EU MDR/IVDR: State of Play & upcoming activities

IMDRF Stakeholder Forum 11 March 2025, Tokyo Japan

Nada ALKHAYAT

Directorate-General for Health and Food Safety – Medical Devices Unit

European Commission

Olivér Várhelyi (HU)
New Commissioner for Health and Animal Welfare

Mission letter – Responsibilities:

Ensuring the availability and competitiveness of medical devices, including by stepping up the implementation of the current framework and evaluating the need for potential legislative changes

Tasked to complete the European Health Union and build on the One Health approach.

Priorities

Continue	Effective implementation of the MDR and IVDR
Accelerate	Short-term actions: both legislative and non-legislative
Finalise	Targeted evaluation (planned for Q4 2025)

Implementation of MDR/IVDR

Objectives

"robust, transparent, predictable and sustainable regulatory framework […] which ensures a high level of safety and health whilst supporting innovation"

Achievements

50 MDR notified bodies (12 applications ongoing)

~8,000 MDR certificates issued

14* IVDR notified bodies (8 applications ongoing)

~900 IVDR certificates issued

Expert panels (hosted by EMA)

EU Reference Laboratories

EUDAMED modules (Actors, UDI/DEV, NB/Certificates) in use

Challenges

Limited capacity of notified bodies

Length and costs of conformity assessment

Stricter requirements (especially pre-market clinical data)

Risk of shortages

Delay of EUDAMED

Remedies

More time to transition from MDD/AIMDD/IVDD to MDR and IVDR (i.e. extension of MDR and IVDR transitional periods)

No lowering of quality and safety requirements

MDCG guidance supporting the transition

Growing number of "harmonised standards" and extended standardisation mandate

EU4Health Program projects

MDR/IVDR amendment

Regulation (EU) 2024/… of 13 June 2024 amending MDR and IVDR as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices (9 July 2024 expected publication in the OJEU)

1

Ensure availability especially of high-risk in vitro diagnostics (IVDs) by extending transition periods

2

Provide healthcare systems **more time to safeguard patient care** by introducing advance warning of interruption or discontinuation of supply of certain medical devices

3

Enhance transparency by enabling a gradual roll-out of the European Database on Medical Devices (EUDAMED)

Regulation (EU) 2024/1860

Q&As on practical aspects related to the implementation:

- ✓ EUDAMED gradual roll-out: published in November 2024
- ✓ Extension of the IVDR transitional periods: published in July 2024
- ✓ Obligation to inform in case of interruption or discontinuation of supply (Art. 10a): published in October 2024

Art. 10a applies as of 10 January 2025!

Art. 10a Manufacturer Information Form

Coordinated assessment for Clinical Investigations and Performance Studies

Article 78 of MDR and Article 74 of IVDR coordinated assessment procedure for clinical investigations (CI) and performance studies. For this purpose, a sponsor may submit a single application.

Until EUDAMED is available the Commission will provide a secretariat and IT tools necessary for the coordinated assessment on a voluntary basis.

Benefits for the sponsor – simplification and burden reduction:

- ✓ Unified engagement
- ✓ Simplified requests for information
- ✓ More transparency and harmonization
- ✓ Faster overall process

The launch: First week of February 2025.

Who to contact: If interested the CA-CIPS Secretariat can be reached at: **SANTE-CA-CIPS@ec.europa.eu**

Other recent publications / activities 1/2

MDCG 2024-13	Regulatory status of ethylene oxide (EtO) intended for the sterilisation of medical devices	October 2024
MDCG 2022-5 rev.1	Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices	October 2024
MDCG 2024-11	Guidance on qualification of in vitro diagnostic medical devices	October 2024
Gradual roll out of EUDAMED	Q&A on practical aspects related to the implementation of the gradual roll-out of EUDAMED	November 2024
MDCG 2024-15	Guidance on the publication of the clinical investigation reports and their summaries in the absence of EUDAMED	November 2024
Q&A rev.1	Q&A Obligation to inform in case of interruption or discontinuation of supply	December 2024

