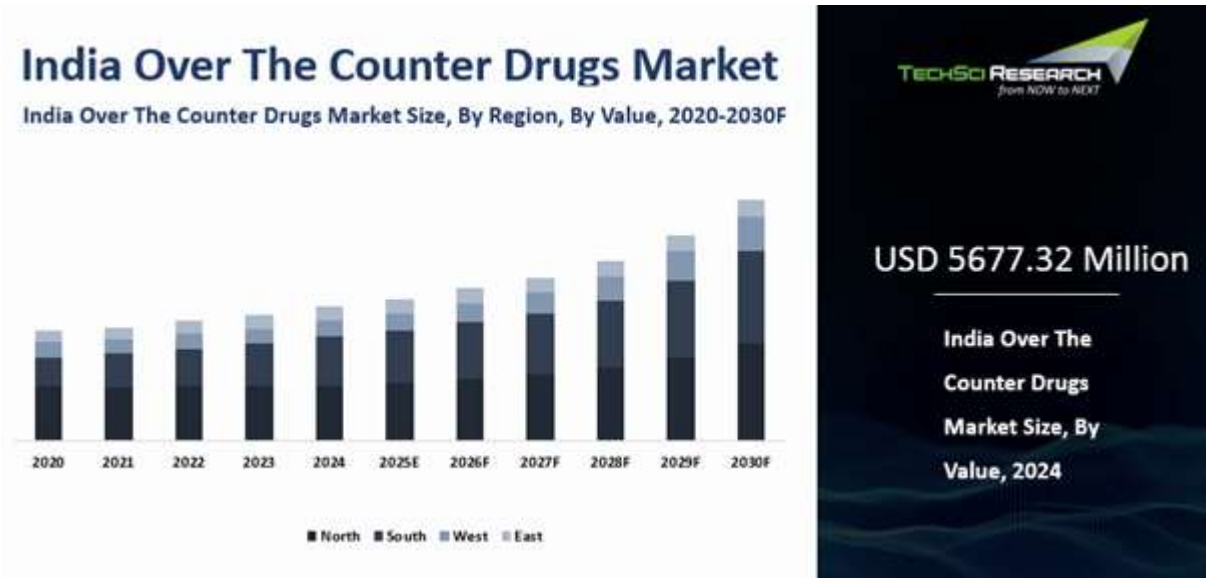

Figure 4: Indian OTC market analysis.

- The OTC Product market world wide is projected to achieve a revenue of US $368.90 billion in 2024
- It is expected to exhibit an annual growth rate(CAGR 2024-2029) of 4.50% leading to a market volume of US $459.70 billion by 2029.
- When considering the total population the per person revenue in 2024 amounts to US dollars 47.60
- The demand for OTC products is growing steadily in countries worldwide, driven by increasing consumer awareness and accessibility.[8]

