FIFARMA

LatAm Playbook
for Electronic Product Information (ePI) Implementation

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Chapter

Content

Abbreviations and definitions

Product Information (PI):

Is a scientifically validated, regulatory-approved set of documents that describe a medicine's identity, composition, therapeutic indications, dosage, method of administration, contraindications, and safety profile. It is intended to ensure the safe, effective, and informed use of the medicine by healthcare professionals and patients. This information is known variously as Summary of Product Characteristics (SmPC), Prescribing Information, Product Monograph, labeling, and/or package leaflet. It must comply with jurisdiction-specific regulations and guidance for clarity, consistency, and accessibility. Regulatory authorities such as the European Medicines Agency (EMA), Health Canada, the United States Food & Drug Administration (FDA), the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) and others around the world define and manage this information to support public health and regulatory compliance (European Medicines Agency [EMA], n.d.-b; EMA, n.d.-e; Health Canada, 2024; Medicines and Healthcare products Regulatory Agency [MHRA], 2025; U.S. Food & Drug Administration [FDA], 2022).

Patient Information Leaflet (PIL):

This document is intended for use by patients and their caregivers. It provides essential, officially approved information on the safe and effective use of the medicine. The PIL is derived from the PI and includes details such as indications, dosage, administration, contraindications, and potential side effects. Ideally, it must be designed and written to be clear and understandable, enabling users to act appropriately, when necessary, with the help of healthcare professionals. If possible, it should be written with a patient-centric approach, meaning that it should be written in lay terms that are easily understood (EMA, n.d.-c; FDA, n.d.; MHRA, 2024).

Electronic Product Information (ePI) /electronic labeling (e-labeling):

ePI and e-labeling are interchangeable terms. ePI as per the EMA's definition, and in most cases globally, refers to the authorized, statutory PI for medicines (including the SmPC, package leaflet and labeling) adapted for handling in electronic format and dissemination via the web, e-platforms and in print (EMA, n.d.-e). e-label, on the other hand, is a more general term and refers to the most up-to-date National Regulatory Authority's approved PI for the safe and effective use of medicines, made available on the web or via e-platforms. It is NOT adapted to be in an electronic format. For ease, the 'umbrella term' used throughout this Playbook is ePI. However, it is important to understand the basic differences between ePI /e-labeling and e-labels.

The recognized official electronic format for ePI is the globally standardized format made available under the Health Level Seven International (HL7) organization. It is called the ePI Fast Healthcare Interoperable Resources format (see below).

National Regulatory Authorities (NRAs):

Are government agencies responsible for the regulation and oversight of medical products, including drugs, biologics, and medical devices. Their core functions include ensuring the safety, efficacy, and quality of these products through activities such as market authorization, post-market surveillance, and enforcement of regulatory standards (FDA, 2024).

Healthcare System:

Consists of all organizations, people, and actions whose primary intent is to promote, restore or maintain health. This includes efforts to influence determinants of health as well as more direct health-improving activities (World Health Organization [WHO], n.d.).

Marketing Authorization Holder (MAH):

Refers to the legal entity that holds the authorization to market a medicinal product in a given jurisdiction and is responsible for ensuring compliance with regulatory obligations (EMA, n.d.-e; FDA, 2022).

Healthcare Professionals (HCPs):

Refers to a provider of healthcare treatment and advice based on formal training and experience. This broad category includes physicians, nurses, pharmacists, dentists, therapists, and many others who are trained to deliver health-related services. These professionals may work in various settings including hospitals, clinics, community health centers, and even in patients' homes. Their roles can range from direct patient care to administrative, research, and educational functions within the healthcare system.

Fast Healthcare Interoperability Resources (FHIR) ePI:

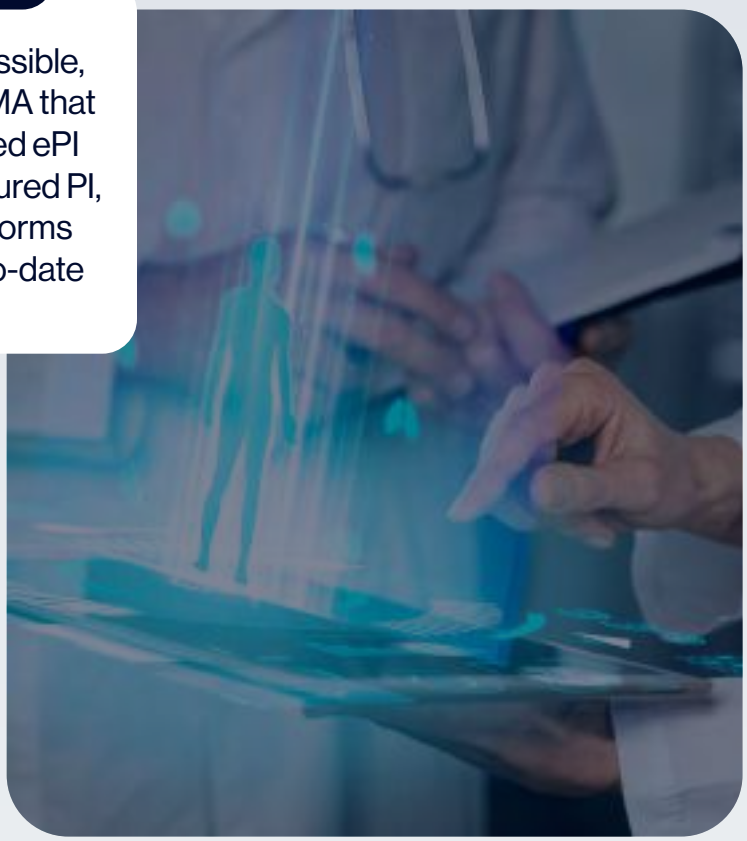
Refers to ePI structured using the FHIR standard developed by HL7. It enables the creation, exchange, and integration of medicine information (e.g., SmPC, PIL) in a machine-readable format, supporting interoperability across healthcare systems and enhancing accessibility, searchability, and multilingual capabilities (EMA, 2023; Health Level Seven International [HL7], 2025).

Product Lifecycle Management (PLM) portal:

Is a secure, web-based platform developed by the EMA that allows MAHs to create, manage, and submit ePI documents. It supports both direct creation of FHIR ePI and submission of externally generated FHIR files, and facilitates regulatory review, publication, and linkage to product data in the Product Management Service (EMA, n.d.-d).

Application Programming Interface (API):

In the context of ePI, an API is a publicly accessible, read-only digital interface provided by the EMA that enables external systems to retrieve published ePI data. It supports automated access to structured PI, enhancing integration with digital health platforms and enabling real-time dissemination of up-to-date medicine data (EMA, n.d.-a).



Preface

Playbook objective and vision

The objective of this Playbook is to offer a comprehensive analysis of the current status and future prospects for ePI in Latin America and the Caribbean region. By examining perspectives from industry, NRAs, and various stakeholders, including patients and HCPs, the ePI Playbook aims to highlight the benefits and challenges of ePI, and share details on the various approaches and technological solutions that could be utilized and adopted for ePI to bring positive changes in the regulatory environment and foster digital transformation in the region. This transformation is expected to be achieved through a structured, step-by-step approach that allows for some flexibility while enabling standardization. Over time, as experience and insights accumulate, this method will lead to progressive improvements, enhancing patient confidence, understanding, and overall healthcare experiences from a PI standpoint.

Ultimately, the vision for implementation of ePI is to enhance the patient's experience by providing information tailored to individual needs, enabling more focused details that encourages better understanding and usage of medications, and facilitating HCPs to make informed decisions based on the latest NRA-approved benefit /risk and prescribing information. Additionally, the vision offers more inclusivity and equity for patients with disabilities and more language options for patients living in a non-native country.

We believe there should be a commitment to innovation and patient safety driving us to adopt pioneering solutions that expedite information sharing and the spread of important educational information such as disease awareness and drug administration content for patients and HCPs alike. ePI is a digital tool that responds to the growing demand for greater interconnectivity among healthcare systems and their users, in particular patients. Additionally, ePI offers the opportunity to streamline regulatory information management processes and can facilitate more efficient communication between manufacturers, NRAs, and HCPs especially when it becomes truly digital and presented in a structured format that makes it interoperable.

What is the Playbook intended for?

The Playbook is intended to provide a detailed examination of ePI for the prescription drugs landscape across Latin America and the Caribbean, capturing the current state and future trajectory from the vantage points of diverse stakeholders in the health ecosystem. The Playbook delves into various approaches adopted within the region, exploring the technological solutions, benefits, and challenges that ePI presents to the population.

By addressing these elements, the Playbook seeks to promote the faster pace of adoption and uptake of ePI, enhance collaborations with NRAs, and foster improvements in the regulatory framework within the region. Ultimately, the Playbook hopes to align and harmonize regulations that not only consider the needs and wellbeing of the patient community but also facilitate regulatory convergence across jurisdictions.

