



AMERICAN JOURNAL OF PHARMTECH RESEARCH

Journal home page: <http://www.ajptr.com/>

Different types, specific packaging and labeling regulatory requirements as per CDSCO in India in comparison with Sweden

Ashok Kumar P*, Rajeev BK, Sahana B, Spandana S, Sowmyashree MS, Srimayee KN
Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left Cross, 3rd Block, Mahalakshmi Nagar, Near Railway Gate, 80 feet Road, Batwadi, Tumkur-572103, Karnataka (India)

ABSTRACT

This project aims to analyze and compare the regulatory requirements related to packaging and labeling of pharmaceutical products in India and Sweden. In India, these regulations are governed by the Central Drugs Standard Control Organization (CDSCO), whereas in Sweden, they fall under the jurisdiction of the Medical Products Agency (MPA), in line with the European Medicines Agency (EMA) directives. The study categorizes the types of pharmaceutical products-such as prescription drugs, over-the-counter (OTC) medicines, biological and medical devices-and examines the specific packaging and labeling requirements for each category. It investigates critical elements such as Language requirements, font size, barcoding, serialization, tamper-evidence features, and safety warnings, highlighting the underlying rationale rooted in patient safety and traceability. Through comparative analysis, the project identifies key differences and similarities between Indian and Swedish regulations. While CDSCO emphasizes local language labeling and rigid compliance with the Drugs and Cosmetics Rules, Sweden follows harmonized European Union (EU) standards with multilingual packaging requirements and Centralized Pharmacovigilance practices. This comparative study provides insights for pharmaceutical companies looking to market their products in both regions, guiding them to navigate regulatory expectations efficiently. The project also highlights potential challenges and opportunities in harmonizing global regulatory practices.

Keywords: Packaging, Labeling, CDSCO, MPA, GMP.

*Corresponding Author Email: ashokkumarscp@gmail.com
Received 10 September 2025, Accepted 28 September 2025

Please cite this article as: Kumar A *et al.*, Different types, specific packaging and labeling regulatory requirements as per CDSCO in India in comparison with Sweden. American Journal of PharmTech Research 2025.

INTRODUCTION

Pharmaceutical products are subject to strict packaging and labeling regulations worldwide to ensure patient safety, product integrity, and compliance with national and international standards. These regulations vary significantly across countries, reflecting differences in healthcare systems, regulatory frameworks, and enforcement practices.

This project explores and compares the regulatory requirements for pharmaceutical packaging and labeling as defined by the Central Drugs Standard Control Organization (CDSCO) in India and the corresponding authorities in Sweden, primarily the Medical Products Agency (MPA). It delves into the types of packaging, such as blister packs, bottles, ampoules, and unit dose forms, and the specific labeling standards covering critical aspects like language, content, font size, warnings, barcoding, and storage instructions.

The study aims to highlight key similarities and differences in regulatory expectations between the two countries, offering insights into global regulatory harmonization challenges and opportunities. It is especially relevant for pharmaceutical companies, regulatory professionals, and students aiming to understand how products must be adapted for compliance in different markets.

Regulatory authority of India:

The Central Drugs Standard Control Organization (CDSCO) serves as India's key regulatory body for drugs, medical devices, cosmetics, and diagnostics. It operates under the Ministry of Health and Family Welfare and is responsible for ensuring that the products in the Indian market meet the standards for efficacy, protection, and quality. The CDSCO is tasked with implementing and monitoring the Drugs and Cosmetics Act, 1940, and its rules, 1945. It establishes guidelines for the sale and quality control of pharmaceutical and medical products. The CDSCO collaborates with international bodies such as the World Health Organization (WHO), the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Pharmaceutical and Medical Devices Agency (PMDA), the European Directorate for the Quality of Medicines and Healthcare (EDQM), the South Asia Regional Cooperation (SAARC), the South East Asia Office (SEARO), and the BRICS nations (Brazil, Russia, India, China, and South Africa).

CDSCO functions as the central licensing authority, featuring a consultative committee (DCC), a technical advisory board (DTAB), and regular inspections in collaboration with state drug controllers.

