COCIR Feedback
EU standardisation strategy[1]

COCIR vision for standardization

In healthcare, standards have an indispensable role for the proper functioning of medical devices, for correct transmission of information, and more. Thus, standards support manufacturers to produce medical devices and digital health technologies with constant high quality and help authorities to ensure that medical devices and digital health technologies provide the safety and performance required.

The EU has long been a promoter of international standards as parts of its commitment to free trade and multilateralism. Its open trade policies have supported EU competitiveness and growth, making it one of the biggest global exporter, importer, and investor in the medical device sector. The COVID-19 crisis has shown the need for European Member States to focus on building greater capabilities and resilience across all sectors of the European economy. However, building EU resilience and a model for strategic autonomy should not mean that Europe resorts to protectionism and restricts its market.

COCIR strongly requests convergence of regulatory processes and frameworks across the world, relying on state-of-the-art international standards and identical regional or national copies. Free worldwide trade of innovative medical technology is in the best interest of citizens, globally. Competitiveness of European medical imaging, radiotherapy, electromedical and health ICT industries is best served by an EU standardization policy that maximally aligns standards in support of European legislation with international consensus standards. In this approach, CEN and CENELEC must optimally support the adoption of these international standards in Europe. Ideally, European experts - from all stakeholders, including regulators - participate in the development of these international standards and the EU harmonisation process, including standardization requests, facilitates the easy harmonisation of international standards.

COCIR feedback to the roadmap

1. whether the current European standardisation system is fit for purpose to support European strategic interests

COCIR is convinced that European strategic interests are supported efficiently by considering ISO and IEC as partner of European Standardisation Organisation instead of competitors. The current European standardisation system including their agreements with ISO and IEC results in significant benefits to COCIR member companies. It ensures that European national standards do not deviate from each other and do not deviate from ISO and IEC standards. Any approach to position the European standardisation system as a competitor to ISO and IEC would result either in a duplication of standardisation efforts, preventing SMEs from effective participation, or leading to companies only staffing ISO and IEC with technical experts. Not only do international standards reflect the strategic interests and needs of Europe-based medical device manufacturers but their quality benefits from the knowledge of the global community of technical experts. That is part of the reason why the European medical device industry is already actively engaged in ISO and IEC standardisation via the national standards bodies. Furthermore, COCIR funds the secretariat for IEC TC 62 “Electrical equipment in medical practice” and has direct liaisons to other relevant Technical Committees in the healthcare and medical device area.

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13099-Standardisation-strategy_en

Recommendation: harmonise and reference ISO and IEC full consensus standards to support EU Regulations and Directives. Any competition or duplication between European and international standards development leads to inefficiencies, unnecessarily diverts resources of industry and stakeholders, creates barriers to trade and endangers the European Standardisation System.

2. how the EU can leverage and promote global leadership in standards-setting

Standards for medical devices can be separated into (1) standards for safety, IT security and processes which are either developed in IEC and ISO and recognized or harmonised (for example, in the US or in the EU) or even mandatory (for example in China) for market access and into (2) standards to ensure interoperability and seamless communication between various products. The vast majority of interoperability and communication standards are developed in globally accepted consortia like DICOM and IHE that operate independently of the European Standardisation System.

Regarding standards in category (1): the medical devices industry is operating at global level and benefits from the recognition of international standards across jurisdictions as it facilitates market access and minimises technical barriers to trade. Leveraging global leadership of European companies in setting standards with regulatory effect should continue to start at international level and requires a cooperative partnership between ISO/IEC and CEN/CENELEC. Any development of standards at ISO or IEC automatically ensures a strong European influence, especially when the community of European stakeholders actively contributes via the various national standards bodies. Important European stakeholders that are still severely underrepresented are the European regulators themselves who may miss their opportunity to influence global leadership in standards-setting.

Recommendation: the European Commission should promote the active participation of experts to Technical Committees at international level where the various national interests are discussed to finally conclude on a technical consensus.

European regulators, especially the European Commission, should accept their role as major stakeholders. Their active participation in standards development would be a suitable way to contribute to the development of ISO or IEC standards. Such involvement should also be coordinated with other jurisdictions outside the EU, including major trade partners such as the United States and China. We recommend the European Commission use its influence in the International Medical Device Regulators Forum (IMDRF) and operationalize its commitment towards working with standards setting bodies to play an active role in ensuring that international standards continue to be effective tools in conforming to essential principles for safety and performance of medical devices.

Lastly, international standards should become a key element of any Free Trade Agreement the EU negotiates. Mutual alignment on the use of ISO and IEC standards for regulatory purposes should become part of any cooperation between the EU and third countries' regulators for medical devices. This should include cooperation on medical device regulations specifically as well as other regulatory frameworks that impact medical and digital health technologies (artificial intelligence, cybersecurity, data protection etc.).

Regarding standards in category (2): interoperability is one of the essential keys to unlock big data analysis and artificial intelligence applications. Any lack of interoperability is one of the major barriers to the deployment of Digital Health. COCIR has been developing efforts to build awareness on the benefits of interoperability at national, regional and local levels and how to achieve it through the use of existing and recognised standards and profiles.

Recommendation: healthcare authorities should reference international standards, profiles and guidelines for interoperability in procurement documents, where relevant. This should be part of a consistent, proven, end-to-end interoperability strategy that spans all aspects of digital health, including mHealth.

3. whether changes in governance and working methods are required to improve the performance of the European standardisation system

Stakeholders in the standardization system have the necessary technical expertise to draft standards aligned with the international state-of-the-art. Standardisation creates most benefit when driven by technology and business needs (including support of the regulatory framework). The European Standardisation Organisations play a key role here by facilitating strategic discussions and landscaping exercises at European level to help better understand the needs of industry. However, it has proven beneficial to perform the actual technical work on standards at international level.

Recognition of standards to support legislation is in the interest of standards developers, manufacturers, and regulators. For the reasons outlined in the section above, a system of international standards adopted in Europe is key. In fact, harmonisation of a standard by the EU is considered a quality mark also for other jurisdictions around the globe. Unfortunately, the processes for drafting and adopting a Standardisation Request as well as harmonising and referencing standards in the Official Journal have encountered several problems over the last years. COCIR has previously explained[2] the issues that our experts experience in the European Standardisation System.

Recommendation: Efficient and effective processes to establish the right set of harmonised standards need to be in place. The detailed recommendations can be found in the recently published joint industry contribution[3]. Besides the recommendations for the European Commission, the European Standardisation Organisations should ensure that their staff can assist, for example with legal analysis or other practical support, the technical experts in the discussions surrounding harmonization, including the development of Annexes Z. Clear and transparent guidelines, jointly agreed by all actors in the system, should be in place to guide the interactions between technical experts, ESOs staff, HAS consultants, and European Commission.

At this point, we doubt that a revision of Regulation 1025 / 2012 would be beneficial. Instead, the European Commission should re-assess how the interpretation of the Regulation is translated into the current processes, including requirements for standardization requests and Annexes Z. Depending on this assessment, further discussions on the potential review of Regulation 1025 / 2021 may take place.

[2] https://www.cocir.org/uploads/media/COCIR_Position_on_Harmonisation_of_Standards_-_Final.pdf
[3] https://www.cocir.org/media-centre/position-papers/article/joint-industry-recommendations-for-effective-harmonisation-of-standards.html