

COCIR feedback to the draft standardisation request for the Medical Device Regulation and IVD Regulation

We appreciate this opportunity to provide industry feedback to the draft standardisation request for the MDR 2017/745 and IVDR 2017/746. COCIR would like to underline again the importance of having Harmonised Standards available and cited in the Official Journal under these Regulations. Ensuring "*a high level of protection of health for patients and users and the smooth functioning of the internal market*" (Recital 1) also means rapid access (without burdensome and administrative delay) to innovative technologies and medical devices that have proven to be beneficial and safe according to the international (state of the art) standards. The internal EU market is seriously jeopardized when international consensus standards are not harmonised in Europe or harmonised with considerable delay, which is the case today.

Unfortunately, the proposed draft standardisation request includes several elements that prevent flexible harmonisation and timely reference of standards in the Official Journal. Here are our main concerns and proposals to overcome the current issues:

- Insert in Recital (1) of the draft Decision "whilst supporting innovation" after "patients and users" to **align with the wording of the Regulation**.
- A **fixed list of standards** contradicts the market-driven and dynamic nature of standards development. Even worse, standards are included with their version and date, making the list even more inflexible. International standards for medical devices are continuously updated and as such represent the generally acknowledged state of the art. Restricting the harmonisation process to dated standards fundamentally contradicts the requirement to take advantage of the generally acknowledged state of the art standards.
- The draft standardisation request only covers **horizontal standards, while product-specific standards (also called vertical standards) are critically needed** by all stakeholders. Delaying the harmonisation of product-specific standards, until a second standardisation request is adopted, is not acceptable for stakeholders. We recommend broadening the scope of the standardisation request to include vertical and product-specific standards.
- The **deadlines set out in the tables of Annex I respectively Annex II** are unnecessarily restrictive. We recommend removing the deadlines from Article 1(1) and 1(2) and from the tables in Annex I and II.
- The proposed procedure for **revisions and amendments** of harmonised standards (Article 1(3)) is unnecessarily restrictive. Revisions and amendments of standards must be harmonized as quickly as possible, to remain concurrent with the internationally acknowledged state of the art. This can be achieved by removing the editions (publication years) from the standards listed in the tables of Annexes I and II. COCIR also recommends to replace Article 1.3 by: "If, for any standard listed in Table 1 of Annex I, or Table 1 in Annex II, CEN or Cenelec has published or will publish a new version of that standard or otherwise a replacement to that standard, the replacement standard can be used as a basis for execution of the request." Article 5 needs to be withdrawn.
- The **deadlines prescribed in articles 3(5) and Annex I and II** are unnecessarily restrictive. Moreover, the required action by the European Commission is not described. These deadlines should be removed.
- Article 6 includes text ("**This Decision shall expire on 27 May 2024**") suggesting that modification of the Decision is impossible. This means that any new information whether stemming from clinical experience, or market need otherwise, cannot be taken

into account during the approximately 5 years the Decision will be valid. This appears conflicting with the desire to have harmonised standards reflect state of the art. COCIR suggests deleting the quoted text.

- Recent experience with HAS consultants helped us to learn that providing the extremely detailed descriptions required for the **Annexes Z** in Article 4(1) causes unnecessary and unjustified delays of the harmonisation process. Moreover, such extreme level of detail is not useful for stakeholders. We recommend removing the words "*clear and precise*" from Article 4(1).

Conclusion: COCIR does not recommend adoption of the standardisation request in its currently proposed form. We hope that our suggestions for improvement are considered and are ready to contribute through our members' experience in standards development. Hereafter, we have also outlined more detailed feedback to the proposed Annexes of the standardisation request.