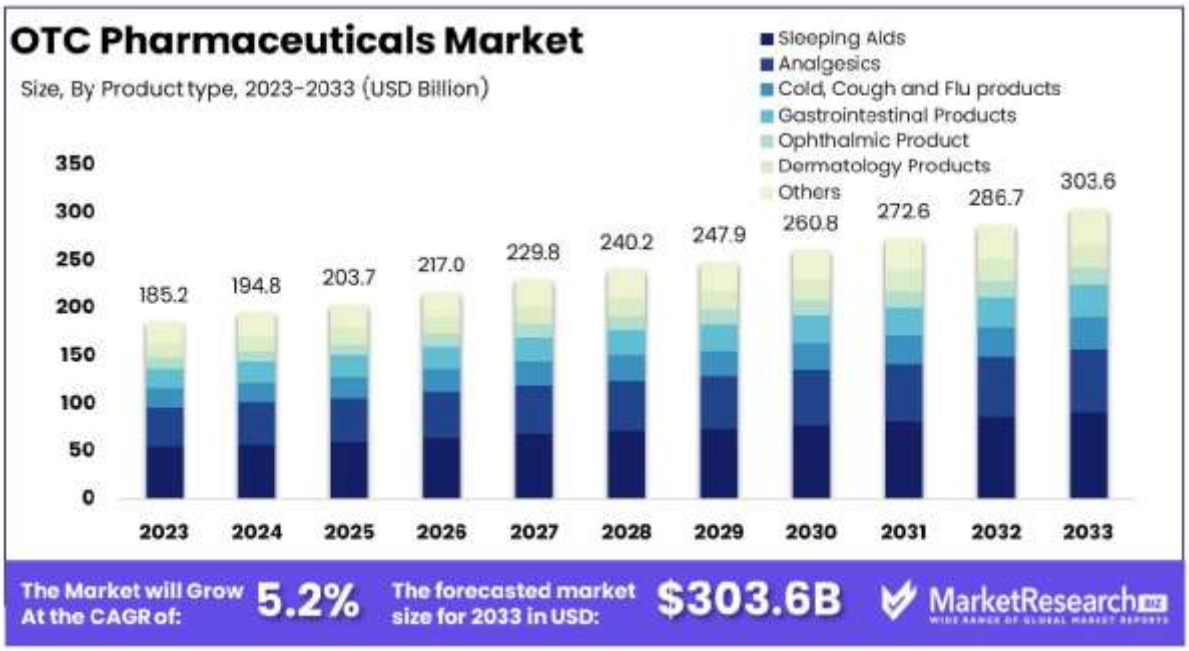

Figure 5: Global OTC market analysis.

Import of OTC Drugs

The importation process for Over-the-counter (OTC) drugs into India guarantees consumers access to safe, effective, and top-tier medicines. The import framework for OTC drugs ensures both stringent monitoring and broad access to numerous medicines. The Drugs and Cosmetics Act of 1940, the Rules of 1945, and guidelines from the CDSCO outline the framework for importing and distributing OTC drugs in India. This article explores the entire procedure for importing OTC drugs into India, encompassing obtaining licenses and adhering to labelling and quality regulations.

Import Procedure include

1. Import License Requirement
2. Registration Certificate of the Manufacturer
3. Labelling and Packaging Requirements
4. Standards of Quality and Testing Requirements
5. No Objection Certificate (NOC)
6. Customs Clearance and Port Inspection
7. Pharmacovigilance and Reporting
8. Fees and Charges

Applicants must submit Form 8, the standard application form for importing pharmaceuticals, in order to be granted an import license. Complete product details, such as the active ingredient strength, dosage form, and manufacturing method, are included in the required documentation. The application also needs to include details on the manufacturing location, particularly regarding Good Manufacturing Practices (GMP) compliance. Accompanying the importer's Wholesale Drug License (Forms 20B and 21B), which permits the import, storage, and distribution of pharmaceuticals in India, is a copy of the foreign manufacturer's Registration Certificate. The required payments as specified by the regulations must be included with the submission. After approval, the CDSCO grants Form 10 licenses, allowing the import of the designated medications. In order to guarantee traceability, importers must keep accurate records and compliance with all legal requirements.

Export of OTC Drugs

India serves as a major global hub for the production and distribution of pharmaceuticals, particularly over-the-counter (OTC) medications. With over 200 nations receiving pharmaceutical exports, the nation has one of the biggest pharmaceutical industries worldwide. India's exports of over-the-counter medications are vital to meeting the world's healthcare needs, particularly in underdeveloped countries where access to reasonably priced medications is crucial. Similar to imports, exporting over-the-counter medications from India is subject to stringent regulatory regulations to guarantee that the products are safe for users and fulfil all relevant quality criteria. The laws governing the export of pharmaceuticals are provided by the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945.

Public health concerns demand that the manufacture of pharmaceutical products and their subsequent handling within the distribution chain, both nationally and internationally must conform to prescribed standards and be rigorously controlled in order to ensure their quality, safety and efficacy. The DRAs in the SADC region have a responsibility of assuring the quality, safety and efficacy of medicinal products moving nationally and internationally. This guidance document is intended to summarize and to explain the basic requirements for exporting and importing medicinal products in the

region. However, the need for the effective use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International 4 Trends in Biosciences 12 (1), 2019 Commerce - a Scheme which constitutes a formal agreement between countries to provide information on any product under consideration for export, notably on its registration status in the country of origin and whether or not the manufacturer complies with WHO's guidelines on Good Manufacturing Practices (GMP) for pharmaceutical products cannot be overemphasized. It is important to note that importers and exporters of medicinal products may be subjected to additional statutory or regulatory requirements beyond those prescribed in this guidance document.[10]

