Sustainable Competence in Advancing Healthcare

MEDICA Tech Forum

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EU Medical Devices Regulation (MDR) – Transition Challenges

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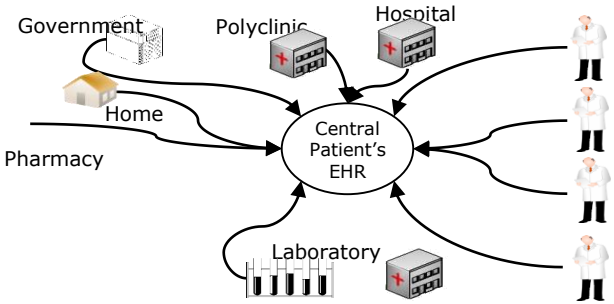
Industry sectors covered by COCIR

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



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Medical Device Regulation – what is new?

- Reinforcement of the criteria for designation and processes for oversight of **Notified Bodies**
- Inclusion of certain **aesthetic devices** which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations
- Improved transparency through the establishment of a comprehensive **EU database on medical devices** and of a device traceability system based on **Unique Device Identification**
- Reinforcement of the rules on **clinical evidence**
- Strengthening of **post-market surveillance** requirements for manufacturers
- Improved coordination mechanisms between EU countries for **market surveillance**
- Roles and responsibilities **for economic operators**

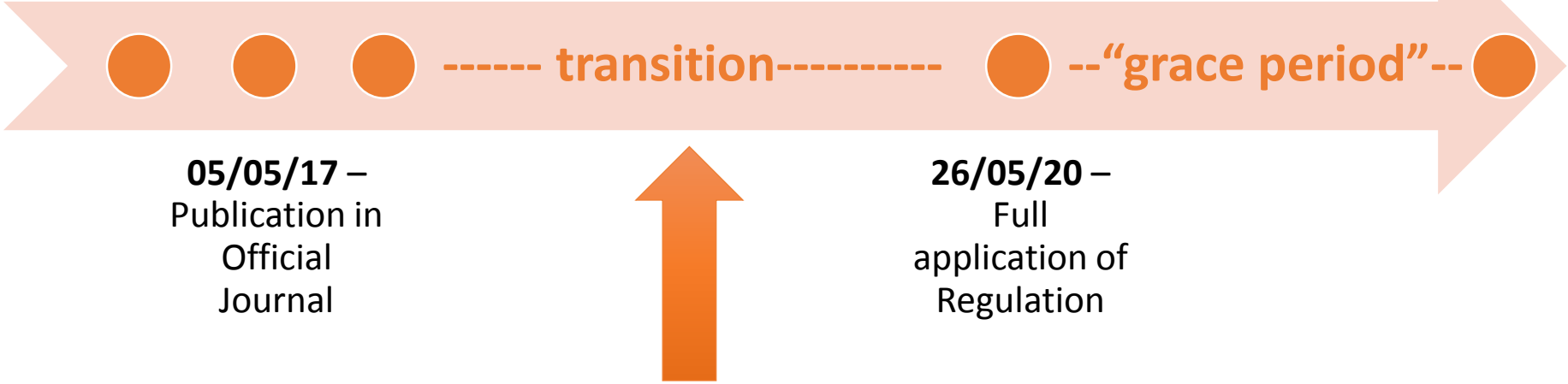
Source: https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

Where do we stand?

05/04/17 – Adoption of MDR

25/05/17– Entering into force in Member States

2024 – End of grace period (art. 120)



05/05/17 – Publication in Official Journal

26/05/20 – Full application of Regulation

Planning by regulators

Competent Authorities for Medical Devices (CAMD)

"Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap", 7 November 2017

	Activity	Recommended responsible parties	Priority level
8.1	**Transitional problems & uncertainties, and risks to continued supply of safe devices** In order to tackle the many uncertainties about the application of provisions in the transition periods, a comprehensive exercise must take place to ensure common interpretation among authorities. Issues addressed should include: Pre-Date of application (DoA) • How products can comply in the transition periods (according to art 120(5) MDR/110(5) IVDR • Legal status of CI/PS being conducted within the transition period. What happens if trial begins according to Directives before DoA but finishes after? • Legal enforcement powers during transition period • Obligations of economic operators • How this works in practice without Eudamed, and expectations on authorities • How do statutory reporting deadlines apply in absence of Eudamed (e.g. 15 day deadlines)?	• Transitional Measures Taskforce has been established • Recommended that legal input is included • Liaison with stakeholders to ensure all issues identified	High

European Commission "Implementing Measures Rolling Plan", 9 October 2018

Current implementation status

30	Working Groups, Sub-groups, Task Forces
7	Published guidance documents (on UDI and requirements for the nomenclature) - out of more than 20 expected
1	Adopted Implementing Acts (Notified Bodies codes) – out of 18 mandatory
0	Common specifications
0	Harmonised Standards - almost 300 needed
0	Designated Notified Bodies

Source: https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

Designation of Notified Bodies

- 55 Notified Bodies currently designated under the **Medical Device Directives**

- Latest official information in July on designation status under the **Medical Device Regulation**
  - **28** applications received by DG SANTE
  - **16** joint assessments scheduled

- Average increase of **staff capacity** of 27% by Team-NB members

What is the “grace period”?

