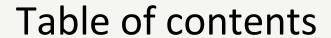


# Electronic Instructions for Use (eIFU) for Medical Devices

Challenges and Opportunities in a dynamic world

Heba Tork Regulatory and Quality Manager-North Africa Roche Diagnostics





- Advantages of Electronic
   Instructions for Use
- 2. Regulatory Landscape
- 3. Challenges of Implementing
- 4. Potential Solution
- 5. Recommendation



Advantages of Electronic Instructions for Use

# **Electronic Instructions for Use (E-IFU)**

## **Advantages**

- Up-to-date Information: Ensures healthcare professionals and users always have access to the latest instructions, including safety updates or recall information.
- 2. **Increased Availability**: Accessible across multiple platforms, crucial in hospital settings where traditional paper IFUs may be misplaced or discarded.
- 3. **Enhanced Searchability**: Searchable content allows quick location of specific information, enabling efficient updates or corrections.
- 4. **Improved Usability**: Offers multiple language options, zoom features, and in some cases, dictation tools, enhancing accessibility for users with disabilities.
- 5. **Support for Innovation**: Facilitates the integration of new technologies and rapid updates, keeping pace with technological advances and evolving regulations.
- 6. **Durability**: Unlike paper IFUs, e-IFUs are resistant to wear, tear, and contamination, ensuring clarity and accessibility over time.
- 7. **Supply Chain Efficiency**: Reduces the need for physical printing and distribution, lowering costs and minimizing risks of disruptions, contributing to a more reliable and resilient supply chain.



**Examples EEMEA** 



#### **Saudi Arabia:**

MDS – G10: Labelling Requirements for Medical Devices

#### **Key Points on eIFU Requirements**

#### 1. Paper IFU Requirement for Lay Users

-Devices intended for **laypersons** must include **paper instructions** for use

#### 2. eIFU Labeling for Professional Use

- Devices using eIFU must clearly state that instructions are provided electronically
- Web Address (URL): Must be provided with a clear navigation path to the eIFU location

#### 3. Devices with Built-in Display for eIFU

- The eIFU display must not interfere with **safe operation** of the device, especially in critical functions (e.g., life-supporting or monitoring systems)

**Examples EEMEA** 



#### **Bahrain:**

Introduction of Electronic IFU (eIFU)

Circular No. 2 (2021) – National Health Regulatory Authority (NHRA)

### **Usage Restrictions**

- 1. **Allowed for:** Professional users with specific eIFU training
- 2. Not allowed for: Lay users, to ensure safe and proper use of devices

**Examples EEMEA** 



## **Turkey:**

**EU IVDR: Electronic Instructions for Use (eIFU) for Professional Use** 

*Key Provisions (Annex I, Chapter III, 20.1(f) & Circular)* 



## **Egypt:**

Medical devices and IVDs

Pharmaceuticals.

# Advocacy for e-IFU Adoption in the MEA Region



Mecomed has actively championed the adoption of Electronic Instructions for Use (e-IFU) within the Middle East and Africa (MEA) region.

By developing and disseminating a position paper, outlining the benefits of e-IFUs, highlights global efforts, and proposes ways the industry can facilitate implementation.

This initiative is part of Mecomed's strategic engagement with regulatory agencies across the region, aiming to <u>increase awareness</u> and <u>drive the adoption</u> of this innovative digital solution.



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## Mecomed Position Paper on Electronic Instruction for Use (E-IFU)

#### Introduction

In a period characterized by rapid digital transformation and technological advancements, the adoption of Electronic Instructions for Use (e-IFU) stands out as a critical evolution in the medical device sector. e-IFUs represent a significant leap towards enhanced efficiency, sustainability, and improved user experience. This position paper explores the integration of e-IFUs addressing the regulatory challenges and potential benefits as the industry moves towards digital solutions.

#### Executive Summary

This paper offers an overview of the Electronic Instructions for Use (e-IFU), highlighting the need for regulatory enhancement and industry collaboration. Representing the Medical Technology industry the Middle East & Africa Region, Mecomed encourages the adoption of eIFU across various device platforms. Globally, eIFUs are embraced for their real-time updates, accessibility, and environmental benefits. Evidence from MedTech Europe supports a strong preference for e-IFU among healthcare professionals due to its ease of access and sustainability. The paper calls for collaborative efforts for higher adoption of E-IFU in the MEA Region and standardized implementation, ensuring security and accessibility to enhance healthcare delivery.

#### Global Adoption and Advantages of e-IFU

Electronic Instructions for Use (e-IFU) have been authorized for professional use across numerous countries globally, including the European Union (for selected product categories), Australia, the United States, Canada, Saudi Arabia, Bahran, Turkey, the United Kingdom, Japan, Singapore, South Korea, and Brazil. This global acceptance highlights the crucial role e-IFU plays in ensuring that healthcare professionals, as well as lay users, have instant access to the most current instruction revisions, thus enhancing safety and efficacy by providing timely and accurate information.

Additionally, e-IFU facilitates a more straightforward process for users to search through content and quickly find necessary information. The shift towards flexible formats in patient information materials aligns with global trends, emphasizing the relevance and timeliness of adopting e-IFU systems.