What is the Playbook not to be used for?

The Playbook is not designed to serve as a comprehensive technical manual, regulatory compliance guide, or a substitute for formal training in ePI. It does not cover detailed software development practices, legal interpretations, or country-specific regulatory requirements. Additionally, it is not intended to prescribe a one-size-fits-all solution; rather, it provides general guidance and best practices that should be adapted to the specific needs, infrastructure, and compliance obligations of each country in the region. It is important to note that, as this is a fast-evolving topic, periodic revisions will be required to keep the Playbook up to date and continuing to meet its objective.

1

Introduction

What is labeling, and why is it important?

PI is a critical risk minimization tool used to ensure prescription and non-prescription healthcare products are understood and used safely and effectively by patients in clinical settings (International Federation of Pharmaceutical Manufacturers & Associations [IFPMA], 2022).

PI can be referred to as 'labeling and/or leaflets', but it refers to PI written to provide information for HCPs and/or patients.

Overall, PI provides essential information about a product's safety, efficacy, and quality, and is updated throughout the active life of the medicine (Matsui et al., 2023). Each update to the PI is reviewed and approved by the NRA according to country-specific regulations.

PI plays a pivotal role and is a powerful tool in ensuring patients' understanding of their treatments while also supporting HCPs to execute informed decision making (IFPMA, 2022).

How do patients or HCPs usually read the labeling?

Traditionally, PI has been provided in paper format within the packaging of medicinal products. However, multiple studies have shown that this format often fails to meet the needs of patients and HCPs for clear, accessible, and usable information. According to the PIL-S study (a study on package leaflets and SmPCs of medicinal products for human use), patients frequently find the language in paper leaflets too complex, and the layout and design are often not user friendly — particularly for older adults, individuals with low literacy, or those with visual impairments (European Commission, 2014; EMA, 2020).

To delve into this point further, paper leaflets often present challenges to the reader such as the presentation of unclear information, which is frequently of a small font size, in one color and often content dense because it may be covering more than one presentation or strength of the medicine or because of the required inclusion of more than one language.

Another challenge relates to updating and delivering the latest NRA-approved PI in paper leaflet format for medicines in a timely manner across Latin America and the Caribbean.

Whenever a medicine's PI is updated, the paper leaflet must be updated, translated, NRA approved and printed in readiness for implementation in the next viable manufacturing run of the medicine's production. All these steps result in a process that is complex, inefficient, time-consuming, and environmentally unsustainable. Latest changes to the PI can at times render entire packaging inventories obsolete, as updates must be implemented within legally mandated timelines (Spalvieri & Wait, 2024).

This can be a lengthy and inconsistent process globally, inclusive of Latin America and the Caribbean region, often taking several months to more than a year to be available inside a medicine's pack on a pharmacy shelf and thereafter dispensed to the patient with their latest prescription.

Variability in paper leaflet implementation is largely due to differences in national regulatory frameworks and often because of the way in which supply chains must operate to meet the needs of markets that may share their medicinal products.

Another key consideration is the complexity of changes being made to the PI, especially those involving safety updates or new indications. Such changes can further extend NRA review and approval timelines, as they often require additional clinical data and more rigorous review.

Finally, a major challenge is the lack of harmonization across the region from a regulations perspective regarding the content, structure and management of PI (Ramírez-Telles & Argotti-Rodríguez, 2022). Some countries have well-defined regulatory procedures, while others operate with less structure, leading to inconsistent and prolonged timelines which all have a residual high impact on the management of PI in shared products across shared markets. The lack of harmonized structure and frequent lack of patient-centric information also leads to various experiences for patients and caregivers who are trying to understand the medicine's PI.

Overall, while efforts are being made to streamline and harmonize these processes, the average time to update a paper leaflet remains variable and can be quite lengthy.

What is ePI?

ePI in its basic form makes available the most up-to-date NRA-approved PI on an electronic platform, viewable in a simple and understandable format that can be easily accessed through a machine-readable code or the Uniform Resource Locator (URL) printed on the product carton.

ePI in its most advanced form makes available the most up-to-date NRA-approved PI for the safe and effective use of medicines in a common structured format using electronic global standards. The format can vary from being semi structured to fully structured.

The game-changer for digital transformation is associated with adoption of the structured ePI, because it is in this format that it becomes fully interoperable with web standards and enables a full spectrum of digital advances to become possible with easier connectivity to other healthcare systems and software applications (EMA, 2020). Structured ePI can open a future that, for example, allows advanced searches, personalization, and will ultimately lead to efficient and seamless information flow across manufacturers, regulators, HCPs, and patients.

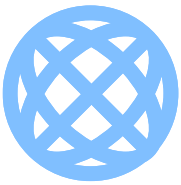
ePI can co-exist with the paper-based PI included in the medicine pack (hybrid model) or it can exist instead of the paper-based PI (paperless model). However, staged withdrawal of paper PI should be encouraged as countries become more confident and mature, and digital literacy and data/internet coverage increases each year. Ultimately, ePI should be pitched as the primary source of PI for the many reasons shared in this ePI Playbook.

The transition from paper-based PI to ePI in the region is essential for improving patient safety, supporting risk minimization, offering a better experience for patients and easing supply chain complexities as well as contributing towards a reduction in CO_2 levels with associated environmental benefits. Indeed, replacing the physical PI with ePI is a tangible and important step in the delivery of sustainable healthcare by reducing the release of CO_2 (IFPMA, 2022).

The growing global interest in ePI aligns with the World Health Organization (WHO)'s *Global Strategy on Digital Health 2020–2025*, which highlights the transformative potential of digital technologies to accelerate human progress, bridge the digital divide, and foster knowledge development. The WHO emphasizes a patient-centric approach, recognizing that digital tools enable data exchange across the health ecosystem, which can enhance health outcomes through data-driven treatment decisions and personalized care (WHO, 2021).

Furthermore, the WHO underscores that digital innovation is a key enabler for achieving the United Nations Sustainable Development Goals, particularly in advancing universal health coverage, protecting against health emergencies, and improving overall wellbeing (WHO, 2024).

Although digital transformation of health care can be disruptive, new technologies—such as the Internet of Things, virtual care, remote monitoring, artificial intelligence, big data analytics, blockchain, smart wearables, platforms, tools enabling data exchange and storage, and tools for remote data capture and information sharing across the health ecosystem—are creating a continuum of care with proven potential to enhance health outcomes. These technologies support improvements in medical diagnosis, data-based treatment decisions, digital therapeutics, clinical trials, self-management of care, and person-centered care, while also contributing to the development of more evidence-based knowledge, skills, and competencies for health professionals (WHO, 2021).



In the Americas, the Pan American Health Organization (PAHO) has echoed these priorities by adapting the WHO strategy into regional action. In 2021, PAHO published the *8 Principles for the Digital Transformation of Public Health,* advocating for inclusive, equitable, and sustainable digital health systems that leave no one behind (Pan American Health Organization [PAHO], 2021).

In 2024, PAHO adopted the *Plan of Action for Strengthening Information Systems for Health 2024–2030*, aiming to improve decision-making, policy development, and health outcome monitoring through enhanced health information systems (PAHO, 2024).

What are the benefits of ePI for different stakeholders across the healthcare continuum?

The adoption of ePI for medicines in Latin America and the Caribbean is relevant for multiple stakeholders including industry, NRAs, HCPs and patients. ePI brings a myriad of benefits, enhancing efficiency, and the accuracy of and accessibility to trusted PI.

Here is a comprehensive overview of the benefits:

Information security and accuracy

Stakeholders benefited: patients, HCPs, MAHs

One of the main benefits of ePI is the guarantee of accessibility to the most up-to-date scientifically-validated PI, approved by the NRA in real time and in corresponding, multiple, if applicable, languages. ePI can make it possible to highlight important changes to the PI, increasing HCP awareness as well as patient safety and security.

The flexibility of ePI allows manufacturers to make quick and accurate updates due to a substantial reduction in the lead time for leaflet printing and packaging, thus ensuring that HCPs and patients always have faster access to the latest PI. This is especially important in emergency situations, where rapid changes can be crucial for patient safety and where novel drugs are launched and latest information is likely to become available (with prior NRA approval) about the safe and effective use of the product (Asia Partnership Conference of Pharmaceutical Associations, 2023; Global Self-Care Federation [GSCF], 2022; Information Technology Industry Council [ITI], 2021; IFPMA, 2022; Spalvieri & Wait, 2024; United States Government Accountability Office [GAO], 2013).

Improved treatment understanding and adherence

Stakeholders benefited: patients, HCPs, healthcare systems

Treatment adherence is a global challenge with almost 50% of people not taking their medicines as prescribed. It is widely accepted that poor understanding of and adherence to PI is directly linked to poor health outcomes and higher costs for national healthcare systems. ePI has the potential to improve adherence by providing personalized approaches and information to the patient, including reminders and alerts about the correct dosage and expiration dates.

