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REGULATORY AND INFRASTRUCTURE CHALLENGES IN UDI IMPLEMENTATION ACROSS EMERGING ECONOMIES

Helen Peter*, Mrs.Neeba Babu

Pharmaceutical Regulatory Affairs, Chemists college of pharmaceutical sciences and research

Department of Pharmaceutics, Chemists college of pharmaceutical sciences and research

Abstract:

Unique Device Identification (UDI) systems play a critical role in improving the traceability, safety, and overall management of medical devices throughout their lifecycle. A UDI consists of a Device Identifier (UDI-DI), which specifies the manufacturer and device model, and a Production Identifier (UDI-PI), which captures manufacturing details such as serial or batch numbers. Regulations require that UDIs appear on device labels in both human-readable and machine-readable formats using automated identification and data capture technologies. While regions such as the United States, European Union, Singapore, Brazil, and China have made substantial progress in establishing robust UDI frameworks, many emerging economies face persistent challenges. This study explores the key barriers to UDI adoption in emerging regions, particularly India, Southeast Asia, and Latin America. It examines regional differences, shared implementation obstacles, and insights gained from early adoption experiences. Understanding these challenges is vital for stakeholders aiming to strengthen UDI uptake and promote safer, more transparent global healthcare systems.

Keywords: *Unique Device Identification (UDI), Medical Device Traceability, Regulatory Compliance, Regional Medical Device Regulation*

Corresponding author:

Helen Peter,

Pharmaceutical Regulatory Affairs,

Chemists College of Pharmaceutical Sciences and Research

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INTRODUCTION:

The medical device industry is growing quickly in developing regions like India, Latin America, and Southeast Asia. (4,10) .As healthcare systems improve in these regions, robust rules to safeguard patient safety and increase device traceability are critical. (5,10)

The Unique Device Identification (UDI) system is a worldwide recognized mechanism for uniquely identifying medical devices throughout their lives, and it has become a major regulatory emphasis. (1,2) Developed economies, including the United States and the European Union, have long had UDI rules. Emerging countries are now working to implement similar systems to meet local regulatory requirements and compete in global markets. (4,10) This article looks at the current status, challenges, and future prospects of UDI implementation in India, Brazil, Colombia, and selected Southeast Asian nations.[5][10] It shows how UDI improves device traceability, supports timely recalls, prevents counterfeiting, and encourages international regulatory coordination. (1,2)

DISCUSSION

WHY UDI MATTERS IN EMERGING MARKETS

- **Regulatory alignment and improved market access.**

Countries like India, Brazil, Colombia, and many across Southeast Asia are working to bring their medical device regulations in line with global UDI standards set by groups like the IMDRF, the FDA, and the European Union. For manufacturers aiming to enter international markets, meeting UDI requirements is quickly becoming a must. Local producers who want to export their devices also need to follow these global standards to improve their chances of accessing new markets. (2)

• Current Status across Regions:

India introduced a UDI system through the Central Drugs Standard Control Organization (CDSCO) in December 2021. However, the rollout is still in progress—key elements like the timeline for implementation and the launch of a national UDI database are still being developed and haven't gone live yet. (5)

Southeast Asia shows different levels of progress. Taiwan will begin implementing UDI laws for Class II and III devices in February 2024, while Singapore and Malaysia are currently in the process of developing regulatory frameworks. (6,7)

Latin America has made tremendous headway, with Brazil's National Health Surveillance Agency (ANVISA) launching a phased UDI deployment in January 2022, which will last six years. Similarly, Colombia's medical authority, INVIMA, has established progressive dates for UDI compliance based on device risk rating, with deadlines stretching until 2026. (5)

• Patient Safety and Traceability

UDI adoption improves healthcare outcomes by enabling for accurate tracking of medical devices throughout their lives. This capability allows for faster and more accurate recall actions when necessary, as well as more efficient identification of devices associated with adverse events by regulatory bodies. Improved traceability also helps to eliminate counterfeit items on the market, resulting in higher overall patient safety. (8,9)

Country	Regulatory Authority	Agency	Responsibilities
Singapore	Health Sciences Authority	**HSA**	Oversees medical device registration, licensing, UDI system implementation, post-market surveillance
Malaysia	Medical Device Authority	**MDA (under MOH)**	Regulates registration (MeDVER), conformity assessment, labeling, UDI pilot studies.
Thailand	Thai Food and Drug Administration	**Thai FDA (Ministry of Public Health)**	Medical device classification, licensing, QMS requirements, post-market controls.
Vietnam	Ministry of Health – Department of Medical Equipment & Construction	**MOH – DMEC**	Controls device import, registration, permits, vigilance, UDI adoption progress.
Indonesia	Ministry of Health – Directorate General of Pharmaceuticals & Medical Devices	**MoH DGFMDA**	Device registration through e-regulation platform, import control, safety monitoring.
Philippines	Food and Drug	**FDA Philippines**	Center for Device Regulation, Radiation