Manufacturers can place legacy devices devices (compliant to AIMDD/MDD) on the market/put them into service **after 26 May 2020**

Conditions:

1. **A valid AIMDD/MDD certificate** according to Art. 120 (2) MDR

2. **Continuous compliance** of the device with the Directives

3. **No significant changes** in the design and intended purpose

See CAMD Transition Sub Group FAQ – MDR Transitional provisions

MDR obligations that apply to legacy devices

Registration of economic operators and of devices (Art. 31 MDR and Art. 29 MDR)

Post market surveillance (PMS)

(Art. 83-86, 92 MDR including Annex III)

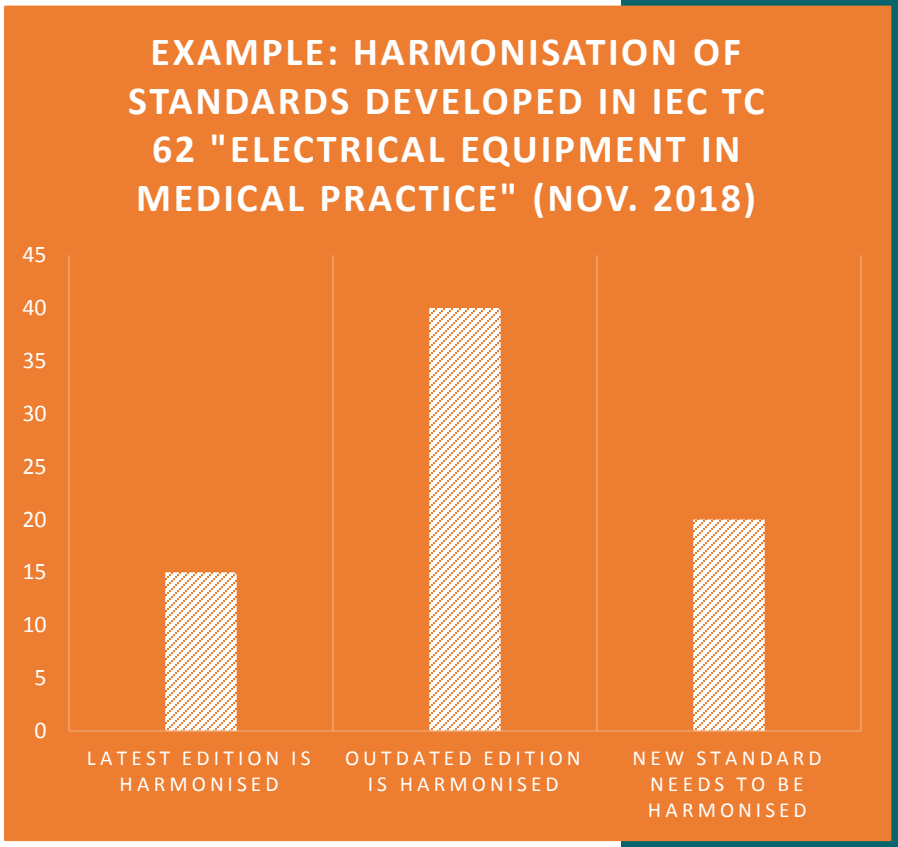
Vigilance (Art. 87-92 MDR)

Market surveillance by Competent Authorities (Art. 93 – 100 MDR)

Source: MDR Transitional provisions

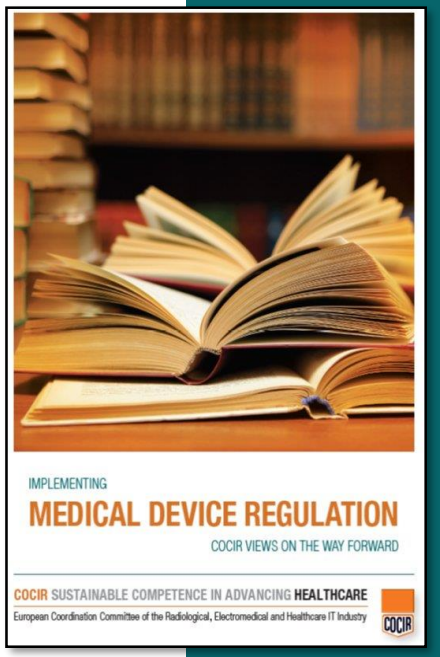
Harmonised Standards: what are the challenges?

- Still huge backlog of **Harmonised Standards under MDD**
- **Decrease of 83% (2010) to 12% (2017)** in Harmonised Standards
- **Standardisation request for the MDR** will only be adopted in 2019
- Will likely only contain a fixed list of a **limited number of standards**



Recap on transition challenges

- Availability and capacity of Notified Bodies
- Functionality of EUDAMED
- Clarity on qualification & classification of medical devices
- Implementing & Delegated Acts, Common Specifications
- Necessary guidance documents
- Harmonised Standards



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Thank you for your attention!

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