Electronic Instructions for Use (eIFU) for Medical Devices

Challenges and Opportunities in a dynamic world

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Advantages of Electronic Instructions for Use

Electronic Instructions for Use (E-IFU)

Advantages

1. **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.

Regulatory Landscape

Regulatory Landscape

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)

Regulatory Landscape

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

Regulatory Landscape

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 increase awareness and drive the adoption of this innovative digital solution.
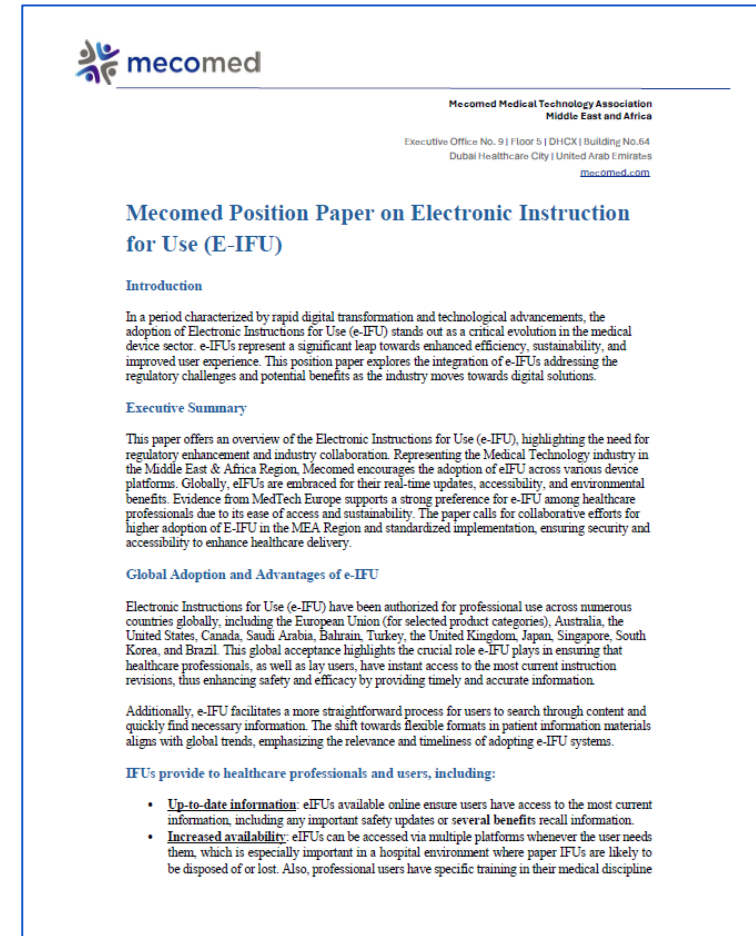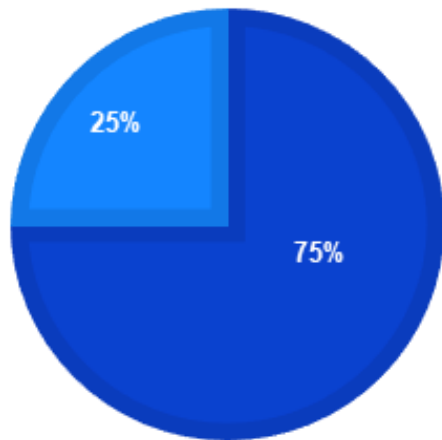
APACMed Survey

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

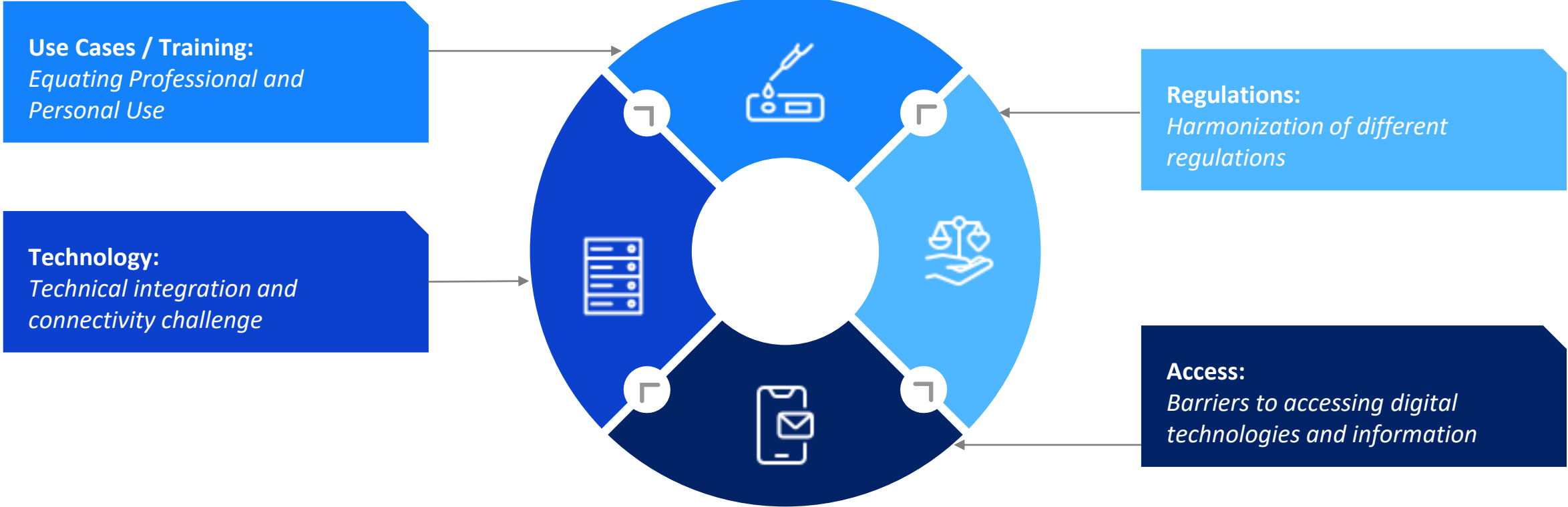Another survey was conducted by the EU Commission from 1 August 2024 -11 October 2024
which may complement the existing knowledge with additional details to be leveraged for the scope extension of e-IFU for professional use medical device products, where we shall keep you informed of respective result findings, as well as future developments.

Challenges of Implementing

Electronic Instructions for Use

Challenges

Use Cases / Training:
Equating Professional and Personal Use

Technology:
Technical integration and connectivity challenge

Regulations:
Harmonization of different regulations

Access:
Barriers to accessing digital technologies and information

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:

Temporary 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 low-connectivity areas and provide tailored digital support, such as offline access and training.

Doing now what patients need next