

## **COCIR Position Paper**

### **Harmonisation of Standards for Medical Devices**

#### **Introduction**

The Medical Device Regulation (745/2017, to become applicable in May 2020)<sup>1</sup> is the most impactful legislative change for the medical devices sector since 1993, when the medical devices directive (93/42/EC) was published. Both legislative schemes follow the “New Approach” (NA) that was updated and replaced by the New Legal Framework (NLF) in 2007. The essence of the NA/NLF is that product regulations provide for general safety and performance requirements called “essential requirements” or “general safety and performance requirements”, and that testable technical requirements addressing them are laid down in standards, developed jointly by all interested stakeholders. Those standards, following regulatory assessment, then become harmonised standards, are referenced in the Official Journal of the EU (OJEU) and thus provide for legal certainty for all stakeholders. Harmonised standards support the competitiveness of European industry, including small and medium enterprises as well as large global companies based in the EU and beyond.

#### **Executive Summary**

In past years, the system for harmonised standards for the medical devices sector has not received proper maintenance anymore. The OJEU has many references to outdated standards, creating confusion and legal uncertainty for stakeholders. That system needs to be put back on track. The forthcoming application of the Medical Device Regulation (MDR) in May 2020 is a good occasion for that. The MDR, which is in line with the concept of the New Legislative Framework (NLF), identifies the use of harmonised standards as preferred mechanism to demonstrate conformity with the regulatory requirements. Therefore, efficient and effective processes to establish the right set of harmonised standards need to be in place. The European Commission needs to take action now to eliminate the remaining backlog of harmonised standards and re-install a sustainable and efficient process for the harmonisation of standards as outlined in their recent Communication<sup>2</sup>.

For the scheme of harmonised standards to be functioning and up to date again, COCIR recommends the following:

1. **Speed up** the approval of the Standardisation Request;
2. **Ensure** a flexible Standardisation Request;
3. **Realize** a flexible publication schedule for the Official Journal of the EU;
4. **Streamline** the assessment of Annexes Z;
5. European Regulators including the European Commission should **actively participate** in standards development;
6. **Provide** for a process for swift harmonization of standards under MDR and IVDR;

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<sup>1</sup> Also including a companion regulation for In-Vitro Diagnostic medical devices (IVDR), 746/2017 applicable in May 2022

<sup>2</sup> [European Commission, "Harmonised Standards: Enhancing transparency and legal certainty for a fully functioning Single Market", COM\(2018\) 764, Nov.22, 2018](#)

## DETAILED BRIEFING

### 1. Introduction

Harmonised standards are an essential building block of the Medical Device Regulation (MDR). However, as the Date of Application of the MDR is drawing closer, it sheds a limelight on the issues apparent in the current process for harmonisation of standards for medical devices. As the recent communication by the European Commission<sup>2</sup> outlines, a backlog of standards that are not referenced in the Official Journal remains despite all past efforts. The practice for referencing in OJEU varies across the European Commission. The speed of the assessment procedure for standards needs to be improved.

In view of the upcoming EU elections, we would like to take the opportunity to explain the challenges the current practice for harmonisation of standards our industry is facing and make some practical recommendations to address them.

### 2. Importance of harmonised standards for the European Union

Harmonised standards which evoke the Presumption of Conformity are more than just European Norms. They are a fundamental element of the "New Legislative Framework". A comprehensive set of harmonised standards is a valuable means to ensure the Single European Market and provides for equal technical market access conditions. Harmonised standards ensure the necessary regulatory certainty for all stakeholders (including medical device manufacturers, Notified Bodies and Competent Authorities) on how to fulfil the Essential Requirements. Eventually, they ensure harmonised and high safety levels for medical devices placed on the EU market.

Without the concept of Presumption of Conformity, Notified Bodies and Competent Authorities might develop individual opinions on the use of International and/or European Standards, endangering the level playing field for all stakeholders, including the state-of-the-art of safety and performance for medical devices, and the Single European Market. The burden on manufacturers and resulting time-to-market for medical devices would substantially increase. The European Court of Justice concluded in its ruling in the Global Garden Case already indirectly that the use of harmonised standards provides the least burdensome approach to fulfil the essential requirements: "*Admittedly, ... the manufacturers and their representatives have **means other** than resorting to harmonised standards whose references have been published in order to conform with the essential health and safety requirements set out in the relevant directive with respect to the machinery that they wish to market. However, it must be noted that those **other means are more onerous.**"<sup>3</sup>.*

The key benefits for the EU when relying on harmonised standards that are technically identical to ISO and IEC Standards are:

