COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR Position Paper

on the Commission Proposal for a Regulation on European Standardisation

The European Commission published on 1 June 2011 a proposal for a Regulation on European Standardisation[1] to revise the current European system.

COCIR welcomes the European Commission's proposal for better and faster standards to advance Europe's competitiveness. We expect that, when the proposal is accepted as a regulation, its implementation will support worldwide trade of medical devices, help reduce the cost of innovative medical technology and improve the quality of healthcare on a global scale. It will also foster innovation in products, services and processes to meet the opportunities and address the challenges in a fast-pace innovation-driven healthcare environment. Finally, it will address the needs of the Information and Communication Technologies (ICT) sector which has developed different structures globally with well established fora and consortia being in the lead of ICT standards development. In this respect COCIR explicitly welcomes Articles 9 and 10 of the proposed regulation which effectively complement the European standardization system with a process that accommodates the urgent needs of the ICT sector.

Convergence of regulatory procedures and international standards are of considerable importance to the medical device and healthcare IT industry. This is precisely what the World Trade Organization is calling for to facilitate international trade. COCIR would appreciate if the regulation would place more emphasis on the adoption of international standards into the European framework. Where international standards reflect the "state of the art" in technical requirements, it is strongly advisable to have an open eye for what those standards contain when revising regulatory procedures.

Our industry has demonstrated to be highly innovative and requires efficient and speedy ways for state-of-the-art standards that support the applicable regulatory framework. COCIR members have actively been involved for many years in formal (consensus) standardisation activities at international, European and national levels as well as in globally accepted fora and consortia with respect to healthcare IT standards. COCIR members have invested substantial time and resources to help build the current set of standards used to demonstrate compliance to requirements of safety and performance of medical equipment and appreciate that this framework is maintained and, where possible, improved with the eventual regulation. COCIR's vision of "once approved, accepted everywhere" remains crucial for Medical Devices and international standards are key elements towards this concept.

COCIR has some concerns with respect to the text of the proposed regulation and wishes to share these, convinced that they are regarded as constructive contributions that will help the new regulation to become even more robust and "fit for the purpose". Given COCIR's scope, concrete recommendations made are intended to help solve the impact of the current proposal on the medical devices sector.

[1] *See 2011/0150 (COD) at* http://ec.europa.eu/enterprise/policies/european-standards/files/standardization/com-2011-315_en.pdf

COCIR has two sets of recommendations:

1. Recommendations of general nature:

A. To maintain the legislation as the only instrument setting requirements, standardization remaining a voluntary instrument for supportive guidance on how to meet the requirements.
B. To ensure that the conditions set up in Article 4.3 to improve transparency of standards will not cause any additional burden and delay in the process.
C. To keep the objections to harmonized standards as an exception in the process (Article 8).
D. To invite the Industry to the Committee as an observer which will increase the transparency of standards processes (Article 18).

2. Recommendations of editorial nature:

A. To replace in the first sentence of Article 5.1 and 5.2 "European standardization bodies shall ensure an appropriate representation of…" by "European standardization bodies shall facilitate the appropriate representation of…"
B. To explicitly state that the list of stakeholders is only limited to the organisations entitled to be publically funded, and not representing all stakeholders. European trade associations representing the industry at large are also considered as stakeholders (Article 5).
C. To delete the point (d) in Article 12 as the verification of the quality and conformity of European standards to relevant EU policies is a public authorities' task.
D. To clarify what "other bodies" means in Article 13.1 (b).
E. To delete point (a) in Article 16 as the appointment of European standardization bodies should stay a legislative competence.
F. To clarify the title of Annex III "European Stakeholder Organisations" as it is misleading. It might be interpreted as an exhaustive list excluding other important stakeholder organizations like European organization representing other industries than SMEs.

DETAILED BRIEFING

1. Recommendations of general nature:

A. The legislation should be the only instrument setting requirements, standardization remaining a voluntary instrument for supportive guidance on how to meet the requirements.

The EC proposal is rightly recognizing standardization as a key instrument to support public policies. However, COCIR is of the opinion that the regulation should better distinguish between legislation and standardization for their different but complementary roles. Although, standardization supports public policies, it must remain a voluntary instrument for the industry, while legislation is the only tool to shape those public policies.

COCIR recommends the regulation to explicitly recall the respective role of standardisation and legislation.

B. The improvement of transparency of standards should not cause any additional burden and delay in the process. Clarification of the requirements set up in Article 4.3 is needed.

COCIR supports the intent for a more transparent, efficient and rapid standardisation process. However, adding requirements without providing added value is counterproductive. In particular, the requirement to national standardisation bodies to publish draft standards in such a way that stakeholders in other Member States have the opportunity to submit comments should not slow down the process.

COCIR recommends clarifying these requirements ensuring transparency of the process while avoiding any additional burden and delay in the process. With respect to article 4.2, COCIR would appreciate a statement that the Commission shall not comment on the technical content of such draft standards.

