COCIR requests negative opinion on the draft standardisation request for the Medical Device Regulations (MDR & IVDR)

The new Medical Device Regulation (MDR) will apply from 26 May 2021 (26 May 2022 for the IVDR) with the intent to provide "a high level of protection of health for patients and users and the smooth functioning of the internal market" (MDR, Recital 1). Articles 8 and 9 of both, MDR and IVDR, indicate that "conformity with the relevant harmonised standards" is the preferred way of demonstrating conformity with the legal requirements to achieve this intent. COCIR, the voice of the European medical imaging, radiotherapy, health ICT and electromedical industries, strongly believes in the need for a comprehensive and coherent set of harmonised standards to support and achieve this goal.

In the Medical Devices sector, standards are developed at international level with a strong European influence. This process supports international trade in line with the WTO recommendations to base technical market access requirements on international standards. The EU thus benefits from the global expertise that has gone into these standards and their global recognition – a benefit now to be jeopardised.

COCIR recommendation

COCIR kindly asks the members of the Committee on Standards to review the draft standardisation request in the light of the COCIR concerns, and submit a negative opinion, including the request to better address the needs of the European medical device sector.

Justification

Regretfully, the version of the draft standardisation request that was made available in January 2021, does not address the fundamental concerns[1] that COCIR has been raising over the past years. The current requirements in Annex III will make it virtually impossible to harmonise international standards in the EU. **Based on our recent experience with attempts to harmonise international standards, the likely consequence of this standardisation request is thus that the European Commission will not be able to cite any harmonised standards in the Official Journal under the Medical Device Regulations.** The development of European standards, individually tailored to EU legislation, as implicitly requested, is highly undesirable. The result would be delays in the placing on the market of state-of-the-art medical devices in the EU, barriers to standardisation for SMEs, and increased costs for European medical device manufacturers.

Beyond medical devices, European industry has repeatedly voiced their opinion (see the Open Letter to the European Presidency[2]) that European competitiveness is seriously endangered when international consensus standards cannot be harmonised in Europe or only with considerable delay.

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[1] *Previous comments on 22 March 2019: https://www.cocir.org/media-centre/position-papers/article/cocir-feedback-to-the-draft-standardisation-request-for-the-medical-device-regulation-and-ivd-regulation.html Previous feedback on 25 July 2019: https://www.cocir.org/fileadmin/Position_Papers_2019/2019.07.25_COCIR_feedback_MDR_standardisation_request_FINAL.pdf*

[2] *https://www.cocir.org/fileadmin/Position_Papers_2021/Open_letter_to_PT_Pcy_.pdf*

Summary of feedback to the draft standardisation request

Annexes I and II

1. Fixed lists of standards focus on title and number instead of the MDR/IVDR safety requirements that need to be supported.
2. Standards are included with their version and date without a provision to have these replaced by later revisions, amendments or corrigenda, making the list inflexible.
3. Standards on new technologies, or new standards for existing subjects cannot qualify for harmonisation.

Annex III

1. It is stated that *"The normative body of a harmonised standard shall not [...] contradict any definitions set out in Regulations (EU) 2017/745 and (EU) 2017/746 or define any legally relevant terms not defined in those Regulations."* Recent experience with the HAS consultants has confirmed that this requirement prevents the adoption of existing international standards for medical devices as harmonised European standards.
2. The section on normatively referencing other standards in the body of a standard reflects thinking that is in conflict with state-of-the-art standards development. Using (chains of) normative references to other standards allows easy and reliable reference to established, tested, and accepted requirements without the need to re-invent the wheel.
3. The requirement to modify EN 82304-1:2017 is written in a language that allows two interpretations, which both cannot be realized: Firstly, it is impossible for an international standard due to its lack of regulatory authority to separate between products (software) within the scope of the MDR and those outside. Secondly, the publication of this standards as a twin – one of them applicable for products regulated by the MDR and the other for products not regulated by the MDR – contradicts the interest of the experts to ensure safe software in healthcare.