Recent EU-level actions to address the risk of shortages of medical devices

MEP Heart Group meeting
Addressing the Shortage of Medical Devices for Cardiovascular Disease Patients in the EU
28 June 2023

Peter Bischoff-Everding
European Commission
Directorate-General Health and Food safety

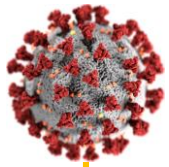
MDR and IVDR timelines

MDR/IVDR entry into force on 26 May

2017

2020

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

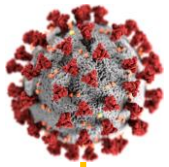


MDR date of application 26 May

2021

2022

Amended transitional provisions for IVDR were adopted in January



IVDR date of application 26 May

2022

2023

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

Application of MDR to certain products without medical purpose 22 March

2023

2025

26 May IVDD certificates become void

End of IVDR transitional period 26 May

2027

2028

31 December End of transitional periods for MDR

Background

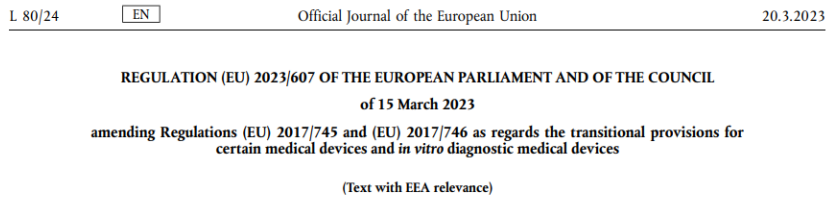
- The „new“ EU Medical Devices Regulation 2017/745 (applicable May 2021)
  - Goal: *robust, transparent and sustainable regulatory framework to maintain a high level of patient safety, while supporting innovation* (MDR recital 1)
- Risk of shortage of medical devices
  - 3,509 (AI)MDD certificates expired May 2021 to December 2022
  - 21,406 (AI)MDD certificates expiring January 2023 to May 2024
  - 8,120 MDR applications submitted (October 2022) → 11,369 MDR applications (March 2023)
  - 1,990 MDR certificates issued (October 2022) → 2,951 MDR certificates (March 2023)

➢ Calls for legislative initiative from Member States, MEPs & stakeholders

Guiding principles for the amendment to the MDR and IVDR

- Ensure **patient access** to wide range of safe and performant devices
- Give **more time to transition**, allow MFRs and 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

Legislative action


L 80/24 EN Official Journal of the European Union 20.3.2023

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 March 2023
amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices
(Text with EEA relevance)

- Commission proposal – 6 January 2023
- **Regulation (EU) 2023/607 of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**
  - Publication in EU Official Journal and entry into force - 20 March 2023
  - Main elements
    - staggered extension of MDR transitional period depending on risk class
    - conditions for extension
    - ‘appropriate surveillance’ by notified bodies during transitional period
    - extension of validity of certificates issued under (AI)MDD
    - derogation for class III custom-made implantable devices
    - removal of ‘sell-off' dates in MDR and IVDR

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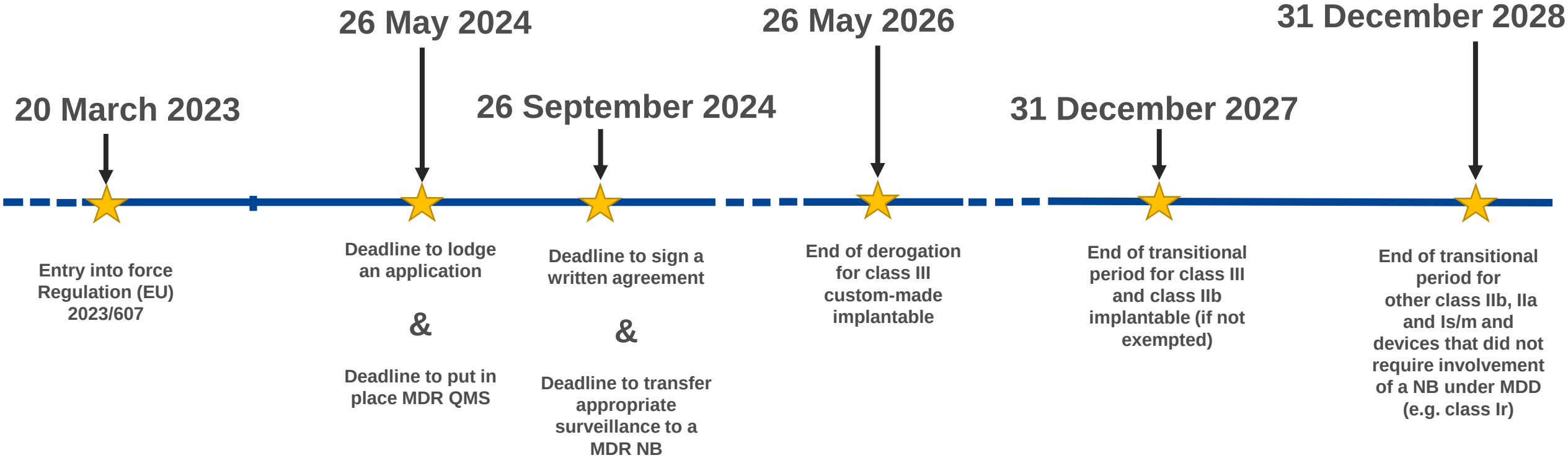
New MDR transitional period

