European Commission

The European Database on Medical Devices (EUDAMED)

EUDAMED Workshop – Stuttgart, 21 May 2025

Directorate-General for Health and Food Safety (DG SANTE)
Unit D.3 – Medical Devices

EUDAMED
European Database
on Medical Devices

Table of content

Regulatory framework

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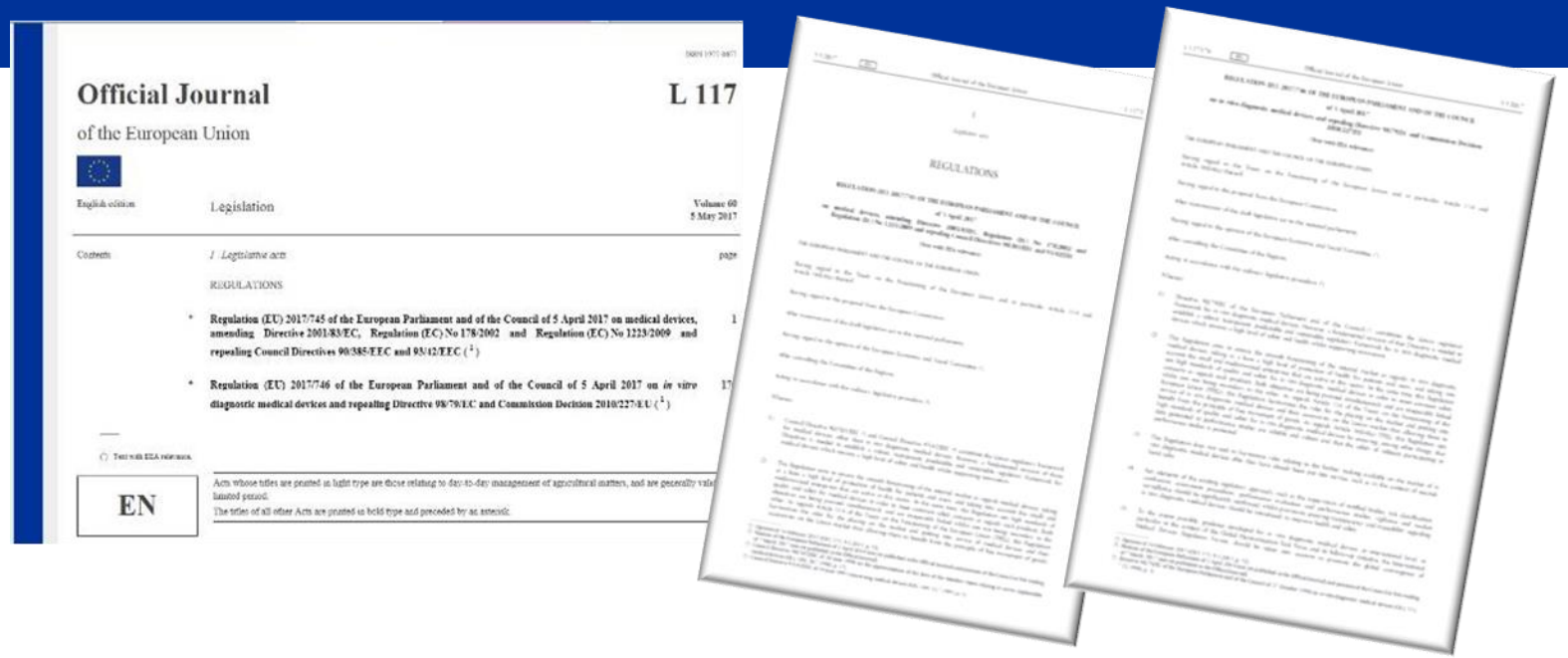
European Database on Medical Devices

Regulation (EU) 2017/745 on medical devices **(MDR)**

applicable since **26 May 2021**,
plus extra transitional period for ‚legacy devices'

Regulation (EU) 2017/746 on in vitro diagnostic medical devices **(IVDR)**

applicable since **26 May 2022**,
plus extra transitional period for ‚legacy devices'