Detailed comments on Annexes I, II & III

Annex I	Stakeholders are required to apply the generally acknowledged state of the art. Restricting the Standards Request to precise editions of standards is unnecessary and opposite to the requirement to apply the generally acknowledged state of the art.	Remove the years of publication (editions and amendments) from the standardisation request. Always the most recent edition of the listed standards must be harmonised as quickly as possible.
Annex I	<p>ISO 14708-1 is important for stakeholders. ISO 20417 is intended to replace EN 1041. EN 82304-1 is intended as a key standard to support placing medical software on the market. This standard applies to health software, which includes medical and non-medical devices, in a similar way as Annex XVI of MDR covers medical and non-medical devices. It focuses on product requirements and should not be confused with EN 62304 which is limited to process requirements. EN 82304-1 has not yet been harmonized under the MDD as it was first published by IEC in October 2016 – in the middle of the discussions on how to move forward with the harmonization of standards. An approach to harmonize EN 82304-1 under the MDD was started in August 2018. The intermediate result agreed upon with the HAS consultant so far is that this standard will cover MDD ER 1, 2, 3, 4, 5, some parts of 9, 10.1, 10.2, 12.1a, and several “sub-requirements” of ER 13. EN 82304-1 does not affect the user. This statement seems to be a misunderstanding. It is intended as a standard to support placing on the market of health software, including medical device software. The international experts involved in the development of EN 82304-1 found out that the technical requirements to ensure the safety of medical device software are also needed to ensure the safety of un-regulated software used in the healthcare area. Therefore, it is more than natural to broaden the scope to health software. In the end, EN 82304-1 is applicable to medical device software, and that is what is needed for the purpose of this Standardisation Request.</p>	The standards currently listed below the tables must be included in the standardisation request.



	Additionally, it is not unusual that the key word “medical device” does not appear in the scope or title of a harmonized standard. See for example EN 62083 which simply focuses on radiotherapy treatment planning systems but has been harmonized for many years.	
Annex I	We do not understand why this list has been severely shortened compared to earlier drafts. De facto, this excludes all medical electrical devices which have to apply product specific standards from the benefits of the New Legislative Framework (NLF). For example: we do not understand the limitation of EN 60601 to just the EN 60601-1 standards. With respect to radiological equipment, all CT Scanners, general X-ray equipment, angiographic x-ray equipment, mammography equipment, ultrasonic equipment and MR scanners cannot benefit from the NLF. On the other hand, with this lack of product standards, the EN 60601-series of standards cannot be applied to these devices and important safety requirements for these devices are not included in the Standardisation Request now.	Use the same list of standards (but without using the publication dates) as in the earlier draft list for the standardisation request.
Annex II	Stakeholders are required to apply the generally acknowledged state of the art. Restricting the Standards Request to precise editions of standards is unnecessary and opposite to the requirement to apply the generally acknowledged state of the art.	Remove the years of publication (editions and amendments) from the standards. Always the most recent edition of the listed standards must be harmonised as quickly as possible.
Annex II	ISO 20417 is intended to replace EN 1041. EN ISO 15189 and EN 22870 are important for stakeholders. EN 82304-1 applies to health software, which includes medical and non-medical devices, in a similar way as Annex XVI of MDR. See our explanations above.	The standards listed below the tables must be included in the Standards Request.
Annex III, section 2, first paragraph	Referencing normatively to "proven requirements" is not only well accepted practice but also enhances consistency in the understanding of those requirements by all users of those standards. It is impossible to structure technical standards only according to the requirements of the Regulations, certainly not for international standards that are the basis for EN standards. Requesting the development of individual EN standards which	Remove the requirement on the structure of the standards.



	would be specifically and individually tailored to the EU regulatory documents but would be different from ISO or IEC standards would severely increase the costs to European medical device manufacturers and delay the placing on the market of state-of-the-art medical devices in the EU.	
Annex III, section 4, first paragraph	Standards are not published all at once. Standards can have normative references to other standards. It is a general principle to apply the latest version of referenced standards (especially through a reference chain), because the latest standards represent state of the art.	Remove the requirement on the reference chain.
Annex III, section 4, second paragraph	Standards can have normative references to other standards, especially for technical requirements that need to be applied, without duplicating text from those other standards. It is mandatory to comply with the other (normatively referenced) standards in order to claim compliance with the given standard.	Remove the second paragraph.
Annex III, section 5	Compliance with a standard can only be claimed when complying with all technical requirements in that standard and nobody would select individual clauses of a standard and document compliance just to a few clauses of a standard. It is sufficient to indicate which General Performance and Safety Requirements of the Regulations are covered when complying with all clauses of a harmonised standard.	Remove the requirement to include detailed information on the correspondence between clauses of a standard and General Performance and Safety Requirements of the Regulations.