



COCIR High Level Contribution To the Proposal for Medical Device Regulation *Revision of Directive 93/42/EEC on Medical Devices*

Introduction

COCIR, the voice of European manufacturers of medical diagnostic and imaging, electromedical and healthcare ICT industries, welcomes the revision of the EU Medical Devices Directive (MDD) and its replacement with a new Medical Devices Regulation (MDR). The new Regulation should build on the many merits of the existing regulatory approach while remaining robust, transparent and adaptable to scientific and technological progress. The primary objective of the revision process must be to achieve smart and efficient regulation delivering patient safety, high quality and rapid access to innovative medical technology.

Since the very beginning of the revision process in 2008, COCIR has continually shared detailed input on all aspects of the proposed Regulation of relevance to our sector. This document is a high level contribution to all stakeholders involved in the revision process, and outlines COCIR's respective comments on key matters. It is an updated version of our [March 2014 contribution](#), taking into account new concerns since the European Parliament adopted its position in October 2013.

Our key messages and recommendations based on current developments and latest discussions at Council level are outlined below. Where relevant, the document refers the reader to more detailed COCIR documents that elaborate on the points made.

Summary and COCIR Key Recommendations

- 1. Scrutiny procedure:** Strengthen Notified Bodies. Minimize and advance any special review of high risk devices, where truly needed for patient safety (Art. 44)
- 2. Vigilance reporting:** Keep the scope limited to 'serious' incidents (Art. 61)
- 3. Transparency:** Support the Parliament's proposal to establish a Medical Device Advisory Committee (MDAC) with stakeholders as contributors (Art. 78)
- 4. Scope, definitions and classification rules:** Ensure clarity and international convergence, and keep pace with technological innovations (Art. 2, Annex VII)
- 5. Standards and CTS:** Maintain the central role of harmonised standards (Art. 6) and use Common Technical Specifications (CTS) only in exceptional cases (Art. 7)
- 6. Delegated acts:** Maintain legal certainty by limiting the use of delegated acts to cases where they are genuinely needed (Art. 41 and 89)
- 7. Chemicals:** Maintain the Commission's original proposal on the management of hazardous substances (Annex I, Point 7.4)
- 8. Transition period:** 3 years can only suffice if manufacturers can make meaningful preparations throughout this period, starting from the availability of the implementing legislation (Art. 97)
- 9. Unique Device Identification:** Support a single EU system and database that is aligned with the US FDA Final Rule (Chapter 3)
- 10. Economic operators:** Clarify the various roles and responsibilities and avoid overlaps (Art. 8-12)
- 11. Clinical data and investigations:** Tailor the system to the unique characteristics of devices and avoid borrowing from the pharmaceutical model (various)
- 12. Reprocessing:** Ensure a high level of patient safety by extending all manufacturer obligations and liabilities to reprocessors (Art. 15)



DETAILED BRIEFING

1. Scrutiny procedure (Art. 44)

COCIR supports the strengthening of the existing CE marking system to increase patient safety. In our view, the best way to do this is to raise the standards by which Notified Bodies are designated and supervised, and also raise the levels to which Notified Bodies perform. The Commission's proposed Articles 32 and 35 go some way towards delivering this, as does the Commission's September 2013 Implementation Recommendation and Recommendation¹, which bring forward the 2012 joint plan for immediate action² agreed with Member States following the PIP scandal.

While COCIR supports the above initiatives, we remain concerned about both the Commission and Parliament proposals for additional pre-market 'scrutiny' of certain conformity assessments. We agree that greater controls are warranted for higher risk devices. However the proposals currently offered both add unnecessary delays to market for life-saving devices, and thereby risk seriously undermining patient safety, innovation and competitiveness.

Moreover, we think it essential for existing Notified Bodies to remain involved in the process, in cases where Notified Bodies have demonstrated expertise in the device technology or conformity assessment element in question. Creation of a new category of Notified Bodies, with its own designation and review procedure, must be avoided.

For new and innovative devices, experience with conformity assessment is lacking. It is important, that experience and expertise with new and innovative devices is collected structurally. This is especially relevant for high risk new and innovative devices.

To improve on the current proposals, COCIR suggests setting up a mechanism for manufactures to obtain a scientific opinion of relevant experts early in the (clinical) development of innovative devices. This scientific opinion could be drafted by one or more relevant (clinical) experts that the Member States have vetted up-front for competence and impartiality. Notified Bodies could take the scientific opinion into account in their conformity assessment. For high-risk innovative devices this scientific opinion procedure should be made obligatory and deviation of the opinion will be only allowed based on proper justification. Once a substantial amount of scientific opinions on similar devices is available, these could be made publicly available as guidance documents. This process should also avoid adding red-tape to the process, without creating new committees, whilst at the same time enhancing availability of clinical expertise early in the lifecycle and developing clinical guidance in a structured way.

