COCIR Feedback

Draft Commission Implementing Regulation on electronic instructions for use of Medical Devices

Introduction

COCIR appreciates the additional opportunity to provide industry feedback to the draft Implementing Regulation[1] on electronic instructions for use (IfU) under the Medical Device Regulation. In general, the availability of electronic IfU is wider than providing one hardcopy. Commonly used technologies provide means for full-text search which has a clear benefit for the usability of the Instructions for Use. The current e-IFU regulation is behind the times in terms of technology and the need to provide ease of access to information for clinicians. In addition, the adverse environmental impact of continuing to require paper manuals for the majority of devices in the EU is extremely wasteful and does not align with the conservation and waste reduction principles central to the EU.

Clearly the future of Instructions for Use, for professional users or lay persons, lies within their electronic provision - independent of being embedded in the software as an online help system, or through separate means. Medical devices should by default be allowed to use e-IfU unless otherwise specified. It should be up to the manufacturer to decide if the Instructions for Use are provided electronically or on paper depending on their analysis of the device use, as long as it can meet all other risk assessment and other provisions within the e-IfU regulation. By following the existing risk management framework already built into the regulation, along with the provisions to ensure paper manuals are provided immediately to any customer who requests them, free of charge, the potential risks are well mitigated, and the regulation can better support the current workflow and expectations of clinicians in today's environment.

Each medical device needs to consider during its design the extent of information supplied to the users as well as aspects of usability by considering the type of user and their knowledge. Risks related from the use of the device are subject to pre-and post-market obligations by state-of-the-art standards. Especially for software, we believe the distinction between professional users and lay persons in times of mobile health and electronic health is no longer considered as meaningful for the purpose of this regulation.

We also note that the proposed Implementing Regulation only covers medical devices in its scope. We expect that similar provisions will be adopted for electronic Instructions for Use for IVD medical devices.

Detailed feedback

Article 3

In Article 3(3) the specific situation of software needs to be considered. We believe if the medical device is standalone software (especially in case of downloads or app repositories), the e-IfU is sufficient as being closer to the characteristic use of the device.
Recommendation: in the case of standalone software, the on-demand print requirement should not be applied. Software providers should be required to provide the information

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12954-Medical-devices-online-manuals-replacing-paper-instructions_en

that the IfU are electronically available at the location from where access to the software is granted (instead of on the packaging or the device itself).

Article 5

Manufacturers face a challenging task to assemble paper copies because these are not used much anymore.
Recommendation: change the requirement in Art. 5.3 to provide Instructions for Use in printed paper form to "7 working days" instead of "7 calendar days."

Article 5(10) states, "*for devices without a defined expiry date and implantable devices, they shall keep the instructions for use available for the users in electronic form for 15 years after the last device has been placed on the market" which* is not aligned with EU MDR article 10.8.
Recommendation: instructions for use should be available for 10 years instead of 15 years for non-implantable devices.

5(8) and 5(12) are not aligned. In article 5(8) it is stated, "*they shall have a system in place to clearly indicate when the instructions for use have been revised and to inform each user of the device thereof if the revision was necessary for safety reasons*" while in article 5(12) it is not restricted to safety reasons only. Article 5(12), as currently proposed, means that the manufacturer will have to track all users that download an e-IfU and need to inform them in case of updates of correctives actions in the IfU. This would be redundant action for the manufacturer as users will always be informed of safety of the IfU via the already existing Field Safety Corrective Action process.
Recommendation: Article 5(12) should be removed.

Article 5(13) specifying that "*all issued historical versions*" is explained in article 7(2.f) " *all previous versions of the instructions for use issued in electronic form*". Article 5(13) is thus a duplication of article 7 (2.f).
Recommendation: Article 5 (13) should be removed or alternatively replaced by "the manufacturer shall keep all issued historical versions of the instructions for use. The instructions for use shall be available on the website for the time indicated in Article 5 (9)"

Article 6

Article 6.1 states, "that information shall be provided on the packaging for each unit or, where appropriate, on the sales packaging. In the case of fixed installed medical devices, that information shall also be provided on the device itself." For fixed installed medical devices, the label on packaging may be misunderstood, because packaging or sales packaging are not for the end user, but for logistics, carriers or technical service people, while the label deals with the user manual and not with other instructions.
Recommendation: in the case of fixed installed medical devices, the information should be provided only on the device.

In Article 6(3)(b), we would like to note that the Basic UDI is not labeled on the product and should thus not be required.
Recommendation: the requirement to include the Basic UDI-DI should be deleted.

Article 7

In Article 7(2)(b), it is not clear what „unauthorized access" means in this context, if (1) only customers who purchased the product should have access to the e-IfUs in the document library, or (2) access to the document library should be protected to prevent tampering of content.

Recommendation: “it shall be protected against unauthorized access and tampering of content in accordance with Article 4(1), point (e)” should be replaced by “it shall be protected against tampering of content in accordance with Article 4(1), point (e)”

The requirement to have all previous versions of the instructions for use available on the website is too burdensome.
Recommendation: Article 7(2)(f) should be removed or alternatively replaced by “the manufacturer shall keep all issued historical versions of the instructions for use. The instructions for use shall be available on the website for the time indicated in Article 5 (9)”