

e-IFU: Strategies to implement as general practice

14-Nov-24



e-IFU Working Group

Problem Statement

- Some countries in LATAM do not accept e-IFU, however, it is a trend adopted for many companies

Main Objective

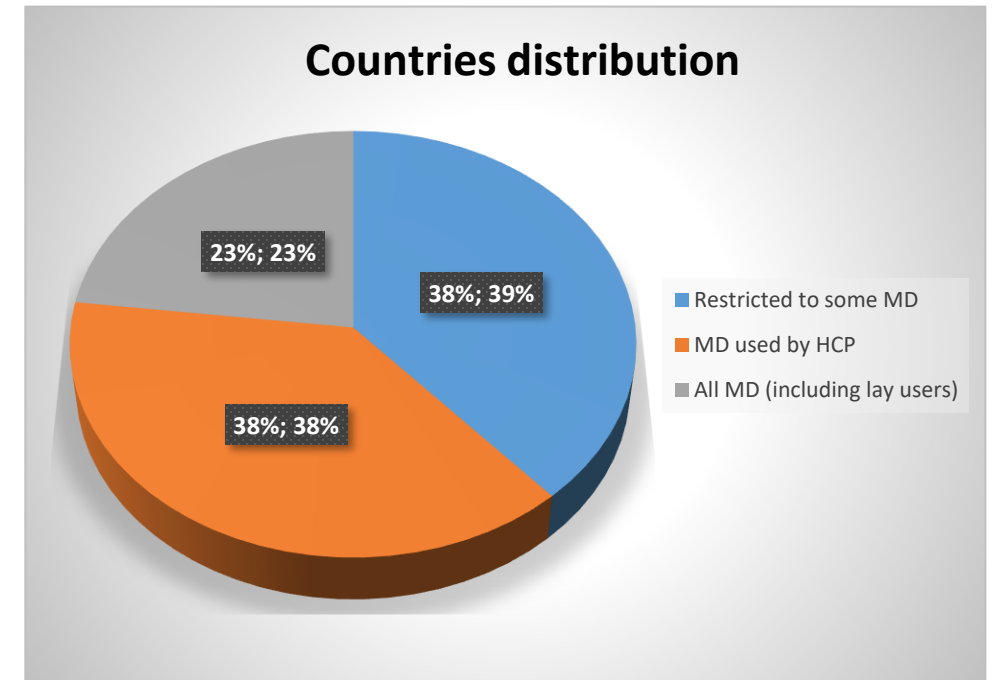
Provide documents/position that support the strategies to advocate e-IFU adoption across the countries.

Main Strategy

1. Review state of art regarding e-IFU:
 - International
 - LATAM countries
2. Identify challenges percibed by regulators.
3. Address Health Authorities concerns.

International state of art

| Jurisdiction | Regulatory Acceptance of Electronic Instructions for Use Instead of Paper | Products scope |
|----------------|---|------------------------------|
| Australia | Expressly Permitted | Restricted to some MD |
| Egypt | Expressly Permitted | |
| European Union | Expressly Permitted | |
| Turkey | Expressly Permitted | |
| United Kingdom | Expressly Permitted | |
| Brazil | Expressly Permitted | MD used by HCP |
| Canada | Expressly Permitted | |
| Japan | Expressly Permitted | |
| Singapore | Expressly Permitted | |
| United States | Expressly Permitted | |
| China | There is no regulation that prohibits | All MD (including lay users) |
| India | Expressly Permitted | |
| South Korea | There is no regulation that prohibits | |



* Reference countries allow e-IFU for specific products or for products used by HCP.

LATAM State of art

| COUNTRY CLASSIFICATON | CHALLENGE | COUNTRIES |
|---|--|--|
| Regulation indicates IFU must be physically with the product, it means a regulatory restriction to adopt e-IFU. | <ul style="list-style-type: none"> It is required to advocate for a regulation change Change could take a long time for implementation. | Colombia - IVD México Paraguay - MD Perú |
| Regulation does not mention IFU release method, it generates uncertainty regarding e-IFU adoption | <ul style="list-style-type: none"> e-IFU acceptance is not explicit in regulation. Different interpretation from same country regulation that means, there is not a clear guidance. Based on some consultation made by some companies, there are some countries that are open to accept e-IFU. These countries demand to have an official position from regulators to avoid different interpretations. | Argentina Bolivia Costa Rica Dominican Rep. El Salvador Guatemala Honduras Nicaragua Panama Uruguay |

---- Regulation draft included e-IFU. Awaiting for final regulation to reclassify them.

