

IFPMA Position Paper on:

# IMPROVING PATIENT SAFETY AND HEALTH SYSTEMS RESILIENCE THROUGH THE USE OF ELECTRONIC LABELING

## INTRODUCTION

Medical product information is designed with the intent to ensure prescription and non-prescription healthcare products are used in an effective and safe manner.

This information is a culmination of clinical development data and post-marketing learnings and data, translated into descriptive text for Healthcare Professionals (HCPs) and in some cases specifically for the patient. It plays a pivotal role in ensuring patient's understanding of their treatments while also supporting HCPs in their decision making. To make this information even more effective, new, digital-enabled tools for delivery of labeling that facilitate access, understanding and usability are key components in enabling more effective use of available treatments and helping raise overall health literacy.

**One emerging trend that fits in this category is electronic labeling, or e-labeling. In this paper, e-labeling is defined as the dissemination of approved product information for medicinal products including in a dynamic digital format.<sup>1</sup>**

The global R&D biopharmaceutical industry's commitment to innovation and patient safety is aligned with the implementation of pioneering solutions to improve speed in information sharing and educating patients and healthcare professionals. Not only is this a response to the need for more interconnectivity between stakeholders in the health systems, but also a way of simplifying and accelerating regulatory information management and process whilst helping to reach environmental sustainability goals (UN SDG 3, 12, 17).

The complexity of industry's globalized supply chains has also been put to the test during the COVID-19 pandemic, which provided a case study on how e-labeling could be leveraged.

**E-labeling will increasingly play a role in facilitating fast deployment of product information and facilitate patient understanding and adherence.**

# WHAT IS THE LANDSCAPE OF E-LABELING REGULATIONS AROUND THE WORLD?

	National Repository	XML Format Adopted	Elimination of Paper
US	✓	✓	
Canada	✓	✓ Voluntary	Voluntary, to be agreed upon by NRA
EMA	✓		
UK	✓		
Japan	✓	✓	✓ Aug. '21
Singapore			Voluntary
Australia	✓		Paper copies needed for injectables
Chinese Taipei	✓		
China			
Brazil	✓		

**Fig.1 – Global overview of selected e-labeling regulations**

E-labeling regulations are moving at different speeds around the world. Japan is an example of a country where e-labeling has advanced considerably over the last few years. In 2019, the Ministry of Health, Labour and Welfare (MHLW) has introduced new regulations in Japan that officially introduce e-labeling and is set to replace paper labeling in commercial packs for prescription drugs and medical devices. The regulations started being enforced on 1 August 2021 with a 2-year transition period towards a paperless system in July 2023.

For countries involved in multilateral regulatory strengthening initiatives such as the African Medicines Regulatory Harmonisation (AMRH), e-labeling can represent an opportunity to leap-frog onto a more agile digitalized regulatory environment. Regardless of different levels of uptake in different countries, the growing importance of the topic and the enhanced accessibility of technical standards that are easier to use and have a lower cost to implement alongside the progressive increase in access to digital tools is an opportunity to enhance equity of access to the most up to date product information for all global citizens.

# WHAT ARE THE BENEFITS OF E-LABELING?



## Protecting patient safety

One of the most important advantages is the guaranteed accessibility to the most up-to-date product information approved and validated by the local NRA virtually in real time and in the corresponding local language. Alerts about major changes to the product information can be added and highlighted, raising awareness and protecting patients more effectively by reducing potential harm due to treatment non-compliance or unrecognized incompatibilities in a patient's medication scheme.



## Promoting better patient and HCP understanding

Poor understanding and adherence to product information has been directly linked to poor health outcomes and increased costs for already burdened healthcare systems.<sup>2</sup> E-labeling can be used to help improve patient understanding, ultimately leading to increased adherence and better use of the medicinal products.

As e-labeling is dynamic, in the sense that it can be adjusted to each user's preference using the authoritative information, it could enhance health literacy by changing how a patient is able to interact with product information by:

- Ensuring the availability of both HCP and patient-type-centric information.
- Providing a wide range of regulatory approved translations (where available), in the language preferred by the patient or HCP.
- Leveraging new formats such as audio, and/or visual. Patients already consult a significant amount of health-related information online, using different kinds of electronic devices. E-labeling provides patients the opportunity of doing so through a trusted channel.
- Providing the ability to search label content to easily find information, especially relevant for the partially sighted or patients with any sort of visual impairment.
- Adaptable font size, improving readability.
- Making it easy to share approved information with wider audiences.
- Facilitating sharing of comprehensible information between patients, their families and caregivers.



