2025-03-21

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Position paper on the extension of the scope for eIFU for medical devices

Comments and proposals on the draft of Commission Implementing Regulation amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form

Introduction

Eurom welcomes the European Commission's initiative to revise EU regulation 2021/2226. Electronic Instructions for Use (eIFU) will improve accessibility, searchability, and flexibility for medical device professionals. It also strongly aligns with goals related to sustainability, resource and climate protection, and the essential digitalization needed in the EU to maintain global competitiveness.
We believe the draft successfully achieves its intention. Although, some sections of the text need clearer wording to avoid any possible misunderstandings. We would like to emphasize the following points:

eIFUs for legacy devices (recital (5) of the Commissions draft)

The intention behind the provision to align with the transitional timelines of the Medical Device Regulation (MDR) is acknowledged. However, the language used in Article 10 of Commission Implementing Regulation (EU) 2021/2226, which stipulates that the previous regulation 'shall continue to apply,' necessitates that legacy devices comply with the now-repealed Regulation 207/2012. As a result, this stipulation restricts legacy devices from benefiting from the broadened scope introduced by the forthcoming update of EU 2021/2226. Instead, these devices will be obligated to continue providing paper documentation for professional use, except for those specifically mentioned in Article 3 of Regulation 2021/2226, until the conclusion of the transition period in 2028.

To address the unique circumstances surrounding legacy devices during the MDR transition period, it is proposed that manufacturers be granted the option to either maintain compliance with Regulation EU 207/2012 or to adopt the updated provisions of EU 2021/2226, thereby enabling them to take advantage of the expanded scope. Consequently, we recommend amending the wording in Recital 3 of the Commission's draft to reflect this suggestion:

3) The scope of application of Implementing Regulation (EU) 2021/2226 should therefore be extended to all medical devices and their accessories covered by Regulation (EU) 2017/745 that are intended for professional users, including all medical devices falling under article 120 of the Regulation (EU) 2017/745.

To cover all legacy devices Article 10 and Preamble 9 of (EU) 2021/2226 should be updated:

Article 10

"Commission Regulation (EU) No 207/2012 is repealed.

However, ~~it~~ manufacturers may ~~shall~~ continue to apply it to devices placed on the market or put into service in accordance with Article 120 (3) of Regulation (EU) 2017/745 ~~until 26 May 2024~~ 'until 31 December 2028, at the latest'."

Preamble (9)

"In order to ensure that the rules as regards electronic instructions for use are adapted to the new requirements of Regulation (EU) 2017/745, Commission Regulation (EU) No 207/2012 should be therefore repealed. It may ~~should~~ however continue to apply to devices placed on the market or put into service during the transitional period set out in Article 120(3) of Regulation (EU) 2017/745."

One common URL adress to access all eIFUs (recital (4) and Article 1 (7) of the Commissions draft)

The feasibility of linking individual eIFU URLs for each European language within EUDAMED is limited, and it is impractical to include a separate URL for every version, including translations and historical iterations, on the device label. To mitigate the risk of misinterpretation, it is recommended that a similar wording as in recital (4) be incorporated into Article 1 (3) of the draft:

„(3) in Article 7, the following paragraph is added:

'(3) All ~~The~~ instructions for use in electronic form shall be persistenly accessible ~~available~~ through ~~a~~ one common ~~persistently accessible~~ Uniform Resource Locator (URL), which the manufacturer shall provide to the UDI database in accordance with Part B, point 22, of Annex VI to Regulation (EU) 2017/745, at the latest when the registration of devices in Eudamed applies in accordance with Article 123(3), points (d) and (e), of that Regulation.';"

Furthermore, we would like to point out, that the field "Manufacturer`s website where additional information about the device (UDI-DI) are available" in EUDAMED is 'optional.' We propose changing this field to "conditional".

Clarification regarding Article 5 (12) of Regulation (EU) 2021/2226

Article 5 (12) of Regulation (EU) 2021/2226 is applicable to implants, software, and active products that incorporate electronic Instructions for Use (eIFU), for which the regulation was initially designed. However, this requirement presents challenges for mass-produced items and a diverse range of products. Monitoring the individuals who have downloaded the Instructions for Use and subsequently reaching out to them when a new version is available is not practical, except in cases of Field Safety Corrective Actions (FSCA) related changes in the Instructions for Use, as governed by Article 5 (8) of Regulation (EU) 2021/2226. The resources required for this process are disproportionate, particularly in light of data protection regulations and other considerations. Additionally, individuals seeking to download the guide would be required to register in advance and log in to access it again.

We therefore recommend to modify Article 5 (12):

Article 5

(12) Only for implants, software and active products:

effective systems and procedures shall be in place to ensure that device users having downloaded instructions for use from the website can be informed in case of updates or corrective actions with regards to those instructions for use.

Clarity regarding Article 1 (4) (EU) 2021/2226

„Article 1 Implementing Regulation (EU) 2021/2226 is amended as follows:

[…]

(2) in Article 6, paragraph (4) is replaced by the following:

'(4) Where, for implantable medical devices and their accessories covered by Regulation (EU) 2017/745, a part of the instructions for use is intended to be provided to the patient, that part shall not be provided in electronic form.';"

By law, the implant card is not considered part of the IfU, but it must convey the same essential information to patients, such as warnings and precautions. As a result, Notified Bodies often view the implant card as part of the Instructions for Use. Since the draft legal text refers to the "part of" the Instructions for Use, we will clarify that implant cards are not included under this wording. Please consider adding an explicit statement regarding implant cards for better clarity:

(4) „For implantable medical devices and their accessories covered by Regulation EU 2017/745, only parts of the instructions for use not intended to be provided to the patient, can be provided in electronic form. All other parts of the instructions for use are to be provided physically."

Future Expansion of the Scope of the eIFU Regulation for medical devices intended for non-professional

Electronic Instructions for Use (eIFU) provide a range of advantages. The adoption of eIFU can mitigate environmental impact, enhance flexibility, improve usability, and potentially raise safety standards. Based on the insights gained from the implementation of eIFU for all medical devices designed for professional use, we advocate for an expansion of the eIFU regulation's scope beyond its existing constraints. This extension would enable the associated benefits to be realized for medical devices intended for non-professional use as well.