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BVMed Submission to the public consultation on the proposal for the COMMISSION IMPLEMENTING REGULATION (EU) 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

BVMed welcomes the extension that MDR software is included in the draft.
However, we also point out our previous call for a scope extension to all professional use medical devices. Especially accessories to non-implantable/professional-use medical devices used in the same procedures and by the same users, medical devices and accessories for use in connection with a device with a built-in system displaying the IFU and systems intended for use with software should be integrated in the new regulation.
The arguments for the extension are outlined in detail in MTE position paper (February 2020) which BVMed fully supports. Electronic format will particularly benefit user and environment and will also facilitate the work of Competent Authorities on vigilance cases, FSCA and MDR compliance for importers/distributors. We furthermore would like to highlight the aspects with regard to digitalisation and the "Green Deal" Policy in Europe.

Article 1:
A descriptive wording is used: "[...] *information on safe and proper use, expected* [...]" instead of the defined term "*Instruction for Use*" per Art. 2(14) MDR.
Proposal: Use the same MDR terminology where possible.

Article 5 (12):
This paragraph is partly a repetition of Art. 5(8). Existing eIFU websites solutions do not have the capacity to track which users downloaded which documents. MDR Annex I, Section 23.4 (y) does not require this. Questionable is also the compliance with Regulation (EU) 2016/679 on data privacy.
Proposal: change Art. 5 (12): [...] *can be informed in case of ~~updates or~~ corrective actions* [...]

Article 6 (3) (b):
As Basic UDI-DI is a regulatory and database management concept; MDCG Guidance 2018-1 Rev. 4, April 2021 stipulate that Basic UDI-DI "is independent and separate from the packaging/ labelling of the device and it does not appear on any trade item". Moreover, Legacy Devices neither have a Basic UDI-DI nor a UDI-DI but need to become part of an eIFU website solution, therefore UDI-DI may be one identifier but we will need alternate identifiers. The term UDI-DI is defined in Annex VI, Part C.1.
Proposal: Remove Requirement to carry the Basic UDI-DI with the eIFU website solution.
The wording shall read:

(*b*) *the ~~Basic UDI-DI and~~ UDI-DI of the device, ~~as respectively referred to in Article 27(6) and Article 27(1)(a)(i),~~ as defined in Annex VI, Part C.1 of Regulation (EU) 2017/745, or the Catalogue Number, Part Number, Model Number, Product Name or Model Name and any additional information allowing the identification of the device~~, including its name and if applicable the model~~;*

Article 10:
The requirements with regards to Article 5 (12) and 6 (3) (b) are significant and require eIFU website design changes, validation, and potentially usability studies, in addition to process updates and last but not least potentially will become part of an QMS audit by a Notified Body. All this will take considerable efforts and time; therefore, an appropriate transition time is required. In addition, it may be required to operate two different eIFU website solutions which may provide for ambiguity for legacy devices and its related MDR compliant devices.
If Articles 5(12) and 6 (3)(b) are not changed as proposed above, the transition period shall be aligned for legacy devices and MDR-compliant devices to the end of the grace period on 26 May 2024 in order to avoid the need to operate two systems in parallel.
Proposal: *Commission Regulation (EU) No 207/2012 is repealed with effect as of 26 May 2024.*

Article 11:
As a result of the proposed change of Article 10:
Proposal:
This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union and shall apply as from 26 May 2024.
Manufacturers who comply with this Regulation before 26 May 2024 shall be considered to comply with Regulation (EU) No 207/2012.

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