Official Journal
of the European Union
L 117
Legislation
REGULATIONS
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
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EUDAMED Implementing Act

Commission Implementing Regulation (EU) 2021/2078

Regulatory framework

EUDAMED
European Database on Medical Devices

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Official Journal of the European Union

EN
L series

2024/1860

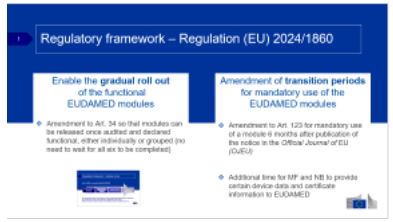
9.7.2024

REGULATION (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 June 2024

amending Regulations (EU) 2017/745 and (EU) 2017/746 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

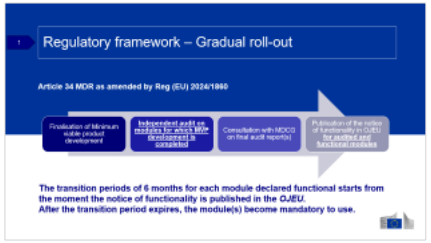
(Text with EEA relevance)



Regulatory framework – Regulation (EU) 2024/1860

Enable the **gradual roll out** of the functional EUDAMED modules

- Amendment to Art. 34 so that modules can be released once audited and declared functional, either individually or grouped (no need to wait for all six to be completed)



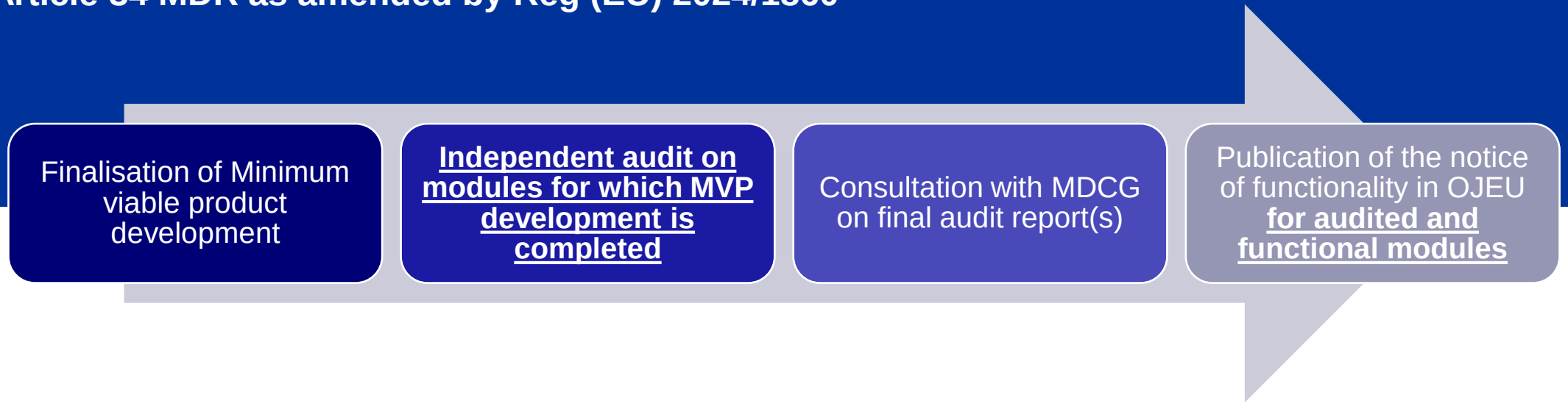
Amendment of **transition periods** for mandatory use of the EUDAMED modules

- Amendment to Art. 123 for mandatory use of a module 6 months after publication of the notice in the *Official Journal of* EU *(OJEU)*

- Additional time for MF and NB to provide certain device data and certificate information to EUDAMED

Regulatory framework – Gradual roll-out

Article 34 MDR as amended by Reg (EU) 2024/1860



The transition periods of 6 months for each module declared functional starts from the moment the notice of functionality is published in the *OJEU*.
After the transition period expires, the module(s) become mandatory to use.