We have also seen that electronic versions of drug labeling have a search function, which facilitates physicians' and pharmacists' access to important safety information, such as potential warnings and drug interactions.

We know from research that ePI can be adjusted to user preferences, can make available approved regulatory translations, and can utilize new formats such as audio and visual which is especially relevant for patients with visual impairments.

Additional features may include explanatory videos, interactive diagrams, and other multimedia resources that make instructions for use and possible side effects of medications easier to understand. This is critical to ensure that patients correctly follow the recommendations for use, thus reducing the incidence of medication errors (Asia Partnership Conference of Pharmaceutical Associations, 2023; GSCF, 2022; IFPMA, 2022; Spalvieri & Wait, 2024; GAO, 2013).

Labeling customization

Stakeholders benefited: patients, HCPs, healthcare systems

ePI allows for the personalization of drug information, adapting it to the needs, preferences and abilities of each person. ePI can offer specific information depending on a person's current medication use, highlighting any risk of contraindications or interactions. This is particularly important for people with multiple conditions who may be taking multiple medications prescribed by different doctors. Personalization can improve outcomes as people have access to more relevant and understandable information (Spalvieri & Wait, 2024; GAO, 2013).

Inclusion and accessibility

Stakeholders benefited: patients, HCPs, healthcare systems

ePI offers accessibility to consumers with diverse needs, such as the elderly, visually impaired, hearing impaired or with low literacy, empowering them to manage their health. Patients can benefit from solutions such as large-sized font, searchable format, high screen contrast and audible formats (use of screen readers and other software that makes information more accessible).

The portability of digital information provided by ePI is especially useful for people who have difficulty accessing healthcare facilities. During the COVID-19 pandemic, telemedicine demonstrated the value of improving access and support for people in rural or remote areas. Similarly, ePI can be made available instantly to people receiving medicines, regardless of their geographical location. ePI can provide information in multiple languages, making it accessible to a broader audience without the constraints of physical space (Asia Partnership Conference of Pharmaceutical Associations, 2023; GSCF, 2022; ITI, 2021; IFPMA, 2022; Spalvieri & Wait, 2024; GAO, 2013).

Advantages for national regulatory authorities

Stakeholders benefited: NRAs, MAHs

ePI simplifies regulatory oversight by enabling real-time monitoring of electronic databases to which labels are linked. This approach not only improves product traceability but also facilitates regulatory compliance and efficient enforcement of standards, resulting in a more robust and responsive system (ITI, 2021; Spalvieri & Wait, 2024).

Integration with digital health initiatives

Stakeholders benefited: patients, HCPs, healthcare systems

ePI is a crucial part of the broader digitalization of health systems. ePI can be integrated with electronic health records and electronic prescribing platforms, creating a more personalized, efficient, and consolidated healthcare system. This integration can provide up-to-date data on medications as part of a person's overall health record, improving treatment safety and efficacy (Asia Partnership Conference of Pharmaceutical Associations, 2023; IFPMA, 2022; Spalvieri & Wait, 2024).

Environmental impact and sustainability

Stakeholders benefited: planet and all

One of the most significant benefits of ePI is the reduction in environmental impact. In 2022, 100 billion PI leaflets were printed worldwide. The transition from paper labels to electronic labels decreases physical waste and material usage, contributing to environmental sustainability.

The production of paper inserts involves a supply chain that generates a significant carbon footprint, from the extraction of raw materials to production, transportation, and disposal. The adoption of ePI will contribute to the reduction of this carbon footprint, aligning with global efforts for more sustainable and climate-resilient healthcare systems.

Additionally, without the need for bulky paper inserts, product packaging can be more compact, leading to less material use and lower transportation emissions. ePI can also contribute to medicinal pack harmonization across multiple countries contributing to environmental sustainability (Asia Partnership Conference of Pharmaceutical Associations, 2023; GSCF, 2022; ITI, 2021; IFPMA, 2022; Spalvieri & Wait, 2024; GAO, 2013).

Operational efficiency for the pharmaceutical industry

Stakeholders benefited: MAHs

For the pharmaceutical industry, ePI offers several economic and operational advantages. ePI can simplify the sharing of new PI, speeding up and facilitating the processes of regulatory applications to label information. Digital formats allow for more detailed information without the need for product package redesigns. This has a positive effect on managing drug shortages and strengthening global pharmaceutical supply chains. In addition, eliminating the need to print labels allow for faster access to new products and reduces operating costs.

Additionally, ePI can integrate with inventory management and logistics systems, allowing for more efficient traceability and quick response to product recalls. Digitizing labeling also facilitates real-time data analysis, allowing MAHs to quickly adjust their processes and continuously improve the quality of their products.

Additionally, ePI can significantly reduce the costs of distributing instruction leaflets. Instead of sending large amounts of paper to various parts of the world, information can be updated and distributed instantly digitally. This not only saves financial resources but also accelerates the delivery of crucial information for the safety and efficacy of medicines (Asia Partnership Conference of Pharmaceutical Associations, 2023; GSCF, 2022; ITI, 2021; Spalvieri & Wait, 2024).

Overall, ePI presents a modern, efficient, and sustainable solution for providing PI. Its benefits span from environmental sustainability and cost savings to improved accessibility and regulatory compliance, making it a valuable innovation for both consumers and industries.

What are the challenges of ePI? And possible solutions to those challenges?

Equitable internet access and mobile connectivity

The diffusion of the internet has dramatically reduced informational frictions and given people unprecedented sources of health information. Internet access is found to be positively correlated with the use of healthcare and health outcomes, underlining its growing importance as a valuable source of health-related information (Yu & Meng, 2022).

Improving access to the internet and smart mobile phone usage is of the utmost importance for achieving an equitable implementation of ePI in which access to information is guaranteed for the entire population, leaving no one behind.

Internet and mobile access in Latin America and the Caribbean has progressed significantly in recent years, although a closer look highlights the challenges of achieving full digital inclusion in the region.

Although the average internet penetration rate in the region was 74.63% as of February 2025 (Statista, 2025), a pronounced digital divide persists. While urban areas enjoy widespread connectivity, rural communities and marginalized groups remain significantly underserved. In Latin America and the Caribbean, internet access in urban households was nearly twice that of rural households (74.8% vs. 35.8%) and, in some countries, fewer than 20% of rural homes are connected (United Nations Development Program, 2024).

By the end of 2024, 64% of the population in Latin America was using mobile internet, equating to 413 million users – an increase of 180 million since 2015 (GMSA, 2025). Uptake is particularly important in rural areas, where fixed broadband is less available. Less than 50% of Latin America has fixed broadband (World Economic Forum, 2024).

Although the numbers are promising and have grown exponentially over the years, the region continues to face the challenge of the gap between those who have access to technology and those who do not. Internet and mobile connectivity are not equally accessible to everyone (Inter-American Development Bank [IDB], 2023). Bridging the gap is crucial to ensure equitable healthcare access for all (Marzouk et al., 2023).

Possible solutions and actions for consideration:

- Invest in expanding internet and mobile infrastructure in rural and underserved areas, including deploying more broadband networks and enhancing mobile connectivity. Encouraging collaboration between governments, private sector companies, and international organizations can fund and implement connectivity projects, leveraging resources and expertise to accelerate progress (IDB, 2023).
- Developing affordable or free internet and mobile service plans linked to medical information that is tailored to low-income populations, along with subsidies or financial assistance programs, can make connectivity more accessible.
- Implementing educational programs to improve digital literacy is crucial for ensuring that people can effectively use the internet and mobile technologies, maximizing the benefits of increased connectivity.
- Governments could create supportive policies and regulatory frameworks that encourage investment in connectivity infrastructure and protect consumer rights. These frameworks should also promote interoperability and data privacy to build trust in digital health solutions.
- Establishing mechanisms to regularly monitor and evaluate the progress of connectivity initiatives will help identify gaps and areas for improvement, ensuring that efforts are effective and equitable.
- Leverage experience and knowledge from non-health care industries such as banking or fashion which have adopted digital tools and from government-driven digitalization initiatives outside the healthcare context, such as digitalization of driving licenses, registrations etc.
- Leverage digital health tools such as ePI to drive demand for connectivity by demonstrating tangible health benefits. As highlighted by the European Federation of Pharmaceutical Industries and Association's Inter-Association Taskforce, ePI can serve as a catalyst for digital health adoption by improving access to up-to-date, user-friendly medicine information, especially in regions where printed leaflets are less accessible or frequently outdated (European Federation of Pharmaceutical Industries and Associations [EFPIA], 2025).

