COCIR

Sustainable Competence in Advancing Healthcare

AmCham EU

SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Breakfast Briefing on Medical Devices

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in cooperation with COCIR and MedTech Europe

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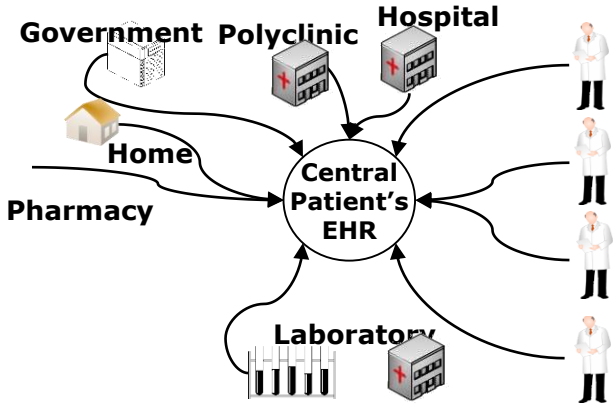
Industry sectors covered by COCIR

COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe

COCIR covers 4 key industry sectors:

- Medical Imaging
- Radiotherapy
- Health ICT
- Electromedical

Our Industry leads in state-of-art advanced technology and provides **integrated solutions** covering the complete care cycle



33 COCIR Company Members

15 COCIR National Trade Associations Members

AGORIA
no future without technology
BELGIUM

FiHTA
FINLAND

snitem
creating the tools for medical progress
FRANCE

bvitg
GERMANY

SPECTARIS
German Industry Association for Optical, Medical and Mechatronical Technologies
GERMANY

ZVEI:
GERMANY

ETOSZ
ASSOCIATION OF HEALTH TECHNOLOGY SUPPLIERS AND MEDICAL DEVICE MANUFACTURERS
HUNGARY

ASSOBIOMEDICA
Federazione nazionale per le tecnologie biomediche, diagnostiche, apparecchiature medicali e servizi, telemedicina
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COCIR Dedicated Efforts on Medical Devices Regulation

- **High Level Contribution Level 1** – Summary focusing on **13 topics** *(available on website)* http://www.cocir.org/uploads/media/COCIR_High_Level_Contribution_on_the_proposal_for_MDR_-_07_September_201....pdf
- **Dedicated Level 2 documents** on **Vigilance**, **Medical Software** and **CS/Standardisation.** Those are not for public but are updated/shared on regular basis with EU Institutions

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

COCIR High Level Contribution
on the Proposal for Medical Devices Regulation
Revision of Directive 2007/47/EC

NEW 7 Sept

Introduction

COCIR, the voice of the European manufacturers of medical imaging, radiotherapy, health ICT and electromedical industries, welcomes the revision of the current Medical Devices Directive (MDD) and its replacement with the proposed Medical Devices Regulation (MDR). The proposed MDR should build on the many merits of the existing regulatory approach while remaining robust, transparent and adaptable to scientific as well as technological progress. The primary objective of the revision process must be to achieve an efficient regulation delivering patient safety, high quality and rapid access to innovative medical technology and last but not least build public trust in the proposed Regulation.

The document is a High Level Contribution addressed to all parties involved in the revision process and is based on the latest developments of the proposed MDR [1]. It outlines COCIR's recommendations articulated through 13 strategic points considered of key importance by COCIR. More detailed documents have as well been developed, such as on software and on vigilance.

COCIR recommendations

1. **Vigilance:** keep the scope limited to '*serious*' incidents; ensure clarity and consistency of reporting time frame (e.g. 15 days after becoming aware of the incident is too short); introduce a tailored post-market surveillance system taking into account the medical device's life cycle; clear obligations must be defined for economic operators (various Articles)
2. **Software (as a Medical Device):** ensure software can be classified commensurate with the risk it possesses by ensuring clarity and international convergence (Article 2, Annex VII)
3. **Harmonised standards and common specifications:** maintain the central role of harmonised standards as per current New Approach (Article 6) and use common specifications only in exceptional cases, ensuring input by all stakeholders (Article 7)
4. **Chemicals:** maintain the European Commission's proposal on the management of hazardous substances (Annex I, Point 7.4)
5. **Transparency:** support the European Parliament's proposal to establish a Medical Device Advisory Committee (MDAC) with all stakeholders as contributors (Article 78a)
6. **Scope and definitions:** delete the term '*indirect*' or define its scope; clarify the definition of term '*clinical benefit*'; define the term '*patient management*' (Article 2)
7. **Delegated acts:** maintain legal certainty by limiting the use of delegated acts to cases where they are genuinely needed (various Articles)
8. **Transition period:** manufacturers require a reasonable preparation period; 3 years can only suffice if they can make meaningful preparations throughout this period, starting from the availability of the implementing legislation (Article 97)
9. **Scrutiny procedure:** strengthen the performance of Notified Bodies; minimise and advance any special review of high risk medical devices, where truly needed for patient safety (various Articles)
10. **Unique Device Identification:** support a single European system and database that is aligned with the United States' FDA Final Rule (Chapter 3)
11. **Economic operators:** clarify the various roles and responsibilities and avoid overlaps (e.g. importer versus Authorised Representative) (various Articles)
12. **Clinical data and investigations:** tailor the system to the unique characteristics of medical devices and avoid borrowing from the pharmaceutical model (various Articles)
13. **Reprocessing:** ensure a high level of patient safety by extending all manufacturer obligations and liabilities to reprocessors (Article 15)

[1] European Commission proposal, European Parliament amendments and Council of the European Union General Approach

1 of 9 07 September 2015

1. Harmonised standards and Common Specifications

- Standards contribute to public health by providing a complementary tool to support regulatory framework at Global level as well as at EU level
- Standards are developed and constantly updated with contribution of stakeholders
- COCIR recommends to maintain the central role of harmonized standards as per current New Approach and use common specifications only where no harmonized standard exist or where there is a need to address public health concerns, ensuring input by all stakeholders
- COCIR is in favor of EP amendment of Art 7(1)

2. Software: Indirect medical purpose and risk classification

- COCIR/DITTA active at International and European level
- COCIR consider important to have harmonized regulations across Europe and beyond
- Regarding indirect medical purpose (Art2.1):
  - COCIR recommends to delete the term 'indirect' or define its scope
- Regarding risk classification:
  - COCIR calls for proper classification rules in Annex VII based on risk class to ensure clarity and international convergence

3. Vigilance

Post-market activities are of high importance and will have direct consequences on the administration at country level

Thus, COCIR recommends to:

1. Keep the scope limited to 'serious' incidents
2. Ensure clarity and consistency of reporting time frame (e.g. 15 days after becoming aware of the incident is too short)
3. Introduce a tailored post-market surveillance system taking into account the medical device's life cycle (differences between single use devices and multi-usage equipment)
4. Clear obligations must be defined for economic operators

4. Transition period

COCIR highlights:

- The importance of having an adopted MDR timely supported by relevant implementing legislation and/or guidance
- The availability of Notified Bodies (avoid bottle necks)
- Concern on legacy products as we need to ensure continued availability of well established technologies delivering value-add to citizens

Thus, Industry/Manufacturers need a reasonable preparation period. 3 years can only suffice if they can make meaningful preparations throughout this period, starting from the availability of the implementing legislation

Thank you for your attention!