CDSCO manages samples and monitoring imported medications through testing laboratories.

It maintains records and produces monthly, quarterly, and annual reports. CDSCO collects and monitors the distribution of drugs and cosmetics, including managing product import and export data¹.

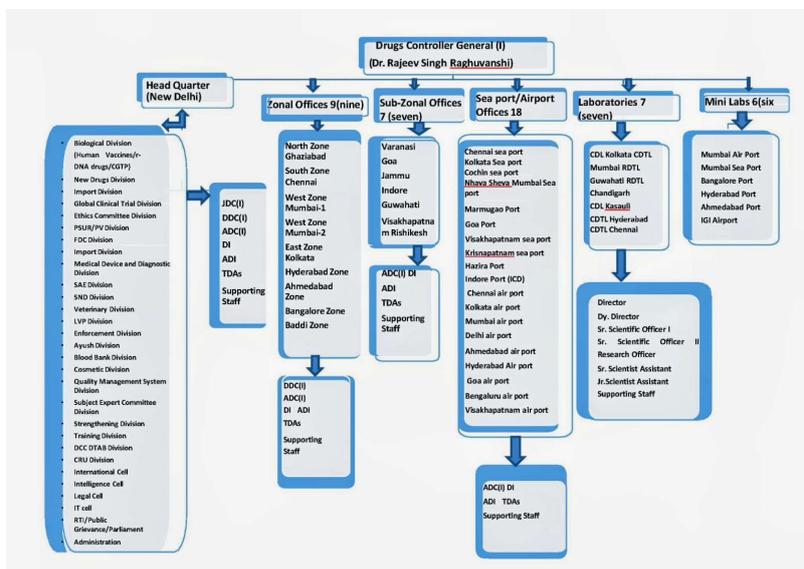


Figure 1: Organization of CDSCO

Packaging:

Packaging is the process of enclosing or protecting products for distribution, storage, sale and use. In the pharmaceutical Industry, packaging refers specifically to the materials, containers, and systems used to contain, protect, and deliver drug products safely to consumers.

Goals:

1. Promote a company and its image.
2. Give an old product a new image.
3. Preserve the product for a time period.
4. Help customers use products better.
5. Introduce new uses for old products.
6. Reduce costs, increase sales and profits.

Types of material used for packaging:

1. Flexible Packaging: Plastic film, Aluminum foil, Paper.
2. Semi-Rigid Packaging: Set-up paper board cartons, molded pulp container, PET bottles.
3. 3 Rigid Packaging: Glass, Metal, Wood, Corrugated Cardboard, Chip board⁸.

Labeling:



Figure 2: Labeling

The term "labeling" includes all such information found on the container or packaging, except for the outer box used for shipping. A label is any written, printed, or graphic information that appears on the container or packaging of a drug.

Types of labels:

Brand Labels:

These show the product's brand name, its parent brand, trademark, logo, and brand message.

Descriptive Labels:

These provide details about the product such as its ingredients, how to use it, care instructions, and performance.

Grade Labels:

These indicate the product's quality according to industry standards and legal rules.

Recent changes in GMP for packaging and labeling:

ISO 15378:2017 ISO 15378:2017 outlines specific requirements for the production and control of primary packaging materials used in medicines. It is based on ISO 9001:2015 and helps organizations show they can consistently deliver products that meet customer and legal needs. This standard is important for patient safety because the packaging materials come into direct contact with the medicine. ISO 15378:2017 follows the structure of ISO/IEC Directives Part 1 Annex L, which provides a common format for ISO management system standards.

This helps ensure consistency and alignment across different standards by using a shared framework, common terms, and definitions³.

Packing material specifications:

Under GMP, specifications for packing materials ensure that they are suitable, safe, and help maintain product quality over time. These specifications are important to prevent contamination, product breakdown, and to ensure the product can be properly identified and tracked.

GMP Packing material specifications:**Material compatibility and functionality:**

Packaging materials must be compatible with the product, providing protection against moisture, light, gases (e.g., oxygen), microbial contamination, and physical damage. Primary packaging materials (e.g., vials, ampules, blisters, bottles, closures) are in direct contact with the product and must ensure product integrity and safety.

