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Review Article

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Harmonization of E-Labelling (Electronic Patient Information Leaflet) in Pharmaceuticals: A Global Perspective

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Abstract

The shift from paper-based patient information leaflets (PILs) to electronic labeling (e-labeling) is revolutionizing the pharmaceutical industry. E-labeling provides greater accessibility, real-time updates, and better patient safety. The lack of a harmonized global e-labeling framework has, however, led to regional inconsistencies, posing difficulties for pharmaceutical firms and regulatory agencies. This article investigates the current regulatory systems in important markets like the USFDA, EMA, PMDA, and CDSCO, and also identifies differences in e-labeling standards. It focuses on standardized data formats, QR code embedment, and multilingual compatibility to maintain worldwide uniformity. A central electronic platform for e-labeling will go a long way in advancing regulatory compliance, minimizing medication mistakes, and increasing patient outcomes. Harmonization will involve coordination among regulatory bodies, pharmaceutical industries, and technology vendors to attain harmonized and efficient implementation of e-labeling systems globally.

Keywords: Electronic Patient Information Leaflet (ePIL), E-Labeling Harmonization, Global Regulatory Framework, Digital Drug Information, Pharmaceutical Compliance, QR code, SPL (Structured Product Labeling), ePI (Electronic Product Information), XML-Based Labeling Format

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1. Introduction

The drug industry is going digital, with e-labeling growing as an imperative technology to enhance the delivery of patient information. Previously, PILs were handed out in print format as paper inserts along with medicine packaging. Yet these printed materials suffer from limitations of size restrictions, delays in updating content, and multiple language translations, weakening their functionality to provide pivotal safety and use details. To meet these challenges, e-labeling has emerged as a digital solution that offers real-time, accessible, and multilingual medicinal information. E-labels are generally distributed via QR codes, mobile apps, or web platforms, allowing patients and healthcare professionals to receive updated and precise medicinal information. Regulatory bodies globally are increasingly embracing e-labeling to improve patient safety, streamline regulatory processes, and facilitate sustainable practices by eliminating paper waste. Although such improvements have been made, the absence of a standardized global approach to e-labeling poses significant hurdles.

2. Objectives

- **Improve Patient Safety and Access to Information** Ensure that patients worldwide receive accurate, up-to-date, and easy-to-understand medication information in digital formats, improving safe and effective drug use.
- **Enhance Regulatory Consistency Across Countries** Align national regulatory standards to streamline approval processes, reduce duplication of work, and improve cooperation between international agencies (e.g., EMA, FDA, PMDA).
- **Facilitate Real-Time Updates and Faster Communication** Enable immediate updates of drug information, including safety warnings, dosage changes, and new indications, across all jurisdictions simultaneously.
- **Promote Environmental Sustainability** Reduce paper usage by shifting toward digital formats, supporting sustainability goals and reducing packaging waste.
- **Support Digital Health Integration** Foster interoperability with electronic health records

(EHRs), mobile apps, and other digital health platforms for enhanced medication management and adherence.

- **Improve Supply Chain Efficiency and Traceability** Link e-labeling to digital product identification systems (e.g., barcodes, QR codes) for real-time tracking and verification throughout the pharmaceutical supply chain.
- **Enhance Accessibility and Multilingual Support** Allow for multilingual access to drug information through digital platforms, ensuring inclusivity and eliminating language barriers.
- **Reduce Errors Due to Outdated Printed Materials** Minimize the risk of using outdated leaflets by enabling dynamic, cloud-based access to the most recent and approved information.
- **Boost Industry Innovation and Global Competitiveness** Encourage pharmaceutical companies to adopt innovative packaging and digital strategies that meet global expectations and regulatory requirements.
- **Ensure Data Integrity and Authentication** Use secure technologies such as blockchain to ensure the authenticity, integrity, and traceability of the labeling information shared with patients and healthcare professionals.