- **ISO and IEC standards represent the generally acknowledged state-of-the-art:** Timely harmonisation of state-of-the-art standards is key for placing medical devices on the European market ensuring a high level of product safety. This is one of the key requirements of the Medical Device Directives and Regulations. Therefore, it is important that CEN and CENELEC ratify European Norms based on ISO and IEC standards without technical changes, and that the European Commission harmonises those European Norms without delay, including their listing in the OJEU.
- **European adoption of international standards is important for medical device manufacturers:** Publication of international standards as European Norms (EN standards) and especially harmonisation by the European Commission is considered a

<sup>3</sup> <http://curia.europa.eu/juris/document/document.jsf?text=&docid=187179&pageIndex=0&doclang=EN>

“quality mark” in developing countries and is supporting the adoption of such standards in these countries. No more harmonisation of international standards at the European level will (1) hamper the global recognition of international standards, (2) give room to conflicting national standards, and (3) have a negative impact on the global competitiveness of European medical device manufacturers.

### 3. Current challenges

Unfortunately, we see a **serious delay in the harmonisation of standards** under the **Medical Device Directives**, including their listing in the OJEU, which concerns not only new standards but also revisions and amendments of already harmonised standards. Since 2010, there has been a huge decline in the percentage of EN’s harmonised and referenced in the Official Journal under the Medical Device Directives - from 83% in 2010 to 12% in 2017. Some 17 new standards of the crucial EN 60601-2-xx series have not yet been listed. The last publication in the Official Journal happened more than one year ago, in November 2017, and only added 3 new and 5 revised standards over a period of 18 months.

The process to prepare and assess an **Annex Z** and subsequently harmonise a standard has become very bureaucratic and lengthy (see Annex II). Extremely detailed assessments by the HAS consultant are followed by quality checks conducted by Ernst & Young (managing the consultant system), further technical checks by the legal staff of the European Commission and more administrative steps before the approved standard can be referenced in the Official Journal of the EU. An example is the Annex Z of EN 82304-1, a standard for software safety, which had been proposed as pilot in the Action Plan to decrease the stock of non-cited harmonised standards<sup>4</sup> in 2017. Despite efforts to draft the Annex Z, the standard is still not referenced.

An additional issue that prolongs the assessment process is possible divergence between ISO/IEC standards and the understanding of EU specific requirements. In contrast to other jurisdictions, EU regulators including the European Commission do not actively participate in the international standards development processes.

The current fixed **publication schedule**, e.g. twice or even only once a year is against the legal obligation of the European Commission to publish harmonised standards “without delay” (Art 10(6) of Directive 1025/2012). It leads to further delays in referencing standards even if the Annex Z has been drafted and approved.

The situation is even worse for the **MDR and IVDR**. All 300+ standards currently published in the OJEU for the MDD, IVDD and the AIMD need to be assessed and harmonized. This harmonisation needs to be finalized well in advance of the enforcement date of the MDR to allow manufacturers, ESOs and Notified Bodies to respond on related changes. The **Standardisation Request** which is a prerequisite for harmonisation of standards under the MDR or IVDR is not even finalised yet (see Annex I for the adoption process). The draft that has been shared recently does not meet industry needs. It refers to a list limited to certain standards with defined publication dates, which disregards the wide variety of medical devices in the scope of the MDR and will block the harmonization of standards needed for innovative technologies as well as not yet published newer editions of existing standards reflecting the evolving state-of-the-art. At this point, it is unclear if any Harmonised Standard will be referenced in the Official Journal by the Date of Application of the MDR on 26 May 2020.

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<sup>4</sup> Action Plan: Structural solutions to decrease the stock of non-cited harmonised standards, October 2017, [https://ec.europa.eu/growth/content/european-commission-launches-action-plan-improve-publication-harmonised-standards-industry\\_en](https://ec.europa.eu/growth/content/european-commission-launches-action-plan-improve-publication-harmonised-standards-industry_en)

#### 4. COCIR Recommendations

It must be the aim to have **all necessary standards<sup>5</sup> harmonised before the Date of Application** of the Medical Device Regulation. At the same time, listings in the Official Journal under the Medical Device Directives need to be kept up to date to support manufacturers placing devices on the market during the “grace period” (article 120 MDR). We believe that these goals are achievable if processes are made more efficient and all actors in the system trust in and collaborate with each other. Our detailed recommendations are as follows:

1. **Speed up the approval of the Standardisation Request:** The development and approval process of the **Standardisation Request** for the Medical Device Regulation needs to be sped-up, otherwise none of the subsequent steps can be performed.
2. **Ensure a flexible Standardisation Request:** The Standardisation Request must accommodate updates with respect to both revisions of harmonized standards already listed and initial editions of standards not yet listed in the Official Journal of the EU, especially relevant for new fields of technology.
3. **Realize a flexible publication schedule for the Official Journal of the EU:** The legal obligation to publish harmonized standards without delay (see regulation 1025/2012) cannot be met by just one or two publications per year.
4. **Streamline the assessment of the Annexes Z:** The assessment process has become the main bottleneck for harmonisation of standards in our sector, mainly due to redundant checks.
5. **European Regulators including the European Commission should actively participate in standards development:** Regulators should find ways to early contribute to the development of the ISO or IEC standards.
6. **Provide for a process for swift harmonization of standards under MDR and IVDR:** The European Commission needs to provide for a mechanism to ensure that the most recent editions of these standards are considered for harmonisation.

