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

EC proposal for Medical Devices Regulation

COCIR contribution to the MHRA public consultation[1]

Introduction
COCIR would like to thank MHRA for having initiated this public consultation on such an important matter which will certainly have an impact on all European Citizens and the stakeholders involved in the healthcare domain. We welcome the opportunity to provide you with our responses to your questionnaire. We do hope that the result of your inquiry will contribute to the harmonization across Europe of the healthcare regulatory framework as COCIR remains highly interested to continuously improve patient safety, quality of care and cost efficiency in Europe.

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.

This document is compiling COCIR's answers on key topics relevant for our Industry.

Hereafter is the executive summary of our main messages:

COCIR is:

1. **proposing** an amended definition of "accessory" and is suggesting a definition of "interoperability" to be added in the regulation (Question 3).
2. **supporting** the mechanism for regulatory status of products (Question 9)
3. **supporting** the inclusion of "internet sales" in the scope of the regulation (Question 12)
4. **inviting** the EU Member States to actively contribute to the development of Harmonised standards to avoid any future formal objection (Question 13)
5. **suggesting** to limit the use of Common technical specifications (CTS) only if no relevant standard exist (Question 14)
6. **underlining** the need to avoid any overlap in the role of economic operators (Questions 16 and 18)
7. **suggesting** to remove the obligation to include relevant standards used and the UDI in the declaration of conformity (Question 22)
8. **supporting** the development of an harmonized UDI system globally (Question 27)
9. **supporting** the creation of a central database (Question 29)
10. **requesting** clarification of Member States' responsibilities when a notification of a Notified Body (NB) is terminated or suspended (Question 38)
11. **strongly proposing** to not change the classification rules and the conformity assessment procedure by delegated act (Questions 39 and 44)
12. **suggesting** to give MDCG the task to monitor the implementation of the new provisions on unannounced inspections by NBs (Question 44)
13. **proposing** the definition of an appropriate scope of Free Sale Certificates (Question 47)

[1] http://www.mhra.gov.uk/Publications/Consultations/Deviceconsultations/CON20536

14. **proposing** an alternative solution for scrutiny procedure as a part of the supervision on Notified Bodies by EU Member States (Questions 48 and 49)
15. **supporting** MHRA proposed solution on clinical investigations (Questions 53, 54 and 55)
16. **suggesting** a longer time to report incidents (Question 56)
17. **proposing** not to extend trend reporting requirement to all medical devices (Questions 57 and 58)
18. **supporting** MHRA proposed solution on Market Surveillance (Questions 59, 60 and 61)
19. **supporting** MHRA position regarding the cooperation between Member States that should include industry as contributors and not only observers. In addition we propose to widen the scope of "Conflict of interests to all healthcare organisations. (Question 62)
20. **believing** that the EU reference laboratories for medical devices would not be useful (Question 63)
21. **believing** that the implementation of the new regulatory framework can be delivered without significant increases in fees and compliance costs (Question 66)
22. **supporting** the three years transition period as suggested by the Commission (Question 67)

Please note that the numbering is not in numerical order but is following MHRA document numbering.

1. Scope and definitions (Medical Devices Regulation)

- Question 3: COCIR welcomes the detailed section on definitions that is giving more clarity. But we would like to raise two additional points. 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".

  In addition, COCIR suggests **moving the classification rule on software into Annex VII on classification (Art. 2.1 (4)).** With the move of the definition of "active medical device" from Annex IX of the current Medical Devices Directive to article 2.1 (4) of the proposed regulation for Medical Devices, the sentence "Stand alone software shall be considered an active device" has been moved to the definition section of the Medical Devices Regulation. However, it is not a definition, but a classification rule.

  COCIR proposal: COCIR suggests to move the sentence "Stand alone software shall be considered an active device" from article 2.1 (4) to Annex VII, Rule 9.

