MedTech Europe
from diagnosis to cure

POSITION PAPER

Electronic Instructions for Use for all professional use Medical Devices:

MedTech Europe calls for scope expansion of EU 2021/2226

November 2022

Introduction

With the rapid evolution of technology, MedTech Europe believes that the Regulation (EU) 2021/2226 (eIFU Regulation) no longer reflects the generally acknowledged state of the art as called out in the Medical Device Regulation 2017/745 (MDR); Annex I General Requirements, Art.1. Regulation (EU) 2021/2226, even though recently published, only allows for a limited extension of the original legislation EU 207/2012 in terms of scope. It falls short of the needed legislation for a digital era that allows for **the use of electronic format Instructions for Use (eIFU) for all professional use medical devices**.

Industry has been asked at various instances to provide data from the field which could support any such extension of scope. MedTech Europe conducted a data collection survey among healthcare professionals and other staff working in hospitals, from which clear messages emerged regarding the healthcare sector's preference for an electronic format IFU.
Therefore, we call on the European Commission and the Member States to amend the Regulation (EU) 2021/2226 to allow for an expanded use of electronic format IFU for all medical devices used by professionals.

The move to electronic IFU (eIFU) for professional use devices started almost two decades ago in major markets like the US and quickly followed by Canada. The trend continues with more recent expansions in electronic IFU use in other markets[1]. An extension of the European legislation to include all professional use medical devices would align with other major markets where electronic IFU has been used successfully and without an increase in vigilance cases[2]. This would further foster regulatory convergence efforts as seen in the IMDRF[3].

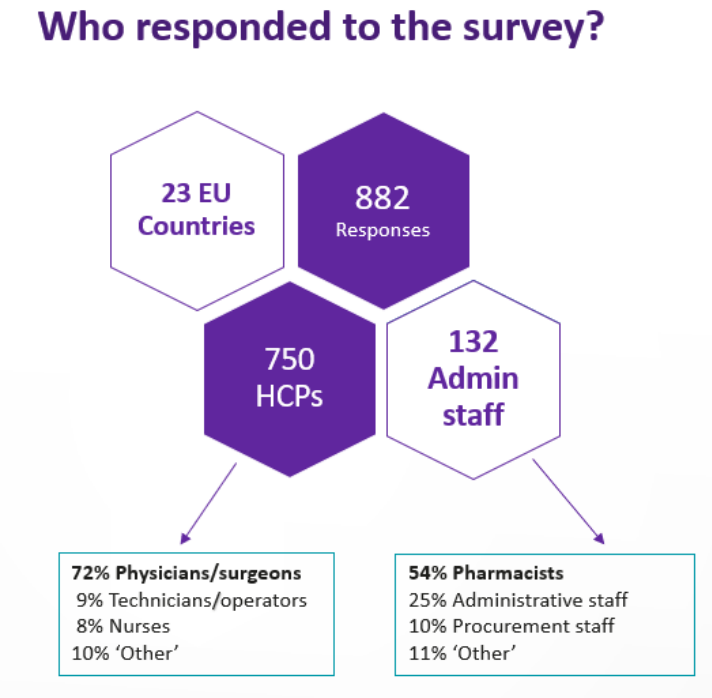
[1] A detailed list of all countries currently allowing the use of eIFU can be found in Annex I.

[2] Vigilance is a safety indicator for the safe use of medical devices in line with the use and intended purpose of the device

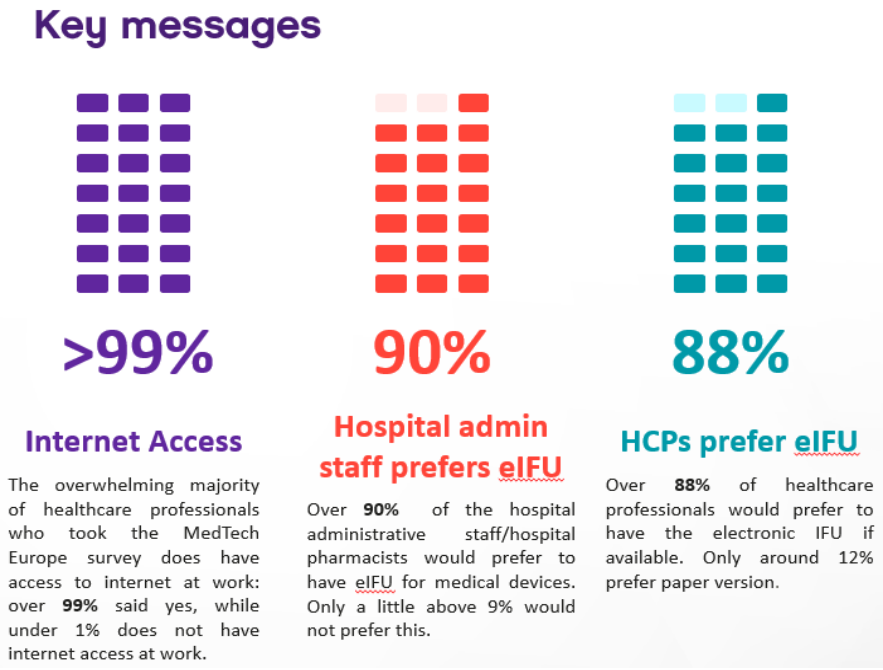
[3] Principles of Labelling for Medical Devices and IVD Medical Devices: https://www.imdrf.org/documents/principles-labelling-medical-devices-and-ivd-medical-devices