Export procedure include

1. Export License and Approvals:
2. Compliance with International Quality Standards:
3. Product Registration in the Importing Country
4. Labelling and Packaging Requirements for Export
5. Customs Clearance and Documentation for Export
6. Compliance with Importing Country's Regulations

A license to export over-the-counter (OTC) pharmaceuticals from India must be obtained; however, the pharmaceuticals and Cosmetics Act does not require one. In order to satisfy the quality standards of the destination country, exporters are required to comply with a number of regulatory obligations. The State Drug Control Authority issues a Manufacturing License (Form 25 for non-scheduled medications, or Form 28 for scheduled drugs) that is essential for adhering to Good Manufacturing Practices (GMP). In particular, unregistered medications made only for export may need an Export No Objection Certificate (NOC) from CDSCO. Exporters who engage in distribution and storage must also get a Wholesale Drug License in Forms 20B and 21B. Drugs that are exported are required to adhere to international quality standards, including pharmacopoeia (USP, EP, BP) and WHO GMP guidelines. Prior to export, goods need to be registered in the nation of import. This entails creating a Product Dossier that contains details on the formulation, manufacturing procedure, stability data, and packaging.

Essential information like as dosing guidelines and storage conditions must be included on labels that comply with both Indian and importing nation legislation. Finally, exporters need to get documentation, such as packing lists, certificates of origin, and export invoices, in order to obtain customs clearance.

Regulatory Body of USA
Food and Drug administration

Figure 6: FDA logo.

The U.S. Food and Drug Administration (FDA) is a federal agency responsible for protecting and promoting public health through the regulation of food, drugs, medical devices, and other products.

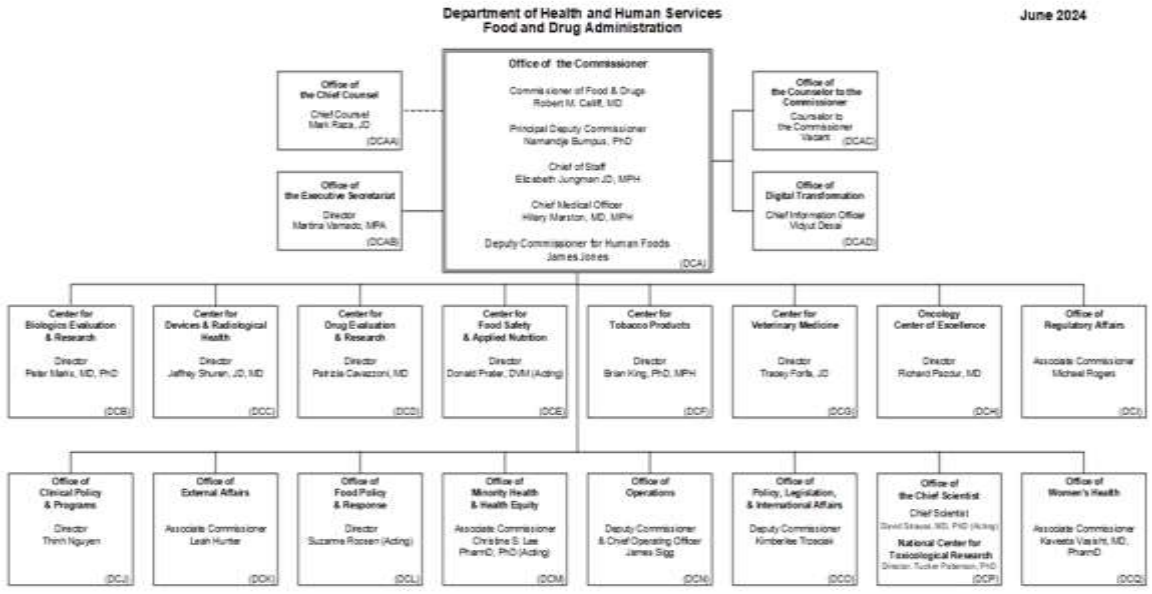

Figure 7: FDA Organization.

