European Union update

Item 8b: Global Harmonisation Working Party – 16 February 2023

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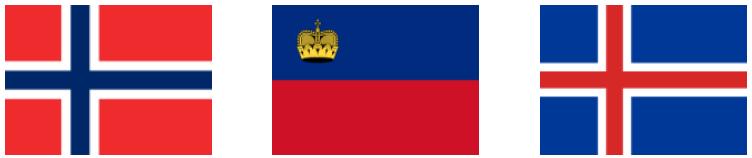
European Commission – Directorate General of Health and Food Safety
Unit D3 – Medical Devices

The EU single market for medical devices

EU (27 MS+EC)

EFTA/EEA

Norway, Liechtenstein, Iceland

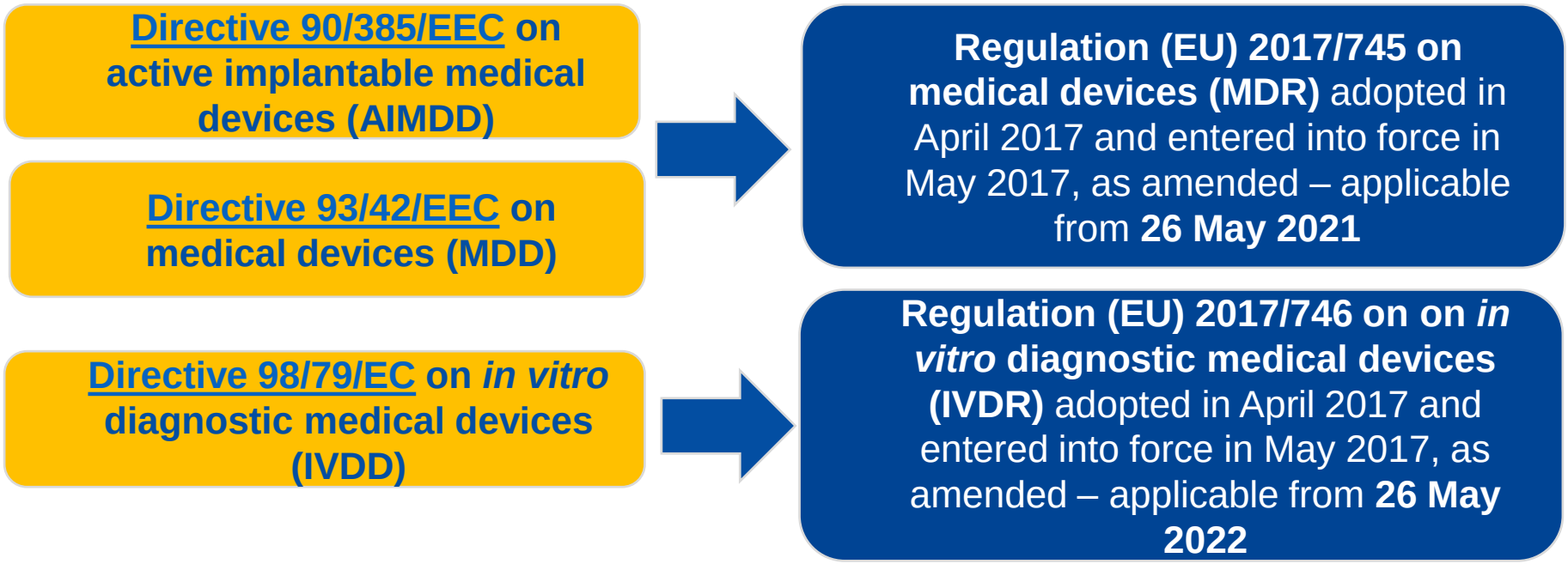


Turkey

Switzerland*

European Commission