3. Existing Worldwide Regulatory Environment for E-Labeling

Numerous regulatory agencies have adopted various e-labeling systems to cater to their specific regional needs:

a) **United States (USFDA):** Applies the Structured Product Labeling (SPL) format, an XML-based system that supports standardized presentation of content. (1)

b) **European Union (EMA):** Rolled out the Electronic Product Information (ePI) initiative. (2)

c) **Japan (PMDA):** Applied XML-based e-labeling standards for integration in the Pharmaceuticals and Medical Devices Information Website. (3)

d) **India (CDSCO):** Exploring digital labeling solutions with QR codes while currently focusing on conventional PILs

e) **Canada** Health Canada is transitioning to a structured format for product monographs using Extensible Markup Language (XML) and Health Level 7 (HL7) standards. This move aims to improve the quality and accessibility of drug product information for Canadians.

f) **Asia-Pacific Region** Several countries in the Asia-Pacific region have initiated e-labelling projects:

- **Singapore**: Voluntary e-labelling initiatives are in place, allowing manufacturers to provide digital labels for professional use.
- **Malaysia**: The National Pharmaceutical Regulatory Agency (NPRA) issued guidelines effective May 1, 2023, permitting electronic provision of approved product information via QR codes on packaging
- **South Korea**: The Ministry of Food and Drug Safety (MFDS) launched a pilot e-labelling project in 2023 for injectable products used in medical institutions, allowing exemption from paper inserts when electronic information is provided.
- **Taiwan**: The Taiwan Food and Drug Administration (TFDA) announced guidance for e-labelling in September 2023, initiating pilot projects for selected prescription products

Table 1. Comparative Table of Worldwide Regulatory Environment for E-Labeling

Region/Country	Regulatory Authority	E-Labeling Status	Key Initiatives	Challenges
European Union	European Medicines Agency (EMA)	Active promotion of ePI (electronic Product Information)	Implementation of structured electronic formats; QR code integration on packaging	Ensuring consistency across member states; technological infrastructure
United States	Food and Drug Administration (FDA)	Encourages electronic distribution of drug labeling	Adoption of Structured Product Labeling (SPL) in XML format	Balancing electronic and printed labeling requirements
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	Mandatory e-labeling for prescription drugs and medical devices since August 2021	Integration with supply chain tracking; use of SGML versions	Transitioning from paper-based systems; stakeholder adaptation
China	National Medical Products Administration (NMPA)	Pilot programs initiated for e-labeling	Focus on imported drugs; alignment with international standards	Diverse regulatory landscape; technological readiness
Middle East	Various national authorities	Transition towards paperless labeling in progress	Harmonization across countries; localization of content	Navigating varying regulations;

				stakeholder alignment
Global Initiatives	International Coalition of Medicines Regulatory Authorities (ICMRA), World Health Organization (WHO)	Development of global e-labeling standards	Promotion of structured formats like HL7 FHIR; support for low- and middle-income countries	Achieving consensus among diverse regulatory environments

4. Harmonization Required

The lack of a global standardized e-labeling system creates major challenges:

- **Different Data Formats:** XML, PDF, HTML, and others create consolidation issues.
- **Delays in Updates:** Asynchronous update cycles across regions.
- **Language Discrepancies:** Inconsistencies in multilingual translations.
- **Technology Gaps:** In developing countries, access and digital literacy may be limited.

Harmonization is crucial to eliminate these disparities and streamline global compliance.

Table 2. Regional Differences in Data Formats for E-Labeling

Region	Standard/Data Format	Description
United States	**SPL (Structured Product Labeling)**	An XML-based standard developed by **HL7** and adopted by the **FDA** for drug labeling submissions. SPL allows standardized, machine-readable product information.
European Union	**ePI (Electronic Product Information)**	Based on FHIR (Fast Healthcare Interoperability Resources) and XML. Managed by the **EMA**, ePI supports digital access to up-to-date patient and healthcare provider information.
Japan	**XML-Based Labeling Format**	Implemented by **PMDA**, Japan uses a unique XML-based schema to structure label information for pharmaceuticals. It aligns with eCTD standards.
India	**QR Code with PDF/XML Links**	The **CDSCO** mandates QR codes on drug packaging that link to electronic labels or PILs, typically in PDF or XML format.
Canada	**eCTD with Regional XML**	Uses eCTD (electronic Common Technical Document) format; health product labeling uses XML files specific to **Health Canada**'s requirements.
United Kingdom	**ePI (UK Variant)**	Post-Brexit, the **MHRA** is developing its own variant of ePI, largely modeled after EU systems but may diverge in future standards.