Improving electronic access to PI in Latin America and the Caribbean

Few health authorities in Latin America and the Caribbean region currently publish PI on their official websites, limiting the ability of patients and healthcare professionals to access accurate and up-to-date data (Ramírez-Telles & Argotti-Rodríguez, 2022). Digital platforms can ensure timely updates, improve usability for diverse populations, and align with global trends toward modernization. Strengthening this infrastructure will help bridge information gaps and support better health outcomes throughout Latin America and the Caribbean.

While some countries are making strides towards digital updates, the overall adoption of ePI remains low due to insufficient investment in digital infrastructure and varying regulatory frameworks. Countries in the region and globally are at different stages in this transition; some countries are discussing legislation to completely replace paper-based information, while others are only contemplating ePI as a complementary tool to paper formats. Although the pace of change may vary considerably between countries globally, the direction towards digital platforms seems clear and inevitable (Spalvieri & Wait, 2024).

Possible solutions and actions for consideration:

- Encouraging collaboration between governments, MAHs, and technology providers can help develop and maintain ePI platforms, leveraging resources and expertise to accelerate the transition to digital information.
- Establishing mechanisms to regularly assess the effectiveness of ePI initiatives will help identify areas for improvement, ensuring that the information provided is accurate, up-to-date, and accessible to all.
- Designing ePI platforms to be user friendly and accessible to individuals with disabilities and low literacy levels is crucial to increase the uptake and benefits for all. Incorporating clear language, visual aids, and compatibility with assistive technologies generates added value for users which would ensure good use of resources and investment made.

Inconsistent uptake of digital health solutions

Digital health adoption in the region has accelerated in recent years, driven by the need for improved healthcare delivery, especially in the wake of the COVID-19 pandemic. Although the improvements are promising, recovery remains uneven, and ongoing efforts are needed to address the long-term impacts of the pandemic in the healthcare system (Transform Health, 2023).

Progress is uneven, with substantial disparities in digital health infrastructure, policies, and systems across the region. Only a few countries have comprehensive digital health strategies and legislation for electronic medical records. The region's health information systems remain fragmented, underfunded, and underutilized, posing significant challenges to the widespread adoption of digital health technologies (IDB, 2022).

Countries in Latin America and the Caribbean region vary in their maturity levels regarding digital health infrastructure, systems, policies, and approaches. According to a publication issued by the International Development Bank in April 2022, in terms of health, only 11 countries in the region have legislation that defines and validates electronic medical records, and only 14 of the 26 countries have a digital health strategy. At the same time, health information systems in the region are isolated, fragmented, underfunded, and underutilized (IDB, 2022).

The WHO recognizes the pressing need to invest in efforts to overcome the major impediments faced by least-developed countries in engaging with and accessing new digital health technologies (WHO, 2021).

Possible solutions and actions for consideration:

- Developing and implementing standardized systems and interoperability frameworks will facilitate seamless data sharing across different HCPs, reducing inefficiencies and improving patient care.
- Establishing robust regulations and infrastructure to protect sensitive medical data from unauthorized access and misuse is vital for building trust in digital health solutions.
- Implementing educational programs to improve digital literacy among HCPs and the general population can help overcome cultural resistance and ensure effective use of digital health technologies.
- Creating clear and supportive policies that encourage the adoption and scaling of digital health initiatives is necessary, as consistent regulatory frameworks across countries will foster innovation and facilitate implementation.
- Encouraging collaboration between governments, HCPs, and the private sector to fund and develop digital health technologies can leverage resources and expertise to accelerate progress.
- Allocating sufficient funding and resources to support the development and deployment of digital health technologies, including addressing the economic impacts of the COVID-19 pandemic, is essential.

ePI challenges for diverse populations

In the digital era, ensuring equitable access to ePI is essential for diverse populations, including elderly individuals, people with low literacy skills, and those with disabilities. While ePI offers customizable and scalable solutions, it also presents challenges that must be addressed to ensure inclusivity.

Elderly patients often face barriers such as limited digital literacy, vision impairments, and concerns about data security. Simplified interfaces, adjustable display settings, and personalized support programs such as HelpAge Canada's Dig-IT initiative can significantly improve usability and confidence among older adults (HelpAge Canada, 2023).

AMERICAN PSYCHOLOGICAL ASSOCIATION

Research from the American Psychological Association emphasizes the importance of intuitive design tailored to cognitive and physical needs (American Psychological Association, 2021).

Individuals with low literacy skills may struggle with comprehension, navigation, and access to digital tools. Several initiatives and frameworks have emerged to support such individuals in navigating digital health tools. The Digital Health Care Equity Framework developed by Johns Hopkins Bloomberg School of Public Health emphasizes participatory design, culturally relevant tools, and equity monitoring to ensure digital health solutions are inclusive and accessible (Johns Hopkins Bloomberg School of Public Health, 2025). The National Action Plan to Improve Health Literacy by the U.S. Centers for Disease Control and Prevention promotes the use of plain language, culturally appropriate communication, and community-based education to enhance health literacy across diverse populations (Centers for Disease Control and Prevention, 2024). Additionally, the Digital Equity Initiative's policy brief advocates for integrating digital literacy education into healthcare services, using visual aids and trusted community spaces such as libraries and places of worship to build digital skills among vulnerable groups (Digital Equity Initiative, 2024).

People with disabilities require ePI systems that are compatible with assistive technologies and compliant with accessibility standards such as the Web Content Accessibility Guidelines (WCAG). Organizations such as the World Wide Web Consortium (W3C) Web Accessibility Initiative advocate for universal design principles to ensure usability across diverse abilities (World Wide Web Consortium [W3C], 2025).

Addressing these challenges requires thoughtful design, regulatory compliance, and ongoing user education. By prioritizing accessibility and inclusivity, ePI can become a powerful tool for improving health literacy and outcomes across all populations.

2

Foundational considerations for adoption of ePI

To ensure a seamless transition to ePI, it is critical that a minimum viable regulatory framework or pilot agreement with the relevant NRA is in place. This allows market conditions and/or NRA concerns to be taken into consideration, minimizing risks, impacts, and compliance issues.

Increasing users' (i.e., patients, caregivers, and HCPs) literacy on the matter (health- and digital-wise) is essential to allow the benefits of ePI to be achieved as much as possible. Engaging stakeholders such as users themselves, HCP councils and pharmacies, through educational campaigns, can address concerns and potential impacts, as well as foster acceptance and support the ease of transition.

Hence, a policy-shaping plan with the NRA and other stakeholders is essential for success. Additionally, it is important to foster cross-industry collaboration through trade associations to ensure a unified and standardized approach to ePI across the pharmaceutical sector. This collaboration can help address common challenges and share best practices, leading to more efficient and effective implementation.

Transitioning to ePI can be phased in if the NRA and pharmaceutical companies find it necessary, starting with hybrid models and gradually moving towards a paperless model, possibly restricted to certain product categories (e.g., HCP-administered products). A phased approach allows for an understanding of the challenges without disrupting supply or interfering with collection of feedback for continuous improvement.

Likewise, transitioning from portable document format (PDF) to structured formats, alongside incorporating advanced usability and communication tools such as text-to-speech, videos, and images, is essential for effective communication with patients of varying abilities. It is important to consider whether the platform should focus solely on PDFs or adopt structured formats such as FHIR, and other supplemental tools. While structured formats demand a larger initial investment, they offer greater scalability and support for future needs. In contrast, PDF-based solutions are easier to implement and are well-suited for pilot projects and proof-of-concept experiences and learnings.

Pilot programs can identify issues and gather insights before full-scale rollout. The collected data, data privacy best practices and legal frameworks support decision-making for further steps. It is also possible to request data insights and learnings from markets that have completed pilots. By applying these insights, certain groups of medicines could transition to ePI. This approach would ease the process towards full adoption of ePI, allowing learnings to be evaluated firsthand to enhance local ePI implementation.

Alternative methods for providing paper versions, such as print-on-demand services, should be considered for those without internet access. Cross-sector collaboration is crucial to address any challenges or concerns and to ensure that the move to paperless does not inadvertently exclude any segment of the population.

Access (codes) – options

In today's digital age, as the public increasingly seeks health information online, ePI offers a convenient and trusted way to access NRA-approved PI (IFPMA, 2022). Providing user-friendly access is a key aspect of ePI. This involves linking the label directly through a machine-readable code, which is also presented in a human-readable format on pharmaceutical product packaging. This setup enables end-users, such as HCPs, patients, consumers, and caregivers, to access PI electronically and in real time, thereby improving the user experience compared to traditional paper leaflets (Asia Partnership Conference of Pharmaceutical Associations, 2023).

In the context of pharmaceutical products, two primary accessibility formats for ePI are recognized: uniform resource locator (URL) and two-dimensional (2D) barcodes. Each format has unique definitions, applications, advantages, and disadvantages.

