IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

09:40 – 09:55

European Union

Nada Alkhayat

Policy Officer

DG SANTE, European Commission

European Commission

European Union

IMDRF International Medical Device Regulators Forum

Update on EU regulatory developments

Nada Alkhayat

European Commission

IMDRF-23 – Stakeholder session

28 March 2022

The EU single market for medical devices

EU

EFTA/EEA

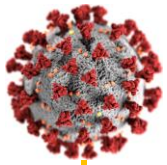
Norway, Liechtenstein, Iceland

Turkey

Timelines

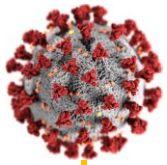
2017 — The two new regulations published in May

2020 — A one-year delay of the MDR was adopted in April



2021 — MDR date of application 26 May

2022 — Amended transitional provisions for IVDR were adopted in January



2022 — IVDR date of application 26 May

2023 — *6 January* Commission proposal to amend MDR transitional provisions

2023* — Entry into force Regulation (EU) 2023/607 *20 March*

2025 — *26 May* All IVDD certificates become void

2027 — End of IVDR transitional period *26 May*

2028 — *31 December* End of transitional periods for MDR

Guiding principles for the amendment proposal

Ensure patient access to wide range of safe and performant devices

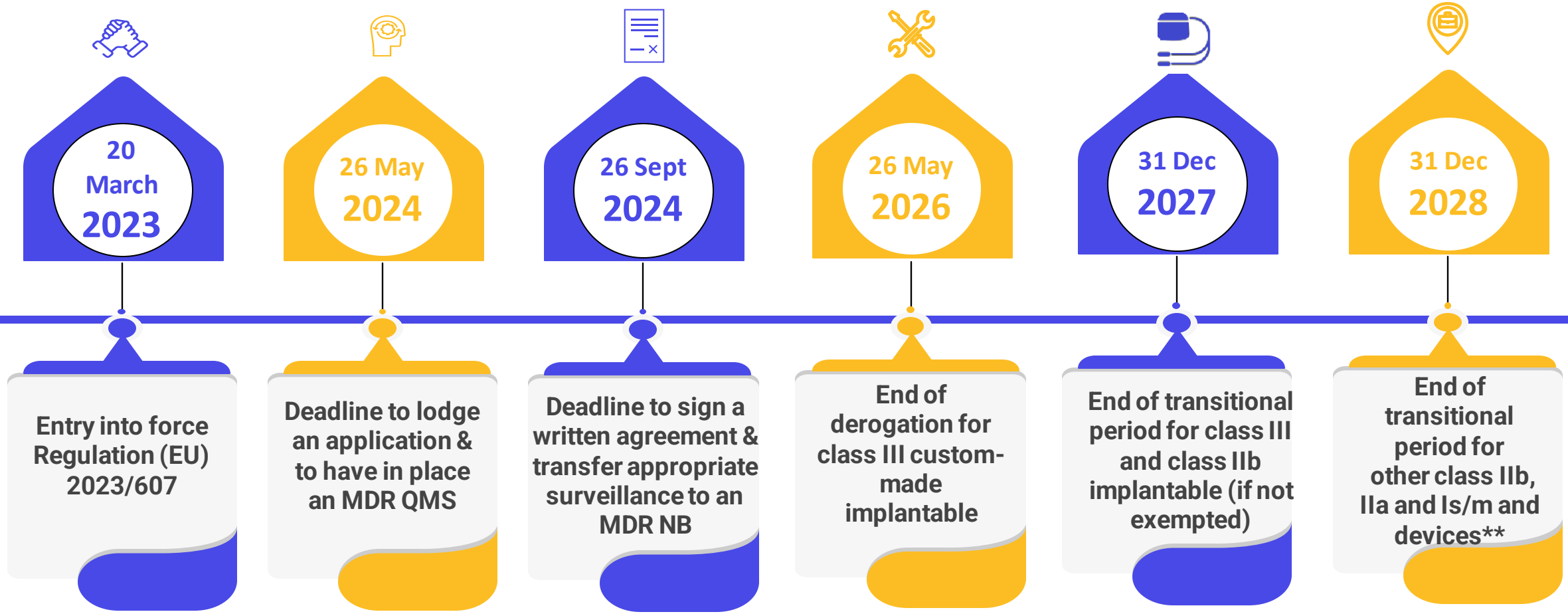
Give **more time to those** who aim to **transition**, allow NBs to complete MDR conformity assessments

Aim at full application of MDR

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

Accompanying non-legislative actions

MDR transitional period per Regulation (EU) 2023/607



* For devices that did not require involvement of a NB under MDD (e.g. Ir)

Non-legislative actions

Q&A on practical aspects of implementation of Reg. 2023/607

Actions to enhance notified body capacity and ensure availability of medical devices (MDCG PP 2022-14)

Uniform application of Article 97 MDR as temporary bridging measure regarding expired certificates (MDCG PP 2022-18)

Gaining momentum in designation process of notified bodies

Seeking tailored solutions for orphan devices

Expert panel scientific advice on clinical development strategies for certain high-risk devices

Targeted support for SMEs through Enterprise Europe Network

Non-legislative actions

Financial support actions under **EU4Health Programme**

- Monitoring implementation progress and availability of medical devices on the EU market
- Grant for capacity-building of notified bodies, better access of SMEs to notified bodies and increased preparedness of manufacturers
- Study on innovation and governance
- Orphan devices support programme, focussed on devices for children
- Joint Action on market surveillance
- Support for stronger coordination of the Notified Bodies Coordination Group

Financial support actions under **EU Horizon 2020 / Horizon Europe Programme**

- CORE-MD project - methodology for clinical data generation for high-risk devices (04/2021-03/2024)
- New call planned in October 2023

COM implementation priorities 2023 (1)

Chairing IMDRF

- Increase and promote relations with other regulatory authorities through new memberships
- Reinforce cooperation with regional harmonisation initiatives via collaboration agreements
- Develop and agree on strategic principles for IMDRF trainings between MC members
- Encourage engagement with healthcare professionals/clinicians

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: 48 (38/**50** MDR+10/**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

- 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)*3

UDI

- 4 issuing entities designated , 15 guidance and factsheets published + UDI helpdesk available
- UDI assignment for contact lenses delegated act in public consultation until mid April

COM implementation priorities 2023 (3)

Nomenclature

- Published for public consultation (Q2 2021)
- Final version launched available in EN, IT, FR. Validations of remaining EU languages (ongoing)
- Work program for 2023-2025 to be announced Q3 2023

Standards

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