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Comparative Study of Regulatory Guidelines for Over-the-Counter (OTC) Drugs in India, the United States, and Europe

Nikhil Bhardwaj, Dheeraj Kumar, Atul Kumar Nasa*, Poonam Arora*

SGT College of Pharmacy, SGT University, Gurugram, Haryana, India
Corresponding Authors:
1. *Dr. Atul Kumar Nasa
SGT College of Pharmacy, SGT University, Chandu-Budhera, Gurugram, Haryana, India
Email id: pvc_aknasa@sgtuniversity.org
ORCID ID: 0009-0009-8030-0268
2. *Dr. Poonam Arora
SGT College of Pharmacy, SGT University, Chandu-Budhera, Gurugram, Haryana, India
Email id: poonamarora_fphs@sgtuniversity.org
ORCID ID: 0000-0002-4118-8180

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Abstract

The regulation of over-the-counter (OTC) medicines plays an important role in ensuring consumer safety and healthcare accessibility. This review compares OTC regulatory frameworks in India (CDSCO), the United States (FDA), and the European Union (EMA), focusing on legislation, classification systems, labelling, and pharmacovigilance. The analysis highlights that India lacks a formal OTC category, a defined Rx-to-OTC switch pathway, and a robust surveillance system for non-prescription medicines. In contrast, the USA's CARES Act (2020) modernised the OTC Monograph System, while the EU maintains a comprehensive regulatory framework through EMA and national authorities. The review identifies key regulatory gaps in India and proposes reforms to improve consumer safety and align with international standards.

1. Introduction

Over-the-counter (OTC) medicines are widely used for self-medication and represent a significant segment of the global pharmaceutical market, projected to exceed USD 276 billion by 2030 (Grand View Research, 2022). In India, increasing self-medication and limited healthcare access have contributed to the growing OTC market (Shankar et al., 2021). OTC medicines play an important role in improving access to healthcare, reducing the burden on healthcare facilities, and supporting the management of minor ailments. However, inappropriate self-medication may result in adverse drug reactions, incorrect diagnosis, drug interactions, and

antimicrobial resistance, highlighting the importance of effective regulatory oversight and consumer awareness (Hughes et al., 2001). The World Health Organization recognizes responsible self-medication as an essential component of self-care and recommends the establishment of appropriate regulatory frameworks to ensure the safety, quality, and efficacy of non-prescription medicines (WHO, 2000).

Regulatory approaches to OTC medicines differ considerably among India, the United States, and the European Union. The USA has established a comprehensive OTC Monograph System supported by structured pharmacovigilance and consumer information requirements, while the European Union follows a harmonized regulatory framework combining EMA oversight with national implementation mechanisms (López Vila et al., 2023). In contrast, India continues to regulate OTC medicines through an exclusion-based approach and lacks a formal OTC classification system. Given the rapid expansion of the OTC market and increasing consumer reliance on self-medication, understanding these regulatory differences has become increasingly important. Therefore, this review compares the regulatory guidelines of India, the USA, and the European Union with respect to legislation, classification systems, labelling requirements, pharmacovigilance mechanisms, and regulatory reforms, while identifying key gaps and future directions for strengthening OTC regulation in India.

2. Regulatory Frameworks

2.1 India (CDSCO)

India regulates OTC medicines under the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials (NDCT) Rules, 2019 administered by the Central Drugs Standard Control Organisation (CDSCO) (MoHFW, 2019). Unlike the USA and European Union, India does not maintain a legally recognised OTC category. Instead, medicines not included in Schedule H or Schedule H1 are generally available without prescription, resulting in an exclusion-based regulatory approach (CDSCO, 2017).

The absence of a formal OTC framework creates uncertainty regarding classification, distribution, and consumer access. Recognising this gap, the CDSCO Expert Committee recommended the introduction of a separate OTC category in 2017; however, these recommendations have not yet been implemented (CDSCO, 2017). Consequently, the regulatory status of many commonly used medicines remains dependent on interpretation of existing schedules rather than explicit classification.

Labelling requirements are governed by Rule 96 of the Drugs and Cosmetics Rules, 1945. Unlike the standardised Drug Facts Label used in the United States, India lacks a consumer-oriented OTC labelling format. Pharmacovigilance activities are conducted through the Pharmacovigilance Programme of India (PvPI), which serves as the national adverse drug reaction monitoring system (CDSCO, 2023). The increasing use of self-medication and growing OTC consumption highlight the need for stronger regulatory oversight and enhanced consumer awareness (Shankar et al., 2021).

