COCIR Feedback

Draft standardisation request

for the Medical Device Regulation and IVD Regulation

Introduction

COCIR appreciates the additional opportunity to provide industry feedback to the draft standardisation request for the MDR 2017/745 and IVDR 2017/746[1]. Regretfully, this version circulated for public consultation addresses almost none of the concerns[2] we have raised during the previous informal consultation and in various discussions over the last months. Our comments were made in the best intent to find a pragmatic way to work with the standardisation request as a new and more formal tool compared to earlier mandates. We believe that many of these concerns are shared by other stakeholders, including the European Standardisation Organisations.

We especially regret the lack of transparency in the process of developing a widely supported draft standardisation request. Following Better Regulation principles and best practices in standards development, we expect that the European Commission makes comments broadly available and provides a justification for their acceptance or rejection.

COCIR would like to underline again the importance of having harmonised standards available and cited in the Official Journal under the new Regulations[3]. Ensuring "a high level of protection of health for patients and users and the smooth functioning of the internal market" (MDR, 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 international (state of the art) standards. The European single market is seriously jeopardized when international consensus standards are not harmonised in Europe or harmonised with considerable delay, which is the case today. In the worst-case scenario international standards are replaced by a variety of (possibly conflicting) national standards developed independently by individual member states.

Unfortunately, the proposed draft standardisation request still includes several elements that prevent flexible harmonisation and timely reference of standards in the Official Journal. COCIR recommends to the European Standardisation Organisations to reject this request if it is adopted in the currently proposed form.

Detailed feedback

Here are our main concerns and recommendations to overcome the current issues. Our detailed feedback can be found in the Annex.

1. The current **limitations to the harmonisation process** as imposed by the draft standardisation request would establish a conflict with the judgement of the European Court of Justice in the Global Garden case (see detailed explanations in Annex).
2. Insert in Recital (1) of the draft Decision "whilst supporting innovation" after "patients and users" to **align with the wording of the Medical Device Regulation**.
3. 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.

---

[1] Published for feedback by 25 July 2019: https://ec.europa.eu/docsroom/documents/36104?locale=en

[2] 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

[3] See detailed position paper: https://www.cocir.org/uploads/media/COCIR_Position_on_Harmonisation_of_Standards_-_Final.pdf

4. The draft standardisation request only covers horizontal standards, while **product-specific standards (also called vertical standards) are critically needed** by our industry and other stakeholders. Delaying the harmonisation of product-specific standards, until a second standardisation request is adopted, is not acceptable. We recommend broadening the scope of the standardisation request to include vertical and product-specific standards.
5. The **deadlines** set out in the tables of Annexes I and II as well as the proposed procedure for **revisions and amendments** of harmonised standards (Article 1(3)) are unnecessarily restrictive. Revisions and amendments of standards must be harmonised as quickly as possible, to remain aligned with the internationally acknowledged state of the art. Removing the editions (publication years) from the standards listed in the tables of Annexes I and II will achieve this goal.
6. 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. COCIR recommends removing these deadlines.
7. Article 6 includes text ("This Decision shall expire on 27 May 2024") suggesting that easy modification of the request is not possible. This means that any new information, whether stemming from clinical experience or other market needs, cannot be considered during the approximately five years the request will be valid. This appears conflicting with the **desire to have harmonised standards reflect state of the art**. COCIR recommends deleting the quoted text.
8. Recent experience with Harmonised Standards (HAS) consultants mandated by the European Commission 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 industry and other stakeholders. COCIR recommends rewording to: "clear and precise, taking into account the users of the standard".

Conclusions

The situation around harmonisation of standards has deteriorated over the last decade. The medical device sector is only one, though dramatic, example of how the European Commission's legalistic implementation of Regulation 1025/2012 on European Standardisation could risk the full development of a European single market. This draft standardisation request also clearly shows that not all elements essential for the implementation of the Medical Device Regulation will be ready by 26 May 2020. The results are increased burden for manufacturers and unnecessary increased costs for healthcare systems.

COCIR is more than ready to engage in further discussions with the European Commission and member states on this topic. We specifically call upon the next Commissioner for the Internal Market to find pragmatic solutions to the current deadlock.