	Administration Philippines	**(CDRRHR)**	Health & Research regulates all medical devices
Brunei Darussalam	Ministry of Health – Department of Pharmaceutical Services	**DPS MoH**	Oversees medical device registration, import permits, and market authorization.
Cambodia	Ministry of Health – Department of Drugs and Food	**DDF MoH**	Regulates devices, pharmaceuticals; strengthening market surveillance systems.
Laos (Lao PDR)	Ministry of Health – Food and Drug Department	**FDD MoH**	Device registration, import control, quality and safety monitoring
Myanmar	Food and Drug Administration	**FDA Myanmar (MoH)**	Responsible for medical device approval, registration, quality control, post-market activities.

UDI IMPLEMENTATION FRAMEWORK IN INDIA

The Unique Device Identification (UDI) system in India is mainly governed by the Medical Devices Rules, 2017, especially Rule 46. This rule requires that medical devices have a UDI to help track them, improve patient safety, and ensure compliance with regulations. The UDI code has two parts: the Device Identifier (DI), which uniquely identifies the device, and the Production Identifier (PI), which contains variable data like batch or serial numbers. (5)

While the original deadline for UDI labeling was January 1, 2022, the implementation has been postponed. The Ministry of Health and Family Welfare is finalizing guidelines on UDI display standards and necessary information. These guidelines follow recommendations from the International Medical Device Regulators Forum (IMDRF). They will require both a human-readable format and an automatic identification component, with GS1 standards likely forming the basis for issuing UDIs in India. (5)

The introduction of UDI brings several benefits to the Indian healthcare sector. It improves traceability of medical devices throughout the supply chain, making it easier to identify and recall defective products. It enhances patient safety by allowing the detection of counterfeit or expired devices. It also helps manage inventory in healthcare settings by tracking device use and expiration dates. Furthermore, it improves communication between manufacturers and end-users, which supports product quality. Lastly, it allows for more accurate billing and reimbursement by linking UDI data with hospital billing systems. (2,8,9)

Currently, India's UDI framework is in the preparatory phase. It is waiting for an official government notification that will outline the implementation process. Industry groups like APACMed support this initiative because it aligns India with global standards for medical device identification. (5,2)

In short, India is working on a UDI system that meets international standards to ensure safety, enhance traceability, and enforce regulatory compliance, with formal enforcement expected soon

UDI IMPLEMENTATON FRAMEWORK IN SOUTHEAST ASIA

The Unique Device Identification (UDI) implementation across Southeast Asia varies by country but is generally aligned with international standards to improve medical device traceability, safety, and regulatory oversight. Countries such as Singapore and Malaysia have made notable progress in adopting UDI frameworks, while others are in preparatory phases or have yet to implement formal mechanisms. (6,7,8)

Singapore's Health Sciences Authority (HSA) introduced UDI regulations effective August 27, 2021, initially targeting higher-risk medical devices (Class B, C, and D). The system requires medical devices to carry UDIs consisting of a Device Identifier (DI) and Production Identifier (PI), facilitating timely recall actions, enhanced tracking, and reduction of medical errors. Singapore's approach aligns with International Medical Device Regulators Forum (IMDRF) principles and permits acceptance of UDIs compliant with U.S. or EU standards when devices are marketed in those regions. The phased compliance schedule spans from 2022 through 2028, depending on device risk classification. (6)

In Malaysia, the Medical Device Authority (MDA) initiated a pilot survey starting mid-2024 to evaluate medical device establishments' readiness for UDI implementation. This pilot will assess the

supply chain's ability to incorporate UDIs and guide the official rollout timeline. The Malaysian UDI framework similarly includes DI and PI components to ensure unique identification throughout a device's lifecycle. (7)

Some other Southeast Asian countries, members of ASEAN, follow the ASEAN Medical Device Directive (AMDD), which promotes harmonization for medical device regulation including device identification. However, actual UDI implementation remains pending in many countries such as Indonesia, Thailand, Philippines, and Vietnam, which rely primarily on the AMDD framework with ongoing national adaptations. (5)

In summary, Southeast Asia's UDI implementation is at different stages: Singapore has a formal phased enforcement schedule consistent with IMDRF guidance, Malaysia is progressing via pilot testing, and other ASEAN states are working toward regulatory harmonization under AMDD, anticipating future UDI enforcement aligned with global standards