3. Regulatory status of products

- Question 9: We support MHRA proposed position. We see a benefit in the proposed mechanism of a group of relevant experts supporting the Commission and subsequently having implementing acts drafted by the European Commission and approved by EU Member States as it will provide legal certainty and consistency across the EU.

6. Internet sales

- Question 12: COCIR agrees with MHRA proposal.

7. Harmonised standards

- Question 13: COCIR partially agrees with MHRA proposed position.
  We fully support MHRA regarding the on-going use of harmonised standards. 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.

  However, we would be more cautious regarding the Formal Objection process. A Formal Objection has a potential for tarnishing, both at European and at global levels, the reputation of the "New Approach", even if the intention is to give better tools for the correct implementation of this effective system of regulation. Nevertheless, COCIR would endorse to maintain the possibility for a Member State to exceptionally issue a formal objection, as already exists in the current legislative framework. COCIR wishes to repeat its strong support for the New Approach which has been instrumental in putting Europe ahead of the rest of the world regarding innovation and patient safety.

  COCIR proposal: COCIR proposes to limit the use of the Formal Objection only in exceptional cases, when a harmonised standard is demonstrably defective or no longer reflecting state-of-the-art. Any Formal Objection should be very carefully and exceptionally launched, duly substantiated. In addition, any situation of defective and/or outdated harmonised standards –and thus Formal Objections– need to be prevented as far as possible by ensuring adequate involvement of regulatory authorities in the process of standards development and maintenance.

8. Common technical specifications (Medical Devices Regulation)

- Question 14: COCIR partially agrees with MHRA proposed position. COCIR shares MHRA's concerns about CTS but not only on the way they will apply but also on the way they will be developed.
  We disagree with the statement that CTS provide more clarity and certainty with the statement that CTS are needed to meet the regulatory requirements.
  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 a 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.

10. General obligations of economic operators

- Question 16: COCIR partially agrees with MHRA proposed position.
  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 is currently developing a detailed paper on economic operators, in close cooperation with other European Trade Associations. This paper will include specific proposals for the role of

importers and their relation with the Authorised Representative. COCIR will of course share this position paper with MHRA once available.

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 importer and the manufacturer and/or the Authorised Representative appointed by the manufacturer in the EU.

- Question 18: Regarding the "qualified person", both the manufacturer and the Authorised Representative need to have a qualified person in their organization. COCIR is of the opinion that this requirement should also apply in cases where the importer takes on the role of the Authorised Representative.

13. Declaration and CE marking of conformity

- Question 22: COCIR does not agree with MHRA proposed position.
  Including a mandatory listing of the voluntary standards in the Declaration of Conformity (DoC) suggests that they provide the best means of demonstrating conformity. Also, a longer list might be erroneously seen as evidence of a "safer" product. For equipment that is in use for some years, the list will show outdated standards, suggesting the device may not be fit for safe use anymore. For highly innovative products, where no relevant harmonised standards yet exist, it could be a disadvantage for a manufacturer who cannot reference to a harmonized standard e.g. when the product is more state of the art than the standard.
  Some DoC can cover many devices (up to more than 1000) with a lot of variants of the same device. Therefore including the UDI reference of the device(s) in the DoC may unnecessary lengthen it. Since there is a link between UDI and the DoC in the European Database, the requirement to put UDI on the DoC seems superfluous.

  COCIR proposal: COCIR suggests deleting the requirement to include a list of voluntary standards and the UDI in the Declaration of Conformity.

15. Identification, traceability and transparency of devices

- Question 27: COCIR is fully supporting the development of a European UDI system.
  However, this UDI system which is planned to be implemented in the European Union should be in line with the IMDRF and US FDA requirements to avoid additional burden for manufacturers, users and authorities. In this respect, it should also be avoided that Members states create their own national UDI systems requiring storing the UDI information in a country specific database. A single EU Database shall be used to store UDI information related to manufacturers and medical devices. As a consequence registrations systems which are currently in place in several countries would be unnecessary. A double registration for manufacturers and medical device should be avoided. In this perspective it seems sensible to extend the coverage to the EEA.