Functions

1. Regulation of Food Safety: The FDA supervises the safety of most food products (except meat, poultry, and some egg products) to guarantee they are safe, sanitary, and properly labelled.
2. Drug Approval and Regulation: It evaluates new drugs for safety, efficacy, and quality before approving them for sale. It also monitors the manufacturing processes of drugs.
3. Food and Drug Labelling: The FDA enforces labelling standards for foods, drugs, and other products to ensure accurate and clear information for consumers.
4. Post Market Surveillance: After approval, the FDA continues to monitor the safety of products, including drugs, medical devices, and vaccines, ensuring ongoing safety through adverse event reporting.
5. Enforcement and Compliance: The FDA has the authority to enforce laws by inspecting manufacturers, issuing recalls, and taking legal action against companies that violate regulations.

Manufacturing of OTC Drugs

The U.S. Food and Drug Administration (FDA) closely monitors the production of over-the-counter (OTC) drugs in order to guarantee the high quality, safety, and efficacy of these widely available pharmaceuticals. OTC medications, which are available over-the-counter and do not require a prescription, are essential for treating common health problems, thus it is critical that they meet strict guidelines. The production of over-the-counter drugs is subject to all FDA rules, which include the implementation of good manufacturing practices, strict labeling requirements, and adherence to approval processes or monographs. The goal of this regulatory monitoring is to safeguard the public's health by making sure over-the-counter medications adhere to strict safety and effectiveness guidelines.

Manufacturing procedure includes

1. Regulatory Overview of OTC Drugs
2. FDA Regulations and Good Manufacturing Practices (GMPs)
3. Facilities and Equipment Requirements
4. Production and Process Controls
5. Quality Control and Testing
6. Packaging and Labelling Controls
7. Stability Testing and Shelf life
8. Adverse Event Reporting and Post Market Surveillance
9. Recalls and Enforcement
10. Regulatory Submissions and Approvals

The OTC Drug Monograph is a standardized process that allows manufacturers to market products that meet specific criteria without needing a pre-market submission. This system includes the active ingredients, dosage forms, labelling, and manufacturing processes and describes the circumstances in which a medication is deemed safe and effective. On the other hand, the FDA reviews and extensive clinical research is required for some over-the-counter medications (OTC) before they may be approved, especially for novel formulations or those with unusual constituents.

The FDA's Current Good Manufacturing Practices (cGMPs), which are outlined in 21 CFR sections 210 and 211, must be followed by manufacturers. These rules, which include multiple important parts, are intended to guarantee constant quality.

1. Quality Assurance and Control: To assure the pharmaceuticals' overall quality, safety, strength, identity, and purity, manufacturers need to put strong quality control procedure in place.
2. Personnel: Manufacturing facilities should have an acceptable number of qualified personnel and employees who have received the necessary training.
3. Facility Standards: Drug production facilities need to be built with a controlled environment and precautions against contamination.
4. Sanitation and Hygiene: To keep equipment and facilities clean, proper sanitation procedures are necessary.

Each stage of the production process is subject to meticulous controls, which are recorded in batch production records (BPRs) and master production records (MPRs). To assure consistency and adherence to requirements, each batch needs to be monitored, with materials, equipment settings, and test results recorded. Testing for quality control is essential. This comprises identification, strength, and purity testing of raw materials as well as in-process testing to keep an eye on vital variables like pH and temperature throughout manufacturing. Completed goods are put through a rigorous testing process to make sure they meet requirements.

For consumer safety, packaging and labelling are essential. For some medications, FDA laws mandate tamper-evident packaging, child-resistant containers, and labelling containing vital information like active components, usage guidelines, cautions, and expiration dates.

Stability testing evaluates how external influences affect product quality over time and helps establish the shelf life of over-the-counter medications. Post-market surveillance falls within the purview of manufacturers as well, and this includes handling consumer complaints and reporting adverse events via the FDA's MedWatch system. The FDA has the authority to start recalls when goods are discovered to be dangerous or mislabelled. Manufacturers are required to notify the public of any possible hazards and have efficient recall protocols in place.

All things considered, a thorough framework governing OTC drug regulation guarantees that these goods are safe, efficient, and of the highest calibre for users.