The URL is an identifier for a web resource that indicates its location on a computer network and provides a means for access. URLs direct users to an online platform where the ePI is hosted. This format allows for real-time updates, ensuring immediate access to the latest information without requiring physical changes to product packaging. Additionally, URLs support comprehensive and multimedia content, making them accessible from any internet-connected device. Drawbacks include dependency on internet access, the necessity for users to have digital literacy, and the need to be aware of potential data security risks (TechTarget, 2024; FDA, 2010). Additionally, this format does not require a device or application for access, but it does require the user to manually enter the URL text into a web browser to access the ePI or ePI platform. A manual entry can lead to encoding errors and inconvenience. Furthermore, printing the URL on packaging can be challenging, especially if the text is long or space is limited. Lengthy URLs are not recommended (Asia Partnership Conference of Pharmaceutical Associations, 2023).

2D barcodes, such as quick response (QR) codes and data matrix (DM) codes, are graphical representations that store information. Printed on product packaging, these codes can be scanned with compatible devices to provide direct access to ePI, either embedded within the code or hosted online. Advantages of 2D barcodes include high data capacity, offline accessibility when data are embedded in the code, and quick information retrieval through scanning. Limitations include the need for specialized equipment such as smartphones or barcode scanners, space constraints on packaging, potential challenges in maintaining symbol effectiveness when reduced dimensions are required, such as decreased readability, specialized equipment needs, and increased costs. These constraints highlight the importance of careful consideration when implementing reduced-dimension barcodes (EFPIA, 2024; GS1 US, n.d.; GS1, 2018; IFPMA, 2022).

Differences between URLs and 2D barcodes

	URLs	2D barcodes
Functionality	URLs are used to locate resources on the internet.	2D barcodes are used to encode data in a compact form.
Usage	URLs are accessed via web browsers.	2D barcodes are scanned using barcode scanners or mobile devices.
Data capacity	Simple address information in URLs.	2D barcodes can hold more data.

Sources: GS1, 2024; GS1, n.d.

In today's current climate, for ease of pilots and progress PI is being made available online, using two widely used electronic standards: PDF (Portable Document Format) and HTML (HyperText Markup Language).

Note: these formats do not offer standard adoption of FHIR ePI:

- PDFs, developed by Adobe, preserve document formatting across platforms and devices. They ensure consistency, enable offline access once downloaded, and offer security features such as encryption and password protection. However, PDFs can have large file sizes, limited interactivity compared to web-based formats and may be difficult to view on devices with smaller screens (Adobe, n.d.).

- HTML, the foundational language for web pages, supports interactive and dynamic product labels. Its advantages include flexibility for incorporating multimedia, responsiveness across devices, and ease of central updates. However, HTML relies on internet connectivity, may encounter browser compatibility issues, and requires robust security measures to mitigate web-based threats (W3C, 2018).

Differences between PDF and HTML

	PDF	HTML
Functionality	PDFs are static documents that preserve the original formatting.	HTML is used to create dynamic web pages.
Usage	PDFs are typically downloaded and viewed using PDF readers.	HTML content is accessed through web browsers.
Interactivity	PDFs are generally static.	HTML allows for interactive elements such as hyperlinks and forms.

Sources: Asia Partnership Conference of Pharmaceutical Associations, 2023; W3C, n.d

The selection of an ePI format depends on factors such as regulatory requirements, target audience, a product's context of use, and available user resources. Successful implementation of ePI requires balancing accessibility, traceability, cybersecurity, and information richness to meet the needs of patients and HCPs (Loh et al., 2024).

Platforms (centralized vs decentralized) – options

ePI platforms are digital systems that store and manage PI, making it accessible to users. Digital systems include apps, software or websites and tools such as computers, mobile devices and wearables. These platforms can range from centralized databases hosted by NRAs or industry organizations (third parties) to private systems, or decentralized, managed by MAHs, including proprietary repositories maintained by industry. ePI platforms can facilitate the dissemination of approved PI, thus enabling efficient searching, reusability, and interoperability with other digital healthcare systems especially when the PI is in the fully structured ePI format (EMA, 2020; IFPMA, 2022).

Repository models

ePI repositories can be managed by MAHs, third parties or operated by NRAs. Each model has distinct characteristics, advantages, and challenges **(Table 1).**

1 *Regulatory authority-managed repositories*

Regulatory authority-managed repositories are centralized systems operated by NRAs to store and disseminate ePI content. This ensures standardization, consistent presentation and dissemination of information across products according to regulatory compliance. Drawbacks include potential delays in content updates due to administrative processes, limited customization options because of standardized systems, and reduced flexibility for the MAHs (EMA, 2024).

To mitigate the drawbacks of regulatory authority-managed platforms, an effective strategy can be to engage NRAs in developing a pilot project. Pilot initiatives provide an opportunity to evaluate the system and offer constructive feedback for improvements. Incorporating user feedback into the development process ensures that platforms are intuitive, accessible, and aligned with user needs, enhancing overall usability and satisfaction (EMA, 2024).

2 *External (third-party) vendor managed repositories*

ePI will also be accessible to third parties who can reproduce and distribute the information to patients and HCPs via a centralized system. A central system has the advantage of offering a standard 'look and feel' of every PI regardless of the products' MAH. Third parties include any entities other than regulators and a medicine MAH; these could encompass companies, not-for-profit organizations, academic institutions, and patient or consumer groups. Examples of such third-party entities are the United Kingdom's Electronic Medicines Compendium

(**https://www.medicines.org.uk/emc#gref; emc, n.d.**) and Norway's Felleskatalogen (**https://www.felleskatalogen.no/medisin/; Felleskatalogen, n.d.**).

3 *MAH repositories*

MAH repositories are decentralized repositories maintained and controlled by the MAH. They provide greater flexibility and customization. As the decision maker, the MAH would choose how to present the ePI taking into consideration any NRA guidance. MAH repositories allow for rapid updates, tailored user experiences, and integration of advanced features. However, they require significant investment in development and maintenance, adherence to strict regulatory guidelines, and robust measures to ensure impartiality and trustworthiness (IFPMA, 2022; Loh et al., 2024; National Electrical Manufacturers Association, 2023).

To develop an effective company-owned ePI repository, MAHs must ensure regulatory compliance by adhering to guidelines from NRAs and implementing regular updates to align with evolving standards. It is also advantageous for MAHs to consider data interoperability as a core consideration throughout the development process, starting from design of the ePI, to ensure seamless integration across platforms and systems. The decision to offer a fully structured ePI is the critical decision point that enables the full features of true digital transformation.

Table 1

Summary of the pros and cons of each repository option.

Repository NRA	PROS	CONS
	Central platform and single trusted site for HCPs, patients and caregivers	Set up and maintenance delays due to knowledge, high investment and a resource burden that some authorities will not be able to assume in the short or medium term
	Ease of use for users who wish to view information on more than one medicine that may have different MAHs	
	One standard look and feel of site encouraging familiarization on repeat visits by users	
	Possibility to link with other national healthcare systems	
	Could be subsided by fees paid by the MAH	

Repository MAH

PROS

- Total ownership & maintenance will be dependent on the MAH
- Trusted site
- Potentially better change control management in terms of updates and availability of newly-approved PI
- Ability to capture data analytics
- Flexibility in terms of:
  - Customization of the website (look & feel) by the MAH (this could be a con for users)
  - Information to be shared: in addition to sharing ePI, additional information approved by the NRA which benefits the patient such as videos, non-promotional educational material, etc

CONS

- Total ownership will be dependent on the MAH which may not have the level of knowledge, investment or resources available to set up and maintain a website; this may mean that especially middle-small sized companies may not adopt or offer very basic functionality and features
- Full responsibility on the MAH for ensuring compliance with local laws and regulations
- Full responsibility on the MAH to ensure robust security for establishing a trustable source of information
- Patients taking more than one medicine may have different experiences depending on the medicine's MAH. Accessing different sites may be a deterrent to update for some patients
- HCPs may not be able to easily compare and search when looking at two or more medicines that may be being prescribed for their patient

Repository External (third-party) vendor

PROS

- Central platform and single trusted site for HCPs, patients and caregivers
- Ease of use for users who wish to view information on more than one medicine that may have different MAHs
- One standard look and feel of site encouraging familiarization on repeat visits by users
- Cost and resources can be shared through the pharmaceutical industry (MAHs) partnership (this could also be a con)
- Potentially better change control management in terms of updates and availability of newly approved PI via Service Level Agreements
- Total ownership & maintenance will be dependent on the third party which can include a mechanism for MAHs to upload their PI directly to the external third-party vendors' platform
- In addition to sharing the ePI, additional information approved by the NRA that benefits the patient such as videos, non-promotional educational material could be made available
- Full responsibility on the third party to ensure robust security for establishing a trustable source of information
- Opportunity for platform improvement based on input from the MAH to address needs not initially foreseen during the early stages of implementation

CONS

- Full responsibility on the MAH for ensuring compliance with local laws and regulations and managing change control
- Monitoring and oversight of the external vendor operation by the MAH will be essential to ensure compliance
- This option might reduce the NRA /MAH effort to maintain the PI externally. However, this will require high investment and maintenance processes in house, which may not be feasible for middle-small sized companies especially local companies
- Development and further investment in the third-party site could be slow

Information and user security

Ensuring a robust, uninterruptible, responsive and secure ePI platform is critical. Therefore, a well-defined contingency plan must be developed to guarantee that, in the event of technical failures or system unavailability, critical PI remains accessible to HCPs and patients.

