MedTech Europe
from diagnosis to cure

MedTech Europe 2025 response to European Commission consultation on draft revision amending EU Regulation 2021/2226 on eIFU

MedTech Europe warmly welcomes the European Commission's proposal for the update of the EU Regulation 2021/2226 *laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices.*

This is a move in the right direction as electronic instructions for use (eIFU) will improve accessibility, searchability and adaptability for professional users of medical devices. The possibility to provide eIFU for all professional use medical devices will also greatly contribute to reduction of paper waste and help manufacturers streamline their process and supply their devices faster. The user will always have the most up-to-date version of the IFU.

Looking towards the future, in the fast-changing digitalisation landscape, a more eco-friendly, paper-free, and efficient healthcare environment is imperative. Further digitalisation is crucial for increasing Europe's competitiveness, streamlining processes and reducing administrative burden of both EU Regulations for medical devices (MDR) and *in vitro* diagnostics (IVDR).

For the medical device sector, further digitalisation initiatives need to be envisaged, such as eIFU for lay users (particularly where the lay user is trained by a professional).

For the IVD sector, MedTech Europe calls for expanding eIFU to all professional use IVDs, including devices intended for near-patient testing.

We would like to urge a start of such discussions in the Medical Devices Coordination Group (MDCG) as soon as possible; in line with the overall broader ambition around EU goals of competitiveness, simplification, digital transformation, and sustainability.

With regards to the current draft, we would like to make 5 comments:

1. Annex XVI devices

In order to ensure consistency and alignment, we suggest that Annex XVI devices (without an intended medical purpose) used by professionals be also included in the scope. The devices included in this Annex follow the MDR, the applicable conformity assessment, and are used by the same healthcare professionals as devices with medical intended purpose.

Notably, there are certain Annex XVI devices with a dual medical-aesthetic purpose, whereby the device is used for a clear medical intended purpose, and the same device is also used for an aesthetic purpose. The procedure remains the same as does the intended user, i.e., healthcare professional. Based on the wording in the current draft, such devices, even though they have a medical intended purpose and are used by healthcare professionals, would still have to supply IFU on paper.

In order to align with the updated scope of this Regulation whereby all devices used by professionals may be supplied with eIFU, we propose to:

a) remove 3rd paragraph of article 1:

~~'This Regulation does not cover products listed in Annex XVI to Regulation (EU) 2017/745'~~

b) adjust Article 3 (1) as follows:

'(1) Manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to ~~medical~~ devices ~~and their accessories~~ covered by Regulation (EU) 2017/745 intended for use by professional users.';"

2. Clarification Art.10 – legacy devices

We recognise the intent of the provision to align with the MDR transitional timelines. However, since Art. 10 says **'shall** continue to apply' this makes mandatory that legacy devices apply the repealed 207/2012 Regulation. As a result of such provision, legacy devices would not benefit from the enlarged scope of the soon-to-be-updated EU 2021/2226 but would have to continue, until end 2028, providing paper for professional use devices other than the ones listed in the current text of 2021/2226 Art. 3.
In order to accommodate the specific situation of legacy devices that would wish to benefit from the newly extended scope of eIFU before the end of the MDR transition period, MedTech Europe asks the European Commission and the EU Member States to allow manufacturers to choose whether to continue in compliance with EU 207/2012 or apply the updated EU 2021/2226 and hereby benefit from the enlarged scope.

Our suggested update for Article 10 and Preamble 9:

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'.***

In this connection, also the preamble number 9 should be updated:

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.*

3. Clarifications regarding the nature of the URL

Our understanding is that the URL to be provided in EUDAMED in accordance with Part B, point 22, of Annex VI to Regulation (EU) 2017/745, is the same as the URL provided by the manufacturer on the device label.

MedTech Europe suggests that:

a) The new Art. 7(3). refers to Art 7(2)e) for clarification and consistency,
b) The reference to the URL being 'persistently accessible' is removed since this is in direct contrast to Art. 7(2)e): *the Internet address as displayed in accordance with Article 6 (2) shall be stable and directly accessible during the periods set out in Article 5, points (9) and (10);*
c) In order to increase language consistency throughout the Regulation EU 2021/2226 text, include *'internet address'* as per Art.7(2) e) instead of Uniform Resource Locator (URL). The reference to the specific URL field in EUDAMED is already captured by: *UDI database in accordance with Part B, point 22, of Annex VI to Regulation (EU) 2017/745*

Based on this the Article 7(3) should be updated as follows:

In Article 7, the following paragraph is added: *'(3) The instructions for use in electronic form shall be available through ~~a persistently accessible~~ ~~Uniform Resource Locator (URL)~~* ***the Internet address as per point 2 e) of this article,*** *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.'*

4. Reiterating comments regarding Article 5 made in 2021

We would like to reiterate our comments made in 2021 on the then-new requirements in Art. 5 (12) and (13). These are considered even more relevant now due to the increase in scope of Regulation EU 2021/2226 and, therefore, the potential to affect many more devices.

a) Art.5(12) is partly repetition of Art.5(8) and implies that manufacturers need to track which users downloaded what documents. Existing websites do not have the capability of tracking downloads and then notifying anyone who has downloaded the document of updated versions posted on the website. **Also, MDR Annex I 23 (4) does not require this**. Further, we are concerned about **contradictions with Regulation (EU) 2016/679 on** data **privacy;** it is unclear if the present legislation **is fit as a legal basis** to allow processing personal data from site users. **Art. 5(8) is sufficient in our view: we ask for removal of Art. 5(12).**
b) Article 5(8) already covers the obligation of manufacturer to inform device users if the instructions have been revised due to a safety issue. This is a standard practice per MDR Art. 87 *vigilance requirements*.
c) Art.7(2) f) specifies that all versions to be made available online are all versions in electronic format (aligned with EU 207/2012) and Art.5(9)/(10) specifies the duration of this requirement.
d) **We ask for the removal of Art. 5(13) mentioning all 'historical versions'**. This may imply manufacturer needs to make available all IFUs ever created (including paper ones), which would create confusion for users and potential safety concerns due to out of date information.

5. Devices used by both professional and lay users

We propose a slight update in the current text of the Regulation EU 2021/2226 in order to avoid that certain devices (e.g. neurostimulators, diabetes management implantable devices) used by both professionals and patients are inadvertently left out of scope. In these cases, the patients always receive the patient-specific IFU in paper, but it should be possible for the professional use IFU to be supplied to the healthcare professional in electronic format – in line with the overall scope of this updated regulation (and in line with HCPs preference for electronic format).

Therefore, we suggest these updates in Art. 3(2):
(2) Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions:
(a) the devices and accessories are intended for ~~exclusive~~ use by professional users, and

(b)the use by other persons is not reasonably foreseeable ***except as outlined in Art 6(4)***

About us

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. www.MedTecheurope.org

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