## Improving supply chain resilience and efficiency

Platforms that allow for streamlined ways of sharing new product information will lead to an acceleration and simplification of processes for post-approval changes to label information. In addition, it offers the opportunity to share labeling between countries when appropriate. This will have a positive effect in better managing drug shortages and further strengthening global pharmaceutical supply chains. The use of e-labeling also cuts out a substantial lead time for leaflet printing and packaging, granting patient faster access to new products.

As illustrated by the COVID-19 pandemic, labeling flexibility is particularly important when increased demand, disruptions in transports and other factors impact the normal flow of products. In this regard, e-labeling can have positive impact on the availability of up-to-date NRA approved product information alongside the product and avoid delays when cross-borders deployment is necessary.

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## WHAT ARE THE OPPORTUNITIES OF E-LABELING FOR HEALTH SYSTEMS?

Implementation of e-labeling requires targeted investment in a country's health system, the impacts of which go well beyond the direct improvements linked to the use of e-labeling.

Broad benefits to health systems include linkage with future digital transformational opportunities such as e-prescribing and e-health records to deliver integrated healthcare solutions and tailored patient care.

From a regulatory perspective, efforts to develop a regulatory framework that is harmonized with global standards and enables the implementation of an e-labeling roadmap will have a direct add-on effect for advancements in important activities such as track and trace (serialization), pharmacovigilance and post-marketing surveillance.

A sound, fit for purpose healthcare system can perceive and adapt to patient's needs as well as environmental and emergency health-care needs. In that sense, digitalization should also be perceived as evolving with social and behavioral digital trends, and a way of improving patient-HCP interactions and therapeutic compliance. This could all ultimately lead to improved health outcomes and reduce healthcare disparities across low- and middle-income countries. Furthermore, the COVID-19 pandemic acted as a catalyst for this evolution, increasing the uptake of digital technologies in healthcare around the world.

While we do recognize the added effort necessary to establish the appropriate infrastructure, a thorough and gradual implementation of e-labeling for product administered by HCP and e-labeling that co-exists with the traditional paper version can make the process less burdensome as we learn along the process. Paper version options could also continue to be available as a print-on-demand service at the point of dispensing if needed. During implementation, the R&D-based biopharmaceutical industry is committed to provide safeguards to ensure alternatives (e.g., call centers) are available to provide hard copies if necessary. This will be particularly important in resource-limited settings, where access to technologies that allow patients to process machine-readable codes may be less accessible. Nonetheless, the latest trends indicate that roughly 5.22 billion people around the world use a mobile phone, and 4.66 billion have internet access.<sup>3</sup> Both figures continue to increase, further highlighting the importance of leveraging systems and approaches that rely on these technologies.

Additionally, the immense positive environmental impact of replacing paper-based product information in the long term (even when just applied to examples like hospital products, vaccines) should not be overlooked.<sup>4</sup>

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## HOW TO IMPLEMENT E-LABELING

One of the challenges in ensuring effective implementation of e-labeling globally is harmonization of general approach, processes and standards – especially since technology in this space is fast-paced.

IFPMA supports the use of an aligned global technical standard to ensure information can easily be exchanged globally (i.e., with Health Level Seven's Fast Healthcare Interoperability Resources (HL7 FHIR)). IFPMA supports the voluntary use of globally harmonized and standardized two-dimensional (2D) barcodes to provide a direct link from packaging to electronic product information (e.g., 2D barcodes based on ISO/IEC 16022 Data Matrix barcode standard). However, because

technology in this space is evolving<sup>5</sup> and there will be an interim period where machine readable codes are changing, the use of these types of code may be associated with added difficulties in granting patients and HCPs in resource-limited contexts access to an electronic version of the product information. Thus, QR codes may be an interim option for linking to product information. Regardless of the type of code used, it is recommended that a URL (website address) in a human-readable format should appear on product labels and accompany the machine-readable code.

For a successful stepwise implementation, a roadmap developed by multi-stakeholder engagement, led by the respective NRA with adequate timelines, milestones and time-bound objectives is a useful tool.

