



COCIR Position Paper

COCIR Vision on Standardisation and Recommendations on European Standardisation

COCIR and its members have considerable knowledge in healthcare operations and related processes, and are well positioned to provide a valid opinion on standardisation, balanced between specific user needs and general requirements of public interest.

COCIR's vision on standardization is based on the following principles:

1. Standards should be developed at the **highest international level** possible with input from and adherence from many countries
2. Healthcare Industry will continue its efforts to provide **state-of-art** input and continue supporting the process of standard development
3. Healthcare Industry will continue to support European regulations based on New Approach with the concept of **harmonized** standards to ensure essential requirements are fulfilled
4. Standards development should be a **fast, efficient** and non-competitive process, with **timely** delivery
5. Standards development shall involve **all the appropriate stakeholders**
6. In the domain of Healthcare ICT, Healthcare Industry supports work done by **fora and consortia**

As the European Standardization Process is under consideration through an established EXPRESS team, COCIR calls for actions and dialogue along 7 recommendations to improve future standardisation policy in Europe in order to be reliably supporting the markets as well as encouraging for innovation:

1. Optimise European standardisation to support European interests in a global scene

- To preserve the quality of our regulatory provisions in support of the single market
- To create favourable innovation and competition conditions for European business
- To promote uniform regulations and standards for globally operating sectors
- To set good European regulations and standards for regionally operating sectors
- To support public policies and lead market initiatives

2. Organise European standardisation tailored to sector needs

- Create a network for collaboration between standards development organisations with the three ESOs at its core for the provision of European Standards
- For globally operating sectors develop standards internationally for adoption in Europe
- Maintain and improve the specific ICT standardisation framework

3. Take account of the characteristics of the healthcare sector

- Keep healthcare related standards and regulations focused and coherent
- Strive for global uniformity, taking into account the GHTF initiative
- Apply elements from the ICT standardisation framework in a tailored manner

4. Improve the system while preserving the benefits of the framework in Directive 98/34/EC

- Introduce consultation and impact assessment to the mandate procedure
- Maintain the recognition of the 3 ESOs

5. Improve the ICT standardisation framework based on Council Decision 87/95/EE

- Improve strategic alignment between private and public stakeholders
- Stick to mandated standards by the 3 ESOs for standards with direct regulatory purpose
- Introduce a strict set of criteria for global fora/consortia and their deliverables in order to be eligible to be taken into account for use and collaboration in the European standardisation context
- Introduce a process for collaboration with fora and consortia, in particular for (i) using their specifications in public policies; (ii) allowing a fast adoption of fora/consortia specifications by ESOs where use in support of regulation/legislation; and (iii) in some specific cases be able to mandate a forum/consortium with the development of a certain standard
- Enable public policies to make direct use of relevant and leading consortia standards

6. Base policies for IPR in standardization on fair principles

- In order to fuel innovation, continue public policies on the basis of achieving a sound balance of rewards for R&D versus sufficient freedom to use new technologies
- Insist on IPR policies in standards development that provide sufficient certainty on the terms of use of patented technologies embedded in the standard

7. Improve efficiency, effectiveness of and access to the existing standardisation system

- Maintain the principle of national delegation while respecting the ETSI mixed model
- Improve New Work Item filtering based on impact assessments and market relevance
- Present the ESOs with stronger stakeholder pressure for continuous improvements
- Make standards easier to comprehend and use and let ESOs develop them faster

COCIR, The European Coordination Committee of the Radiological, Electrometrical and Healthcare IT Industry, is an industry association founded in 1959, representing major health industry suppliers in Europe. COCIR members support innovative point of care solutions and IT technology along the complete social and health value chain, from prevention to acute care towards home care and rehabilitation, and its vendors deliver "the backbone" for seamless care delivery and information exchange. Jointly, COCIR members have a strong and very positive impact on the economies of Europe and play a critical role in our health economy and the well-being of the population. In the industry represented by COCIR (27 companies and national associations) 40,000 people are employed. Medical and information technologies provided by its members can be found in every healthcare delivery organisation in Europe, making COCIR a major stakeholder in European healthcare.