---- Countries classification under revision

LATAM State of art

| COUNTRY CLASSIFICATON | CHALLENGE | COUNTRIES |
|--|--|---------------------------------|
| Despite regulation includes e-IFU option (Digital IFU), it is not explicit, or regulator do not accept to replace paper IFU by e-IFU | <ul style="list-style-type: none"> Regulatory framework support e-IFU, however it is required to advocate for clarifying the rules of e-IFU application and to promote paper IFU remotion. | Colombia – MD Ecuador |
| Regulation accept e-IFU for some products, however it is considering the scope is not enough | <ul style="list-style-type: none"> These countries already allow e-IFU for some type of products; however, team interest is to cover more products. | Brazil Chile* |
| There is not any challenge (e-IFU already accepted) | <ul style="list-style-type: none"> Based on regulation it is already allowed e-IFU for products under regulation, for these countries there are not actions required from this working group. | Paraguay - IVD |

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e-IFU Advantages and challenges

Advantages

- Information availability
- Environmental sustainability
- Cost-effectiveness
- Patient safety
- Interactivity
- Durability
- Efficiency

Challenges perceived by HA

- Internet connection and permanent access
- Users do not feel comfortable with e-IFU
- e-IFU version control
- Mechanism to provide paper IFU in case it is required by HCP or patients

1. Internet connection

Internet penetration data

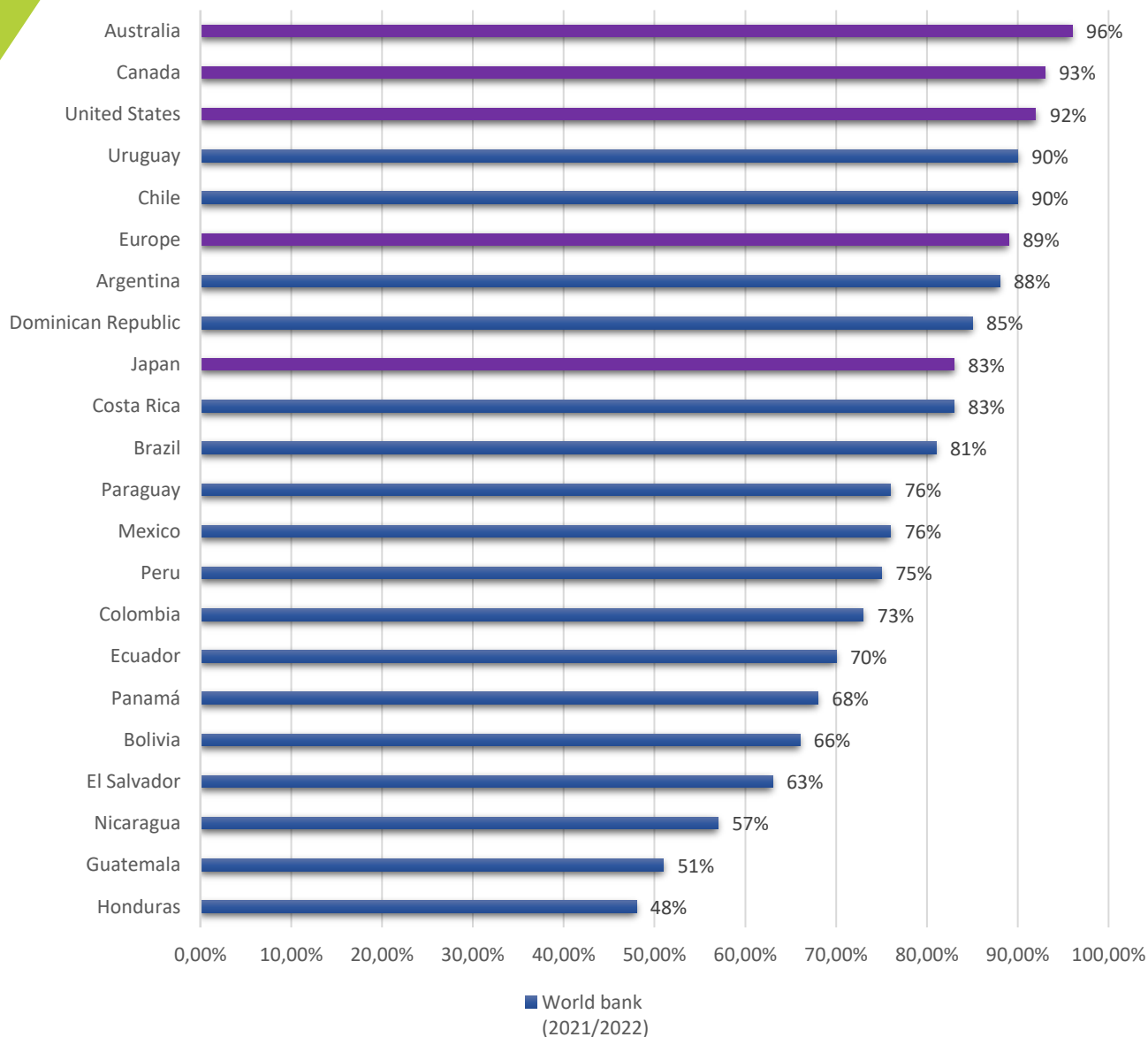
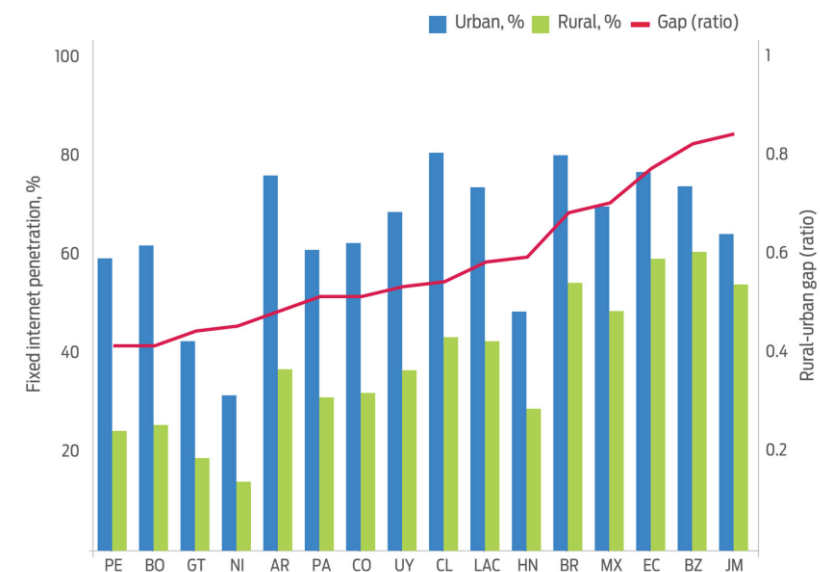