EU legislation on medical devices



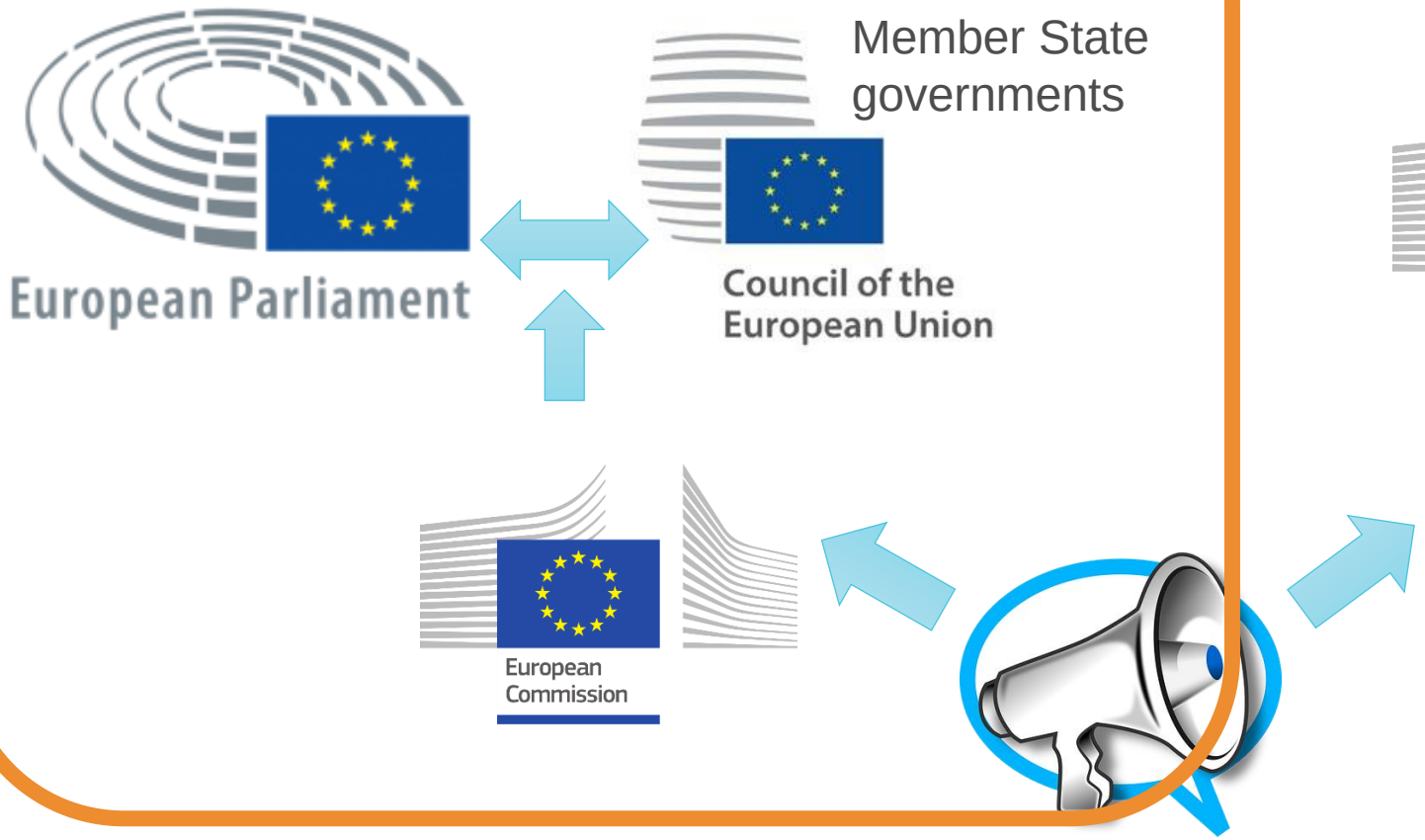
Update 6 January 2023 : → Commission proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the **transitional provisions** for certain medical devices and in vitro diagnostic medical devices.

European Commission

Commission proposal of 6.1.2023 for a targeted amendment of the transitional provisions of the EU Medical Devices Regulations

How are decisions made in the EU?

