IMDRF International Medical Device Regulators Forum

Update on EU regulatory developments

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European Commission

IMDRF-24 Session – Stakeholder Forum

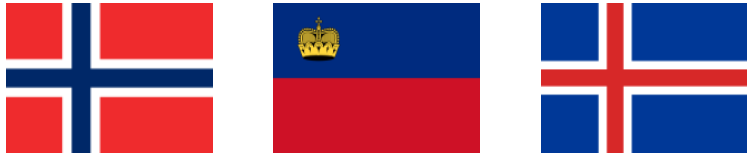
26 September 2023

The EU single market for medical devices

EU

EFTA/EEA

Norway, Liechtenstein, Iceland

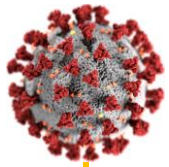


Turkey

Timelines

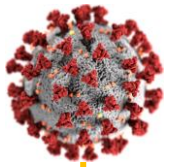
2017 — The two new regulations published in May

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

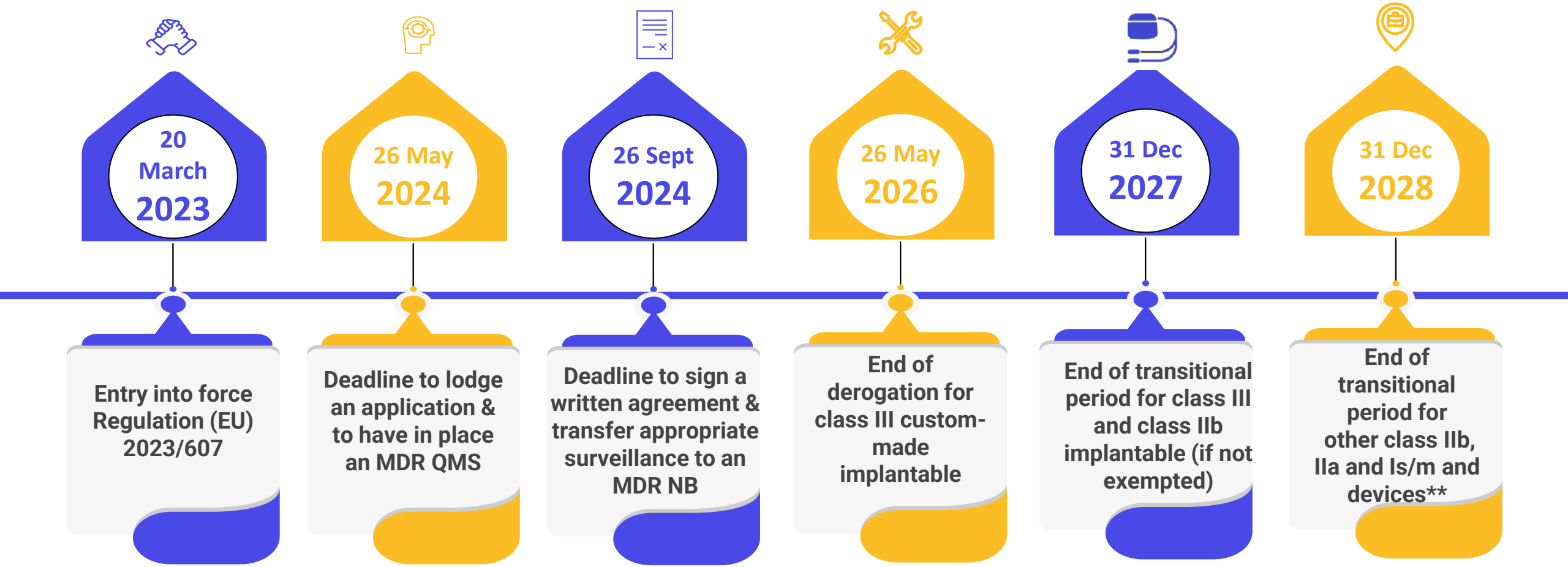
2023* — Entry into force Regulation (EU) 2023/607 *20 March*

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

MDR transitional period per Regulation (EU) 2023/607



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

Supportive 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, including on inspections, supported by EU Medical Device Inspectors Task Force (MDITF), coordinated by DK
- 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)

Supportive actions

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

Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices

Targeted support for SMEs through Enterprise Europe Network

'COMBINE' project on combined studies involving MP/IVD/MD

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

Priorities for 2023

Chairing IMDRF

- Increase and promote **relations** with **other regulatory authorities** through new type of membership
- Reinforce **cooperation with harmonisation initiatives** via collaboration agreements
- Encourage **engagement with healthcare professionals/clinicians**
- Develop and agree **on strategic principles** for **IMDRF trainings between MC members**
- Deliver on the **first IMDRF training** in the form of a pilot

Priorities for 2023

Facilitating a smooth transition to MDR and IVDR

- Increasing number and capacity of notified bodies: **50** (**39 MDR**+**11 IVDR**) notified bodies designated under MDR and IVDR*
- MDCG 2022-14 position paper on notified body capacity and availability of medical devices and IVDs*

Scientific Structures

- Expert panels designated (2019) and running since (Q2 2021) with opinions issued
- Designated experts re-appointed (Q3 2023) (Q2 2023)*
- Selection of EU reference laboratories completed (IVDR) (Q2 2023)*

Priorities for 2023-2024

EUDAMED

- Modules released: actor registration (Q4 2020), UDI, notified bodies & certificates (Q3 2021)
- Modules in functional testing with users: Vigilance & PMS, Clinical Investigations & Performance Studies, Market Surveillance (continuous)*

UDI

- 4 issuing entities designated, 15 guidance and factsheets published, UDI helpdesk and platform available
- Commission Delegated Regulation (EU) xx/xx UDI assignment for highly individualised devices (specifically contact lenses) adopted
- Preparatory work on other medical devices requiring specific considerations (2024)