C. The objections to harmonized standards should be kept as an exception in the process.

The process to object to a standard and the unification of the procedure are certainly necessary. However, the eventual regulation should emphasize, at least in a preamble, that such objections must remain an “emergency brake” based on demonstrated flaws in the requirements of the standard. The occurrence of such objections can be minimized by the active participation of Member States competent authorities in the development of standards, in particular when public interests are at stake. Authorities should be aware that any resulting European deviation from international standards will add burden to the European industry which is the basis of the economic power of the EU and will have a negative impact on the cost of healthcare.

COCIR recommends the regulation to emphasize that Member States need to contribute more actively to the development of standards and to ensure that Public authorities consider themselves as key stakeholders and actively participate in the development of standards that will support public policies.

Public authorities should make sure that Essential Requirements are based on state-of-the art standards, e.g. be revising European standards in advance.

D. The Industry should be invited to participate to the Committee set up in Article 18.

COCIR understands that the European standardization bodies and other external stakeholders like the industry will not have a seat at the Committee that will assist the European Commission. Such participation would increase the transparency of standards processes, by creating a broader support for decisions that require all stakeholders' engagement and thus improving the quality of standards.
COCIR recommends the creation of observer seats for industry representatives under specific conditions.

2. Recommendations of editorial nature:

A. The way to ensure appropriate participation of stakeholder should be more realistic.

The requirement for European standardization bodies to *ensure* appropriate participation of stakeholders is questionable. Although COCIR welcomes the emphasis to involve all stakeholders to standardization work, it is questionable whether a group can be forced to participate and to contribute, especially against its deliberate decision not to participate or to contribute. What is important is that everyone and every group have the opportunity to participate and contribute. Obviously, the key question is not the participation in itself but the existence of the relevant expertise of such stakeholders. Participation without a real expertise will not improve but rather deteriorate the process. The European standardization bodies should only be required to facilitate this appropriate representation.

It is important to realize that, increasingly, standards are developed at the global level, and not exclusively at the European level. While European influence in many standards setting bodies remains substantial, the level of influence will decrease over the years to come with the rise of new economic powers such as China, India, and Brazil. It is important that the European contribution in that international scene remains focused on the interest of the European industry and the European consumer without creating barriers to trade.

COCIR recommends replacing in the first sentence of Article 5.1 and 5.2 "European standardization bodies shall *ensure an* appropriate representation of…" by "European standardization bodies shall *facilitate the* appropriate representation of…".

B. It should be clarified that the stakeholders referred to in Article 5 are "societal stakeholders" that are publically funded for representing certain groups in European standardisation activities. It should be explicitly stated that this list of stakeholders is only limited to the organisations entitled to be publically funded, and not representing all stakeholders.

The EC proposal is identifying a limited group of societal stakeholders. While COCIR fully understand the rationale behind the EC choice and recognizes the need for continued subsidies, the EC proposal creates confusion as these organisations seem to be the only European Stakeholder Organisations to be involved in standardisation process. This excludes all other non-subsidised stakeholders, above all the industry and its organisations. The standardization process should be open to all stakeholders. The industry, small and large, and societal organizations should be consulted and heard on

equal footing, at least in consultations for standardization mandates or the definition of the European standardization programme.
COCIR recommends rewording Article 5 explicitly stating that this list is only limited to the organisations entitled to be publically funded, and not representing all stakeholders.

C. The verification of the quality and conformity of European standards to relevant EU policies should be exclusively a public authorities' task.

The proposed role for the societal stakeholders to verify if standards have the right quality and comply with the European legislation and policies is not appropriate. These organizations participate already in the development of standards and thus may be not impartial. It is also unclear if these organizations would have the relevant expertise and skills to perform this verification.
COCIR recommends deleting the point (d) in Article 12.

D. The term "other bodies" in Article 13.1 (b) should be clarified.

This comment applies to standardization that is supporting the European regulatory system and does not apply to standardization addressing interoperability. The current wording of this article may imply the participation of non-European standardization bodies in EN standards development, even funded by the European Commission. We believe this participation would weaken rather than strengthen the European standardization framework, cause confusion and lead to an undesired dispersion of resources. This article should be better understood as the intention of the EC to enable smoother cooperation amongst European standardization bodies, and between them and other standards setting bodies. It will certainly faster and better realise mandated work in domains where leading specifications from other bodies already exist and should be taken into account.
COCIR recommends clarifying what is meant with "other bodies" in Article 13.1 (b).

E. The appointment of European standardization bodies should stay a legislative competence.

COCIR does not see the need to solely give the European Commission the role to appoint European standardization bodies. Furthermore, any changes to this list would be very exceptional, and hence the current European legislative process remains acceptable.
COCIR recommends deleting point (a) in Article 16.

F. The title of Annex III "European Stakeholder Organisations" is misleading.

Annex III might be interpreted as an exhaustive list excluding other important stakeholder organizations like European organization representing other industries than SMEs.
COCIR recommends modifying the title of Annex III as "European organisations representing SME, Consumers, Environmental and Social interests".

COCIR is a non-profit trade association, founded in 1959, representing the Radiological, Electromedical and Healthcare IT Industry in Europe. COCIR's members play a driving role in developing the future of healthcare in Europe and worldwide.