Quality management system:

Manufacturers of packaging materials must establish a quality management system compliant with ISO 15378:2017, which integrates GMP principles specifically for primary packaging materials for medicinal products. This system covers design, manufacture, procurement, testing, storage, and supply of packaging materials.

Material types and manufacturing processes:

Packaging components can be made from paper, paperboard, plastics (rigid and flexible), glass, metal, or natural materials. Various manufacturing processes like injection molding, blow molding, extrusion, and converting are used and each must meet quality and safety standards.

Specifications Content:

- Written specifications for packaging materials should include:
- Identification of the material and batch number
- Physical and chemical characteristics (e.g., dimensions, thickness, moisture barrier properties)
- Functional requirements (e.g., seal integrity, closure performance)
- Acceptance criteria and testing methods
- Storage conditions and handling precautions
- Shelf life and expiry date of packaging materials.

Traceability and documentation:

Each batch of packaging material should have a unique batch number for traceability. Batch records must document production, testing, and release, ensuring full traceability from raw material to finished packaging.

Storage and handling:

Packaging materials must be stored under controlled conditions to prevent damage or contamination. Storage areas should be clearly designated, and materials should be handled to avoid mix-ups or deterioration.

Regulatory compliance:

Packaging materials must comply with applicable regulations and standards, including GMP guidelines, ISO standards, and specific pharmacopeia requirements. This ensures that the packaging is suitable for pharmaceutical use and meets safety and quality expectations.

Naming, labeling, and packaging as per CDSCO in relation to trade dress essentials in India⁴:

Trade dress refers to the overall look & feel of a product and its packaging that signifies its source in the minds of consumers.

Includes: colors, shapes, designs, graphics, textures, layout, and even the way the label & pack are presented. Protected under Trademark Law (India: Trademarks Act, 1999, US: Lanham Act).

1. Naming (Brand Name / Trade Name):

CDSCO Requirements:

Brand names must be distinct and non-misleading.

Avoid similarity with existing names to prevent confusion.

No implied claims of superiority unless proven.

CDSCO/DCGI may reject names similar to scheduled drugs or existing trademarks.

Trade Dress Implication:

A distinctive brand name helps protect product identity.

Names should be trademark registered to secure trade dress rights.

2. Labeling:

CDSCO Requirements (Drugs and Cosmetics Rules, 1945):

Labels must display generic and brand names, manufacturer details, batch no., Mfg./Exp. dates, MRP, dosage, storage, schedule category, and statutory warnings.

Trade Dress Implication:

Fonts, layout, color, and design on labels are essential for product identity.

Labeling is part of the visual appearance protected under trade dress.

3. Packaging:

CDSCO Requirements:

Must be tamper-evident and ensure product safety.

Follow specific color codes for drug classes (e.g., red line for antibiotics).

Misleading packaging is prohibited.

Trade Dress Implication:

Shape, size, design, and color of packaging contribute to trade dress.

Unique packaging can be protected under trademark/design law.

WHO Guidance on packaging and labeling for COPP:

"Packaging must protect against all adverse external influences... carry the correct information and identification of the product... and must not have an adverse effect on the product or vice versa.

Labels must provide clear identification and information as required by regulations."

Table 1: COPP Packaging and Labeling Content

COPP Section	Packaging/labeling Content Included
Nature of Containers	Type/material of primary and secondary packaging
Contents of Container	Quantity, dosage form, presentation
Labeling	Approved text/specimen, regulatory compliance
Storage Conditions	Temperature, humidity, light protection, etc.
Shelf Life	Duration supported by stability data
Batch/Manufacturing Details	Batch number, manufacture/expiry dates (on packaging/label)
Quality Assurance	GMP compliance, packaging meets Pharmacopoeia/spec standards

INDIA:

Packaging requirements: tamper-evident packaging:

Tamper evident packaging has special features that let people know if a product has been opened or changed. If someone tries to tamper with the product, there are clear signs that show up, like broken seals or torn materials. This helps people know the product might not be safe to use. CDSCO says it should have indicators or barriers that show if someone has tried to open it or removed them, so people can see that tampering happened⁵.