2 Legal basis and obligations

MDR Article 33 - *The Commission, after consulting the Medical Device Coordination Group, shall set up, maintain and manage the European database on medical devices ('**Eudamed**')* […]

- Keep the public adequately informed
- Facilitate traceability of devices
- Economic operators and Notified Bodies compliance with MDRs
- Competent authorities and Commission to perform their tasks under MDRs

Legal basis and obligations

EUDAMED
European Database on Medical Devices

Manufacturers, Authorised representatives, Importers

To register as actors in EUDAMED (SRN)

Article 31 MDR and 28 IVDR

Manufacturers, System/Procedure Pack Producers (SPPP)

To provide UDI and other device/SPPs data elements as per Annex VI

Articles 28-9 MDR and 25-26 IVDR

Notified bodies

To provide certificates information (issued, refused) and applications information (refusal, withdrawal)

Article 57 MDR and 52 IVDR

Legal basis and obligations

EUDAMED
European Database on Medical Devices

Sponsors and Competent Authorities	Manufacturers, Authorised representatives, Competent authorities	Competent authorities
Life-cycle of clinical investigations/ performance studies managed in EUDAMED	Submission of Vigilance reports (MIR, FSCA..) and post-market reports (PSUR)	To provide information on market surveillance measures taken (FIR, other summary reports)
Article 73 MDR and 69 IVDR	**Article 92 MDR and 87 IVDR**	**Article 100 MDR and 95 IVDR**

The EUDAMED system

Restricted website

For **registered actors** to provide/access data in the different EUDAMED modules and be **compliant with the MDRs**

EUDAMED

Public website

For the public to be **adequately informed** about devices placed on the EU market, as well as certificates data, vigilance issues and clinical investigations ongoing