DETAILED BRIEFING

1. Optimise European standardisation to support European interests in a global scene

European standardisation has been established several decades ago as an instrument to remove trade barriers and to establish the internal market. For the coming decades the strong focus on replacing the legacy of national standards by unified European standards can be relaxed since this work has largely been completed.

Vienna and Dresden agreements have proven over years (especially for IEC/CENELEC published standards) efficient process, avoiding redundant work at European and National levels.

European standardisation should be an instrument to support European interests in a global scene where new rising powers such as China, India and Brazil will increase their influence. Key European interests related to standardisation include:

- Preserving and exporting our high quality regulatory framework and regulations matching European needs;
- Maintaining a level playing field for European Business with favourable conditions to innovate and to compete in the global scene;
- Promoting uniform regulations and standards across the globe for global sectors and setting good European ones for regionally oriented sectors;
- Supporting public policies and ventures of general interest such as lead market initiatives.

2. Organize European standardisation tailored to sector needs

There are various differences between sectors, such as products versus services, and regionally bound markets versus progressing integration of a single global market. Europe should organise standardisation such that the needs of specific sectors are served in tailored manners. Therefore the three ESO's each have their reason for existence and should be sustained as strong organisations in their own right. Co-operation and alignment to avoid duplicate work or misaligned work allocation should be improved.

Specifically in the healthcare domain, efforts have been developed centralising European work through a forum called ABHS, monitoring work done through the three ESOs. Efforts should continue to make this forum more efficient.

On the other hand, the ICT sector has quite specific characteristics and needs due to *inter alia* high speed of innovation, strong network effects, and a very low ratio of reproduction cost versus development cost. A specific ICT standardisation framework is therefore justified.

For globally oriented sectors, such as healthcare, standards development should always start in ISO, IEC or ITU and the results should be adopted in Europe without modifications via the existing Vienna and Dresden mechanisms and agreements. In these cases the role of European standardisation should be to guard the consistency with European regulatory needs and to support other European interests. Regional deviations should be limited to unavoidable cases.

COCIR recommends fair representation of all stakeholders into standardisation processes and work portfolio. We observe that there are clear differences in this respect between the three ESOs at present, so there is room for improvement.

3. Take account of the characteristics of the healthcare sector

The healthcare sector has several years ago identified the necessity to have a global uniformity in standards and regulations. COCIR has always given preference to uniformity of international standards and ENs. Since 1992, date of creation of the Global Harmonisation Task Force (GHTF), COCIR has always been actively involved in order to drive global harmonisation of regulations based on International Standards.

Healthcare products and services are founded on a broad range of technologies. ICT has become a key element. Ever more healthcare sector products mainly consist of ICT elements such as software or communication technologies.

In the rapidly developing Healthcare ICT world, it was the use-case oriented approach of fora and consortia based on the effective inclusion of all stakeholders that has successfully identified and prioritised the relevant use-cases. COCIR would welcome if ESOs increased their cooperation with fora and consortia.

4. Improve the system while preserving the benefits of the framework in Directive 98/34/EC

The benefits of the present standardisation system as set up under Directive 98/34/EC need to be preserved:

- The current list of recognised European Standardisation Organisations is appropriate.
- A general possibility to issue mandates to standardisation organisations other than the ESOs is undesired.

COCIR would support an extension of the scope of the Directive to include all services.

The procedure for the issuing of standardisation mandates should be improved to require the Commission to carry out a thorough business impact assessment on the basis of a broad stakeholder consultation before any draft mandate is submitted to the Committee 98/34.

5. Improve ICT standardisation framework based on Council Decision 87/95/EE

As argued above it is appropriate to maintain a specific framework for ICT standardisation. COCIR supports the idea to set up a permanent structure for strategic orientation and alignment between private and public stakeholders on matters related to ICT technologies and standards. Such a structure should have a sector orientation.

COCIR does not recommend recognising specific standard development organisations with a view to enable the use of their standards for public policies. Instead, COCIR supports to introduce the possibility to use relevant and leading deliverables from non-ESO standardisation organisations for public policy and legislative purposes under the following conditions:

- The standards in question are relevant and among the most recognised and supported in their field
- No conflicts can arise with standards from the ESOs that exist or are in development and that enjoy a broad de facto recognition as well
- The overall coherence of the European standardisation system is preserved and no conflicting standards are introduced
- Verification of the standard development process using a set of international standardisation principles, to be complemented on a per case basis by either the FRAND¹ or the Royalty-free² principle for IPR and the principle of adequate membership and voting rules.