2.2 United States (FDA)

OTC medicines in the United States are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act, 1938. A major regulatory reform occurred through the Coronavirus Aid, Relief, and Economic Security (CARES) Act, 2020, which modernised the OTC Monograph System by introducing Over-the-Counter Monograph Orders (OMOs) and streamlining the process for updating safety and efficacy requirements (FDA, 2020a).

The FDA maintains a well-defined OTC classification system and provides a structured Rx-to-OTC switch pathway for medicines that demonstrate adequate safety and effectiveness for consumer use without professional supervision. This framework has facilitated the transition of several medicines from prescription-only to non-prescription status. A notable example was the approval of Opill (norgestrel) as the first OTC daily oral contraceptive in 2023 (FDA, 2023).

Consumer protection is strengthened through the mandatory Drug Facts Label, which standardises information regarding indications, dosage, warnings, contraindications, and storage conditions (FDA, 2021). Post-marketing safety monitoring is supported through systems such as MedWatch and FAERS, ensuring continuous surveillance of adverse drug reactions and product safety concerns. These measures make the FDA framework one of the most comprehensive OTC regulatory systems globally.

2.3 European Union (EMA)

Within the European Union, OTC medicines are regulated through Directive 2001/83/EC and Regulation (EC) 726/2004 under the oversight of the European Medicines Agency (EMA) and national competent authorities (EMA, 2006). Unlike the centralised approach of the FDA, the EU combines European-level regulation with member-state implementation, creating a multi-layered regulatory framework.

Article 71 of Directive 2001/83/EC establishes the criteria for non-prescription medicines and provides the basis for OTC classification across member states (Vogler et al., 2021). Although common regulatory principles exist, individual countries retain discretion regarding product classification, resulting in differences in OTC availability throughout the European region.

A distinctive feature of the EU system is its emphasis on patient communication and consumer understanding. Patient Information Leaflets (PILs) must undergo readability testing to ensure that information is understandable and accessible to the general public (EMA, 2020). In addition, multilingual labelling requirements support safe medicine use across diverse linguistic populations.

The EU pharmacovigilance framework is centred on EudraVigilance, which facilitates adverse drug reaction reporting and safety monitoring throughout member states (EMA, 2022). According to McGettigan et al. (2023), recent pharmacovigilance reforms have strengthened OTC medicine safety surveillance and improved regulatory coordination across Europe. Consequently, the EU framework is widely regarded as a balanced model that combines consumer accessibility with strong safety oversight.

3. Comparative Analysis

Table 1 provides a structured comparison of the three regulatory frameworks across five key domains. India's absence of a formal OTC category, combined with state-level enforcement variation, creates a regulatory vacuum that enables inconsistent drug availability and safety oversight. The USA's reformed monograph system is the most modernised globally, while the EU's dual central/national architecture offers depth but generates cross-national variation in OTC product availability — the same active ingredient can require prescription in one EU state while being freely available in another (Vogler et al., 2021).

Table 1. Comparative Overview of OTC Regulatory Frameworks: India, USA, and EU

Parameter	India (CDSCO)	USA (FDA)	EU (EMA)
Governing Law	Drugs and Cosmetics Act, 1940; NDCT Rules, 2019	Federal Food, Drug and Cosmetic Act, 1938; 21 CFR Parts 330–358	Directive 2001/83/EC as amended by Directive 2004/27/EC; Regulation (EC) 726/2004

	administered by CDSCO		
OTC Category	No formal OTC schedule; medicines available by exclusion from Schedule H and H1	Explicit OTC classification through OTC Monograph System and OMOs under CARES Act 2020	Non-prescription medicines defined under Article 71; classification may vary among member states
Switch Pathway	No published Rx-to-OTC pathway; approvals handled on a case-by-case basis	Monograph amendment or supplemental NDA; generally completed within 6–12 months	Article 71 reclassification procedure through centralised, decentralised, or mutual-recognition routes (~30 months)
Labelling	Rule 96 of D&C Rules; no standardised consumer-oriented OTC format	Mandatory Drug Facts Label with standardised safety, dosage, and warning information	Patient Information Leaflet (PIL) with readability testing, multilingual requirements, and user validation
Pharmacovigilance	PvPI monitors ADRs; limited OTC-specific reporting and consumer participation	FAERS, MedWatch, and Sentinel systems provide active and passive safety surveillance	EudraVigilance supports ADR monitoring; mandatory PSUR/PBRER submissions and WHO-UMC collaboration