EUDAMED Public

Environments

EUDAMED Playground

Dummy data, test the functionalities before they go in Production

EUDAMED training

…to come

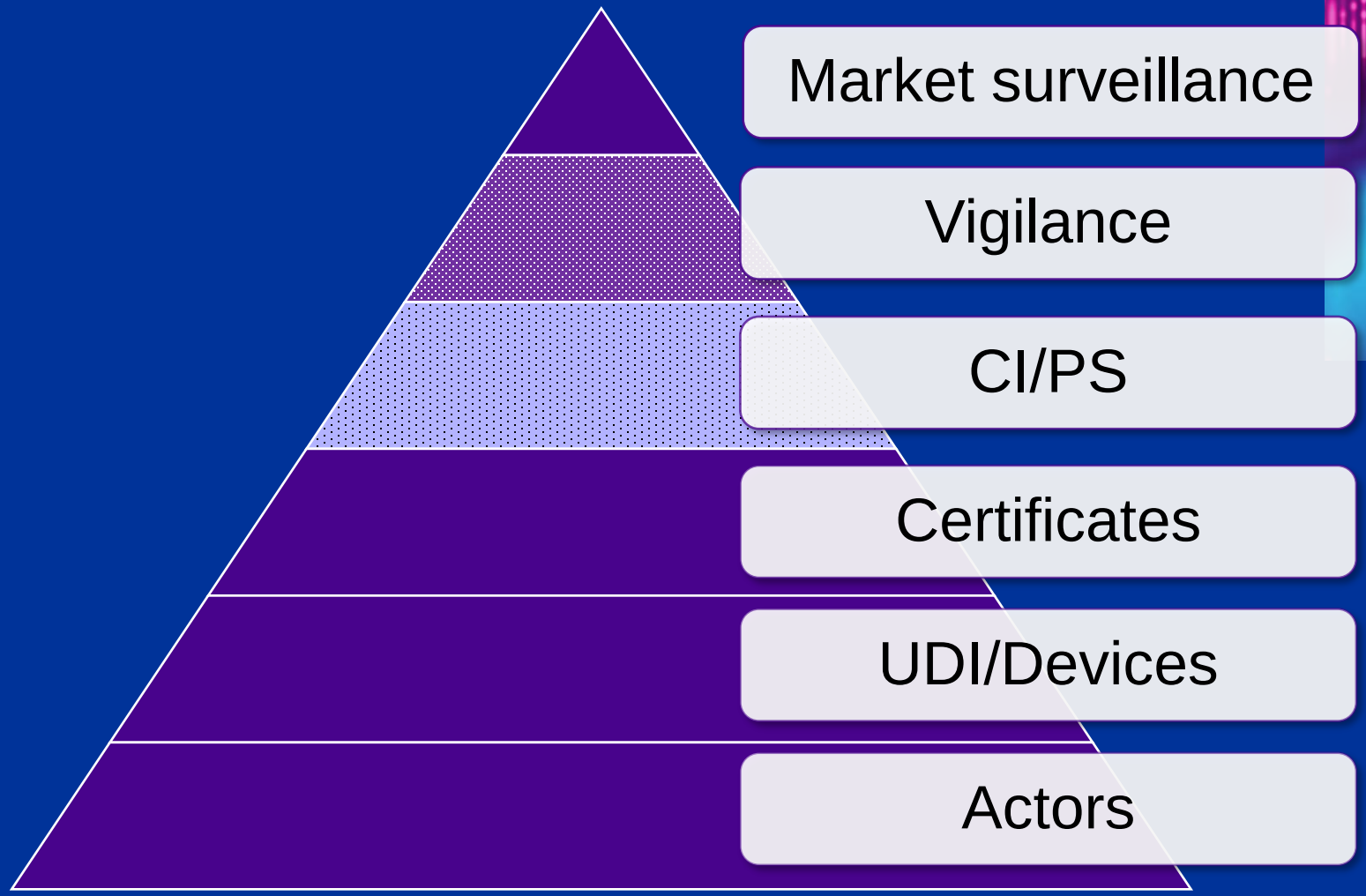
EUDAMED Production

Real data only, no test to be conducted here, compliance with MDRs

Data Input

- User interface (webform)
- Bulk upload (XML upload via user interface)
- Machine to machine data exchange

The EUDAMED system – Structure



- Market surveillance
- Vigilance
- CI/PS
- Certificates
- UDI/Devices
- Actors

Gradual roll out and timeline - Draft planning of the next steps

2025			2026				2027
Q2 2025	Q3 2025	Q4 2025	Q1 2026	Q2 2026	Q3 2026	Q4 2026	Q1 2027

Finalization of MVP Audit on 4 Modules

NonMVP Mandatory Use Development for 4 Modules

Mandatory use of Actor, UDI/Devices, NBs & Certificates, MSU

MVP Audit Vigilance

NonMVP Mandatory Use Development Vigilance

Mandatory use of Vigilance module

Publication of the notice of functionality in OJEU (Actor, UDI/Device, NB&CRF, MSU)

Gradual roll out and timelines – Terminology

Old device

Devices placed on the market under the Directives or before, for which the last sales unit has been placed on the market before the MDR/IVDR dates of application.

Legacy device

Devices placed on the market in conformity with the Directives, and for which individual sales unit are placed on the market after MDR/IVDR dates of application.

Regulation device

Devices placed on the market as being in conformity with the MDR/IVDR.

For more info: *MDCG 2021-25 Rev.1 and MDCG 2022-8 and Regulations (EU) 2023/607 and (EU) 2024/1860*

Gradual roll out and timelines – Terminology

Note! In MDR and IVDR the term ‘device’ almost exclusively refers to each individual device, which means each (sales) unit or single product item that is produced and placed on the market at a certain point in time. However, **in Eudamed, device/SPP registration in the UDI/DEV module means registering a device/SPP at the level of the device identifier** (excluding production identifiers).

For more info: *MDCG 2021-25 Rev.1 and MDCG 2022-8 and Regulations (EU) 2023/607 and (EU) 2024/1860*

Gradual roll out and timelines – Registration obligations timelines

Actor registration:

Now: voluntary use

6 Months after publication of the notice in the OJEU: mandatory use of the module

Register now!