COCIR proposal: Strengthen Notified Bodies, avoid unnecessary red tape, enhance the availability of clinical expertise for the highest risk innovative devices as early as possible in the device's lifecycle and develop clinical guidance.

2. Vigilance reporting (Art. 61)

The Commission's MDR proposal includes a different notion of 'incident'³ and 'serious incident'⁴ to what exists under the current MDD. An 'incident' as defined under the current MDD is called a 'serious incident' under the Commission's proposal. The events to be reported in both texts have not changed.

¹ http://europa.eu/rapid/press-release_IP-13-854_en.htm

² http://europa.eu/rapid/press-release_IP-12-119_en.htm

³ Article 2(1)(43): '**incident**' means **any** malfunction or deterioration in the characteristics or performance of a device made available on the market, **any** inadequacy in the information supplied by the manufacturer and **any unexpected undesirable side-effect**.

⁴ Article 2(1)(44): '**serious incident**' means any **incident** that directly or indirectly led, might have led or might lead to any of the following:

- **Death** of a patient, user or other person,
- Temporary or permanent **serious deterioration** of the patient's, user's or other person's state of health,
- Serious public **health threat**.



The continued reporting by manufacturers of serious incidents (as newly defined) for vigilance purposes is acceptable and proportionate. However, the Parliament has proposed that all events meeting the MDR definition of 'incident' be reported in the future. COCIR considers this an extreme and disproportionate expansion of the scope, and estimates that it would result in a **many hundredfold increase in the number of manufacturer reports** to the electronic system.

The vast majority of these new reports would be routine corrective maintenance calls that are not relevant to patient or user safety and COCIR shares the Commission concern that it would render the rapid identification of serious incidents and their proper follow-up more difficult. In addition, it would add a significant administrative burden on manufacturers and it would very likely overload both competent authorities, who must conduct a risk assessment on each event reported, and Notified Bodies, who must evaluate whether the event reported, has an impact on the device's certificate. Moreover, for higher class devices, there are additional requirements on trend-reporting for the incidents that are non-serious incidents, which would anyhow allow Competent Authorities to react on an increase of frequency or severity of such incidents.

By keeping such reports limited to serious incidents – as is the case today under the current MDD – the information uploaded to the electronic system will remain focused on patient safety and Member States' post-market surveillance activities.

COCIR proposal: Maintain the Commission's proposed Article 61.

3. Transparency (Art. 78)

9.1 MDCG/MDAC

COCIR values the establishment of the Medical Device Coordination Group (MDCG) 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 active contributors.

For this reason, COCIR greatly welcomes the Parliament's proposal to supplement the MDCG with a Medical Device Advisory Committee (MDAC) that is composed of stakeholders and is actively involved in many aspects of MDR implementation.

COCIR proposal: Support the Parliament's proposed Article 78a.

9.2 Data accessibility

COCIR supports an efficient communication process, which would concur to improve patients' and users' safety. Nevertheless, access to vigilance and other relevant information should be organized in order to protect privacy, confidentiality and intellectual property. COCIR is also concerned by making accessible information either at a too early stage or to a too large public, which could lead to unnecessary concerns.

COCIR recommends to define appropriate access levels for public but also for Healthcare professionals as well as making the information accessible only after review and approval by Competent Authority.

COCIR proposal: Support the original Commission proposal for appropriate levels of access to sensitive data and define the criteria (per target audience) to make such information available.

4. Scope, definitions and classification rules (Art. 2 and Annex VII)

COCIR is concerned by the Parliament's proposed amendment to the definition of 'medical device' (Article 2.1(1)) to include products with 'indirect' medical purposes and welcomes the Council position of keeping the original Commission text in this respect.

Taken together with the definition of 'accessory to a medical device' (Article. 2.1(2)), this **risks unjustifiably bringing a great many products**, such as general purpose, non-medical software,



and consumer electronics like smartphones and tablets, **into the scope** of the Regulation. More generally, the imprecise nature of the term 'indirect' presents the risk of provoking many new disputes about how to regulate borderline products. Many such disputes have taken place in the context of today's Directive, and the new Regulation should aim to correct, rather than exacerbate, this situation.

To avoid this situation the term 'indirect' should be deleted, or at least the legislator should provide an exact and precise guidance on its scope.