UDI IMPLEMENTATION FRAMEWORK IN LATIN AMERICA

The adoption of Unique Device Identification (UDI) in Latin America is most advanced in Brazil. Other countries in the region are at different stages of development. Brazil has established a national UDI regulation under ANVISA, primarily guided by RDC 591/2021. This regulation requires medical devices to have a UDI, which includes a Device Identifier (DI) and a Production Identifier (PI). This helps ensure effective traceability and improves patient safety. A centralized UDI database called SIUD is being set up, with plans for it to be fully operational by mid-2025. Enforcement will start with high-risk Class IV devices on July 10, 2025, and will gradually include other device categories through 2027 and beyond. Brazil's approach focuses on following international standards and aims to strengthen post-market monitoring and regulatory oversight. (3,8) The framework recently went through public consultation to finalize the technical requirements for data submission to the SIUD system. (3)

In neighboring countries, the speed of UDI adoption differs. Colombia's INVIMA is building a UDI database, expecting to implement it around 2025 to 2026, initially targeting higher-risk devices. Several other Latin American nations are still preparing, influenced by Brazil's model and global harmonization efforts from groups like the International Medical Device Regulators Forum (IMDRF).(5)

In summary, Brazil leads the region in UDI deployment with a clear regulatory timeline and database structure. Other Latin American countries are progressing toward similar regulatory frameworks, which are expected to align with international standards soon.

CHALLENGES IN INPLEMENTING UDI IN INDIA, LATIN AMERICA AND SOUTHEST ASIA

The implementation of Unique Device Identification (UDI) in India, Latin America, and Southeast Asia experiences several common and region-specific challenges:

INDIA:

- Regulatory delays and unclear guidelines:

UDI labeling was mandated under Rule 46 of the Medical Devices Rules, 2017, with an initial deadline of January 2022. However, implementation has been postponed as the Ministry of Health and Family Welfare is still refining rules about UDI display and required information. (11,12)

- Complex regulatory environment: Frequent regulatory updates, misclassification issues, and the need to comply with international standards (IMDRF) create challenges, particularly for smaller manufacturers. (10)
- Infrastructure limitations: A lack of enough accredited labs, clinical research facilities, and supply chain infrastructure leads to delays and higher compliance costs. (11)
- Cost and resistance to change: Smaller manufacturers find it hard to manage costs and integrate processes. (2)
- Data management issues: Effectively managing UDI data calls for strong IT systems and trained staff, which many organizations currently do not have. (10)

LATIN AMERICA:

- Uneven progress among countries:

Brazil has a strong regulatory framework (ANVISA RDC 591/2021) and a centralized UDI database. However, other countries like Colombia are still developing, leading to inconsistent regional practices. (13)

- Regulatory harmonization challenges: Different regulatory environments make it hard to create a unified approach. (10)
- Resource and expertise deficits: Smaller manufacturers and regulators struggle with a lack of technology, skilled workers, and funding. (9)

SOUTHEAST ASIA:

• Phased and pilot implementations:
Singapore and Malaysia are testing or slowly introducing UDI systems; this leads to longer timelines. (13,14)

• Balancing global standards with local rules makes things more complicated. (5)

• Infrastructure and supply chain gaps: Many ASEAN members lack the IT and logistics systems needed to support UDI adoption. (14)

• Awareness and stakeholder engagement: Different levels of knowledge and commitment among manufacturers, healthcare institutions, and regulators slow down adoption. (13)

Overall, these challenges are linked to regulatory uncertainty, infrastructural and technological inadequacies, cost burdens, data management complexities, and stakeholder resistance or lack of awareness across these regions.

CONCLUSION:

The introduction of Unique Device Identification (UDI) systems in India, Latin America, and Southeast Asia is crucial for improving medical device safety, traceability, and regulatory compliance. Each region faces specific challenges that impact how quickly and effectively these systems are put in place. India deals with regulatory uncertainties, limited infrastructure, and high compliance costs, which slow its progress. In Latin America, Brazil leads, but progress is uneven due to differing regulatory readiness and available resources. Southeast Asia is taking a gradual approach with phased rollouts and pilot projects, but it still struggles with infrastructure gaps and complex regulatory issues. Despite these challenges, government agencies, industry stakeholders, and global regulators are increasingly committed to addressing them. To fully realize the potential of UDI, it is important to focus on clear regulatory frameworks, improve technical infrastructure and workforce skills, and boost stakeholder involvement. This will enhance patient safety and healthcare quality in these emerging markets.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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