Devices registration:

Now: voluntary use

6 Months after publication of the notice in the OJEU: mandatory use of the module

Certificates registration:

Now: voluntary use

6 Months after publication of the notice in the OJEU: mandatory use of the module

Market surveillance:

No voluntary use

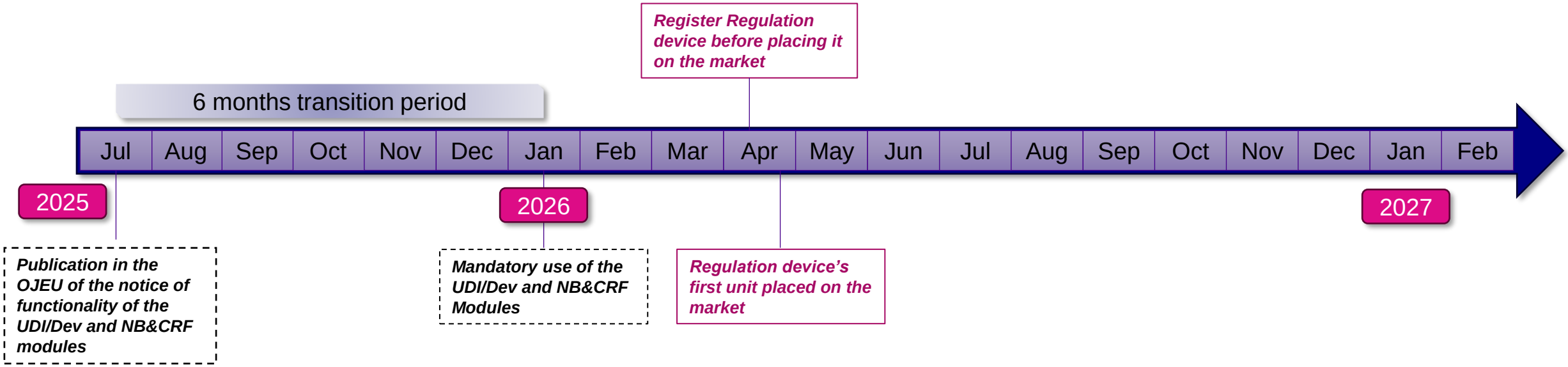
6 Months after publication of the notice in the OJEU: mandatory use of the module

Gradual roll out and timelines – Devices & certificates registration

- In case the **first individual (sales) unit** of a Regulation device (except for custom-made devices, investigational devices and devices for performance studies which should not be registered in the UDI/DEV module) or an SPP with a certain UDI-DI is **placed on the EU market on or after the date of mandatory use of the UDI/DEV module**, the corresponding device **registration** in the UDI/DEV module must be done **before the first individual unit is placed on the EU market.**