Such a roadmap should leverage the adoption of digital tools over time as infrastructure and considerations like internet accessibility increase, enabling a mixed maturity model by market. The roadmap should reflect and build upon ongoing and future pilots and tests, especially in countries that lack capacity, experience or infrastructure to generate sufficient traction. Implementation will benefit from experience-sharing among countries and should take into account the importance of health literacy and the value of patient centric product information being available to patients in their style of language alongside the HCP product information.

**Below we propose a stepwise roadmap to guide implementation of e-labeling:**

1

**Approved product information available in any electronic format on a central platform (addition to paper Inserts)**

As a first step, countries may simply establish a repository of approved labeling that is updated in timely manner in PDF format. This would ensure that patients and prescribers can always get to the current label even if the package insert is lost.

2

**Link to the electronic product information via a machine-readable code on packaging and include a human readable format**

Linking directly to the electronic product information would be a next step to ensure patients and prescribers can easily locate and read the current labeling.

3

**Intermediate flexibilities to reduce the requirements for printed product information**

Implementation of electronic product information for certain products as first step (e.g., hospital products); Extended implementation period for printed product information.

4

**Remove the requirement for printed package inserts**

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, removal of the printed product information can be envisioned.

5

**Structured format to enable searching and interoperability with other systems**

The end-state involves electronic product information hosted in a repository in a structured format allowing searching, re-use and interoperability with other digital healthcare platforms. The electronic product information is implemented using an internationally recognised data exchange standard such as HL7 FHIR.

Harmonized regulations across multiple countries will increase the success of uptake of e-labeling, improve efficiency and would be key in supporting the creation of central trusted e-labeling platforms. Such platforms may be regional or national and owned or recognized by the NRA, but the underlying standards and fundamental principles should be harmonized around the globe.

Implementation is already happening in different regions around the globe. As we move forward it is important to leverage lessons learned from these experiences. For example, the Belgium-Luxembourg [Pioneer Pilot Project](#), which allowed provision of sufficient, adequate and tailored (e.g., language) information to HCPs and patients with no need to print the patient information has had a positive impact on daily practice of hospital pharmacists.

The TFDA, Chinese Taipei is building a centrally structured database with open access. This database will be linked to the labeling review process in order to increase regulatory review efficiency. Hence, HCPs can use smart device applications to access the database to support their daily interaction with patients. The end goal is to eventually remove the need for a paper insert and have a user-friendly fully digitalized labeling system in Chinese Taipei. A pilot project for the Flu vaccine is underway, aiming at adapting to using e-labeling without the paper insert in 2021.

In Singapore, features such as information-for-use videos and audio-read enabled functions that can help the visually impaired patients, are some of the extra features that can be added on e-labeling.

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## CONCLUSION

The R&D-based biopharmaceutical industry recognizes the value of e-labeling, acknowledging its benefits to patients, NRAs, HCPs, the environment, and the industry itself.

In the process of implementing e-labeling in different regions around the globe, IFPMA highlights the importance of establishing channels for dialogue between all involved stakeholders. The R&D-based biopharmaceutical industry is open to share its expertise in this field and lead a collaborative effort amongst stakeholders including patients and HCPs to co-develop more detailed and country-specific roadmaps to realize the discussed e-labeling benefits in this position paper. Amongst other deliverables, such roadmaps should include a technical implementation guide to support the use of HL7 FHIR data exchange standards.

- 1 Roberts, Khyati et al. "Creating E-Labeling Platforms: An Industry Vision." *Clinical pharmacology and therapeutics* vol. 108,4 (2020): 716-718. [doi:10.1002/cpt.1865](https://doi.org/10.1002/cpt.1865)
- 2 *Advancing Community Pharmacy Practice in Challenging Times*. Brussels: Pharmaceutical Group of the European Union 2013.
- 3 DataReportal (2021), "Digital 2021 Global Digital Overview," retrieved from <https://datareportal.com/reports/digital-2021-global-digital-overview>
- 4 Data from the [Alliance to Modernize Prescription Information](#), (Source: Sierra Club & U.S. Food and Drug Administration).
- 5 IFPMA, [Identification & Traceability of Medicinal Products – A tool towards strengthening health systems](#) (2021)