Annex: detailed additional comments (including feedback to Annexes I, II & III)

Reference	Detailed comments	COCIR recommendation
General	We would like to point out that the situation to be expected for medical devices can be compared with a past situation for machinery which was already assessed by the European Court of Justice (ECJ) in 2017 (Case T-474/15, 26 Jan 2017, "Global Garden Case"): - As described in paragraph 66, the ECJ had to consider a situation where the number of harmonized standards listed in the OJEU went down from 57 pages to 37 pages when changing from Directive 98/37 to Directive 2006/42. - According to paragraph 67, the ECJ considered the use of other means than harmonized standards as "more onerous". - In addition, the Court also had to consider a situation which resulted "… in a type of machinery which has been covered for several years by a published harmonised standard being ´without a harmonised standard´ during a not insignificant period of time … before obtaining a new published harmonised standard. …". The ECJ assessed this situation at the end of paragraph 66 as "incompatible with the important role given to the mechanism of conformity with harmonised standards by the two successive directives". At the end of paragraph 67, the ECJ continued: "Consequently, the Commission's position does not contribute, at least during a certain period, to facilitating the free movement of goods in the internal market whilst ensuring a high level or protection of health and safety of users, as is required by the legal basis of Directive 2006/42, namely Article 114 TFEU." The ECJ further assessed this situation in paragraph 68 and encouraged the European Commission to rapidly adopt harmonised standards: "It is true, as the Commission pointed out at the hearing, that, on different aspects, the essential health and safety requirements set out in Directive 2006/42 are more extensive than those set out in Directive 98/37, but it was then, as the case may be, <u>for the Commission to encourage the rapid adoption</u>, with respect to certain types of machinery or other equipment covered by the new directive, of a new harmonised standard allowing a response to those new requirements…". The current situation for medical devices is very likely to result in a much smaller number of standards harmonised under MDR than under the MDD/AIMD. In that respect, the situation is very similar to the Global Garden case.	Follow the recommendations of the European Court of Justice as documented in case T-474/15 of Jan 26, 2017: - do not reduce the number of harmonized standards; - ensure a quick harmonisation of all relevant standards.
Recital 3	It is not clear why the text has been changed from "harmonised standards" to "Voluntary harmonised standards", especially the meaning of "voluntary harmonised standards". We recommend instead changing Recital 3 to express that the use of harmonised standards is always voluntary.	Change existing text as follows: "Harmonised standards, the use of them is always

		voluntary, should help to ensure…"
Recital 11	Recital 11 is in clear opposition to the ECJ's decision in the Global Garden case. With this prioritisation the European Commission considerably limits the number of harmonised standards.	Delete Recital 11
Recital 12	In general, we appreciate that the draft request shows some flexibility here ("It may therefore be necessary to adjust the scope of this request accordingly."). However, we are missing that approach in the mandatory text of the Articles 1 – 7.	Add a respective Article that describes how the scope of this request can be changed accordingly (without lengthy administrative processes).
Article 1(3)	This Article can be read as if CEN and CENELEC have to wait with the replacement of an outdated standard for a standardization request from the European Commission. As the approval of a request may need several months, it needs to be made clear that CEN and CENELEC can start working even when no request has been adopted. This would also speed up the development of harmonised standards which should be the high-priority goal.	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. Cen or CENELEC is requested to start the development process based on the technical

		need of the interested stakeholders."
Annex I	Stakeholders are required to apply the generally acknowledged state of the art. Restricting the request to precise editions of standards is unnecessary and contradicts 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	This list has been severely shortened compared to earlier drafts as well as compared to the standards harmonised under the Directives. De facto, it excludes all medical electrical devices which have to apply product specific standards from the benefits of the New Legislative Framework (NLF). For example: 1. We object to 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 harmonised standards. On the other hand, due to the 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. 2. EN ISO 14971:2012 should be replaced by EN ISO 14971:2019 as the revision of the standard is about to be published by ISO under the Vienna Agreement. 3. EN 82304-1 is missing: it 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	Include all necessary standards for harmonisation (but without using the publication dates). A starting point should be the current standards harmonised under the Medical Device Directives. That also includes EN 82304-1 in table 2 for both Regulations.

	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 realised 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. Additionally, it is not unusual that the key word "medical device" does not appear in the scope or title of a harmonised standard. See for example EN 62083 which simply focuses on radiotherapy treatment planning systems but has been harmonized for many years.	
Annex II	Stakeholders are required to apply the generally acknowledged state of the art. Restricting the standardisation request to precise editions of standards is unnecessary and contradicts 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 III, section 1	We understand that harmonised standards shall not simply reproduce requirements of Regulation (EU) 2017/745 or Regulation (EU) 2017/746 without any further explanation on how to fulfil a requirement of these Regulations. However, it may be useful for the reader of a standard to be introduced to a technical requirement with one or a few sentences which are very similar or even identical to text of the above-mentioned Regulations.	Change the first bullet of section 1 as follows: - make any references to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 or reproduce their requirements in the normative body without providing more details on

		how to fulfill the requirements of the Regulation in this respect;
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 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.	Remove the requirement on the structure of the standards.
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 to just a few clauses of a standard. It is enough to indicate what 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.