5. Strategies of Proposed Harmonization

5.1 Standardized Data Format: Standardizing the structure of labelling data using Extensible Markup Language (XML) and Fast Healthcare Interoperability Resources (FHIR) protocols enhances interoperability and consistency. These standards allow for seamless integration across regulatory databases and health systems, promoting faster and more accurate updates to product information.

5.2 Centralized Digital Repository: A centralized digital repository or global submission portal facilitates efficient storage, management, and dissemination of approved e-labels. It ensures that the most current regulatory-compliant information is readily accessible to healthcare professionals and patients.

5.3 QR Code Integration: QR codes printed on pharmaceutical packaging offer immediate access to updated electronic labels. These codes bridge physical and digital information, empowering patients with accurate, real-time content such as safety updates, dosing instructions, and multilingual versions. (4)

5.4 Multilingual Support: Implementing multilingual support using standardized terminologies such as MedDRA (Medical Dictionary for Regulatory Activities) ensures the information is comprehensible across populations. Culturally sensitive and accurate translations improve compliance and health literacy globally.

5.5 Integration of Artificial Intelligence and Machine Learning: AI and ML technologies can support the automatic generation, translation, and updating of electronic labels. These tools also aid in detecting inconsistencies, thereby ensuring compliance with real-time regulatory changes.

5.6 Centralized Regulatory Frameworks: The establishment of unified frameworks or supranational regulatory bodies can standardize submission formats, label structure, and compliance timelines across jurisdictions. This minimizes redundancy and facilitates mutual recognition agreements.

5.7 Stakeholder Engagement and Training: Effective harmonization requires continuous input from stakeholders, including patients, regulators, manufacturers, and healthcare providers. Education, training, and collaborative feedback loops are essential for successful implementation and user acceptance.

5.8 Pilot Programs and Phased Rollouts Pilot studies and gradual implementation phases allow regulatory bodies and pharmaceutical companies to assess system effectiveness, identify technical barriers, and refine processes before broader deployment.

5.9 Collaborative Regulatory Efforts Global collaboration among organizations like the International Council for Harmonisation (ICH), the World Health Organization (WHO), and national authorities fosters the development of aligned standards. These efforts ensure consistency and accelerate patient access to essential medicines. (5)