About MedTech Europe survey

MedTech Europe conducted a data collection survey among healthcare professionals (HCPs) in the EU between February and September 2022 and an additional survey among hospital administrative staff/hospital pharmacists during the same time frame. Both surveys were available in 15 European languages.



Clear messages of support for electronic IFU have emerged:



1. Risk management & safety

The concept of eIFU in Europe has always been driven by the risk management process. This includes the obligation of manufacturers to investigate accessibility by professional users to electronic labelling. Such access ensures that users will be in a position to use devices safely.

MedTech Europe survey confirms widespread internet access among health care professionals – over 99% of respondents indicate that they have internet access in their workplace.

EIFU has been accepted for high-risk devices such as active implantable devices since 2013, while low risk devices are still not included in the most recent legislation. Our proposal seeks to put all professional use devices on equal footing by extending the current EU eIFU legal framework. Each manufacturer that choses to apply this legislation must make an application to their Notified Body (NB) who will evaluate their compliance to the legislation before granting certification. This is true under the original and revised legislation, and this would not change with our proposed extension.

It should be also reiterated that any professional user can always request a paper copy from the manufacturer if they wish, and the manufacturer has the obligation to provide it as stated in the Regulation (EU) 2021/2226.

2. Healthcare sector prefers electronic format

The overwhelming preference of healthcare professionals for eIFU – over 88% of the survey respondents – renders paper redundant.

Other key employees in the healthcare sector expressed an even stronger preference for electronic format: **Over 90% of respondents of the second MedTech Europe survey for hospital pharmacists, procurement and other admin staff indicate that they prefer eIFU.**

Between both surveys, the response was clear:

- eIFU are easier to
  - store and access
  - search and navigate
  - find the latest version
- eIFU can be consulted anywhere
- eIFU reduce waste

Waste reduction in particular ranks high for the healthcare sector employees, which is aligned with general drive of the EU towards sustainability (Green Deal). National legislations in various EU Member States are

already introducing waste reduction measures at their local level in order to drive sustainability forward. Additionally, some manufacturers have continued to receive feedback for many years that hospitals do not want paper IFU, even for devices that are not eligible for an eIFU under the current eIFU regulation.

Conclusion

In order to consider expanding the scope of the eIFU regulation, industry was asked to provide supportive data from the healthcare sector which would show that there is no safety concern and healthcare professionals feel comfortable using the electronic format. The data gathered by MedTech Europe shows precisely that:

a) there is no safety concern about healthcare professionals not being able to access the eIFU as internet coverage in hospital is extremely high.
b) healthcare professionals themselves are highly supportive of the electronic format and would prefer it as opposed to paper format.

As outlined in this paper, the proposed scope expansion does not in any way alter the established risk management procedures and evaluation of compliance by the Notified Body for each device applying the eIFU regulation. Moreover, high risk devices have already benefitted from the electronic format for nearly a decade while low risk devices do not. Our proposal, supported by data from the field, is simply to allow an electronic IFU format for all professional use medical devices.

Putting all professional use devices on equal footing by expanding the scope of Regulation (EU) 2021/2226 will create a fair and level playing field for all, respond to the demands of the healthcare professionals and other key hospital staff as well as lead to global regulatory convergence with the EU firmly in the centre.

We are, therefore, calling on the European Commission and the Member States to seize this opportunity and we are offering our support in this endeavour.

ANNEX I – use of e-IFU worldwide: examples

Please note that this list may be non-exhaustive.

