ECUADOR; CURRENT LABELING SITUATION & THE ROUTE TO E-LABELING

A journey towards implementing E-labeling in Pharmaceuticals

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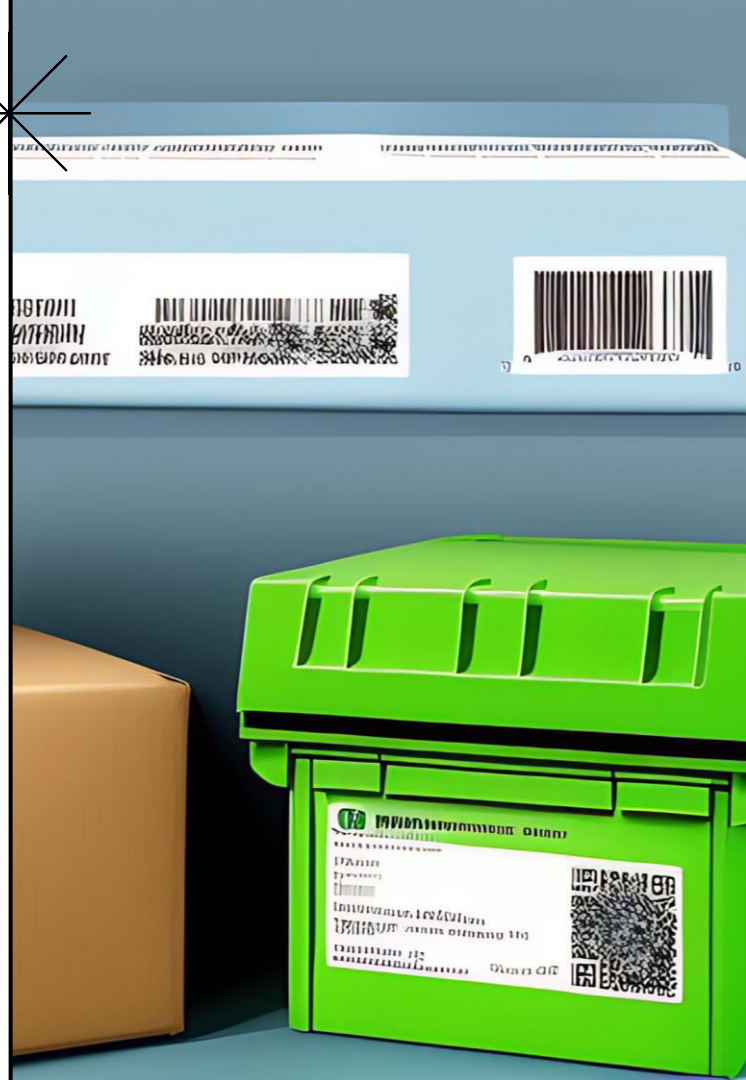
DECLARATIONS