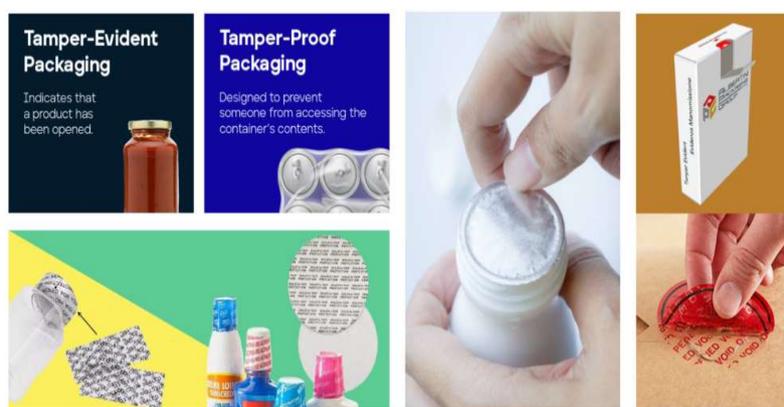


Figure 5: Tamper Evident Labels in Pharmaceutical Packaging

Void Labels:

These labels show a “VOID” message when they are removed, which means someone tried to open the package. They can also have logos or other messages to help with branding.

Destructible Labels:

These are made from a weak material that breaks into pieces when someone tries to remove them. This makes it easy to see if the package has been opened.

Total Transfer Labels:

These labels show hidden messages or designs when someone tries to open them. This clearly shows that the product has been tampered with.

Perforated Labels:

These labels have small cuts or holes. When someone opens them, they tear along these lines, making it clear that the package has been opened.

Tamper Evident Shrink Bands:

These are plastic bands that go around the neck of bottles or jars. They need to be torn to open the product, which leaves a clear sign that someone has tried to open it. It's a safety measure mainly to stop accidental poisoning or someone eating something dangerous.

Applicable Guidelines and Standards⁷:

Though not required, CDSCO suggests following these standards: IS/ISO 8317:2004 – Testing for re-closable child-resistant packaging IS/ISO 28862:2018 – Testing for non-re-closable child-resistant packaging WHO Guidelines- US 16 CFR 1700 standards for products being exported Example: Iron Supplement Syrup (100mg elemental iron per 5mL) uses a push-down-and-turn cap.

Labeling:**Drugs (Pharmaceutical Products):**

According to the Drugs and Cosmetics Rules, 1945, drug labels must have: Name of the drug (either generic or brand name). Name and address of the manufacturer, and if needed, the importer. Batch or lot number to track the product.

Manufacturing license number. Date of manufacture and date of expiry (or shelf life). Net contents (weight, volume, or number of units).

Active ingredients and their amounts. Instructions on how to store and handle the product (like temperature or light sensitivity). Schedule and warning statements (for prescription or special drugs). MRP (Maximum Retail Price) including all taxes. Directions for use and warnings or precautions when relevant. For prescription drugs, the symbol “Rx” and proper caution statements.

These labeling requirements must be on both the immediate container and outer packaging. The labels must be in English or Hindi written in Devnagari script, or in regional languages as necessary.

Cosmetics:

For cosmetic products, the labeling rules are based on the same law but have some special rules: The product name. The list of ingredients, written in order from the most to least amount used. The total amount of product in the package. The name and address of the company that made, packed, or brought in the product. The license number for manufacturing. The batch number. The date the product was made or imported. The date by which the product should be used or its expiry date. Instructions on how to use the product and any necessary warnings. The price including all taxes. For cosmetics that are brought in from another country, the label must also include a registration number and the country where it was made. Labels must be in English, but it's okay to add the local language too if it helps the user understand better.

SWEDEN:**Tamper evident Packaging:**

The Swedish Medical Products Agency (MPA) requires that medicine packaging must have two important safety features to show if someone has opened or tampered with it. This can be a seal, a cap that breaks when opened, a shrink band, or an adhesive label that can't remove or changed without leaving visible sign.