#### 5. Conclusions

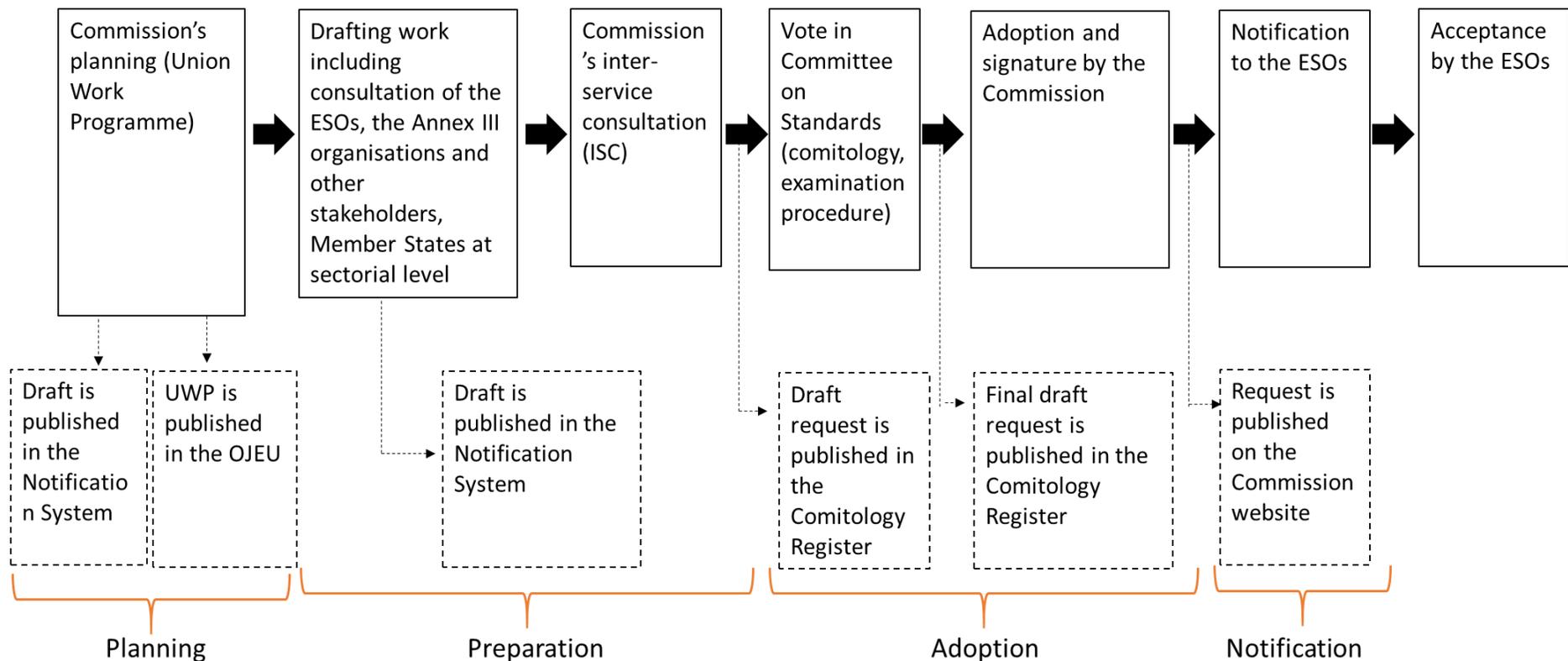
The processes for drafting and adopting a Standardisation Request as well as harmonising and referencing standards in the Official Journal have clearly become too burdensome. Not only standardisers but also the European Commission requires lighter procedures with fewer administrative checks. Such lighter procedure can speed up the harmonisation process and still provide clarity on the (legal) coverage of the essential requirements.

COCIR expects that its recommendations are taken up in the forthcoming European Commission guidance document on practical aspects of implementing the Standardisation Request. COCIR is ready to contribute our members’ expertise in the process.

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<sup>5</sup> COCIR has compiled a list of candidate standards for harmonisation under the Medical Device Regulation.

### Annex I: Process for issuing a Standardisation Request



**Source:** Vademecum on European standardisation [[LINK](#)]

**Annex II: Simplified illustration of process for harmonisation of a standard**