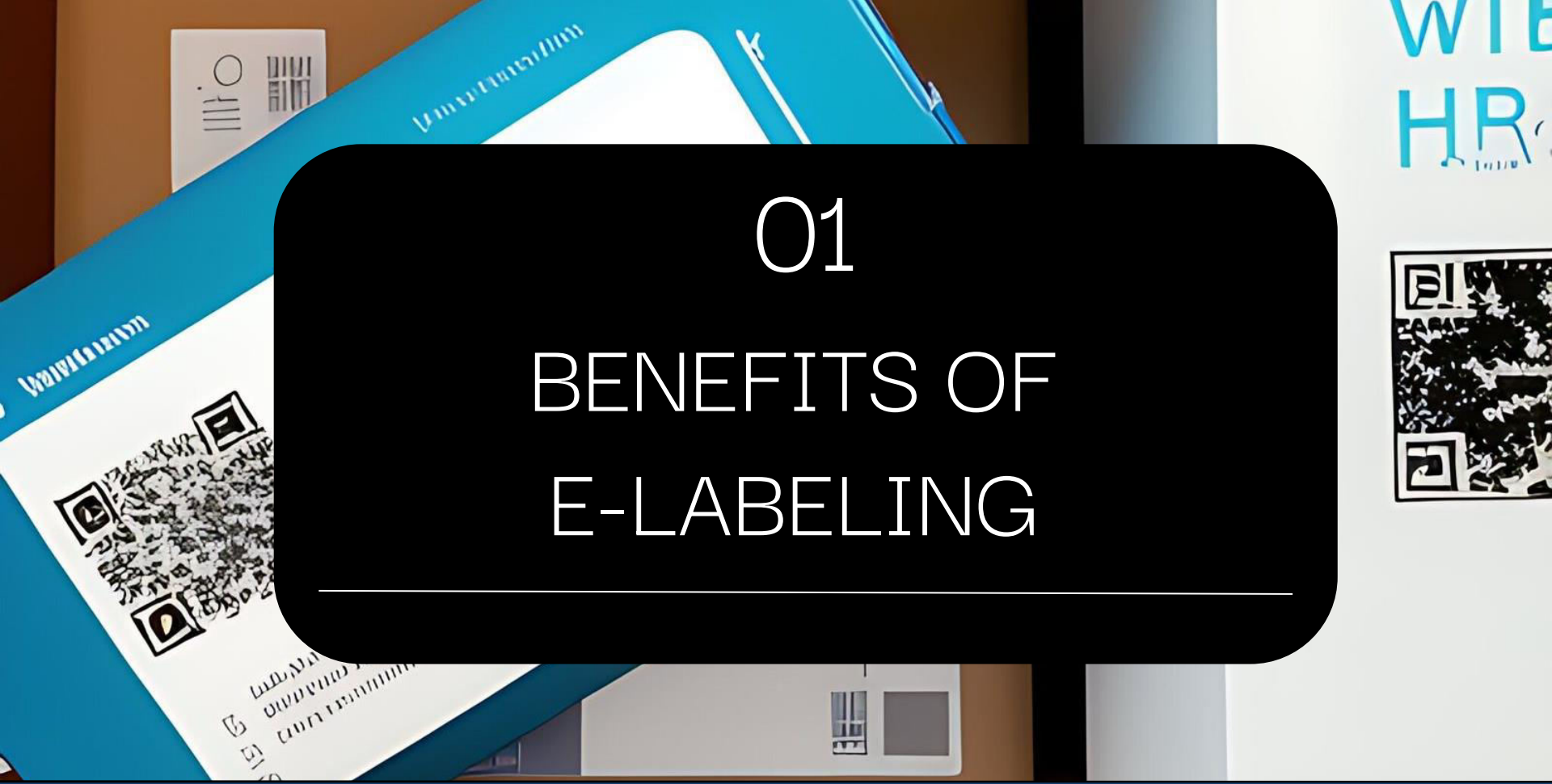
- I declare that all the opinions of this work are personal and that under no circumstances do they represent the opinions or points of view of my current employer; I also declare that I have no conflict of interest in reference to the topic of the presentation in relation to my employer or any current project in which I am immersed.

INTRODUCTION

The rapid evolution of technology is reshaping the way we work and interact, including within the healthcare sector. The integration of emerging advancements in Digital Health offers a unique opportunity to enhance patient care quality, deliver personalized therapies, optimize resource utilization, and establish more efficient healthcare systems.

The Dynamic Digital Labeling (DDL) or Electronic Labeling (ePI) in this changing landscape, introducing approval processes and product information approaches aligned with the future of healthcare.





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BENEFITS OF E-LABELING

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Dynamic Digital Labeling (DDL) offers the capacity to swiftly share pertinent, authoritative, and real-time information whenever changes are made to product labels.

Moreover, it provides the flexibility to customize this information to cater to the specific requirements of various stakeholders, including patients, physicians, regulators, and healthcare record holders.

Ultimately, this transformative approach benefits all parties involved, enhancing healthcare and resource utilization within the pharmaceutical and healthcare sector at large.

02

THE POSITIVE IMPACT OF DDL

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Regulators	Improved Effectiveness	Increased Transparency
Regulators	Streamlined Processes	More Informed Decision-Making
Physicians	Rapid Access to Reliable Information	Well-Informed Treatment Decisions
Patients	Evidence-Based Care	Enhanced Healthcare Experience
Healthcare Record Holders	Understanding Drug Trends and Advancements	Enhanced Patient Care

03

DEFINITION OF THE PROBLEM

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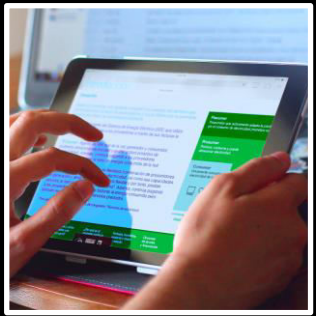
Ministerial Agreement 385 of Biological Medicines and Regulation 586 of general medicines "mentions that the package leaflet must be included in the medicine, our understanding is that it can be physical or digital/electronic since the Regulation does not limit it" have the following drawbacks:

Challenges

- Lengthy Update Process (1.5 to 2 years)
- Limited User Experience (affecting prescription quality)
- Rising Supply Chain Costs and Environmental Concerns (due to printed leaflets)

Potential Solutions

- Digital Leaflets
- Faster Updates
- Sustainability Focus



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OBJECTIVE SET

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Establish co-creation tables that involve the industry and the different government actors that are members of the Ecuadorian Quality System to build a proposal for the implementation of E-labeling as a sustainability and forest conservation program and as a way of reducing the ecological footprint of this industry sector.