#### IFUs provide to healthcare professionals and users, including:

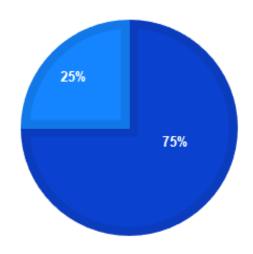
- <u>Up-to-date information</u>: eIFUs available online ensure users have access to the most current information, including any important safety updates or several benefits recall information.
- Increased availability: eIFUs can be accessed via multiple platforms whenever the user needs them, which is especially important in a hospital environment where paper IFUs are likely to be disposed of or lost. Also, professional users have specific training in their medical discipline

# **APACMed Survey**

Insights from 45 industry respondents

#### REGULATORY LANDSCAPE OVERVIEW

- Country with e-IFU Regulation
- Country with no e-IFU Regulation



\* This data originates from APACMed Position Paper on Electronic Label and Electronic Instructions for Use (e-IFU)

**75** % with e-IFU Regulation in place.

#### **55%**

Of the current e-IFU Regulations are allowing Professional Use while only **45%** of them covering both, **professional & home** use device.

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# MedTech Europe Survey on e-IFU Regulation Expansion

MedTech Europe's recent survey targeted at expanding e-IFU regulations within the EU reveals a strong preference among healthcare professionals for electronic formats.

Key findings from the survey indicate:

- Over 90% of hospital pharmacists, procurement officers, and administrative staff favor e-IFUs.
- There are no safety concerns about healthcare professionals accessing e-IFUs
- Healthcare professionals significantly favor the electronic format over paper, highlighting a
  preference for digital accessibility.
- Many consumers are digitally savvy, suggesting a smooth transition and positive reception towards e-IFUs.

These insights highlight the substantial benefits and growing support for e-IFUs across the European healthcare sector.

# **European Commission Survey**

On Electronic instructions for use for professional use medical devices

Another survey was conducted by the EU Commission from 1 August 2024 -11 October 2024

which may complement the existing knowledge with additional details to be leveraged for the scope extension of e-IFU for professional use medical device products, where we shall keep you informed of respective result findings, as well as future developments.



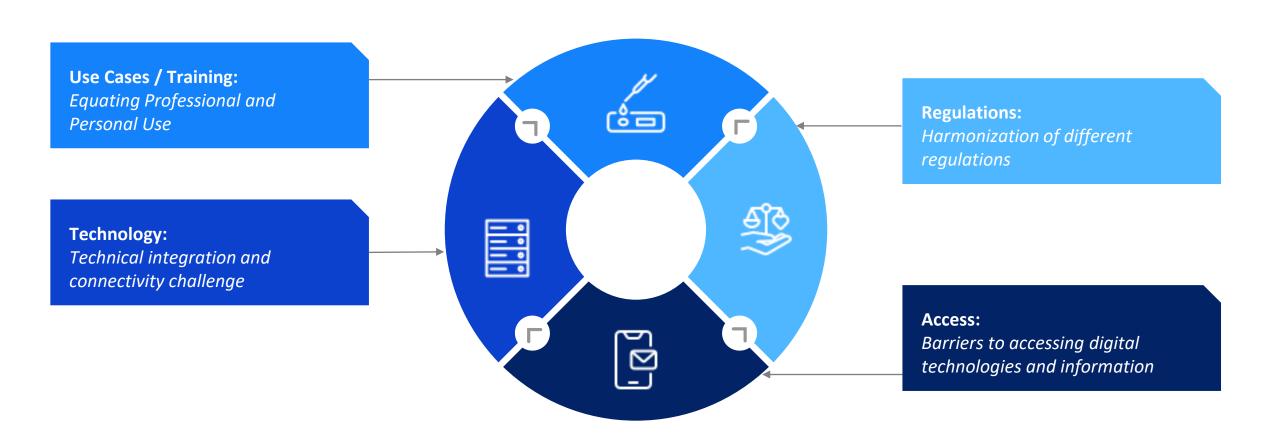


Challenges of Implementing





Challenges



# **Potential Solution**





## Recommendations

## Moving forward

#### **Use Cases:**

Making eIFU accessible for both professionals and lay users.

Offering easy-to-navigate, understandable, and visual content

**Training Programs:** in the case of home-use devices, digital literacy programs can be introduced

#### **Technology:**

Digital literacy programs and local partnerships for skill-building.

Manufacturers can develop **offline** solutions such as preloaded tablets or USB drives.

Improved **infrastructure** in low-access areas; paper copies on request.

#### **Regulations:**

International standards, with global organizations like the WHO or IMDRF developing common guidelines for medical devices

Bilateral and multilateral agreements between countries or regions

#### Access:

remporary use of traditional printed and electronic labels to ensure Educational initiatives and local partnerships to support users with limited digital skills through hands-on training

Expansion of digital infrastructure in underserved areas, with optional paper copies available on request.

# Recommendation





# Recommendations

Moving forward



e-Label and e-IFU Solutions in Healthcare

# Adopt Electronic Labels for Compliance and Flexibility

- Real-time updates, multilingual support, and cost savings.
- Environmentally friendly by reducing paper use.

# Expand e-IFU to Home-Use Devices

 Include consumer devices in e-IFU standards for clarity and safety, supporting this growing market.

# Harmonize Standards Across Markets

 Standardization simplifies compliance, promotes safety, and boosts quality across regions.



# Recommendations

Moving forward



e-Label and e-IFU Solutions in Healthcare

# Conduct Thorough Risk Assessments

 Ensure digital solutions are safe, addressing risks like digital literacy and platform reliability.

# Support Sustainability and Cost Savings

Reduces
 environmental
 impact and
 enhances
 distribution
 efficiency in the
 healthcare sector.

# Address Connectivity and Digital Literacy

 Identify lowconnectivity areas and provide tailored digital support, such as offline access and training. Doing now what patients need next