- Question 29: COCIR supports MHRA proposed position to develop an efficient and operating central database.

16. Notified Bodies

- Question 38: COCIR would like to make an additional comment.
  We are calling for a clarification of the procedure when a notification is restricted, suspended or withdrawn (Art. 36.3). Failure to meet the requirements of Annex VI by Notified Bodies (NBs) may lead to the suspension or withdrawal of certificates. We suggest clarifying that the Member States have the responsibility to ensure continuity in the process of placing medical devices on the market even in case of a restriction, suspension or withdrawal of the notification of the Notified Body processing the files.

COCIR proposal: COCIR recommends adding the text in bold in Art. 36.3 as follows: "In the event of restriction, suspension or withdrawal of notification, the Member State shall take appropriate steps to ensure that the files of the Notified Body concerned are either processed by another Notified Body **–specifically in cases where the manufacturer wishes to continue the conformity assessment process–** or kept available for the national authorities responsible for Notified Bodies and for market surveillance at their request."

17. Classification

- Question 39: COCIR agrees with MHRA proposal that the competent authority notifies the Commission and the MDCG of their decision afterwards, as it would avoid any additional delay. However, we object to the principle that classification rules can be amended by delegated act, as it creates substantial regulatory uncertainty. COCIR suggests limiting the use of delegated acts to the non-essential elements of the legislative act according to Article 290 of the Treaty of Lisbon[2]. COCIR considers the classification rules (Art. 41.4) as a key element of the proposed Regulation, which should not be altered, amended or supplemented by delegated acts.

  COCIR proposal: COCIR proposes to delete article 41.4 and to amend article 89 accordingly.

18. Classification (Medical Devices Regulation)

- Question 41: *Please see our response to Question 3 above.*

20. Conformity assessment (Medical Devices Regulation)

- Question 44: COCIR partially agrees with MHRA proposed position.
  The 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. COCIR considers 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 article 42.11 and to amend article 89 accordingly.

  In addition, COCIR suggest clarifying the process for the unannounced inspections by Notified Bodies (Annex VIII, 4.4 and Art. 80). The proposed regulation is giving the Notified Bodies a clear and appropriate mandate to ensure thorough testing and regular checks, including unannounced factory inspections. COCIR fully supports these proposals.

A. Therefore, COCIR is of the opinion that the process to perform unannounced inspections should be clarified. It is essential to ensure an equal playing field for all manufacturers by a better coordination amongst Notified Bodies. Member States –through the Medical Device Coordination Group (MDCG)– should furthermore control that the Notified Bodies are adequately and consistently performing these unannounced inspections.
B. In addition, COCIR sees practical difficulties in implementing the new requirements of Annex VIII and in particular for Small and Medium Enterprises (SMEs) and for manufacturers which only provide few high prize products (i.e. heart supporting systems). They might not have the appropriate resources and staff to be able to fully support Notified Bodies requests during unannounced visits. The sampling requirement might also lead to strong difficulties for those manufacturers.

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

COCIR proposals: COCIR suggests:

A. Amending Article 80 by adding the following task for the MDCG: "(g) to verify the compliance of Notified Bodies with the requirements set out in Annex VIII, 4.4, in particular to ensure a consistent and reasonable use of the unannounced inspections requirement by Notified Bodies."
B. Adding the following sentence at the end of the first paragraph in Annex VIII, 4.4: "Such plan should carefully take into account the specificities of each manufacturer subject to unannounced inspections".

22. Derogations, choosing a notified body, and certificates

- Question 47: COCIR partially agrees to MHRA proposed position.
  In addition, COCIR suggests defining an appropriate scope of Free Sale Certificates (Art. 48.1).