Gradual roll out and timelines – Devices & certificates registration

Draft timeline assuming publication of the notice in July 2025



Gradual roll out and timelines – Devices & certificates registration

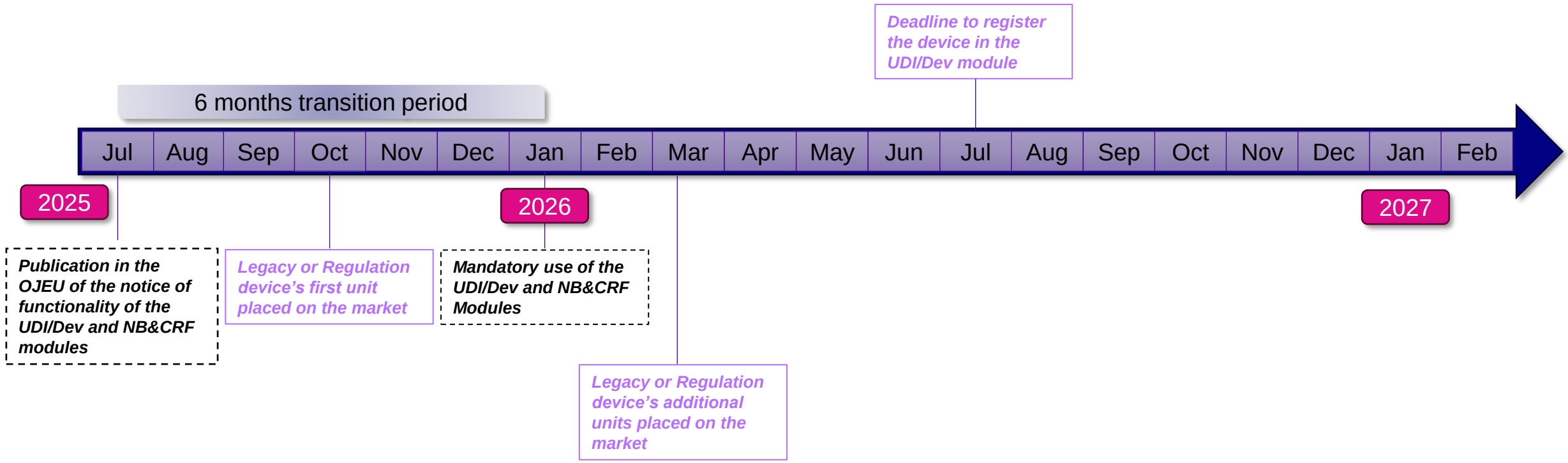
- In case the **first (sales) unit of a legacy device or Regulation device** (except for custom-made devices, investigational devices and devices for performance studies which should not be registered in the UDI/DEV module) or an SPP with a certain UDI-DI has been **placed on the EU market before the date of mandatory use of the UDI/DEV module**, and where **additional (sales) units belonging to the same UDI-DI will be placed on the market on or after that date**, the corresponding device **registration** in the UDI/DEV module must be done **within 12 months from the publication in the OJEU of the notice** confirming the functionality of the UDI/DEV module

- **Legacy devices do not need to be registered if 'the same device' is already registered as a Regulation device.** In this context, 'the same device' means that Regulation device and legacy device have the same identification such as UDI-DI, and/or catalogue/reference number and/or trade name which follows from shared characteristics.

- Legacy and Regulation devices for which individual (sales) unit are **no longer placed on the market** when the UDI/DEV module becomes mandatory, do not need to be registered, **unless a vigilance action occurs**.