05

CO-CREATION TABLES

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Mapping of actors from the different industry unions and government representatives members of the Ecuadorian Quality System and sending the call to the working group.

Confirm the participation of members of the pharmaceutical industry and government stakeholders by registering their delegates.

Circulate among the confirmed participants a Draft of the Dynamic Digital Labeling (DDL) or Electronic Labeling (ePI) proposal.

Call the co-creation tables.

Draft final document of the Dynamic Digital Labeling (DDL) or Electronic Labeling (ePI) proposal.

Submit the document to the health authority, MSP and its affiliate ARCSA.

STOPPERS

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Lack of HA Autonomy

Lack of Local Regulation

Lack of HA Experience" (HA: Health Authority)

WHAT REALLY HAPPENS!

One pharmaceutical company present and individual proposal to the Environmental Authority

The proposal was politely rejected for the Health Authority.

One pharmaceutical company present and individual proposal to the Environmental Authority

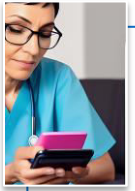
They realized that aligned with the Executive Decree N°68 issued by the Presidency of the Republic on June 09, 2021; in which it declares as priority public policy the trade and production facilitation, the simplification of procedures and the competitiveness agenda; the cornerstone of this tactic was an inter institutional approach to this matter focused in first instance on environmental perspectives.

What Really Happens!

On july 6th they sent an official letter to the Ecuadorian Ministry of the Environment, Water and Ecological

Transition in which we presented a short debrief of the environmental negative impact of the continuous use of printed leaflets, offering an overview of their own operation in the country.

The Ecuadorian Ministry of the Environment, Water and Ecological Transition considered a proposal extremely good, totally aligned with the country's policies; nevertheless, they did not support it because it was presented by a single company. They only would support it if the proposal were presented by all the companies united or at least by a local trade association.



Active Participation

- The company, a member of the association, spearheaded the initiative

Initial Proposal

- We introduced the idea and garnered support from other member companies

Collaboration

- We worked together to develop a joint proposal

Engaging the Authority

- We presented the proposal to the regulatory authority.

Seizing Opportunities

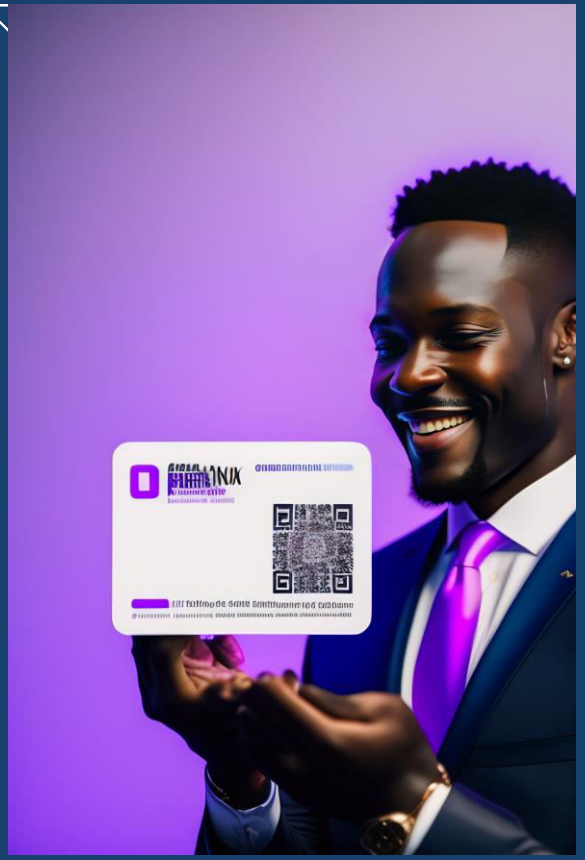
- We took advantage of the ongoing regulatory update for synthetic medicines.

Achievement

- The authority accepted including Dynamic Digital Labeling (DDL) as an option in the regulations

All working together through the local trade association.