Import of OTC Drugs

In recent years, the US Food and Drug Administration has faced increasing challenges in overseeing the safety of agency-regulated products generally, and particularly imported pharmaceutical products from developing countries. The agency carries out several hundred inspections each year of foreign pharmaceutical establishments that ship products to the US. The number inspected each year, however, is only a small fraction of the total.[9]

OTC monograph regulations allow for the importation of OTC drug goods. OTC monographs serve as regulatory guidelines for the sale of over-the-counter medications without a new drug application being authorized. Under an approved new drug application, an approved abbreviated new drug application, or in accordance with an OTC monograph, an over-the-counter medication may be imported into the United States.

Import Procedure include

1. Pre-Market Approval and Compliance
2. Labelling Requirements for OTC Drugs
3. Good Manufacturing Practices (GMP)
4. FDA Registration and Drug Listing
5. Customs and Border Protection (CBP) and FDA Import Requirements
6. Adverse Event Reporting and Pharmacovigilance

1. Pre-Market Approval and Compliance

A New Drug Application (NDA) is not necessary for the majority of over-the-counter (OTC) medications because of established FDA monographs. These monographs describe safe and effective guidelines, including acceptable ingredients, doses, and labelling specifications, for a range of over-the-counter medications. The NDA procedure, which requires a more thorough and expensive assessment of the drug's safety and efficacy, must be followed by makers of over-the-counter medications if they do not comply with these standards.

2. Labelling requirements

OTC drugs must adhere to strict labelling standards set by the FDA to ensure safe consumer use. Key elements include:

- Drug Facts Label: Must include active ingredients, purposes, uses, warnings, and dosage instructions.
- Directions for Use: Clear guidelines on correct dosage and usage.
- Warnings: Information on potential side effects and interactions.
- Manufacturer Information: Includes name, address, lot number, and expiration date.

3. GMPs

OTC medications that are imported must be produced in compliance with FDA GMP guidelines to guarantee both quality and safety. Complying entails:

Facility certification: Producers are required to register and are subject to FDA inspections.

Quality control: Effective procedures for examining raw materials and completed goods.

Record keeping: Comprehensive records to ensure accountability.

4. Customs and Border Protection (CBP) Import Requirements

In order to comply with CBP laws, imported over-the-counter medications must also have certain paperwork, including a business invoice, bill of lading, FDA Prior Notice, evidence of registration, and a drug listing. If there is any suspicion of noncompliance, products may be inspected and held.

5. Reporting adverse events

Through the FDA's Med Watch program, importers are required to monitor product safety after it has been marketed and to report any adverse events. Based on safety findings, the FDA may issue warnings, amend product labels, or recall items.

Export of OTC drugs from the USA

Pharmaceuticals, especially over-the-counter (OTC) medications, are in high demand worldwide and the US is one of the top exporters of these products. OTC pharmaceuticals, or over-the-counter medications, are goods including vitamins, antacids, pain relievers, and cold remedies that can be purchased without a prescription. Because of the U.S. Food and Drug Administration's strict regulatory control, over-the-counter medications manufactured in the United States are well recognized globally for their safety, efficacy, and quality. (FDA).

1. Regulatory Framework for Exporting OTC Drugs

OTC medicine exportation necessitates adherence to both US and import nation restrictions. This procedure is governed by the Federal Food, Drug, and Cosmetic Act (FD&C Act), which allows drug exports under specific circumstances: Adherence to GMPs, or good manufacturing practices. Packaging and labelling that meet the requirements of the importing nation. compliance with US legislation prohibiting adulteration and misbranding. Export certificates from the FDA are essential for proving compliance. Types consist of: A Certificate of Free Sale certifies that a medication is legal for sale and is being advertised in the United States. A Certificate of a Pharmaceutical Product (CPP) is frequently mandated by foreign countries and conforms to World Health Organization requirements. Exporters need to confirm the importing nation's unique certificate requirements.

2. GMP

GMP compliance is essential for both domestic and export markets. Key aspects include:

Manufacturing Procedures: In order to avoid mistakes and contamination, facilities must follow tight GMP regulations.

Quality Control: To guarantee that products fulfil requirements for safety, potency, and purity, a strong quality control system is necessary. Record-Keeping: It is necessary to keep thorough records of all manufacturing, testing, and batch production activities. FDA inspections of American producers are conducted to verify compliance; failure may result in the suspension of exports.