The plan should be co-created with all key stakeholders such as NRAs, MAHs, HCPs and patients so that all aspects are considered, resulting in clear and concise instructions being recorded. For an example plan, please refer to ***Appendix A*** where an outline has been shared from the Centers for Medicare & Medicaid Services guidelines for effective risk management and contingency planning.

By implementing a robust contingency plan, stakeholders can ensure the continuity and reliability of ePI platforms, safeguarding access to critical PI in all circumstances.

Robust security measures are essential to protect sensitive data and comply with privacy regulations. Additionally, the repository should support real-time updates, version control, and ideally incorporate non-promotional multimedia educational elements that enhance both accessibility and user comprehension (GDPR, n.d.; GSCF, 2022).

Maintaining traceability of changes is also essential to ensure the integrity and compliance of ePI repositories. Tools such as version control systems, audit trails, and change logs are crucial for tracking modifications, documenting updates, and validating compliance with regulatory standards. The adoption of these tools not only ensures compliance with NRA regulations but also strengthens the reliability and transparency of ePI systems, supporting the lifecycle integrity of PI (IFPMA, 2021).

According to the EMA's ePI Pilot Report, ensuring compliance in uploading labels in a timely manner and maintaining version control for ePI involves several key strategies (EMA, 2020). Please refer to ***Appendix B*** where the key strategies have been included for reference.

Understanding for patients (health literacy plus the value of educational materials, patient-friendly content, plus digital literacy) and HCPs (educational materials for devices, solutions, etc)

To ensure the successful adoption of ePI, a strategic communication plan must address the specific needs of HCPs and patients, with particular attention to elderly patients, those with disabilities and their caregivers, who may face challenges adapting to digital platforms. For an example plan, please refer to ***Appendix C*** where an outline has been shared from the WHO Guidance on Strategic Communications Framework to support an effective communication plan.

It is crucial to evaluate the impact of communication efforts to ensure they achieve their objectives. Assessments should determine whether messages reached the target audience, improved understanding, and influenced behaviors. Evaluations should identify strengths, uncover gaps, and provide actionable insights for continuous improvement, ensuring communication strategies remain relevant and effective throughout ePI implementation.

3

Global ePI status (guidances, pilots)

Valuable insights from ePI implementation in various regions worldwide offer critical lessons and insights. Leveraging these examples and fostering experience-sharing can facilitate a more agile approach, enabling countries to achieve the proposed goals of ePI collaboratively and more efficiently.

A snapshot of ePI progress in some key international markets

The regulatory landscape for ePI is evolving globally, with varying degrees of implementation across different regions:

Australia:

PI/PIL must be made available to patients and HCPs via the Health Authority's website for all products. Flexibility for paper PIL provided in non-parenteral product packs has been in place since 1990. In 2023, the flexibility widened to parenteral products administered by the HCP. Only self-administered injectables and devices require paper PI and paper instructions, respectively, for use in packs (Therapeutic Goods Administration, 2024).

Japan:

The Pharmaceutical and Medicinal Devices Agency (PMDA) in Japan has made significant advancements in ePI regulations. In 2019, the Ministry of Health, Labour and Welfare introduced regulations to replace paper labeling with ePI for prescription drugs and medical devices. These regulations began enforcement on August 1, 2021, with a transition period leading to a fully paperless system by July 2023. The PMDA has long required pharmaceutical companies to submit Standard Generalized Markup Language (SGML) versions of the Japanese Package Inserts (JPIs), which are the HCP labeling documents. Starting in 2019, PMDA began transitioning from SGML to XML, a more modern and flexible format. This transition was scheduled to be completed by March 2024.

Jordan:

The Jordan Food & Drug Administration (JFDA) has initiated the implementation of ePI using FHIR standards and enabling access to pharmaceutical labels via a 2D barcode or DM codes on outer packaging, with advanced features such as text-to-speech, accessibility tools, interactive content, dynamic updates, augmented reality, and support for individuals with special needs. JFDA's ePI system was launched in July 2024 with mandatory implementation set for November 2025 following a six-month grace period. The e-labeling framework includes three components: a dedicated system for submitting and accrediting electronic leaflets, a centralized submission and approval platform, and an artificial intelligence (AI)- and augmented reality (AR)-powered mobile app (XML Viewer) for patients and healthcare professionals to read and interact with pharmaceutical information.

United States:

Currently, ePI is not implemented in the U.S. The FDA mandates that risk: benefit information for drug products be available in print form when dispensed. However, some labeling exemptions exist, particularly for prescription devices used in healthcare settings. The FDA has proposed new rules to allow electronic options for patient medication information, expanding choices for patients while maintaining the requirement for paper formats. Additionally, the FDA has adopted Structured Product Labeling (SPL), a standardized format developed by HL7, to support the electronic exchange of product and facility information.

Europe:

The EMA, together with an Innovative Health Initiative project called Gravitate Health and under the umbrella of the HL7 standards development organization, developed the ePI Common Standard, which was adopted by the EMA in September 2021. This standard includes technical specifications for ePI and is part of a broader initiative involving the EMA and NRAs.

In the European Union, a comprehensive pilot program was undertaken supported by EU4Health funding to evaluate the feasibility of incorporating ePI into existing regulatory frameworks. The findings of the pilot program were positive, indicating no significant barriers to the integration of ePI with current systems. While recommendations for enhancements were noted, the overall results strongly support progress towards ePI implementation using the FHIR ePI standard.

The implementation strategy involves a future go-live at the EMA, followed by expected adoption by early-adopter National Competent Authorities (NCAs). In this pilot, key participation came from Spain (AEMPS), Denmark (DKMA), the Netherlands (MEB), and Sweden (MPA), all of which played significant roles working with MAHs in managing and supporting the pilot project.

Specific actions planned throughout 2025 aim to prioritize the development of essential functionalities crucial for the successful integration of ePI.

In summary, recognizing the needs of patients (patient-centered proposal), a smooth transition towards ePI and the steps associated with moving towards a fully digital-only healthcare ecosystem need to be agreed upon. Implementation of electronic labeling will require a case-by-case assessment in each country/region and adoption of measures that ensure, as necessary, an adequate implementation of the concept (e.g., adopting temporary hybrid transition periods, providing printed paper leaflets in ‘just in time’ pharmacies.

4

Latin America and the Caribbean ePI status

Regulatory framework opportunities in the region

The Latin America and the Caribbean landscape presents contextual challenges in drug labeling, particularly regarding information access and accessibility, and regulatory frameworks (EMA, 2024). To effectively address the region's specific needs and complexities, it is imperative to comprehend and strategize around these challenges. The transition towards digital transformation in drug labeling, notably ePI, necessitates a nuanced understanding of the existing contextual barriers to ensure the efficacy and inclusivity of any initiative. Barriers encompass disparities in information accessibility due to socioeconomic factors, technological infrastructure, and linguistic and literacy diversity, as well as fragmented regulatory environments with varying requirements across different countries, impacting the standardization of ePI practices.

From a regulatory standpoint, crafting a framework that aligns with global standards and facilitates the implementation of an ePI roadmap is expected to have a significant positive impact on key activities such as track and trace (serialization), pharmacovigilance, and post-marketing surveillance (Ramírez-Telles & Argotti-Rodríguez, 2022). Some countries in the Caribbean region continue to face challenges of having a formal and updated framework for drug labeling (EMA, 2024).

Harmonized regulations across multiple countries will enhance the adoption of ePI, improve efficiency, and support the development of central, trusted ePI platforms. These platforms, whether regional or national, and overseen by NRAs, should adhere to globally harmonized standards and fundamental principles (Ramírez-Telles & Argotti-Rodríguez, 2022). In the region, informal reliance on previously approved information by reference agencies has made the NRA review of PI more efficient and predictable. This approach accelerates the availability of information, a process that could be further enhanced through ePI, especially for shared products that are quite common in the region and which could further support the efforts of regulatory convergence.