The healthcare sector applies ICT technology and standards for information exchange. For standards specifying communication mechanisms and information formats the framework for ICT can be applied:

- Permanent structure for strategic alignment between stakeholders specifically for healthcare ICT matters
- Only mandated standards from the ESOs shall give presumption of conformity
- Non-ESO standards can be directly used in public policies under certain conditions

For other aspects of healthcare products the ICT framework should not be applied.

6. Base policies for IPR in standardization on fair principles

The relationship between intellectual property rights and standards is complex.

COCIR recommends that, in order to fuel innovation, all public policies, including in particular those for standardisation and public procurement, should continue on the basis of achieving a sound balance of rewards for R&D versus sufficient freedom to use new technologies. Solid rules on IPR handling are thus indispensable in standards developments.

Standards development organizations should adopt principles with regard to IPR being essential to standards to bring sufficient certainty to potential users of the standard on the terms of use of embedded patented technologies. Patent owners should be obliged to timely report essential IPR and to declare the willingness to grant licenses to these patents on the basis of FRAND principles or allow use of the technology through other, voluntary schemes that are in particular accepted in specific domains including the open source community. One possible way which COCIR sees for increasing certainty and facilitating the licensing practice is via licensing pools in order to enable "one-stop shopping" and rapid convergence into a total bill of licenses on a standard that the market will bear.

In the context of the discussion around standardisation and IPRs in relation to EU policies as well as to innovation, COCIR would like to re-emphasise that specific needs per sector need to be taken into consideration.

¹ FRAND= Fair, Reasonable And Non-Discriminatory

² Sometimes Royalty-free is considered to be a sub-category of FRAND. However, sometimes FRAND is also explicitly used in opposition to Royalty-free. For the avoidance of doubt both are therefore listed in the text above.

There are different mechanisms regarding innovation, standards development and implementation at work in different sectors. In particular, the principles as defined in the European Interoperability Framework (EIF) for interoperability of eGovernment services can and should not be applied to the healthcare sector.

7. Improve efficiency, effectiveness of and access to the existing standardisation system

COCIR values the principle of national delegation as a way to provide low threshold participation possibilities for all, especially in the healthcare domain. No specific additional participation mechanisms are needed at European level. Support to bodies representing public interests should not be generic but be focused on specific causes that are politically recognised as publicly valued.

COCIR asks for a sustainable and balanced approach to facilitate better access to standards documents, especially for SMEs. Free access to standards documents seems as 'nice to have' but in comparison to the total challenge of implementation of standards for companies it is minor, while it would jeopardise the financial stability of the national standardisation bodies and of the ESOs and raise copyright issues linked to agreements with IEC and ISO.

COCIR believes that measures like free abstracts including the list of normative references, reduced fee for referred standards and transparent presentation of what standards are relevant to what business domains can bring substantial improvement.

Public authorities should see to it that no standards are allowed to become de facto unavoidable to businesses unless there is a clear justification for it, rooted in market realities or regulatory necessity. Better filtering of New Work Item Proposals based on market relevance and impact assessment would be one excellent measure to achieve this and to avoid a waste of resources on useless standards.

Improvements are needed on the readability of standards and the speed of their development. COCIR suggests that public authorities use their funding to create stronger stakeholder pressure to the three ESOs to continually improve their efficiency and effectiveness. Periodic revision of targets for key performance parameters could fuel such a process.

COCIR values the participation of authorities in development of standards for regulatory purposes, so as to guarantee up front that essential requirements are covered adequately. As to authorities in multi-stakeholder groups there should be a balance so EU authorities are not less represented than other authorities like FDA.

COCIR suggests that ICT standards contain detailed and comprehensive criteria to determine conformity. Considerable efforts have been wasted in the past in standardisation projects which never made it possible to determine whether real-life system conform to such standards or not. Effective interoperability however requires clear acceptance criteria.