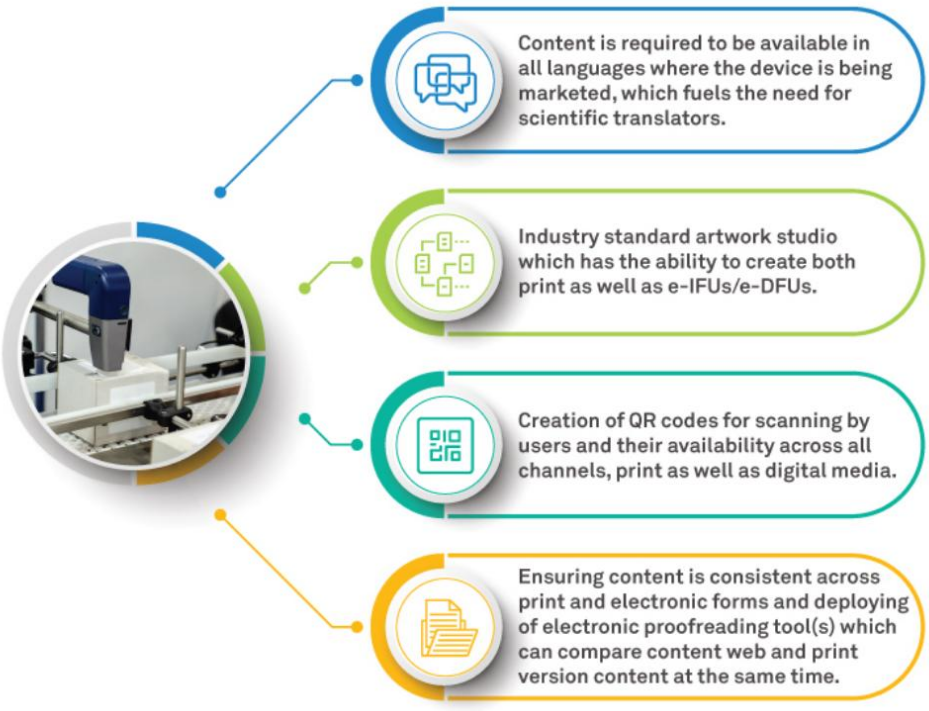

Figure1. E-Labeling Workflow in Pharmaceutical

6. Technological Innovations in E-Labeling

The pharmaceutical industry's transition from traditional paper-based labeling to electronic labeling (e-labeling) has been significantly accelerated by advancements in digital technologies. These innovations aim to enhance the accuracy, accessibility, and efficiency of drug information dissemination. (6-8)

Emerging digital tools offer major enhancements:

6.1 Artificial Intelligence (AI) and Machine Learning (ML) in Labeling Processes

AI and ML are revolutionizing labeling by automating complex tasks such as content generation, translation, and compliance checks. These technologies reduce manual errors and expedite the updating process of product information. (9)

6.2 Adoption of Fast Healthcare Interoperability Resources (FHIR) Standards

FHIR, developed by HL7, provides a standardized framework for exchanging healthcare information electronically. Its adoption in e-labeling ensures interoperability and real-time access to drug information.The integration of FHIR enables personalized drug labels that consider individual patient factors such as allergies and drug interactions, enhancing patient safety.(10)

6.3 Integration of QR Codes for Real-Time Information Access

QR codes on pharmaceutical packaging allow instant access to the most current drug information, ensuring that patients and healthcare providers have up-to-date data. (11)

6.4 Structured Product Labeling (SPL) for Consistency and Compliance

SPL, an HL7 standard, defines the content and format of human prescription drug labeling in an XML format. It ensures consistency and facilitates regulatory compliance across different jurisdictions. The FDA mandates the use of SPL for drug labeling submissions, promoting uniformity and ease of access to drug information. (12)

6.5 Digital Transformation and Paperless Labeling Initiatives

The shift towards digital labeling reduces environmental impact and enhances the efficiency of the labeling process. It also allows for easier updates and distribution of drug information. (13)

6.6 Block chain Technology: Blockchain technology is revolutionizing smart packaging and e-labeling by enhancing transparency, traceability, and consumer trust across various industries. By integrating blockchain with smart labels—such as QR codes, RFID, and NFC tags—products can carry a secure digital identity, enabling real-time tracking and verification throughout the supply chain. (14)

7. Challenges and Considerations

7.1. Regulatory Divergence

- **Challenge**: Different countries have varying regulatory frameworks, definitions, and requirements for e-labelling.

- **Consideration**: Achieving mutual recognition or standardization through collaboration among regulatory agencies like the FDA (USA), EMA (EU), PMDA (Japan), and others is essential. (15)

