IMPLEMENTING
MEDICAL DEVICE REGULATION
COCIR HALF-TIME ASSESSMENT

COCIR SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
26 May 2020 is rapidly approaching; with a further 18 months to go, we are now at the midpoint for the implementation of the Medical Device Regulation. The European Commission recently published their implementing measures rolling plan for the Medical Device Regulation (MDR) and In-vitro Diagnostics Regulation (IVDR)\(^1\), following the publication of the CAMD roadmap\(^2\) last year. This makes it an appropriate time to assess where we stand in the implementation and map the way forward.

COCIR published its recommendations for implementing the MDR at the beginning of this year\(^3\). Based on these initial recommendations, we offer this follow-up assessment. COCIR is currently active in all relevant sub-groups and task forces of the MDR. We are increasingly concerned that secondary legislation, including implementing acts, guidance documents and Harmonised Standards, will not be ready on time to allow industry to prepare and diligently implement the Regulation.

COCIR members are at the forefront of innovation, including the digitisation of the healthcare sector. The innovative medical devices they offer make the delivery of healthcare safer, more efficient and more effective. Delays in implementation, the addition of requirements in guidance and uncertainties over the interpretation of the MDR provisions could create a situation where the European Union becomes a less attractive region for investment by medical device manufacturers, in comparison with other leading economies and markets.

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1. MDR and IVDR Implementing Measures Rolling Plan, September 2018
2. CAMD, Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap, November 2017
3. Implementing the Medical Device Regulation – COCIR views on the way forward, February 2018
ADVERSE IMPACT ON SOCIETY

- **Delays in patient access**, whereby patients with life-threatening diseases would have to wait for the re-approval and re-authorisation of diagnostic and treatment devices that are currently certified and where patient safety is assured.

- **Increasing costs and delays** for hospitals accessing the most advanced and efficient medical devices.

- **Unnecessary ethical complications** arising from clinical investigations, e.g. for devices that have a decades-long safety record

ADVERSE IMPACT ON INDUSTRY

- Adding to the administrative burden and increasing time-to-market that might lead to some innovative medical devices not reaching the European market.
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| **GENERAL FRAMEWORK**          | - Six guidance documents published to date<sup>4</sup>  
- Striving for convergence with global efforts at IMDRF level as far as the Regulation permits  
- Need to clarify relationship between Basic UDI-DI and EC Certificates  
- Still unclear on how UDI assignment for systems/procedure packs is done |
| **EUROPEAN DATABASE FOR MEDICAL DEVICES** | - Implementation plan published on time  
- Functional specifications for several modules delayed  
- Technical specifications delayed |
| **HARMONISED STANDARDS**        | - Standardisation request will only be adopted in Q1 2019  
- List of candidate standards unclear and insufficient  
- Worsening administrative processes for harmonisation of standards |
| **TRANSITIONAL PROVISIONS**     | - No clarity on interpretation of significant change according to Article 120.3  
- Guidance for legacy devices (UDI obligation, sufficient clinical evidence etc.) delayed |
| **PRE-MARKET**                  | - Field Safety Notice and MIR form published<sup>4</sup>  
- Development of several guidance documents and templates (e.g. PSUR) delayed  
- No clarity on possible delegation of activities between Economic Operators (e.g. pre-evaluation of incidents to distributors) |
| **MEDICAL SOFTWARE**            | - Guidance on qualification and classification delayed  
- Unresolved discussion on definitions (rev IMDRF)  
- Guidance on clinical evaluation of software progressing well |
| **POST-MARKET SURVEILLANCE AND VIGILANCE** | - Uncertainty on sub-contracting of verification activities between different economic operators within the same organisation  
- No clarity on use of sampling methods by importers  
- Original Equipment Manufacturer/Own Brand Labeller obligations under discussion |
| **ECONOMIC OPERATORS**          | - 34 applications for designation under the MDR/IVDR have been received by the EC  
- Significant increase in demand expected for Notified Bodies, particularly for software and apps, due to changes to classification rules  
- Uncertainty on MDR interpretation among Notified Bodies |

<sup>4</sup> All guidance documents are published here: https://ec.europa.eu/growth/sectors/medical-devices/guidance_en
COCIR RECOMMENDATIONS

To ensure a successful implementation of the Regulation, COCIR makes the following recommendations to European Commission and EU Member States:

1. Ensure sufficient availability and capacity of **NOTIFIED BODIES** as well as a European contingency plan for manufacturers that lose their Notified Body. Commission and Competent Authorities should harmonise their interpretation of MDR requirements in order to avoid lengthy designation procedures.

2. Issue the standardisation request as early as possible, harmonise the **NECESSARY STANDARDS** on time, and regularly publish the references in the Official Journal.

3. Avoid unnecessary up-classification of **MEDICAL SOFTWARE** and ensure that provisions for clinical evaluation and investigations are fit for purpose.

4. Provide a clear interpretation of significant change, including the possibility of changing an MDD certificate, during the ‘**GRACE PERIOD**’.

5. Continue efforts regarding global coherence of **UNIQUE DEVICE IDENTIFICATION (UDI)** requirements.

6. Ensure timely functioning of the European Medical Device Database **EUDAMED** allowing actors to access and manufacturers to upload the necessary data, including machine-to-machine functionality. This includes timely availability of specifications for implementation by industry, Competent Authorities and Notified Bodies.

7. Provide clear and timely guidance for **CLINICAL EVALUATION** of IIa and IIb devices.

8. Finalise the necessary guidance, templates and forms for **POST MARKET SURVEILLANCE AND VIGILANCE**.

9. Allow pragmatic cooperation for CE marking verification and incident reporting between **ECONOMIC OPERATORS**.
GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

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COCIR HOW TO JOIN US
COCIR aisbl  |  Blueprint Building  |  Boulevard A. Reyerslaan 80  |  1030 Brussels  |  Belgium
Tel +32 (0)2 706 89 60  |  Email info@cocir.org  |  www.cocir.org  |  @COCIR