OUTCOME



OUTCOME

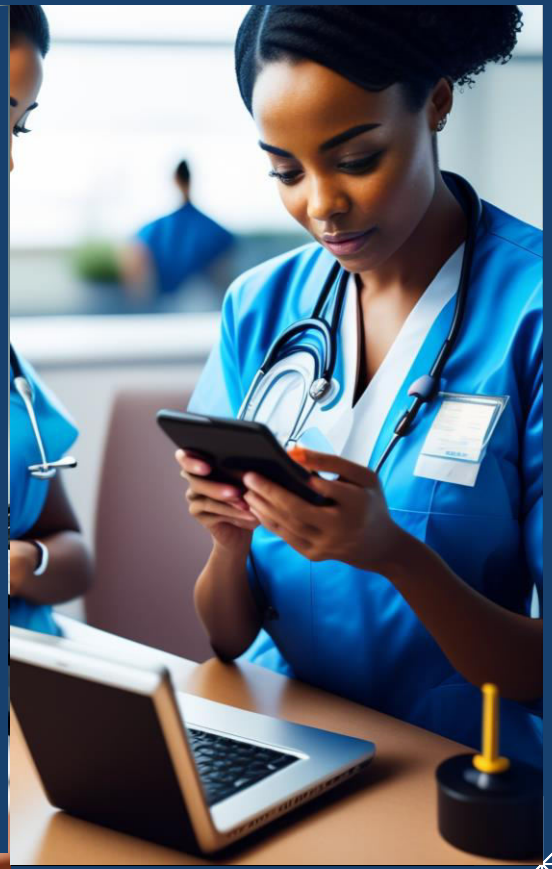
New regulation permits electronic leaflets for over-the-counter meds, optionally.

For prescription meds, both physical and digital leaflets are allowed.

Review within a year for extending digital leaflets to other sales types.

NEW CHALLENGES

The current regulation is insufficient.
Starting with hospital-use medicines is proposed.
Greater collaboration with the regulatory authority is required.
The introduction of electronic labeling is being pursued in the amendment to Ministerial Agreement 385.



WORKING IN PROGRESS PROJECT FOR THE IMPLEMENTATION OF DIGITAL DYNAMIC LABELING IN MEDICINES

Phase One: Preparation and Authorization

In this initial phase, two crucial events are expected to occur:

1. Authorization for the use of e-labeling: The health authority will allow pharmaceutical companies that are able to use digital applications of their choice for the implementation of e-labeling, in medicines for hospital use.
2. Connection of Stakeholders: The health authority will partner with the Inter-American Development Bank and a specialist partner in IT issues and infrastructure to design the system and the centralized repository that will house the digital drug prospectuses, in the second phase.

Phase Two: Implementation and Control

Once the central repository is operational, the following actions will be implemented:

1. Authorization of Connections: The health authority will allow pharmaceutical companies to link from the codes of their secondary packaging of their products using barcodes, QR or matrices through an interface to the repository of approved digital prospectuses.
2. Control and Monitoring: The health authority will supervise and control the digital repository, ensuring the integrity of the information and the authenticity of the digital prospectuses.
3. Medicines for Hospital Use: The first medicines to be incorporated into the system will be those for hospital use, which will allow an initial evaluation of the effectiveness of the project.

Phase Three: Evaluation and Expansion

In this final phase, the following actions will be considered:

1. Results Evaluation: A comprehensive evaluation of the results and acceptance of the system by health professionals, including physicians and pharmacists, as well as by patients and caregivers, will be carried out.
2. 2. Possible Expansion: If the results are satisfactory and the effectiveness of the authority's control over digital package inserts is demonstrated, the possibility of extending the use of the system to other types of drugs dispensed in pharmaceutical units will be considered.

It is important to note that participation in this project would be voluntary for pharmaceutical companies. Those who wish to continue using physical prospectuses may do so.

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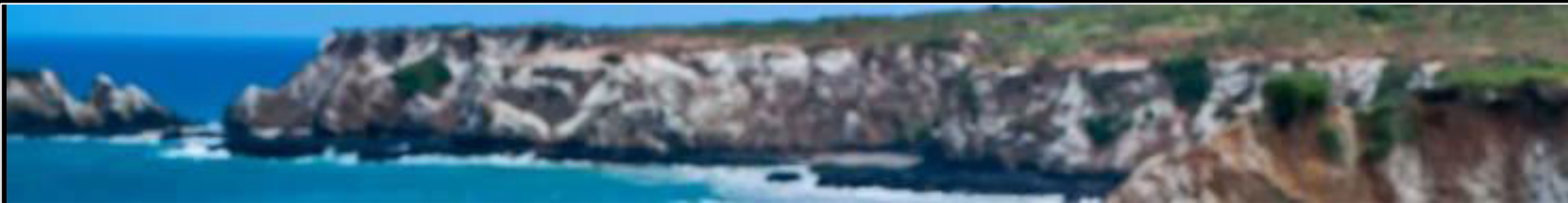
CONCLUSION

E-labeling represents a significant advance towards more efficient and safe medical care in the region, taking advantage of digital technologies for the benefit of all the actors involved in the pharmaceutical industry.



QUESTIONS

THANK YOU