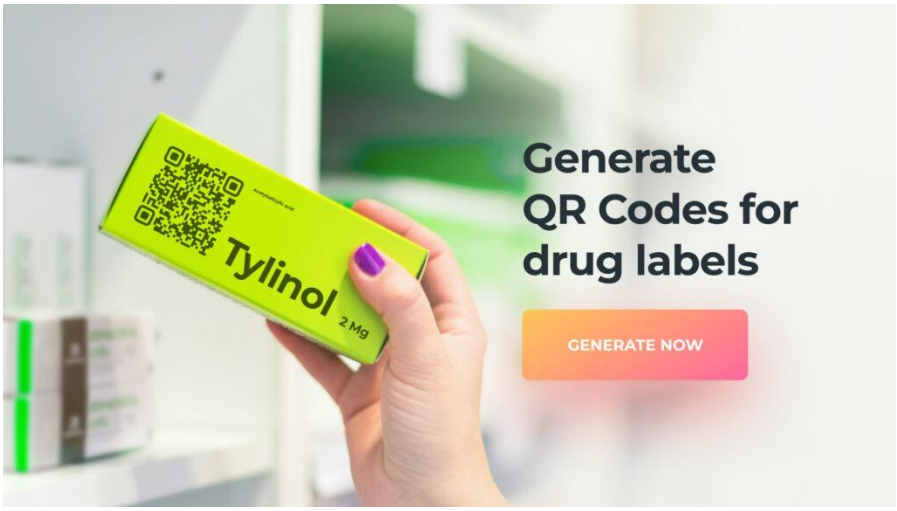

Figure2. QR Code Integration on Medication Packaging

7.2. Technological Infrastructure Disparities

- **Challenge**: Not all countries or healthcare systems have the necessary digital infrastructure (e.g., internet access, electronic health records) to support e-labelling.
- **Consideration**: Solutions must be adaptable to both high- and low-resource settings, with hybrid models possibly required.

7.3. Data Standardization and Interoperability

- **Challenge**: Lack of uniform data standards (e.g., HL7, IDMP, XML) hinders consistent formatting and interpretation of e-labels across regions.
- **Consideration**: Global adoption of standardized data formats is needed to enable seamless integration with regulatory systems and hospital IT platforms.

7.4. Language and Localization Issues

- **Challenge**: Labels must be available in the local language(s) and adapted culturally and clinically for regional needs.
- **Consideration**: Robust translation frameworks and localization protocols should be incorporated to ensure patient safety and comprehension.

7.5. Legal and Compliance Barriers

- **Challenge**: Some jurisdictions still require printed labels by law or are hesitant to fully accept e-labels due to legal liability concerns.
- **Consideration**: Clear regulatory guidance and legal frameworks need to evolve to accept and enforce e-labelling standards.