(applicable only to 'legacy devices')*



*Devices covered by notified body certificate or manufacturer's declaration of conformity issued under MDD/AIMDD before 26 May 2021

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Main elements of MDR/IVDR amendment (1)

- Staggered extension of MDR transitional period depending on risk class
  - 31 Dec. 2027 for class III and class IIb implantable (except sutures, staples, … [WET])
  - 31 Dec. 2028 for other class IIb (including sutures, staples, … [WET]), class IIa, Im, Is and ‘upclassified’ devices that did not require NB under MDD
- Only for devices covered by notified body certificate or manufacturer‘s declaration of conformity issued under MDD/AIMDD before 26 May 2021 (‚legacy devices‘)

Main elements of MDR/IVDR amendment (2)

- Conditions for extension
  - continuous compliance with (AI)MDD
  - no significant changes in design and intended purpose
  - *new:* no unacceptable risk to health or safety
  - *new:* manufacturer's QMS pursuant to MDR in place by 26 May 2024
  - *new:* application for conformity assessment by 26 May 2024 and
  - *new:* contract between manufacturer and notified body by 26 September 2024

Main elements of MDR/IVDR amendment (3)

- ‘Appropriate surveillance’ by notified bodies during transitional period
  - *already in current Article 120(3) MDR (see MDCG 2022-4 rev.1)*
  - *new:* transfer of surveillance to MDR notified body by 26 September 2024 at the latest

- *reminder: application of certain MDR requirements during transition period*
  - *post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices (same as in old Article 120(3) MDR)*

Main elements of MDR/IVDR amendment (4)

- Extension of validity of certificates issued under (AI)MDD
  - until dates of extended transition period (i.e. only if conditions are met)
  - additional conditions for certificates expired between 26.5.2021 and 20.3.2023
    - contract for MDR certification signed between manufacturer and notified body before certificate's expiry or
    - NCA has granted an Article 59 MDR derogation or 97 MDR application

Main elements of MDR/IVDR amendment (5)

- Derogation for class III custom-made implantable devices
  - no QMS certificate required until 26 May 2026
  - *if* application for conformity assessment by 26 May 2024 and contract between manufacturer and notified body by 26 September 2024

Main elements of MDR/IVDR amendment (6)

- Removal of ‘sell-off' dates in MDR and IVDR
  - devices **placed on the market** before MDR/IVDR application or during MDR/IVDR transitional periods
  - still in the supply chain at the end of transitional periods
    - ➢ may continue to be made available on the market (no time limitation other than device‘s shelf-life or expiry date)

Non-legislative actions

- Q&A on practical aspects of implementation of Reg. 2023/607 (March 2023)
- Implementation of mitigating actions to enhance notified body capacity and ensure availability of medical devices (MDCG position paper 2022-14)
- Uniform application of Article 97 MDR as temporary bridging measure regarding expired certificates (MDCG position paper 2022-18)
- **Seeking tailored solutions for ‚orphan devices' (MDCG taskforce on orphan devices)**
- Gaining momentum in designation process of notified bodies
- Expert panel scientific advice on clinical development strategies for certain high-risk devices (focus of pilot phase: orphan devices, unmet medical needs, novel devices)
- Targeted support for SMEs through Enterprise Europe Network

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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

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Cooperation with stakeholders

- Bilateral
  - Strengthen exchanges with healthcare professionals and patients‘ associations
    - e.g. feedback on possible shortages of devices
- Medical Device Coordination Group (MDCG)
  - Trade and business associations
  - Professionals‘ associations (e.g. BioMed Alliance, CED, ECOO, EFORT, ESC, EAHP)
  - Patients‘ and other associations
- International Medical Device Regulators Forum (IMDRF)
  - EU chairmanship in 2023 IMDRF 2023

Thank you

European Commission