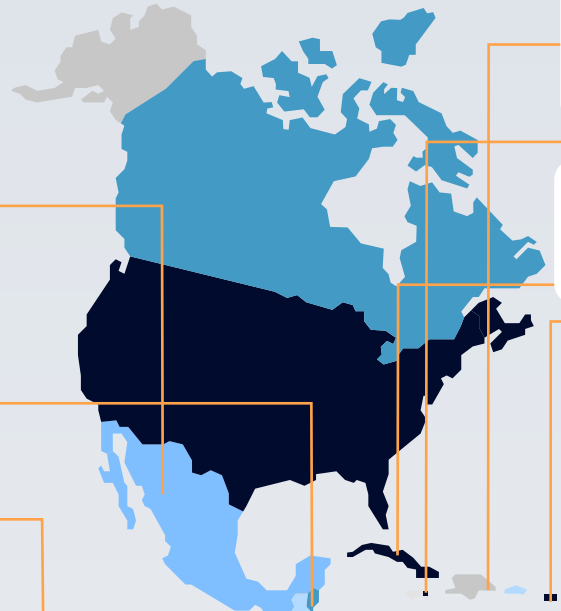
A snapshot of ePI progress in Latin America and the Caribbean markets

A key challenge in the global implementation of ePI lies in the harmonization of overarching approaches, processes, and standards, particularly given the rapid advancements in technology within this domain (Ramírez-Telles & Argotti-Rodríguez, 2022). In this context, it is crucial to evaluate the progress achieved in each country to prioritize efforts and integrate them effectively with existing initiatives. In alignment with the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) position paper (Ramírez-Telles & Argotti-Rodríguez, 2022), the adoption of a unified global technical standard, such as HL7's FHIR, along with the voluntary and flexible implementation of globally harmonized 2D barcodes, are vital steps that need to be taken. These actions aim to facilitate seamless global information exchange and establish a direct link between packaging and ePI. Addressing these aspects will enhance the end-user experience and unlock the full potential of ePI benefits.

As outlined below **(Table 2)**, the Latin American and Caribbean region exhibits varying stages of progress concerning key elements required to bring added value to the patient and health ecosystem. The elements follow the stepwise approach suggested by IFPMA for a roadmap to guide the implementation of ePI (Ramírez-Telles & Argotti-Rodríguez, 2022): centralized electronic national platform, machine-readable codes in drug packaging, transitory policy to streamline the requirement of printed PI, and a structured format to allow interoperability and data exchange with other systems.

Table 2

Mapping key ePI milestones in Latin American and Caribbean countries.



Dominican Republic
- NA
- NA
- NA

Jamaica
- NA
- NA
- NA

Mexico
- NA
- NA
- NA

Cuba
- X
- NA
- NA

Sint Maarten
- NA
- NA
- NA

Belize
- NA
- NA
- NA

Costa Rica
- NA
- NA
- NA

Curacao
- NA
- NA
- NA

Guatemala
- NA
- NA
- Case-by-case

Guayana
- NA
- NA
- NA

Suriname
- NA
- NA
- NA

El Salvador
- X
- NA
- NA

Honduras
- NA
- NA
- NA

Colombia
- X
- NA
- Paper coexisting with electronic versions

Venezuela
- X
- NA
- NA

Trinidad and Tobago
- NA
- NA
- NA

Ecuador
- NA
- NA
- NA

Peru
- X
- NA
- NA

Panama
- X
- NA
- X (if redirected to the NRA platform)

Brazil
- X*
- Under discussion
- Partially

Nicaragua
- NA
- NA
- NA

Bolivia
- NA
- NA
- NA

Paraguay
- X
- NA
- NA

Uruguay
- NA
- NA
- NA

Argentina
- X
- NA
- Partially

Chile
- X
- NA
- NA

National repository Structured format Elimination of paper

NA: Not available
*Not used in ePI pilot

Latin America ePI legislation and guidelines

Official regulations and/or guidelines:

- **Brazil:** RDC #768/22 (allow use of QR codes at packs).
- **Nicaragua:** MS-ASNR-DF-KVDM-7941-12-22, effective on 01 February 2023.
- **Paraguay:** Resolution 477/2023, effective on 20 December 2023.
- **Guatemala:** DRCPFA-27-2024, providing guidelines on the use of QR codes for the last approved version of the local PI. An additional URL must be included as a mean to access the information.
- **Argentina:** Disposition 3294/2025, effective on 19 May 2025.
- **Ecuador:** Resolution ARCSA-DE-2024-049-DASP, effective on 20 June 2025 and Resolution ARCSA-DE-2024-058-DASP, effective on 30 June 2025.

Pilot projects and initiatives:

- **Brazil:** RDC #885/24, effective on 10 September 2024 (allow paperless pilot to a limited scope).
- **Chile:** Pilot proposed in 2021 and Phase 1 approved by ISP in November 2021 through Ord. 1269.
- **Peru:** A 3-phased proposal was presented to Digemid on May 2023 and approved in February 2025.

5

Recommendations for a Latin America and the Caribbean stepwise approach to adoption of ePI

Foundational considerations for adoption of ePI and suggested roadmap for ePI implementation

The proposal advocates for a phased implementation of ePI, aligned with strategies successfully developed and executed in other markets, in collaboration with their respective NRAs (Inter-Association Taskforce [IATF], 2025). This approach has proven effective and can be adapted to benefit the citizens of Latin America and the Caribbean.

A successful stepwise implementation requires a roadmap developed through multi-stakeholder engagement, led by the respective NRA, with adequate timelines, milestones, and time-bound objectives (IATF, 2025; IFPMA, 2022).

The steps outlined in this roadmap are not required to be followed sequentially and should be tailored to the specific realities, population needs, and digital environments of each country in the region. Each market will progress at its own pace, allowing for a mixed maturity model across different markets (IFPMA, 2022).

This roadmap should leverage digital tools over time, reflecting and building upon ongoing and future pilot projects, especially for countries lacking capacity, experience, or infrastructure to generate sufficient traction (IFPMA, 2022).

Key steps

1 *Approved PI on a repository (addition to paper inserts)*

- ☑ Establish a repository of approved labeling in PDF or HTML format to ensure patients and prescribers can always access the most up-to-date regulatory authority-approved PI (IFPMA, 2022).
- ☑ Publicly accessible websites with the latest PI can improve patient safety, trust in medicines, and user experience by enhancing navigation and understanding of medication usage (IATF, 2025).
- ☑ It is advisable, where feasible, to establish a centralized repository owned by the NRA or an external third-party vendor, with the primary goal of ensuring standardization of PI and enhancing patient confidence and experience, particularly for poly-medicated patients. However, in recognizing that this may not always be possible, ePI could be made available via platforms managed by the MAH.
- ☑ At this stage, the paper insert could be maintained to support the ease of ePI implementation for all stakeholders (especially as there are multiple factors to consider when removing paper PI).

2 *Link to ePI via machine-readable code*

- Include a machine-readable code on packaging that links directly to the ePI, ensuring easy access for patients and prescribers (EFPIA, 2024; IFPMA, 2022). This code (due to increased familiarization with and use of codes in other sectors) acts like a 'nudging' opportunity for patients to scan the code and read the most up-to-date ePI (European Commission, 2019).

3 *Intermediate flexibilities for removal of printed PI*

- Implement ePI initially for certain products only (e.g., hospital products as the medicine is administered by a HCP in this setting) and extend the implementation period for printed PI where both ePI and paper are still made available (IATF, 2025; IFPMA, 2022).
- The phasing in of ePI should precede the phasing out of paper package leaflets (IATF, 2025).
- The selection of products for initial implementation should consider the impact on the carton used for packaging these presentations, since the paper leaflet may have a structural or other feature that supports the product inside the pack, e.g., to act as a cushion material for blister introduction (Nagaoka & Takamine, 2022).

4 *Remove the requirement for printed package inserts for most products*

- Once well-established processes and systems are in place to support HCPs and patients who are less digitally able, and the system has been proved to be working, the move to ePI becoming the primary and single source of PI should be encouraged to avoid confusion between potentially differing versions of electronic and paper versions (IFPMA, 2022).

5 *Structured format and interoperability with other systems*

- Adoption of globally accepted structured formats such as Identification of Medicinal Products, HL7 and FHIR should be encouraged in earlier phases with further adoption as they evolve, so that interoperability with other digital healthcare platforms is possible, integrating the ePI in the digital continuum of care (IFPMA, 2022).

Considerations for implementing ePI - the basic approach

Leverage lessons learned and advances from other regions

Regional guidance

It is suggested that the experience and learning from Brazil and other regions such as Asia and the European Union around the development of regional guidance for ePI initiatives be taken as a reference to ensure a consistent approach across markets. Collaboration between NRAs, HCPs, patients, and industry associations will be crucial, as will the agreed review and evaluation of continued ePI guidance refinement at specified time points to enable iterative learnings and developments to continue. This will support global harmonization and standardization enabling faster, more efficient adoption of ePI (IFPMA, 2022).

Latin America and the Caribbean - wide campaign

The recommendation is also to execute an educational and awareness campaign to inform Latin America and the Caribbean citizens, patients, and HCPs about ePI and its advantages, ensuring a smooth transition (IATF, 2025).