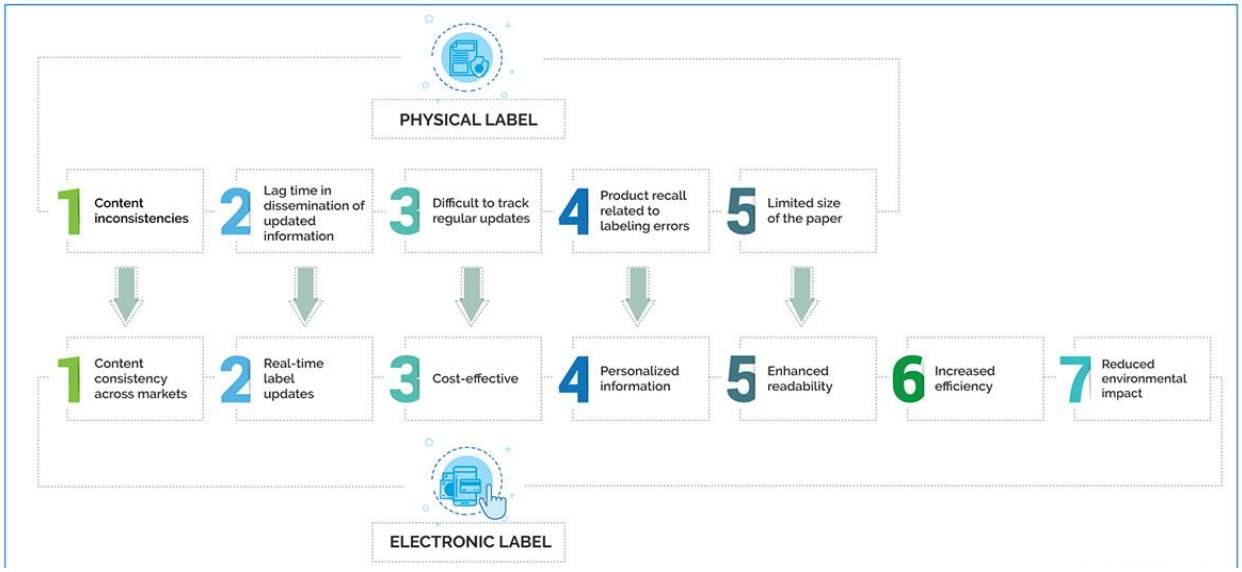

Figure3. Benefits of E-Labelling

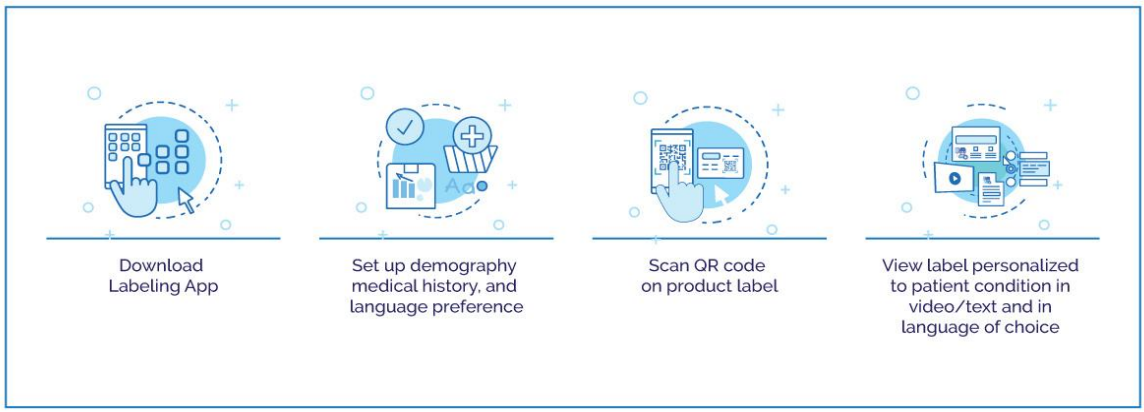

Figure 4. Personalized Drug Information via E-Labeling

7.6. Cybersecurity and Data Privacy

- **Challenge**: E-labelling systems are exposed to cybersecurity threats, especially when cloud-based or accessible through QR codes and mobile apps.
- **Consideration**: Systems must comply with data protection laws like GDPR and incorporate robust encryption and access controls.

7.7. User Accessibility and Digital Literacy

- **Challenge**: Patients and healthcare providers may have varying levels of digital literacy, which could limit the effective use of e-labels.
- **Consideration**: User-friendly interfaces and education campaigns are necessary to ensure proper access and understanding.

7.8. Version Control and Update Synchronization

- **Challenge**: Ensuring that the most up-to-date version of the label is always accessible and verifiable is complex across borders.
- **Consideration**: Systems must include real-time update capabilities and audit trails to ensure regulatory compliance and traceability.

7.9 Stakeholder Buy-In

- **Challenge:** There is hesitancy among pharmaceutical companies, healthcare providers, and patients regarding the adoption of e-labeling systems due to perceived complexities, costs, and workflow disruptions.
- **Consideration:** Building trust and acceptance can be achieved through collaborative pilot initiatives and strategic incentive programs.

7.10 Cost and Resource Allocation

- **Challenge:** Establishing an e-labeling infrastructure demands a substantial initial investment in areas such as technology integration, staff training, and system development.
- **Consideration:** This burden can be eased through phased rollouts, public-private cost-sharing models, and financial backing from government agencies.