The Parliament's proposal includes several new definitions in respect to the Commission's proposal. COCIR supports any clarification that can potentially lead to a better understanding of the Regulation and suggests aligning such definitions as much as possible to the ones already used in the international landscape.

COCIR believes that **device classification rules must evolve** alongside technological innovation and progress. The majority of the Annex VII classification rules have been maintained from today's Directive. COCIR suggests a careful approach towards up-classification of well-established technologies, on the base of sound evidence of a need of stronger regulatory requirements. On the other hand, experience in recent years has shown that certain classification rules do not fit well with certain device technologies. There are **real-life examples of national competent authorities, Notified Bodies and other actors classifying devices like medical software differently**, even though these actors apply the same rules to the same device.

In general, **COCIR supports** the significant efforts made for the past 20+ years to harmonise requirements at international level. Definitions of core terms, and classification of devices into risk classes, should therefore match as much as possible EU's commitments at international level, particularly within the International Medical Device Regulators Forum (IMDRF). These efforts have included a definition for Software as a Medical Device (SaMD) and a related risk categorization. COCIR **recommends** that the Regulation integrates the IMDRF definition for Software as a Medical Device and establishes a dedicated classification rule for software-only products (not embedded in medical devices) based on the IMDRF risk categorization.

COCIR proposal: Oppose Parliament's amendment of Article 2.1(1). Keep the Commission proposal of Annex VII for well-established technologies. Revise Annex VII to keep pace with technological innovation. Align with international convergence efforts for definitions of core terms and device classification.

5. Standards and CTS (Art. 6-7)

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 across the European Union. Harmonised standards are – and must remain – the preferred tool to support compliance with EU regulations.

COCIR considers 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.

In view of the above, COCIR supports the Parliament's proposed amendment of Article 7(1). This amendment improves greatly on the Commission's originally-proposed text, by limiting the range of scenarios in which CTS are justified, by requiring the prior consultation of the MDAC and MDCG, and by obliging the Commission to ensure coherence between any proposed CTS and the European and international standardisation system. However, we note that the Commission's old language of "or where relevant harmonised standards are not sufficient" is still in the new Article 15(c)(5) and should be removed.

COCIR proposal: Support the Parliament's proposed amendment to Article 7(1), and remove the phrase "or where relevant harmonised standards are not sufficient" from the new Article 15(c)(5).



6. Delegated acts (Art. 41.4 and 89)

The Commission proposal's 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 Lisbon⁵. COCIR therefore strongly supports the Parliament's proposals to avoid modification of the General Safety and Performance Requirements (Art. 4.5), the technical documentation rules (Art. 8.2) and the conformity assessment procedures (Art. 42.11) via delegated acts.

However, COCIR remains concerned that the Commission retains the power to amend or supplement the Annex VII classification criteria (Art. 41.4) and also has rejected Parliament's amendments to include a consultation of stakeholders in this process. This is a key element of the proposed Regulation. It may be justified in special cases to use delegated acts to *decide* that a device (or category/group thereof) should be classified in another class, by way of derogation from the classification criteria. However, amending or supplementing the classification *criteria* should only happen through the full EU legislative procedure involving all institutions and stakeholders.

COCIR proposal: Amend Articles 41.4 and 89 accordingly.

7. Chemicals (Annex I, Point 7.4)

The MDD ensured that the use of hazardous substances in medical devices was subject to a risk-benefit analysis, performed by the manufacturer. The Commission's MDR proposal seeks to strengthen this system, by addressing additional substances such as endocrine disruptors and improving the functioning of Notified Bodies.

The Commission's proposal is effective for ensuring that medical devices are safe and that hazardous substances are only used in cases where feasible alternatives providing equal benefits for patients are unavailable. Moreover the Commission's proposal allows for a proper enforcement and verification without overburdening companies, Notified Bodies and the inspection staff of Competent Authorities.

We deem it extremely important that Member States, the Commission and the Parliament be aware and in full agreement that there is no need for additional provisions on chemicals to ensure safety of medical devices.

COCIR proposal: Maintain the Commission's proposed Point 7.4 in Annex I.

8. Transition period (Art. 97)

A 3-year transition period is only sufficient for industry if economic operators are able to make **full use** of this time and if it is starting from the availability of the implementing legislation. For many obligations, it is only possible to start making meaningful preparations **after** other parts of the Regulation have been implemented, *e.g.*, once a Notified Body has been re-notified, or once a Delegated Act or Implementing Act has been published.

To give but one example, provisions on Unique Device Identification (UDI) are only given in general detail in Chapter III. Much of the detail regarding UDI will only be given at a later date, in the form of a Delegated Act. Either this Delegated Act, or the Regulation itself, will need to specify that the corresponding obligations only apply 3 years after the *Delegated Act* enters into force.