❑Legislative decisions:



❑Technical decisions:

European Commission

Expert group of national competent authorities (Medical Device Coordination Group)

European Commission

Guiding principles for the amendment proposal

Ensure patient access to wide range of safe and performant devices

Give **more time to those** who aim to **transition**, allow NBs to complete MDR conformity assessments

Aim at full application of MDR

Avoid unnecessary disposal of safe and performant devices in the supply chain

Accompanying non-legislative actions

European Commission

Amendment COM(2023)10 of 6.1.2023 (1)

Extension of transition period – staggered **and** conditional

- **Timing (Article 120(3b) and (3c) MDR):**
  - until 31 December 2027 for class III devices and class IIb implantable devices, except certain devices considered ‘well-established technologies’,
  - until 31 December 2028 for class IIa devices; class I sterile, measuring or reusable surgical instruments, ‘for class IIb implantable devices considered ‘well-established technologies’, class IIb non-implantable upclassified’ devices.
- **Conditions (Article 120(3d) MDR):**
  - continuous compliance with applicable directives;
  - no significant changes;
  - no unacceptable risk to health or safety;
  - manufacturer’s QMS in place in accordance with MDR by 26 May 2024;
  - **formal application for conformity assessment by 26 May 2024 & contract established by 26 September 2024.**

European Commission

Amendment COM(2023)10 of 6.1.2023 (2)

- Derogation for **class III implantable custom-made devices**
  - suspension of requirement for QMS certificate until 26 May 2026
  - if formal application for conformity assessment by 26 May 2024 and contract between manufacturer and notified body by 26 September 2024

- **Removal of 'sell-off' date** in MDR and **IVDR**, i.e. no withdrawal of devices
  - placed on the market before or during transition periods
  - still in the supply chain at the end of transition periods

How are decisions made in the EU?

- Legislative decisions:

Member State governments

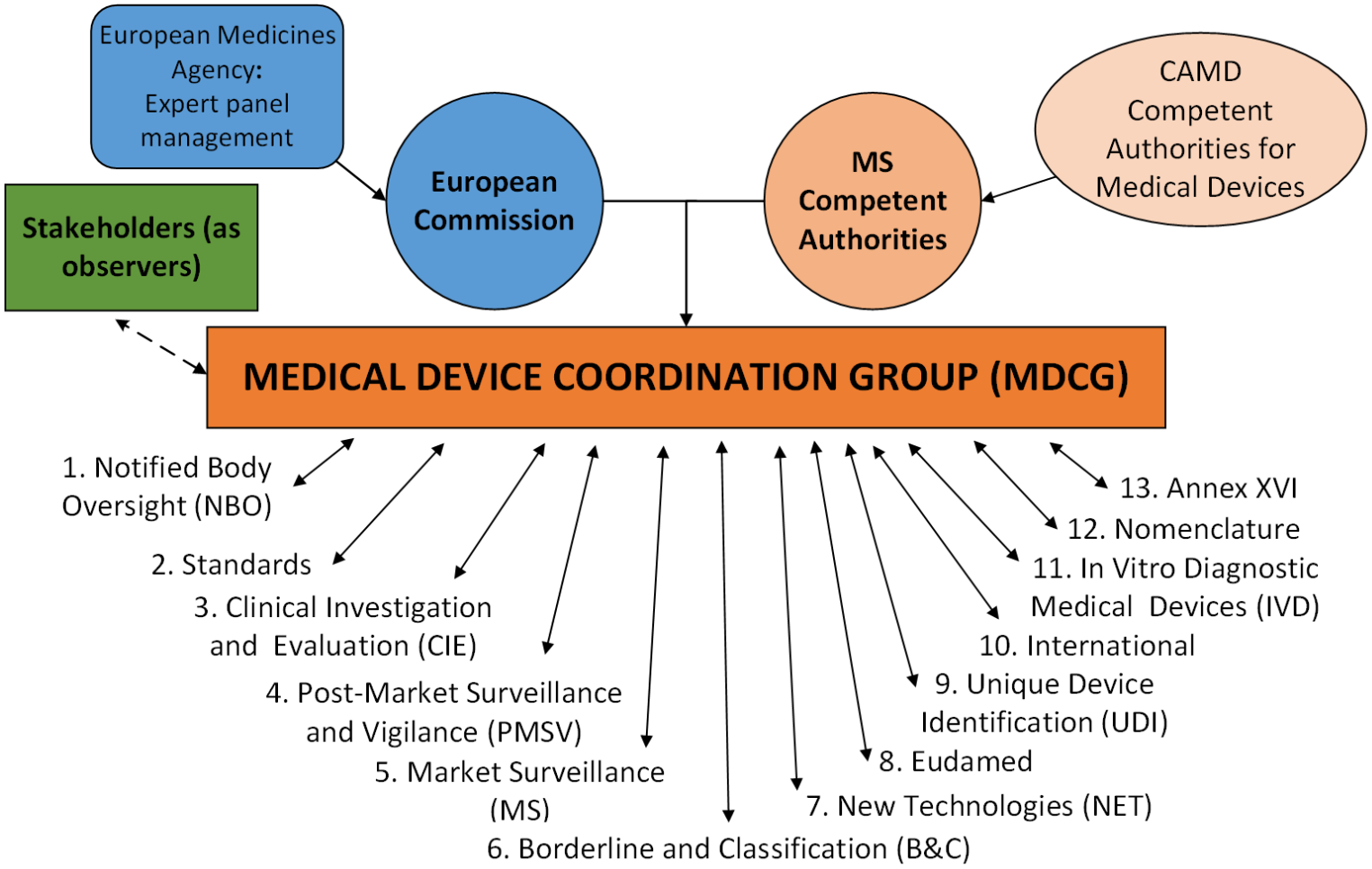
Council of the European Union

Stakeholder input

- Technical decisions:

Expert group of national competent authorities (Medical Device Coordination Group)

How we work on implementation of medical device legislation at EU level



European Commission

COM implementation priorities 2023 (1)

IMDRF

- EU Chair of IMDRF for 2023
- Aim to continue to deliver on IMDRF strategic plan and increase cooperation activities with all relevant actors
- Open invite to all to participate in IMDRF 23rd session in Brussels, Belgium on 27-28 March 2023
- Register now at: **WWW.IMDRF2023.COM**

Facilitating a smooth transition to MDR and IVDR

- MDCG 2022-14 position paper on notified body capacity and availability of medical devices and IVDs*
- Increasing number and capacity of notified bodies: 39 (37/**50** MDR+8/**18** IVDR) notified bodies designated under MDR and IVDR*

EUDAMED

- Core actor registration module (Q4 2020) and UDI module (Q3 2021) made available
- Functional testing with users (continuous)
- Preparations for full functionality audit (ongoing) *

COM implementation priorities 2023 (2)

Scientific Structures

- Expert panels designated (2019) and designated experts (Q1 2021)
- Expert panels running (Q2 2021) and number of opinions issued
- Transfer of expert panels to European Medicines Agency (Q1 2022)*
- Call for EU reference laboratories (IVDR) (Q3 2022)*

Tertiary legislation: Common Specifications/ Implementing Acts

- Reprocessing of single-use devices (Q3 2020)
- Devices without medical purpose (Annex XVI devices) (draft published Q2 2022)*
- Common specifications in accordance with Regulation (EU) 2017/746 (for Class D devices) (Q2 2022)*
- Commission Implementing Regulation (EU) 2022/944 on tasks and criteria for the EURLs (Q3 2022)*
- Commission Implementing Regulation (EU) 2022/945 on fees that the EURLs may levy from notified bodies and Member States (Q3 2022)*

COM implementation priorities 2023 (3)

UDI

- 4 issuing entities designated and +15 guidance and factsheets published
- UDI helpdesk up & running (Q1 2021)
- Work on solutions for contact lenses and non-sterile surgical implants (ongoing)*

Nomenclature

- Published for public consultation (Q2 2021)
- Final version launched available in EN, IT, FR. Validations of remaining EU languages (ongoing)*

Standards

- Lists of harmonised standards published (Q3 2021), (Q1 2022), (Q2 2022)
- New Standardisation request approved by relevant Committee on 31 January 2023*

Guidance development

- Continue to deliver on guidance across the 13 MDCG sub-groups to support all actors

Thank you

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