Inclusivity and accessibility

Ensuring no patient is left behind when a paper PI is removed

The pharmaceutical industry should be committed to providing printed information for those who may still require it, balancing digital innovation with practical needs (IATF, 2025).

There will be no 'one-size-fits-all' solution; the optimal approach must be tailored to each specific country, leveraging existing processes, services, and infrastructure. Additionally, it is essential to consider the diverse types of products, patients, consumers, and the various methods of supplying and dispensing medicinal products within each country (IATF, 2025).

These proposals should be further discussed and analyzed with stakeholders and tested through real-life pilots to confirm their viability in terms of implementation and acceptance. This process will also help familiarize patients and consumers with the concept of electronic package leaflets.

By following this roadmap, stakeholders can ensure smooth and effective implementation of ePI, ultimately enhancing public health and regulatory efficiency (IFPMA, 2022).

Practical recommendations for implementation of hybrid approach pilots

The proposal is to implement pilot programs that provide access to PI and non-promotional educational materials (such as videos), if possible, in electronic format via an official repository. This access will be facilitated by scanning a QR or DM code, based on preference, placed on the outer secondary packaging of the selected medicines for the pilot.

The codes can be scanned by any camera-enabled device, thereby directing patients, caregivers, and HCPs to the NRA-approved PI on an official website repository (whether managed by the NRA, the MAH, or a third party). As applicable, relevant non-promotional educational materials in electronic format will also be available. The link embedded in the QR or DM code will consistently redirect to the same location on the chosen repository, ensuring users always have access to the most up-to-date PI approved by the health authority. The QR or DM code on the secondary packaging needs to be updated only in specific situations, such as a formulation change whereby batches with different product conditions may be available on the market at the same time.

Current legislation for the region does not require regulatory changes for this phase. MAHs are encouraged to advance this implementation, ensuring that the ePI corresponds to the latest approved version. However, health authorities must be presented with the value statement and market status over several years to agree on potential version differences between the electronic and paper PI, considering manufacturing implementation times. The primary objective is to provide users with the most current and approved PI, directing them to the official repository for any medication or therapy-related queries.

6

Conclusions

The transition to ePI represents a pivotal and transformational opportunity to modernize healthcare communication across Latin America and the Caribbean. By adopting a phased, flexible, and inclusive approach—grounded in global best practices and tailored to regional realities—stakeholders can collectively enhance patient safety, regulatory efficiency, and access to reliable information.

This ePI Playbook outlines a practical roadmap that encourages collaboration among NRAs, industry partners, HCPs, and patients. It emphasizes the importance of digital readiness, stakeholder engagement, and pilot programs that reflect the diversity of healthcare systems in the region.

As we move forward, it is essential to maintain a patient-centric mindset, ensuring that no individual is left behind in the shift from paper to digital. Through thoughtful implementation, continuous learning, and transparent communication, Latin America and the Caribbean can lead the way in shaping a future where trusted, up-to-date PI is accessible to all.

Let this ePI Playbook serve not only as a guide, but as a catalyst for action—empowering stakeholders to take the next steps toward a more connected, informed, and resilient healthcare ecosystem.

Appendices

Appendix A

Centers for Medicare & Medicaid Services guidelines for effective risk management and contingency planning (Centers for Medicare & Medicaid Services, n.d.).

Assess the situation

Identify critical processes and systems within an ePI repository that are most susceptible to disruptions. Evaluate potential risks and analyze the financial and operational impacts of such disruptions.

Identify risks

Assess the likelihood and potential impact of disruptions on each critical process. Determine whether risks stem from the holder's internal readiness or from external vendors and evaluate the ability to maintain operations during a contingency scenario.

Develop an action plan

Create strategies to mitigate identified risks, focusing on reducing their likelihood and impact. These strategies may include reallocating resources, implementing redundancies, or improving communication protocols. Incorporate these measures into operational planning to ensure readiness.

Define activation triggers

Establish clear criteria for activating the contingency plan, including specific circumstances or events that necessitate its implementation. Assign decision-making responsibilities and outline the actions to be taken once a trigger is identified.

Contingency plan communication

Document the complete contingency strategy, specifying roles, responsibilities, and required actions. Share the plan with all responsible parties to ensure clarity and preparedness.

Contingency plan testing

Regularly test the contingency plan with key participants to identify gaps or weaknesses. Use findings from these reviews to adjust and improve the plan as needed.

Treat the contingency plan as an evolving process

Continuously monitor and update the contingency plan to address new risks, changes in operations, or feedback from testing. Maintain open communication with stakeholders to ensure alignment and preparedness.

Appendix B

Key strategies for ensuring compliance in uploading labels in a timely manner and maintaining version control for ePI from the EMA's ePI Pilot Report (EMA, 2020).

Timely uploading of labels (key actions)

- NRAs and stakeholders must establish clear timelines for submitting and updating ePI to ensure accessibility.
- Automated systems can facilitate real-time updates, reducing delays in label publications.
- Early engagement with NRAs and pilot projects can help identify potential bottlenecks and streamline processes.

Version control mechanisms (implementation strategies)

- Implementing a structured versioning system ensures that HCPs and patients access the most up-to-date information.
- Digital platforms should support historical tracking of label changes, allowing users to verify previous versions when needed.
- Standardized procedures for updating ePI must be in place to prevent inconsistencies and ensure regulatory compliance.

Collaboration and oversight (stakeholder engagement)

- Stakeholders, including MAHs and regulators, should collaborate to maintain consistency in ePI updates.
- Regular audits and feedback loops can help refine version control practices and improve compliance.
- Training programs for HCPs and industry representatives can enhance understanding of ePI management.

Continued improvement (long-term success strategies)

- Monitor the impact of version control and timely updates through ongoing assessments.
- Adjust the implementation strategies based on real-world challenges and on the stakeholder's feedback.
- Advocate regular policies that promote efficiency, transparency, and consistency in ePI adoption.

These measures contribute to a reliable and efficient ePI system, ensuring that patients and HCPs receive accurate and timely PI.

Appendix C

Six principles to support an effective communication plan from the WHO Guidance on Strategic Communications Framework (WHO, 2017):

Accessible

Communication must be accessible to all audiences, including patients, caregivers, and HCPs. Effective communication channels should cater to the preferences and needs of each group, such as mass media, community networks, and interpersonal interactions. Materials should be designed for individuals with sensory impairments or low digital literacy, incorporating features like large fonts, visual aids, audio formats, and compatibility with assistive technologies.

Accessibility should be prioritized through a user-friendly, multilingual interface compatible with various devices and inclusive features for users with disabilities. To verify accessibility, companies can use tools like "Easy Checks – A First Review of Web Accessibility" for initial assessments and "ACT (Accessibility Conformance Testing) Rules" to evaluate conformance with WCAG 2.0 success criteria (W3C, 2025).

Actionable

Effective communication should deliver clear and practical steps for accessing and using ePI. Messaging must highlight the benefits of ePI, such as timely updates and ease of access, while addressing barriers such as digital literacy and internet connectivity. Campaigns should guide users in scanning QR codes or navigating ePI platforms, with tailored instructions for elderly patients and caregivers. For HCPs, communication should emphasize their critical role as facilitators in educating patients, showcasing how ePI supports medication adherence and enhances patient safety.

Credible and trusted

Transparent messaging should ensure technical accuracy and address concerns about the reliability of ePI platforms. Endorsements from NRAs and professional associations can reinforce trustworthiness. HCPs, as trusted advocates, must be equipped with accurate information to educate patients and caregivers about the benefits and proper use of ePI. Honest communication that acknowledges uncertainties and challenges will build confidence and promote ePI as a reliable tool.

Relevant

Communication must demonstrate the direct relevance of ePI to the needs of patients, caregivers, and HCPs. Messaging should focus on practical benefits, such as simplified access to critical information and user-friendly features for patients and caregivers. For HCPs, it should emphasize how ePI enhances patient interactions and improves medication safety.

Timely

Communication efforts should begin well before ePI implementation to allow patients, caregivers, and HCPs sufficient time to understand and adapt. Early messaging should introduce the purpose, benefits, and usage of ePI to minimize confusion at the launch. Post-implementation, communication must persist in reinforcing understanding, providing updates, and addressing challenges, ensuring sustained acceptance and success.

Understandable

Messages must be clear and easy to comprehend for all stakeholders. Communication should use plain language and incorporate visuals to enhance understanding, particularly for those with limited literacy or familiarity with digital platforms.

Appendix D

Access Global ePI-related regulations (public sources)

Australia	Click here	New Zealand	Click here
Korea	Click here	Egypt	Click here
Taiwan	Click here	Argentina	Click here
Malaysia	Click here	Brazil	Click here Click here
Singapore	Click here	Paraguay	Click here

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