Other recent publications / activities 2/2

MDCG 2024-16	Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices	December 2024
MDCG 2024-16 Annex	Device Identification table	December 2024
MDCG 2022-3 rev.1	Verification of manufactured class D IVDs by notified bodies	December 2024
MDCG 2019-13 rev.1	Guidance on sampling of devices for the assessment of the technical documentation	December 2024
MDCG 2024-2 rev.1	Procedures for the updates of the EMDN	January 2025
MDCG 2021-12 rev.1	FAQon the European Medical Device Nomenclature (EMDN)	January 2025
MDCG 2025-1	EMDN Ad hoc procedure	January 2025
MDCG 2025-2	Summary of EMDN 2024 Submissions and outcome of annual revision	January 2025
MDCG 2025-3	EMDN Version History	January 2025
MDCG 2019-6 rev.5	Questions and answers: Requirements relating to notified bodies	February 2025

Short-term actions: both legal and non-legal

Legal actions

1 Implementing regulation for e-IFUs for medical devices

- Planned adoption date: **Q2 2025**

2 Establishment of an Expert Panel on orphan and paediatric devices

- Planned adoption date: **Q2 2025**

3 Reclassification of well-established technologies (WET)

- Request for evidence: processing input
- Planned adoption date: **Q4 2025**

4 Expansion of the list of well-established technologies (WET)

- Request for evidence: processing input
- To be discussed on 24-28 February
- Planned adoption date: **Q3 2025**

5 Implementing rules regarding requirements to be met by Notified Bodies

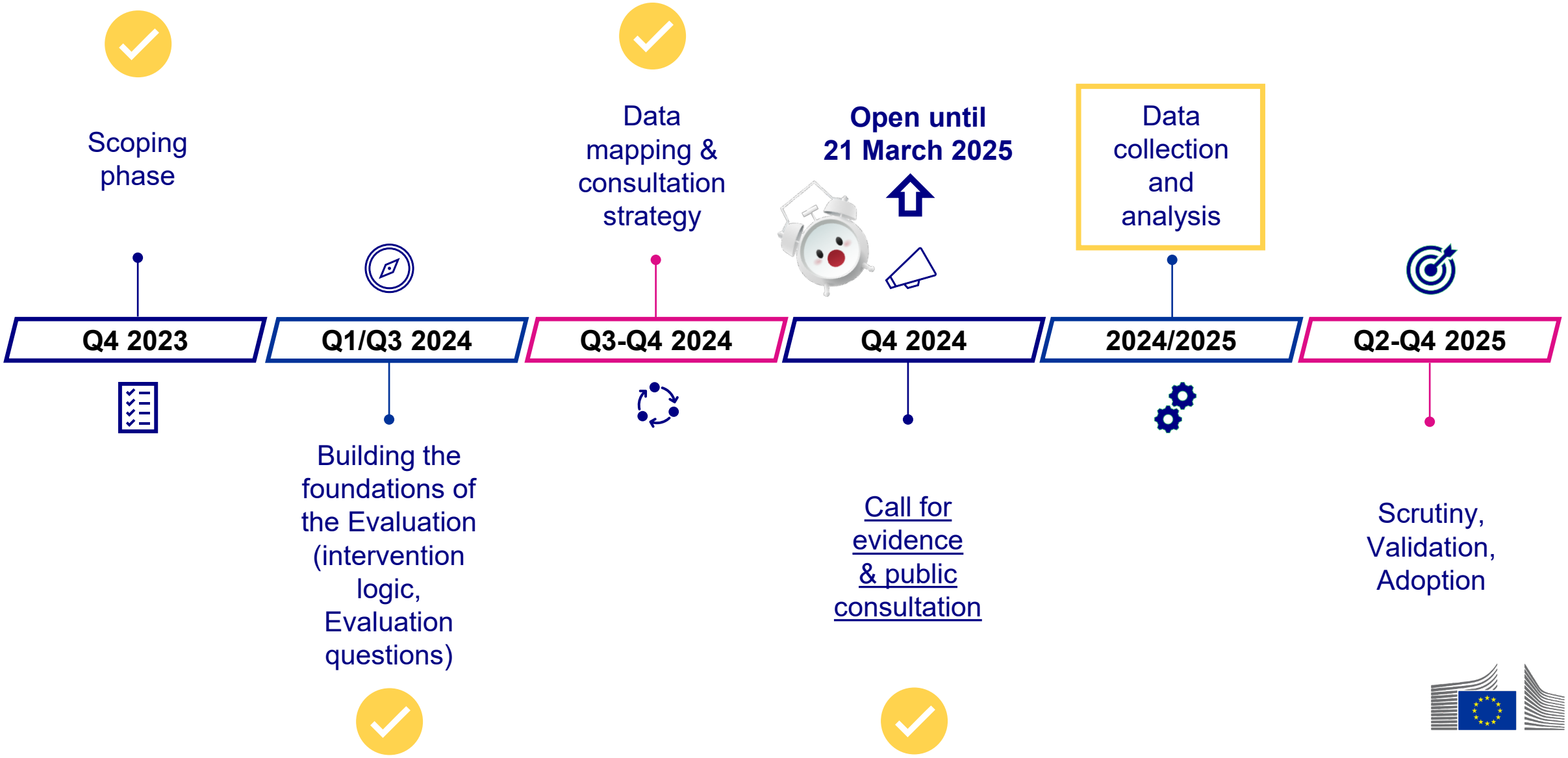
- Identification of high priorities and discussion on input received
- Workshop with stakeholders: 20 February
- Planned adoption date: **Q4 2025**

