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

COCIR High Level Contribution to the EC proposal for Medical Devices Regulation

1. Introduction

COCIR represents the European Medical Diagnostic and Imaging, Electromedical and Healthcare IT Industries. This is a sector of medical technology with a long history of innovative development and manufacture in Europe and which, under existing EU legislation and CE marking, has an excellent record of delivering safe and effective products to improve both citizen's health and Europe's healthcare systems.

2. EU Regulation versus EU Directive

COCIR welcomes the proposed new legal framework for Medical Devices[1]. We are supporting the proposal to be an EU Regulation rather than an EU Directive, as it will ensure the new regime is interpreted and applied consistently throughout all Member States. The new regulatory structure should remain robust, transparent and adaptable to scientific and technological progress. The over-riding objective must be for smart and efficient regulation delivering patient safety, high quality and rapid access to highly-innovative medical technology.

3. Regulatory compliance costs, fees and charges

COCIR believes the above objective can be delivered without significant increases in regulatory fees and compliance costs. In particular, in the current economic climate and while the EU is encouraging policies to attract more investment in medical technology in Europe, there can be no question of using increased levels of regulation as a mechanism to fund new or significantly enlarged Regulatory Authorities or to impose unnecessary levels of regulation that are not commensurate with proven risks. To do so will simply further erode Europe's global competitiveness for R&D and new product launches to the detriment of the medical technology sector, European patients and economic recovery.

4. EU Notified Bodies

Much comment has been made recently on the role and performance of Notified Bodies in the Medical Device approval process. COCIR acknowledges that there must be better oversight of Notified Bodies, what they do and how they work. We look forward to the European Commission's separate proposals on this which we urge are progressed independently of the proposed EU Medical Devices Regulation.

5. Major issues of specific concern

Separately and hereafter, COCIR will continue to share detailed comments on all aspects of the proposed EU Regulation of relevance to our sector. This document reflects on the next page COCIR's additional detailed contribution on key issues raised in the proposed EU Regulation some of which we fear may cause additional administrative burdens, without additional gain on public health or patient safety.

6. COCIR's commitment to dialogue

COCIR stands ready to play an active part in the discussions and debates that will determine the final shape of the proposed new regulatory system for Medical Devices in Europe. The sector is very broad and individual components may face different challenges and needs. However, for COCIR, our sector has worked and developed well in Europe under the current CE Marking scheme and we believe the core components of this must remain, strengthened through better cooperation between Member State's Regulatory bodies, harmonised standards and approvals and improved access to market for innovative medical technologies.

We look forward to discussing our views and expanding upon them in the weeks and months to come and will be happy to provide further detailed information on the points raised above.

[1] *COM(2012) 542 final, http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf*

Our key issues and our initial response to each are outlined below:

Summary:

A. Support establishment of the Medical Device Coordination Group (MDCG) with stakeholders as contributors (Art. 78)

B. Keep the role of Harmonised Standards (Art. 6) and use Common Technical Specifications only in exceptional cases (Art. 7)

C. Consider the use of the scrutiny procedure as a mechanism to enhance performance of Notified Bodies (Art. 44)

D. Clarify role and responsibilities for economic operators (Art. 8-12)

E. Limit the use of delegated acts (Art. 4.5, 41.4, 42.11 and 89)

F. Revise definition for "Accessory" and include definition for "Interoperability" (Art. 2)

Detailed explanations:

A. Support establishment of the Medical Device Coordination Group (MDCG) with stakeholders as contributors (Art. 78)

COCIR values the establishment of the Medical Device Coordination Group as a group of representatives of EU Member States, supported by the European Commission, tasked to coordinate and harmonise activities amongst EU Member States and contribute to the elaboration of EU guidance. We believe that the currently established Medical Device Expert Group (MDEG) including other stakeholders has proven its value over years. We consider other stakeholders including industry should not be relegated to an observer role but as contributors.

COCIR proposal: COCIR proposes to delete the words "in the capacity of observers" in the second sentence of art 78.7.