Note: D&C = Drugs and Cosmetics Act; NDCT = New Drugs and Clinical Trials; OMO = OTC Monograph Order; NDA = New Drug Application; DCP = Decentralised Procedure; MRP = Mutual Recognition Procedure; PIL = Patient Information Leaflet; ADR = Adverse Drug Reaction; PvPI = Pharmacovigilance Programme of India; FAERS = FDA Adverse Event Reporting System; PSUR = Periodic Safety Update Report; PBRER = Periodic Benefit-Risk Evaluation Report; WHO-UMC = World Health Organization–Uppsala Monitoring Centre. Sources: CDSCO (2017, 2023); FDA (2020a, 2021, 2023); EMA (2006, 2020, 2022); Vogler et al. (2021); McGettigan et al. (2023).

Figure 1 shows OTC market size across jurisdictions (2020 vs 2024). India's market, while smallest in absolute terms, shows the highest proportionate growth (~62%), underscoring the urgency of regulatory reform given expanding consumer exposure (IQVIA Institute, 2024).

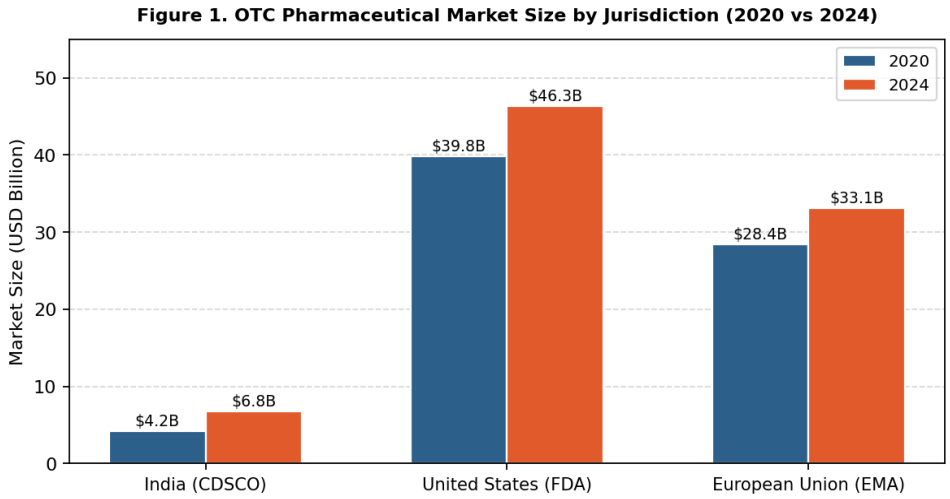

Figure 1. OTC Pharmaceutical Market Size by Regulatory Jurisdiction (2020 vs 2024).

Sources: IQVIA Institute (2024); Grand View Research (2022).

4. Key Challenges

India faces the most significant regulatory challenges among the three jurisdictions due to the absence of a formal OTC classification system. Federated enforcement mechanisms, a large network of approximately 800,000 retail pharmacies, low health literacy levels, particularly in rural areas, and the rapid expansion of e-pharmacy platforms collectively increase the risk of inappropriate self-medication and unsafe medicine use (Shankar et al., 2021). The lack of a dedicated OTC framework also contributes to inconsistencies in medicine

availability and enforcement across states, while limited consumer awareness may increase the likelihood of incorrect dosing, adverse drug reactions, and delayed medical consultation. According to WHO guidelines, effective self-medication requires both regulatory safeguards and informed consumer participation, emphasizing the need for stronger oversight and public education initiatives (WHO, 2000; Hughes et al., 2001).

Although the USA and European Union possess more mature OTC regulatory systems, important challenges remain. In the USA, concerns persist regarding consumer comprehension of medicine labels, particularly among elderly and low-literacy populations, despite the mandatory Drug Facts Label and extensive pharmacovigilance infrastructure. The opioid crisis has further highlighted the limitations of label-based risk communication and the need for continuous regulatory adaptation. In the European Union, harmonisation remains a key challenge because individual member states retain discretion in OTC classification under Article 71, resulting in variations in medicine availability across countries (Vogler et al., 2021). Additional complexities arise from post-Brexit regulatory divergence and the costs associated with multilingual labelling and patient information requirements (McGettigan et al., 2023). Consequently, all three jurisdictions continue to face the challenge of balancing consumer accessibility, medicine safety, and effective regulatory oversight in an evolving healthcare environment.