Gradual roll out and timelines – Devices & certificates registration

Draft timeline assuming publication of the notice in July 2025



Gradual roll out and timelines – Devices & certificates registration

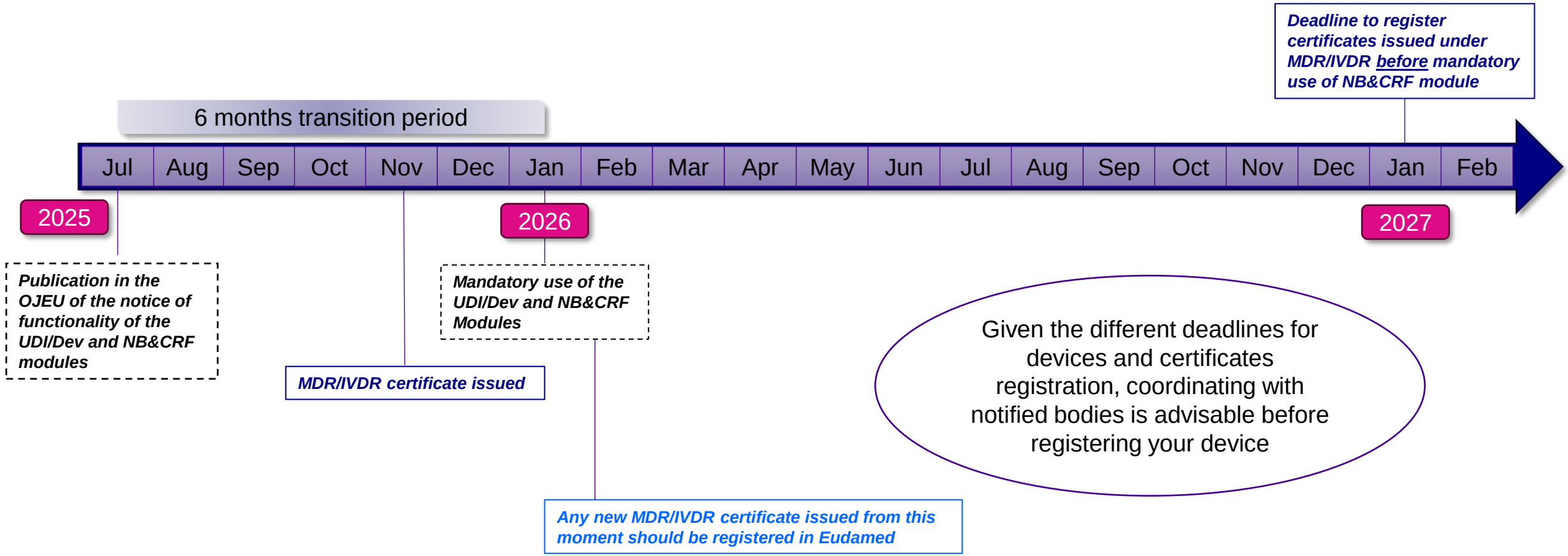
- Certificates issued under MDR/IVDR **after** mandatory use of the NB&CRF module shall be registered in EUDAMED

- **Updates and decisions** issued **after** the mandatory use of the NB/CRF module **in relation to Regulation certificates issued before the mandatory use of the NB/CRF module**, must be registered in the NB/CRF module

- For **valid** certificates issued in accordance with the MDR/IVDR **before** the mandatory use of the NB/CRF module the NBs have to register the related information in Eudamed **within 18 months from the date of publication in the OJEU of the notice of functionality of the module**. This only applies to Regulation devices that need to be or are registered in the UDI/DEV module. Moreover, only the latest certificate version and, if applicable, the latest NB decision taken in relation to that certificate version should be registered in Eudamed.

Gradual roll out and timelines – Devices & certificates registration

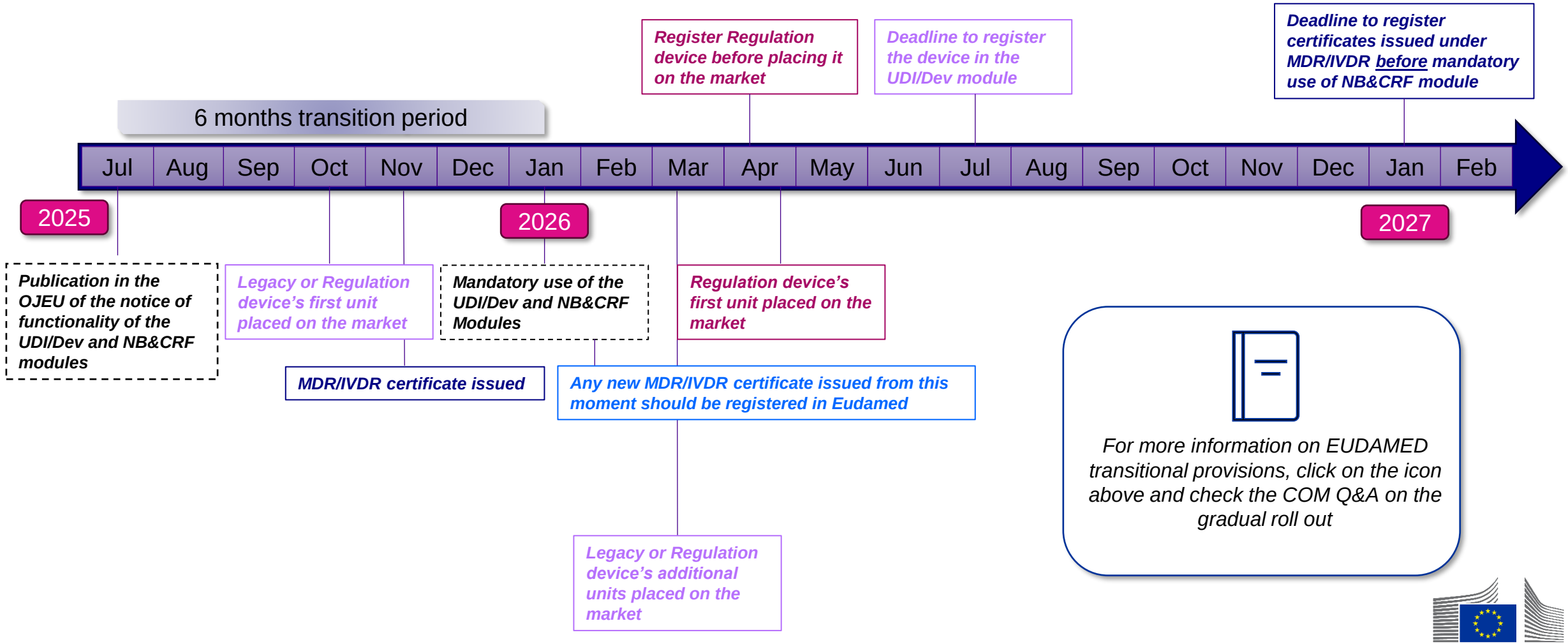
Draft timeline assuming publication of the notice in July 2025