3. Labelling and Packaging requirements

Labelling and packaging for over-the-counter medications that are exported must adhere to import nation and FDA rules. A standardized Drug Facts Label that contains the active components, usage guidelines, cautions, and manufacturer details is mandated by the FDA. Additionally, exporters must consider: Language Requirements: Local language translation of labels may be necessary. Extra Caution: Certain nations might mandate particular cautionary tales. Packaging standards: Adherence to regional laws pertaining to child-resistant packaging and tamper-evident seals is essential.

4. Customs and Documentation for export

U.S. Customs and Border Protection (CBP) enforces customs regulations pertaining to the export of over-the-counter medications. Important records consist of:

Commercial Invoice: Contains pricing, quantity, and product details.

Packing List: Enumerates every item that will be shipped.

A transport agreement between the shipper and the carrier is called a bill of lading.

Export Certificate: Attests to adherence to US legal requirements.

The product's Certificate of Origin attests to its American-made nature.

Customs Declaration: Gives CBP details about the shipment.

It is advisable to collaborate with freight forwarders and customs brokers to guarantee correct documentation and adherence to import and export laws.

5. Adherence to importing country's regulations

The regulatory requirements of the importing nation, which can differ greatly, must also be followed by exporters. Key considerations include:

Registration and Licensing: A few nations mandate that products be registered with their national regulatory bodies.

Standards of Quality: Standards of quality and stability may differ between countries.

Import Permits: In certain nations, imports require permits.

Table 1: Comparative Analysis of OTC Drug Regulation in India and the United States.

Regulatory aspects	INDIA	USA
Regulatory Body	Central Drugs Standard Control Organization	Food and Drug Administration
Legal Frame work	Drug and Cosmetics Act 1940 and Rules, 1945	Federal Food, Drug, and Cosmetic Act (FD&C Act)
Approval process	New drugs require approval from CDSCO; for OTC, no separate category exists, but certain drugs can be sold OTC if listed in specific schedules.	OTC Monograph Process or New Drug Application (NDA) depending on drug category. OTC monographs define approved active ingredients, doses, and labelling.
Classification of Drugs	Drugs are classified into Prescription (Rx) and OTC, but there is no clear and distinct separate regulation for OTC drugs.	Drugs classified as Prescription (Rx) or OTC based on safety profile, dosage, and intended use. OTC drugs further classified by monographs or NDA.
Labelling Requirements	Governed by the Drugs and Cosmetics Act, including product name, ingredients, expiration date, batch number, and manufacturer details.	Standardized "Drug Facts" labelling required, including uses, warnings, directions, inactive ingredients, and expiration date.
Advertising Regulations	Governed by the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, limiting claims for certain medical conditions.	Regulated by FDA and the Federal Trade Commission (FTC). Strict rules on advertising, including prohibitions on false/misleading claims.
Manufacturing Standards	Good Manufacturing Practices (GMP) as per Schedule M of the Drugs and Cosmetics Act.	Good Manufacturing Practices (GMP) enforced under the FD&C Act. Compliance with Current

		Good Manufacturing Practices (cGMP).
Post-Market Surveillance	Pharmacovigilance is mandatory, but the system is still developing. CDSCO oversees adverse drug reaction monitoring. Robust post-market surveillance. Adverse Event	Robust post-market surveillance. Adverse Event Reporting System (FAERS) and MedWatch used to track safety issues.
Recall Procedures	Recalls are manufacturer-initiated, CDSCO may issue alerts and take action in cases of violations.	FDA can request or enforce recalls of products that are found to be unsafe or misbranded.
Switching Rx to OTC	No formalized system; decisions made on a case-by-case basis.	The FDA has a formal process for switching prescription drugs to OTC status after evaluation of safety and efficacy.
Duration of Approval Process	Can be longer and depends on state and central approvals, especially for new drug approvals.	Relatively faster under the OTC monograph system, but may take longer if an NDA is required.
Price Regulation	Drug prices, including OTC, are subject to regulation by the National Pharmaceutical Pricing Authority (NPPA).	No direct government price control over OTC drugs, although prices can be influenced by market forces.

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