The Regulation should recognize this reality and specify that the 3-year period starts to be counted only once preparations within companies can meaningfully begin. If this does not happen, operators risk falling out of compliance, or even be punished, for factors **outside their control**. Moreover, in many third countries, device registration is based on EU CE marking. In these markets, it will be necessary to re-register devices due to updated labels, technical files, declarations of conformity and EC certificates.

⁵ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E290:EN:HTML>



To correct this problem, **COCIR recommends amendment of the derogations in Article 97(3)**. The amended Article should list all provisions for which an implementing measure will be published, and specify that the transition period for those provisions is 3 years **after the implementing measure's date of application**.

COCIR proposal: Expand the list of derogations in Article 97(3).

9. Unique Device Identification (Chapter 3)

COCIR welcomes the Parliament's call for a **single EU UDI system and database** (Article 24.1) and not multiple systems across the EU. We also welcome the Commission's April 2013 Recommendation⁶, which called for a common EU UDI framework and warned Member States against launching national UDI initiatives in isolation of each other.

To enable true worldwide traceability, the single EU system should be as aligned as possible with the UDI system recently put in place via the United States FDA's Final Rule. The core UDI features, including the label and the data elements for the EU database, should be as interoperable as possible with what exists in the United States.

Despite the Parliament's welcome amendment, important details are still missing from the draft Regulation regarding who will administer the single EU system, what the transition times will be for the different device classes, and how many entities the Commission will designate to assign UDIs. If these details cannot be specified in the Regulation, they should be clearly laid out in the forthcoming Delegated Act.

COCIR proposal: Support the Parliament's amendment to Article 24.1, ensure maximum alignment with the FDA Final Rule when implementing the single EU system, and clarify important roles, responsibilities and timelines in either the Regulation or the forthcoming Delegated Act.

10. Economic operators (Art. 8-12 and 18)

The roles and responsibilities of all economic operators need to be as clear and distinct as possible. In COCIR's view, certain of the described tasks overlap and thus add unnecessary administrative burden with no obvious benefit for the patients. In particular, the obligations of importers versus authorised representatives need further clarification.

For imported devices, COCIR considers it counterproductive for the importers' identification and contact details on the device label. In order to ensure smooth operation of the post-market vigilance system, only the details of the importer's Authorised Representative in Europe should appear on-pack. Article 11.3 should therefore be deleted.

In addition, the proposal of Parliament (and Council) for the words "*medical device*" to accompany the CE marking is unnecessary and overly burdensome, as operators would need to translate this term into 20 different languages when labelling their devices.

COCIR proposals:

- 1) Modify Articles 9 and 11 to ensure that regulatory obligations for importers only apply when there is no organisational or legal relation (contract) between the importer and the Authorised Representative.
- 2) Delete the Article 11.3 obligation for importers to indicate their identification and contact details on the device label
- 3) Keep Article 18 free of any obligations to accompany the CE marking with the term "*medical device*"

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:099:0017:0024:EN:PDF>



11. Clinical data and investigations (various Articles)

COCIR firmly believes that clinical investigations for medical devices are fundamentally different from clinical trials conducted in the pharmaceutical world. As such, we are concerned about various proposals, from all 3 EU institutions, that seem to incoherently borrow ideas from the recent review of the Clinical Trials Directive 2001/20/EC and they do not readily fit with the concepts set out in EN ISO 14155 on good clinical practice.

We are particularly concerned about the Parliament's proposal for mandatory submission of clinical investigation results to an electronic system that will be made partially available to the public (Article 57.3). Full clinical investigation reports should only be accessible to professionals who are qualified to understand them, and commercially-sensitive information potentially present in these reports must be protected whenever access is granted to the electronic system.

COCIR proposal: Devise clinical requirements that are tailored to the unique characteristics of medical technology, and protect commercially-sensitive information.

12. Reprocessing (Art. 15)

To ensure a consistently high level of patient safety, it is appropriate that any reproprocessors of medical devices be subject to the same liabilities and obligations incumbent upon devices manufacturers. It would endanger public health and against the MDR's goal of reducing risk "*as far as possible*" to adopt alternative approaches such as treating devices as reusable by default, or excusing reproprocessors from obligations linked to the conformity assessment procedure. Devices should not be reprocessed if the suitability of reprocessing has not been rigorously demonstrated, and any reprocessing that takes place should be subject to the same level of regulatory controls as newly-manufactured devices.

COCIR proposal: Maintain the Commission's proposed Article 15.