B. Keep the role of Harmonised Standards (Art. 6) and use Common Technical Specifications only in exceptional cases (Art. 7)

A reliable and simple regulation supported by "state of the art" standards covering requirements on safety and performance, which are developed by stakeholders in consensus, is essential to ensure safe and equitable access to healthcare in the European Union.
Harmonised standards are –and must remain- the preferred tool to support compliance with the EU regulations. We consider that the proposed concept of Common Technical Specifications (CTS) should be used only where no relevant harmonised or international standards exist, as it may otherwise lead to contradicting requirements. There shall not be concurrently a harmonized standard and CTS for the same category of medical devices which potentially would bring confusion.
COCIR considers that, where there are no harmonized standards, first serious attempts should be made to arrive at such consensus document, possibly with a specific mandate of the European Commission for a new standard.

COCIR proposal: COCIR suggests deleting the words "where relevant harmonised standards are not sufficient" in the first sentence of Article 7.

C. Consider the use of the scrutiny procedure as a mechanism to enhance performance of Notified Bodies (Art. 44)

Art. 44 introduces the possibility for the Medical Devices Coordination Group (MDCG) to comment and potentially intervene on the preliminary conformity assessment of Notified Bodies for 'new' certificates for class III devices, with the possibility to extend the procedure to lower risk classes by implementing act. This procedure will substantially delay the placing on the market.

Therefore, the scrutiny procedure as defined in article 44 should be limited to class III devices and devices of other classes where a potential of risk for the safety of patients has been identified via effective post market surveillance (reactive approach).
In addition, in a proactive manner, such process should be also used for Notified Body assessment for novel devices and in specific cases for which there are discrepancies in conformity assessment for some specific medical devices among different Notified Bodies. During the annual assessment of the Notified Body, the Competent Authority and MDCG members could perform a review of the Notified Body conformity assessments for medical devices in section 5 (a) and (d).

COCIR proposal: COCIR suggests limiting the scrutiny procedure to class III devices as defined in article 44.1 to the criteria as listed in section 5 (b), (c) and (e). For devices as defined in article 44.1 and falling under the criteria listed in section 5 (a) and (d) those should be covered during the Notified Body's annual assessment performed by the authorities.

D. Clarify role and responsibilities for economic operators (Art. 8-12)

Although the draft regulation provides more clarity on the role and responsibilities for all economic operators, COCIR is of the opinion that several of the described tasks overlap and thus add unnecessary administrative burden with no obvious benefit for the patients.

COCIR proposal with regards to Importers: COCIR suggests that the importer obligations should only apply in situations where there is no organisational or legal relation (contract) between the manufacturer and the importer and the manufacturer has appointed an Authorised Representative in the EU.

E. Limit the use of delegated acts (Art. 4.5, 41.4, 42.11 and 89)

The frequent reference to delegated acts creates substantial regulatory uncertainty. COCIR suggests limiting the use of delegated acts to the non-essential elements of the legislative act measures according to Article 290 of the Treaty of Lisbon[2]. COCIR considers the general safety and performance requirements (Art. 4.5), the classification rules (Art. 41.4) and the conformity assessment procedures (Art. 42.11) as key elements of the proposed Regulation, which should not be altered, amended or supplemented by delegated acts.

COCIR proposal: COCIR proposes to delete articles 4.5, 41.4 and 42.11 and to amend article 89 accordingly.

F. Revise definition for "Accessory" and include definition for "Interoperability" (Art. 2)

COCIR welcomes the detailed section on definitions that is giving more clarity. However, we are of the opinion that the current proposed definition for "accessory" might lead to different interpretations. In addition, as there is an essential requirement introduced in this EC draft regulation (Annex I – ER. 11.5), bringing the term of "interoperability", we believe this term should be well defined to prevent different interpretations.

COCIR proposal:

- "**Accessory**": COCIR suggests replacing the EC proposed definition with the following GHTF definition: "Accessory to a medical device means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use."
- "**Interoperability**": COCIR suggests adding the following definition in Article 2, Section on "Definitions related to devices": "Interoperability means the ability to exchange information and use the information that has been exchanged".

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E290:EN:HTML