Non- legal actions

1. Guidance on breakthrough technologies (BtX)
2. Guidance on orphan IVDs
3. Guidance on sampling of technical documentation
4. Guidance on certificates under conditions
5. Guidance on structured dialogue
6. IMDRF Guidance of high priority: Pre-Determined Change Control Plans, Good Machine Learning Practices, Quality Management Systems, IVD Clinical Evidence and the Reliance Playbook
7. MDSAP mapping activities (NBCG-Med and MDCG)
8. […]

Targeted evaluation

Our overall timeline



Consultation activities – Have your say

CALL FOR EVIDENCE

Document describing:

- context of the evaluation
- purpose and scope (criteria, time period, countries)
- how it will be carried out (consultation strategy; data collection and methodology)

‘feedback’: one open text field

PUBLIC CONSULTATION

Web-based questionnaire:

- to collect general information, views and opinions;

includes:

- questions tailored to specific stakeholders;
- written answers on closed and open questions;

Possible to submit additional information.

Opportunity for targeted discussions with international regulators

"*robust, transparent, predictable and sustainable regulatory framework […] which ensures a high level of safety and health whilst supporting innovation*"

SAVE THE DATE 6 MAY 2025 12:00-14:30 CEST

What? Session with any and all interested international **regulators**

Why? To gather feedback on their views and experiences with the EU MD/IVD regulatory framework

Purpose? Feedback will be channeled into the currently ongoing public consultation

+ Targeted discussions with a number of targeted regulators, notably those that are directly impacted by any changes made to the EU system (e.g. Australia, Switzerland, UK).

If interested: please contact us at sante-md-international@ec.europa.eu

MDR – transitional period

20 March 2023

Entry into force Regulation (EU) 2023/607

26 May 2024

Deadline to lodge an application & to have in place an MDR QMS

26 Sept 2024

Deadline to sign a written agreement & transfer appropriate surveillance to an MDR NB

26 May 2026

End of derogation for class III custom-made implantable

31 Dec 2027

End of transitional period for class III and class IIb implantable (if not exempted)

31 Dec 2028

End of transitional period for other class IIb, IIa, Is/m and MD with no NB involvement under MDD

IVDR – Transitional periods