8. Regulatory Oversight and Future Outlook

Effective regulatory oversight is fundamental to achieving global alignment in e-labeling for pharmaceuticals and medical devices. The overarching goal is to ensure that e-labels are accurate, up-to-date, and uniformly accessible, while remaining compliant with regional legal and ethical standards.

8.1 International Cooperation and Harmonization Efforts

- **International Council for Harmonisation (ICH):**
  - Although ICH currently lacks specific guidelines for e-labeling, its framework on structured documentation (e.g., CTD, IDMP) provides a strong foundation for future global harmonization.
  - Upcoming revisions may include recommendations for structured and digital labeling. (16)
- **International Medical Device Regulators Forum (IMDRF):**
  - Advocates for harmonized regulatory practices for medical devices.
  - Its initiatives on Unique Device Identification (UDI) and electronic document frameworks support broader e-labeling standardization.
- **World Health Organization (WHO):**
  - WHO plays a key role in promoting digital health strategies, including frameworks that can guide e-labeling in developing regions.

8.2 Regional and National Frameworks

- **European Union (EMA):**
  - The EMA, together with the Heads of Medicines Agencies (HMA), is spearheading the implementation of

structured electronic product information (ePI).

- This system is built on the HL7 FHIR standard and aims to make digital labeling mandatory across EU nations in the future.

- **United States (FDA):**
  - The FDA permits electronic labeling for certain drugs and medical devices under defined regulations.
  - To ensure compliance, e-labels must align with printed versions and meet 21 CFR Part 11 requirements related to electronic records and signatures.
  - QR codes and web-based formats are encouraged for product labeling.
- **Japan (PMDA):**
  - The PMDA endorses digital labeling and utilizes structured data formats for packaging inserts.
  - Their system includes centralized repositories and stringent version control mechanisms.
- **Singapore (HSA):**
  - Singapore's Health Sciences Authority has issued electronic labeling guidelines for medical devices.
  - It supports QR code-based access to electronic Instructions for Use (eIFUs).

8.3 Areas of Regulatory Focus

- **Validation of Label Content:** Authorities must verify that the digital content reflects the approved label and maintains clarity and safety. (17)
- **Version Control and Auditing:** Regulatory systems must track label versions accurately and provide audit trails for updates.
- **Accessibility and Inclusivity:** E-labels must be designed to be usable by individuals with disabilities and those in areas with limited digital access.
- **Language and Localization Compliance:** Labels must meet requirements for local language translation and cultural adaptation.
- **Security and Data Protection:** Robust cybersecurity measures must be in place to safeguard label data from tampering or unauthorized access.

8.4 Oversight Challenges

- The absence of universally accepted e-labeling standards.
- Uneven recognition of digital labels in place of printed ones.
- Limited technological and regulatory capacity in some lower-income nations.
- Disparate legal and regulatory systems that complicate global standardization.

8.5 Future Directions

- Adoption of universal technical formats like HL7 FHIR for consistent label structuring.
- Expansion of joint regulatory pilots and workshops to align policies.
- Transition toward centralized, cloud-based platforms managed by regulatory bodies.
- Integration of artificial intelligence to support faster, more accurate regulatory review and approval processes. (18)

9. Case Studies and Implementation Challenges

9.1 European Union ePI Pilot

The EMA's electronic product information initiative introduced a harmonized labeling approach using XML, enabling multi-language access to updated drug data across EU countries. (19)

9.2 Common Barriers Identified

- **Digital Competency Gaps:** Elderly individuals or those unfamiliar with technology faced difficulties navigating digital labels. (20)
- **Infrastructure Limitations:** Users in remote or underserved areas encountered challenges accessing online label content due to unreliable internet connections.

10. Conclusion

Harmonization of e-labeling practices is essential for providing consistent, reliable, and accessible drug information globally. Through adoption of standardized data formats, emerging technologies, and global collaboration, the pharmaceutical sector can significantly improve patient outcomes and medication safety. E-labeling is not just a regulatory trend—it is a crucial innovation toward safer and more transparent healthcare.

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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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