An anti-tampering device (ATD) that clearly shows if the package has been opened or touched. A unique code, usually a two-dimensional (2D) Data Matrix barcode, that helps check if the medicine is real and genuine⁶.

Child resistant Packaging:

Child-resistant packaging must be hard for children under about 4.5 years old (42-51 months) to open quickly, but still easy for adults, including older people, to open.

Tests often involve groups of children in this age range trying to open the package within a set time, following ISO 8317 standards, to make sure at least 85% of them can't open it in the time allowed. Both types of child-resistant packaging that can be closed again and those that can't be closed again are accepted. Common ways include push-and-turn caps, safety closures, or seals on blister packs. The packaging should be safe for children but not too hard for adults, including the elderly or people with disabilities, to use. Sweden follows the same rules as the EU for medicine packaging, and the MPA decides whether child-resistant packaging is needed based on how risky

the medicine is. There is a focus on clear checks and following testing standards to make sure that child-resistant packaging really stops kids from getting into medicine by accident.

2. LABELING REGULATORY REQUIREMENTS:

The Swedish Medical Products Agency (MPA) requires that pharmaceutical product labeling includes specific information to ensure safety, correct use, and compliance with regulatory standards. Key labeling requirements per the Swedish MPA include:

- Name of the medicinal product, including strength and pharmaceutical form.
- Active substance(s) and composition (including excipients if necessary).
- Package size.
- Method and route of administration if applicable.
- Necessary warnings and special precautions.
- Expiry date (month/year).
- Storage conditions if required.
- Instructions for disposal of unused medicine or packaging if applicable.
- Name and address of the marketing authorization holder (and authorized representative if applicable).
- Marketing authorization number.
- Batch number.
- Nordic product number.
- Dosage instructions for non-prescription medicines.

Marking for non-prescription medicines with text like "Itsehoitolaake / Receptfritt läke-medel" on the outer package.

Labeling must be provided in Swedish and typically also in Finnish if marketed in those regions, especially for Nordic packages shared across countries. The labeling requirements follow templates such as the QRD (Quality Review of Documents) template and comply with guidelines including Fimea's Administrative Regulation 3/2019 and Normative Guideline 1/2019 on labeling and package leaflets. The MPA reviews and approves proposed labeling during marketing authorization procedures, and changes to labeling post-approval require notification or approval. Additional guidance exists for Nordic packages to harmonize labeling across Nordic countries under specific joint guidelines coordinated by authorities including the Swedish MPA. The label lettering must be legible with a minimum character size (at least 7 points or 1.4 mm x-height) and appropriate spacing to ensure readability².

Special regulatory requirements on packaging and labeling:

Sustainability compliance: From August 2026, packaging must comply with the EU Regulation 2025/40 on packaging and packaging waste, including requirements to minimize packaging weight and volume, use recycled materials progressively, limit harmful substances (e.g., PFAS, heavy metals), and feature clear, harmonized recycling labels or QR codes to facilitate proper waste sorting and recycling. Maximum empty space ratio: Packaging should avoid excessive empty space, with a specified maximum ratio of 50%.

Comparative study requirements:

Table 2: Comparative study

PARAMETERS	INDIA	SWEDEN
Regulatory body	Central Drugs Standard Control Organization (CDSCO); Drug Controller General of India (DCGI)	Medical Products Agency (Lakemedelsverket)
Main laws and regulations	Drugs & Cosmetics Act, 1940 Drugs & Cosmetics Rules, 1945 (esp. Part IX, Rules 95–106) 2025 labeling draft norms	Swedish Medicines Act EU Directive 2001/83/EC EU Falsified Medicines Directive
Labeling requirements	Product name (generic/brand) Active ingredients Batch number Manufacturing & expiry date Manufacturer's details Manufacturing license Schedule/category warning MRP Indelible ink; both inner and outer pack, Often in English, sometimes regional languages. No alteration without approval Clear, legible fonts	Product name & strength Dosage form Active substances Batch number Expiry & manufacture dates Marketing authorization holder Multi-language (Swedish mandatory) Braille on outer packaging Tamper evidence Serialization per EU FMD
Recent Regulatory Changes (2025)	Draft rules mandate Braille on mono-cartons and voice QR codes for all prescription drugs. Bigger font, matte, non-reflective surfaces. Mandatory inclusion of expiry/manufacture date in high contrast. QR codes needed on primary, secondary, tertiary packs. Review of suppliers of packaging/foil under regulatory scope. Public consultation for new rules closed June 2025; enforcement anticipated late 2025	No recent drastic changes, but enforcement of current EU and local laws remains strict. Serialization and tamper-evidence per Falsified Medicines Directive. Braille required for name/strength. New/emerging digital health or antimicrobial requirements generally implemented via EU channels.
Packaging Amount Rules	Rule 105: Specific pack sizes for tablets/capsules; e.g. multiples of 5 after 10 units. Defined sizes for liquids, eye/ear/nasal drops, ointments. Special rules for narcotics (Schedule X), single-dose mandatory for some injectables. New pack sizes need regulatory review.	Pack size and configuration as per approved product information with Lakemedelsverket. Suitability, safety, and child-resistance mandated by EU and agency. Prescription and retail packs defined in marketing authorization.
labeling Operations	Strict control on font size, legibility, indelibility. Braille and voice-assist tech under review for patient safety. Manufacturers must retrofit lines, revalidate systems for compliance. No overprinting or stickering on imported drugs without license.	Braille and anti-counterfeit features must be part of packaging design. Printing in Swedish mandatory. Packaging artwork and content approved by Lakemedelsverket. Serialization requires unique packaging-

		level printing elements.
Labels & Printed Material	Labels must have clear warnings, branded/unbranded distinction (future symbol under review). All printed info indelible; no misleading info. Patient information leaflet (PIL) in English; accessible formats under review (Braille, QR-based audio).	Labels and Patient Information Leaflet (PIL) in Swedish. PIL format, structure and text must meet EU readability standards. All required printed components (label, leaflet, outer carton) reviewed and approved. Mandatory Braille and serialization.
Enforcement/Penalties	Recalls, suspension of manufacturing/marketing licenses, fines for non-compliance. New rules will extend liability to packaging suppliers.	Product recall, fines, or suspension of authorization for violations; enforced strictly per EU and Swedish law.

CONCLUSION:

Comparing packaging and labeling between India and Sweden reveals notable differences, primarily driven by regulatory requirements and consumer expectations. Both countries prioritize product safety, environmental sustainability, and transparency in packaging. However, Sweden tends to focus more on eco-friendly packaging solutions, reflecting the country's strong environmental ethos. In contrast, India is also moving towards sustainable packaging, but the emphasis varies depending on the industry and region. Regulatory requirements: India and Sweden have different regulatory frameworks governing packaging and labeling. Sweden's regulations are often more stringent, particularly regarding environmental impact and sustainability. Labeling requirements: Both countries require labels to provide essential product information, but Sweden's labeling regulations may be more detailed, especially for food and pharmaceutical products. Packaging design: Packaging design in Sweden often prioritizes minimalism and sustainability, while Indian packaging may focus more on visual appeal and brand recognition.

Despite these differences, both countries recognize the importance of packaging and labeling in product marketing, consumer safety, and environmental sustainability. By understanding these differences, businesses can tailor their packaging strategies to meet the specific needs of each market.

ACKNOWLEDGEMENT:

We would like to express our sincere gratitude to all those who have supported us in completing this comparative study on the packaging and labeling regulatory requirements as per CDSCO guidelines in India and the Swedish regulatory framework.

First and foremost, We thank our faculty Sir Dr. P Ashok Kumar, a professor in the Pharmaceutical regulatory science department at Sree Siddaganga College of Pharmacy in Tumkur, for valuable guidance, encouragement, and constructive suggestions throughout the course of this work. We are grateful to our institution for providing us with the resources and a learning platform to carry out this project. We also extend our thanks to the Central Drugs Standard Control Organization (CDSCO) and the Medical Products Agency (Sweden) for making regulatory information accessible, which served as the foundation of this comparison. Finally, we express our heartfelt appreciation to our families and friends for their constant support and motivation, without which this work would not have been possible

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