A. Article 48 limits the possibility to request Certificates of Free Sale to a Medical Devices manufacturers based in the EU.
B. The requirement to limit the validity of certificates of free sale to the validity of the certificate referred to in Article 45 is not practical, since it could limit the validity period of such a document to a few days depending on the point in time when it is issued.

COCIR proposals:

A. Amending the first sentence of Article 48.1 as follows: "For the purpose of export and upon request by ~~a manufacturer~~ **an economic operator or the device manufacturing facility**, the Member State in which the ~~manufacturer~~ **economic operator or device manufacturing facility** has its registered place of business shall issue a certificate of free sale declaring that the manufacturer is properly established and that the device in question bearing the CE-marking in accordance with this Regulation may be legally marketed in the Union."
B. Amending the last sentence of Article 48.1 as follows: "The certificate of free sale shall be valid for the period indicated on it which shall not exceed five years ~~and shall not exceed the validity of only in combination with the certificate referred to in Article 45 issued for the device in question."~~

23. Additional pre-market scrutiny for higher risk devices

- Question 48 and Question 49: COCIR agrees with MHRA rationale and proposes an alternative solution.

We consider the use of the scrutiny procedure as a mechanism to enhance performance of Notified Bodies. 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.

26. Clinical investigations

- Question 53: COCIR supports MHRA's opinion that the establishment of a central European database for clinical investigations would simplify compliance and information sharing.

- Question 54: COCIR supports the concept of coordinating Member States as proposed by the European Commission in Article 58.

- Question 55: COCIR agrees with MHRA proposed position.

27. Vigilance

- Question 56: COCIR partially agrees with MHRA proposal.
  In the proposed Regulation for Medical Devices the reporting timeline for incidents has been shortened to 15 days compared with a maximum of 30 days in accordance with the current MEDDEV and GHTF documents. The reason for this step remains unclear and we expect that the number of reports will increase significantly.

  COCIR proposal: COCIR proposes to amend Article 61 Section 1 as follows:
  "Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than ~~15~~ **30** days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible."

  COCIR welcomes Commission's proposal to require trend reporting for high-risk medical devices. However there is a lack of appropriate guidance which may lead to different practices and therefore do not allow for direct comparison on trends between manufacturers. Defining trigger levels for reporting is complex, as it needs to take into account multiple factors. The limitation on the ability to standardize these approaches is also recognized by the GHTF document and reflected in joint industry position paper on trend reporting.

- Question 57: COCIR agrees with MHRA proposed position.

- Question 58: COCIR agrees with MHRA proposed position.

28. Market surveillance

- Question 59: COCIR agrees with MHRA proposed position.

- Question 60: COCIR agrees with MHRA proposed position.

- Question 61: COCIR agrees with MHRA proposed position.

29. Cooperation between Member States

- Question 62: COCIR agrees with MHRA position and in particular on the need for greater clarity about how the Commission intends to engage with key stakeholders.
  We 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 article 78.7.

In addition, COCIR would request to **widen the scope of Art. 82.1 on "Conflict of interests".** COCIR understands that this article is only applicable to interests in the medical devices industry. However, other stakeholders, e.g. doctors and insurance companies, might also have potential conflicts of interest which might bias their impartiality. The conflict of interest should not be limited exclusively to links with the medical device industry but could be extended to any other healthcare related organisations.

COCIR proposal: COCIR proposes adding the words "or in any other relevant healthcare organisation" after "in the medical device industry" in article 82.1.

30. EU reference laboratories

- Question 63: COCIR does not believe that EU reference laboratories for medical devices would be useful. This concept should be clarified. It may also add to additional unnecessary administrative burden and costs without adding safety.

32. Confidentiality, data protection, funding, penalties

- Question 66: 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.

33. Final provisions

- Question 67: COCIR would suggest not shortening the period of transition and is supporting the 3 years period as proposed by the European Commission. All stakeholders would need at least 3 years to ensure an effective and smooth implementation of the new legal framework.