Note: **Updates and decisions** issued **after** the mandatory use of the NB/CRF module **in relation to Regulation certificates issued before the mandatory use of the NB/CRF module**, must be registered in the NB/CRF module

Gradual roll out and timelines – Devices & certificates registration

Draft timeline assuming publication of the notice in July 2025



For more information on EUDAMED transitional provisions, click on the icon above and check the COM Q&A on the gradual roll out

Sources of information and onboarding activities

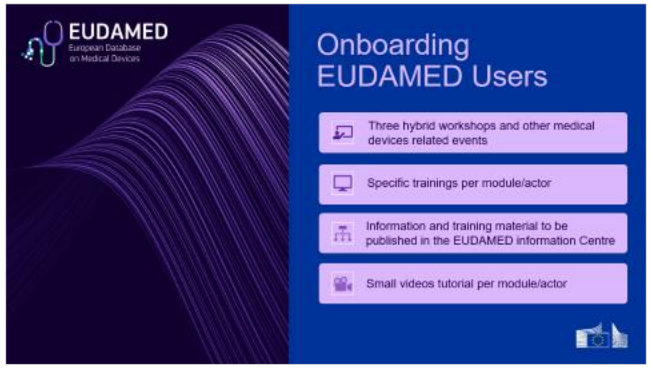
Contacts:
SANTE-EUDAMED-SUPPORT@ec.europa.eu

EUDAMED information centre

Medical devices Europa website

MDCG Guidance documents

Onboarding activities



Workshops

Timeline

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Onboarding EUDAMED Users

- Three hybrid workshops and other medical devices related events
- Specific trainings per module/actor
- Information and training material to be published in the EUDAMED information Centre
- Small videos tutorial per module/actor

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European Database on Medical Devices

Three hybrid workshops organised by COM

Save the Dates!

All types of actors involved

08 October 2025

- Rome (IT)

03 December 2025

- Brussels (BE)

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Draft Timelines – Onboarding activities

- Workshop Stuttgart — **21 May 2025**
- Trainings on ACT and UDI/DEV modules — **June 2025**
- Delivery of additional material for onboarding/training users (ACT and UDI/DEV) — **July/August 2025**
- Trainings on CRF and MSU modules — **September 2025**
- Workshop Rome — **8 October 2025**
- Delivery of additional material for onboarding/training users (CRF and MSU) — **October 2025**
- Workshop Brussels — **3 December 2025**

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Thank you!

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