Nomenclature

- Published for public consultation (Q2 2021)
- Final version launched available in EN, IT, FR, HU. Validations of remaining EU languages (ongoing)
- Work program for 2023-2025 to be announced Q3 2023
- lenses)
- Preparatory work on other medical devices requiring specific considerations (2024)

Priorities for 2023-2024

Tertiary legislation: Common Specifications/ Implementing Acts

Commission Implementing Regulations:

- 2022/2346 – Common specifications for Annex XVI products **(EOF Q2 2023)***
- 2022/2347 – Re-classification of groups of certain active products without an intended medical purpose **(EOF Q4 2022)**
- 2022/945 designating EURLs and designation of 5 EURLs expected **(Q4 2023)***
- for Class D devices **(Q4 2023)***

Standards

- Lists of harmonised standards published (Q3 2021), (Q1 2022), (Q2 2022)
- First amendment to the Standardisation request was adopted on 31 January 2023, second amendment under development to adapt deadlines for adoption of new standards*
- New publication under preparation (Q4 2023) *

Implementation of MDCG Position Paper MDCG 2022-14

1. Make use of hybrid audits

2. Leveraging evidence from previous assessments conducted under the Directives

8. Gaining momentum - speed-up the assessment, designation and notification process

12. Make standard fees publicly available and take into account interest of SMEs

13. Allocate notified bodies capacity for SME manufacturers

14. Call on manufacturers to ensure timely compliance to MDR/IVDR

15. Structured dialogue before and during the conformity assessment process

16. Increase preparedness of manufacturers

18. Orphan devices

IMDRF International Medical Device Regulators Forum

Updates from IMDRF WGs co-chaired by the EU

IMDRF International Medical Device Regulators Forum

Adverse Event Terminology and Coding Working Group

Nancy Pressly/ Evan Jacobs – Food and Drug Administration, United States of America

Andrea Hanson – Health Products Regulatory Authority, Ireland.

IMDRF 24th Session – Berlin, Germany

Adverse Event Terminology WG

About the WG:

- The Adverse Event Terminology and Coding working group was established in 2015.
- The group is composed of members from 11 regions.
- The group has two Co-Chairs (FDA & HPRA) and a AEWG Maintenance Chair (MHRA).
- The group convenes every 3 weeks via teleconference. A face-to-face meeting will be held in October 2023.

Publications:

- IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes IMDRF/AE WG/N43FINAL: 2020 (Edition 4), **including 7 annexes**
- Maintenance of IMDRF AE Terminologies IMDRF/AE WG/N44FINAL:2020 (Edition3)

Ongoing work

1. Leverage post-market monitoring and surveillance

a) The development of a Common Data Set for Adverse Event Data Exchange between IMDRF Regulators

b) The continued development and improvement of the Adverse Event Terminology and coding system to ensure that it is accurate, agile and moving with innovation, through the management of queries and the **annual maintenance cycle**.

2. Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance

a) The development of a training presentation / video to reinforce the key principles of the system (N43 document).

b) The development of a guidance document to support the exchange of the Common Data Set.

c) The development of a **new** guidance document and a video to further support the practical use of the Adverse Event Terminology and coding system.

Opportunities and Challenges

- Regulatory convergence with increased use of the Adverse Event Terminology and coding system.
- Increased harmonisation with use of common terminology.
- Opportunity for increased oversight and signal detection.
- Easier exchange of information.

- More guidance is needed to support the practical use of the codes.
- Confidentiality arrangement and EU General Data Protection Regulation (GDPR) need to be factored into the use and the exchange of the Common Data Set.
- Further development of analytical algorithms is required.

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Quality Management System (QMS) Working Group Update

Co-Chairs:

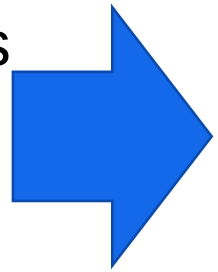
Máiréad Finucane / Maria Del Carmen Sanz – EC

Melissa Torres – US FDA

IMDRF 24th Session – Berlin, Germany

About US

- Quality management systems and risk management activities are integral principles to ensuring the design and manufacture of safe and effective medical devices
- QMS and risk management principles have evolved since the creation of the original GHTF documents (2004-2010) which were based on previous versions of ISO 13485 and ISO 14971
- Requirements within the various jurisdictions have also evolved



- The aim of the working group is to have up to date guidance on QMS and risk management requirements (outlined in ISO 13485 and ISO 14971) in order to assure an appropriate balance between pre-market and post-market requirements as part of a total product lifecycle regulatory approach to medical devices.

Working Group Establishment

Approval of work	Collaboration agreements	Working Group nominations	Documents for revision
New Work Item Proposal approved by the IMDRF Management Committee in September	Received agreement amongst leadership of IMDRF, GHWP, and ISO to do this work jointly amongst the 3 organisations	Representatives from: - IMDRF regulatory authorities - GHWP regulatory authorities - ISO TC 210 WG1 - Industry, and Notified bodies	- GHTF/SG3/N17:2008 Guidance on the Control of Products and Services Obtained from Suppliers - GHTF/SG3/N18:2010 Guidance on Corrective and Preventive Action - GHTF/SG3 N15R8: 2005 Risk Management Principles - GHTF/SG3/N99-10:2004 Process Validation Guidance

Opportunities and Challenges

- Transfer of old GHTF documents into IMDRF templates
- Prioritisation of work items
- Proposal to begin with the update supplier controls (GHTF/SG3/N17:2008 Guidance on the Control of Products and Services Obtained from Suppliers)
- First meeting of the working group to be scheduled after Management Committee meeting

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Thank you/Questions

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