5. Regulatory Gaps and Recommendations for India

Table 2 maps India's five critical regulatory gaps to actionable recommendations informed by FDA and EMA best practices. The overarching imperative is legislative reform: introducing a formal OTC Schedule within the D&C Act, publishing CDSCO switch guidelines, mandating a standardised label format, expanding PvPI to cover OTC ADRs, and enacting an e-pharmacy regulatory framework.

Table 2. Regulatory Gaps and Evidence-Based Recommendations for India

Regulatory Domain	Identified Gap	Recommendation for India

OTC Classification	No statutory OTC category; medicines are available through exclusion from Schedule H and H1, creating ambiguity in classification and enforcement.	Introduce a dedicated OTC Schedule in the Drugs and Cosmetics Act with transparent classification criteria, safety requirements, and periodic review mechanisms.
Switch Pathway	No formal Rx-to-OTC reclassification guidelines published by CDSCO; approvals are handled on a case-by-case basis.	Develop and gazette a formal Rx-to-OTC switch framework modelled on FDA and EMA systems, including eligibility criteria, safety evaluation, and post-switch monitoring.
Labelling	No standardized OTC label; Rule 96 does not adequately support consumer understanding of dosage, warnings, contraindications, and adverse effects.	Mandate a uniform Drug Facts-style label in English and regional languages with standardized sections on indications, dosage, warnings, precautions, and storage conditions.
Pharmacovigilance	PvPI under-captures OTC adverse drug reactions (ADRs); pharmacist and consumer reporting remain limited.	Mandate OTC ADR reporting by pharmacists, strengthen PvPI digital reporting systems, and conduct public awareness campaigns to improve consumer participation.
E-Pharmacy	Lack of a dedicated regulatory framework for online OTC sales despite rapid growth of e-pharmacy platforms and digital healthcare services.	Establish a CDSCO-led e-pharmacy regulatory framework incorporating product authentication, vendor registration, online monitoring, consumer grievance mechanisms, and safety compliance requirements.

Note. D&C = Drugs and Cosmetics Act; CDSCO = Central Drugs Standard Control Organisation; OTC = Over-the-Counter; ADR = Adverse Drug Reaction; PvPI = Pharmacovigilance Programme of India; FDA = U.S. Food and Drug Administration; EMA = European Medicines Agency. Sources: CDSCO (2017, 2023); FDA (2021); WHO (2022).

6. Future Perspectives

AI-driven pharmacovigilance tools—utilizing electronic health records, social media platforms, mobile health applications, and wearable devices—have the potential to significantly enhance OTC medicine safety surveillance. Advanced machine-learning algorithms can facilitate early detection of adverse drug reaction (ADR) signals and improve real-time safety monitoring across large populations. India's CDSCO is developing a national digital health ecosystem; however, integration of these technologies with the Pharmacovigilance Programme of India (PvPI) remains at an early stage. Strengthening digital reporting infrastructure and encouraging direct consumer reporting may improve the quality and quantity of OTC safety data.

Future regulatory frameworks are also expected to place greater emphasis on e-pharmacy regulation, digital health technologies, and international harmonisation of OTC standards. Greater collaboration among CDSCO, FDA, and EMA through ICH initiatives and electronic ADR reporting standards could facilitate regulatory convergence and improve public health outcomes (Poudel et al., 2021). Furthermore, the WHO advocates responsible self-care and evidence-based self-medication as important components of universal health coverage (WHO, 2022). Emerging regulatory strategies increasingly focus on patient-centred healthcare, digital pharmacovigilance, and transparent risk communication, which may shape the future development of OTC medicine regulation worldwide (European Commission, 2020).

7. Conclusion

This review demonstrates that India's OTC regulatory framework remains less developed than those of the USA and the European Union. While the FDA operates a structured OTC Monograph System supported by comprehensive pharmacovigilance and consumer information requirements, and the EU employs a harmonised framework supported by EudraVigilance and robust patient-information standards, India continues to rely on an exclusion-based approach without a formally recognised OTC category. These regulatory differences have important implications for consumer safety, medicine accessibility, and post-marketing surveillance.

With India's OTC market expanding rapidly and self-medication becoming increasingly common, regulatory modernization has become a public health priority. Establishing a formal OTC classification system, introducing transparent Rx-to-OTC switch guidelines, strengthening PvPI reporting mechanisms, standardising consumer-oriented labelling, and regulating e-pharmacy operations could substantially improve patient safety and regulatory effectiveness. Adoption of international best practices, while considering local healthcare realities, would support responsible self-medication, enhance consumer confidence, and strengthen India's position within the global pharmaceutical sector. The future of OTC regulation will depend on achieving an appropriate balance between accessibility, affordability, innovation, and patient protection.

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