USA

General Program Memorandum #G03-1 (MDUFMA), Dated: 31-Mar-2003:
Section 206 of MDUFMA amended Section 502(f) of the Federal Food, Drug, and Cosmetic Act (the Act) to authorize the use of electronic labelling, rather than the traditional paper labelling, under specified circumstances. Upon enactment, distributors of prescription devices who intend those devices to be used within the confines of a health care facility may provide labelling for those devices solely in electronic form, so long as they afford users the opportunity to request the labelling in paper form and promptly provide such labelling to requestors without additional cost.
The 2004 Medical Devices Technical Corrections Act (MDTCA), P.L 108-214 amended and expanded the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

Section 2(b)(2)(B)(i) extends the electronic labeling provision (section 502(f) of the FD&C Act)
To

- Prescription devices used by a health care professional, regardless of the setting in which the device is used.

Australia

Electronic Instructions for Use – e-IFU, For professional users of MDs (including IVDs) Guidance, V 1.0, Aug 2018: Eligible devices are limited to those intended for use by professional users, and not for supply to the general public.

Canada

File No. 15-107097-797 26-Jun-2015>
For devices that are not sold to the general public, this information may be provided as downloadable from the internet and/or on electronic data storage devices, such as compact disc, digital video disc or universal serial bus (USB) flash drive.

Brazil

ANVISA Collegiate Board of Directors RDC 751/2022 Dated: Sep 15th, 2022
(*previous provision on eIFU: Normative Instruction – IN No. 4, Article 2; 15 June 2012)*
Article 54
The exclusive availability of non-printed format instructions for the following products is prohibited:

I – health use equipment that has an indication of:
a) domestic use in general, including those for use in home care service – SAD; and
b) Lay operation, regardless of the place of use;
II – health materials used by lay public

Japan

The new Japanese regulation eliminates the ability to provide eIFU (previously called “Tempu Bunsho”) in physical format for professional users. The new law requires all IFUs to be provided in electronic-only format, uploaded and maintained on a regulator-owned application, accessible by all customers. This does not apply to patient IFUs.

- PMD Act Article 63, Paragraph 2 Item1(Code etc. to be stated on containers).
  - This article state requirement about code etc. to be stated on containers to obtain eTempubunsho, which shall contain information defined by PMD Act Article 68, Paragraph 2 Item2, and shall be published in accordance with PMD Act Article 68, Paragraph 2 Item1.
- PMD Act Article 68, Paragraph 2 (Publishing eTempubunsho)
  - PMD Act Article 68, Paragraph 2 Item1 states requirement about eTempubunsho to be published on PMDA web site.
  - PMD Act Article 68, Paragraph 2 Item2 states requirement about items to be contained in eTempubunsho.

Saudi Arabia

MDS – G10: Guidance on Labelling Requirements for Medical Devices, Dated: 18-Jan-2015:
Where the device is intended for use by lay persons, the IFU shall be provided in a paper format.

South Korea

MFDS notification 2018-500. This notification amended the Medical Device Act to specifically call out that providing required labeling via the internet is permitted. No other requirements were included in the notification, but only products which are specifically permitted per the notification may be eLabeled. Home-use labeling may not be eLabeled.

Singapore

Singapore's labeling requirements are guided by GN-23 (June 2018) 'Guidance on Labeling for Medical Devices'. This document notes that paper IFUs should be provided except where specified. Several additional requirements note that for eLabeling:

- IFU may be provided in paper or non-paper format for professional-use devices
- When provided in a form other than paper, the customer must have instructions on how to view and access the IFU
- The internet address must be clearly printed on the physical label of the device. The electronic labeling must be identical to what would be provided in paper, and what is submitted.

Bahrain

Circular No. 2 (2021), Date: 17 January 2021
Subject: Using "Electronic IFU
To: all importers of medical devices and manufacturers
As per NHRA role in monitoring the import and marketing of medical devices in the Bahrain market and ensuring safety and public health protection. the authority would like to draw the attention of all importers of medical devices and manufacturers to the fact that in addition to the many benefits of using "Electronic IFU" including:
• Easy access to the latest information related to the use of the medical device.
• Searchable, which reduces search time for specific information.
• It offers more language options and the ability to enlarge text and image. However, the use of this type of IFU is limited only to professional users who receive training on the use of E-IFU and it is not permissible to use it by lay people in order to ensure the safety use of the medical device.

Serbia

Official Gazette of RS", No. 105/2017, Article 93:
In the case where exclusively healthcare professionals use the medical device and the accompanying equipment, or if their use is not foreseen by persons other than healthcare workers, the manufacturer may provide instructions for use in electronic form instead of in paper form.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

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