Figure 3: Fixed internet penetration in urban and rural areas (% of households)



Source: World bank, September 2022

Conclusions:

- Despite internet connection is a challenge in some countries, this is also the reality Health care systems are facing daily, so it should not be a restriction for e-IFU adoption.
- Usually, Health care institutions are located in main cities in which internet connection is not a big issue.
- This internet data could represent a challenge for lay user products.

2. Users do not feel comfortable with e-IFU

Product users' perspective regarding e-IFU adoption is not clear, but it is a concern for Health Authorities. With the purpose to map HCP perspective it will be released a survey to capture their preferences regarding IFU.

Methodology

| | |
|-----------------------|--|
| Audience | Health Care professionals |
| Scope | LATAM Countries (Except Brazil) |
| Distribution strategy | Coalition will send the survey to Health care professional associations (Professionals focus on DM and IVD) identified by the working group. |
| Type of questions | Intended to understand what are the preferences of HCP regarding IFU (paper vs. e-IFU). |

- Lay user audience was not considered because it supposed a big complexity to connect with a broad number of patient associations.
- A lot of monthly meetings were focus on discussing the questions included in the survey.
- It was run a pilot with HCPs into the companies to validate the survey.
- There are other surveys released or in progress to identify HCP position regarding e-IFU:

*MedTech Europe

*European union

*TGA- Australia

3. e-IFU version control

It should cover to different scenarios:

- Countries in which IFU versions/changes required approval.
- Countries that do not require approval.

After several discussions, it was defined the best approach could be each company define the mechanism to control it by QMS and focus our defense in this proposal.

4. Mechanism to provide paper IFU in case it is required by HCP or patients

Initial proposal focus on having a customer service line to request it, however, not all companies could ensure it. Topic already under discussion.

General schedule

| | Activity | Estatus | jul-24 | Aug-24 | sep-24 | oct-24 | nov-24 | Dec-24 | Jan -25 | feb-25 | mar-25 |
|-----|--|-------------|--------|--------|--------|--------|--------|--------|---------|--------|--------|
| 1 | Compiling state of art | Completed | | | | | | | | | |
| 2 | Discussion position papers available | Completed | | | | | | | | | |
| 3 | Main concerns of Health Authorities | In progress | | | | | | | | | |
| 3.1 | Internet connection | Completed | | | | | | | | | |
| 3.2 | Users do not feel comfortable with e-IFU (Survey) | In progress | | | | | | | | | |
| | Define audience (HCPs, HC Institutions, HCP associations) and ways to contact them | In progress | | | | | | | | | |
| | Survey question | In progress | | | | | | | | | |
| | Pilot of the survey | In progress | | | | | | | | | |
| | Survey release | Not started | | | | | | | | | |
| | Data collection | Not started | | | | | | | | | |
| | Data analysis | Not started | | | | | | | | | |
| 3.3 | IFU printed on demand | In progress | | | | | | | | | |
| 3.4 | version control | In progress | | | | | | | | | |
| 4 | Position document to recommend e-IFU | Not started | | | | | | | | | |
| 5 | General Strategy to negotiate with Health Authorities | Not started | | | | | | | | | |



THANK YOU