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The new EU Medical Device Regulations: device identification and traceability

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Revision of the EU Medical Devices Legislation - Background

Directive 90/385/EEC on active implantable medical devices

Directive 93/42/EEC on medical devices

Proposal for a Regulation on medical devices

Directive 98/79/EC on in vitro diagnostic medical devices

Proposal for a Regulation on in vitro diagnostic medical devices

State of play and next steps

- 26 September 2012: adoption of the two Commission proposals on medical devices and IVDs.
- 15 June 2016: Council and Parliament reached agreement on the final text
- 20 September 2016: Council's political agreement
- Early 2017 (expected): Adoption of the Council's first reading position
- Early 2017 (expected): EP second-reading vote

Main (horizontal) features of the compromise texts 1/2

- Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level.
- Inclusion of certain aesthetic devices within the scope.
- Reinforced designation and oversight processes of notified bodies.
- Establishment of a comprehensive EU database on medical devices (EUDAMED) and of a UDI system.
- Reinforcement of the rules on clinical evaluation (and performance evaluation) and clinical investigation (and performance studies), including introduction of a coordinated assessment of a clinical investigation conducted in more than one Member State.

Main (horizontal) features of the compromise texts 2/2

- Improved coordination between Member States in the fields of vigilance and market surveillance.
- Stronger role for the Commission in the context of decisions on the regulatory status of products.
- Specific regime for devices manufactured and used in the same health institution.
- Clarification of the role and responsibilities of economic operators. Certain new obligations for manufacturers and authorised representatives.
- New classification system for IVDs based on international guidance.

Transition period

Final adoption and publication of Regulations in Official Journal of European Union

Full application of MDR at 3 years

Full application of IVDR at 5 years

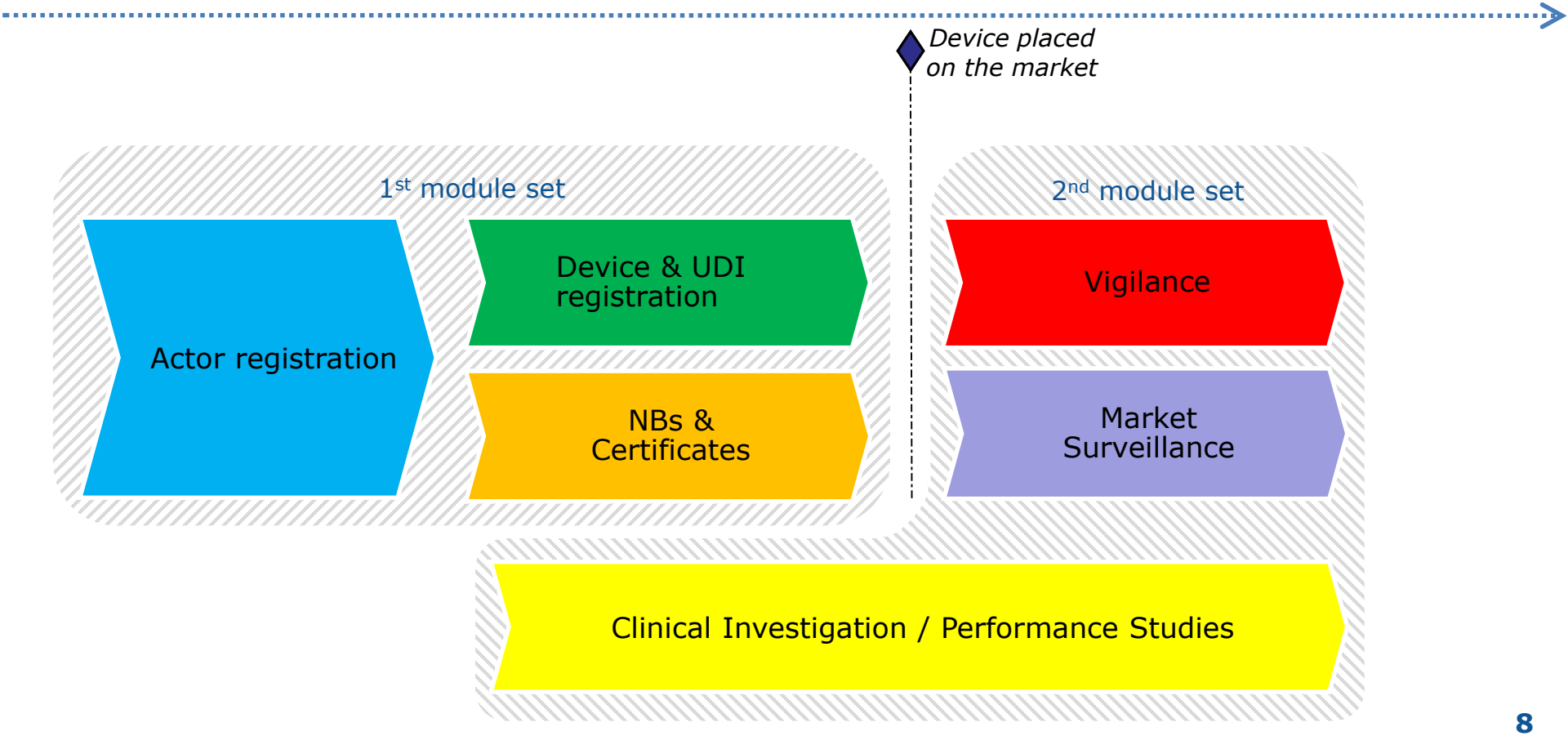
Existing certificates can be re-issued for up to 5 years

Existing certs void after 4 years from full application of MDR and 2 years for IVDR

Specific aspects regarding EUDAMED, UDI, traceability obligations

NB: The following slides are based on the texts agreed by the co-legislators in June 2016. Prior to final formal adoption expected in early 2017, a control of technical inconsistencies is to be done (currently ongoing).

EUDAMED: Processes of the Device lifecycle



European Commission

UDI Overview

EU UDI System:

Definition of Unique Device Identification ('UDI')

- a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that **allows unambiguous identification of specific devices on the market** (Definition 13)

Scope:

- Apply to **all medical devices placed on the market except custom-made devices**

Approach:

- Substantially based on internationally recognised principles and guidance

UDI issuing entities

- The European Commission shall designate UDI issuing entities provided that they satisfy certain criteria.

- Such criteria include:

- the entity system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of the Regulation;
- the entity system for the assignment of UDIs conforms to the relevant international standards;
- the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions.

- Until the Commission has designated UDI issuing entities, **GS1, HIBCC, ICCBBA** shall be considered as designated issuing entities.

Assignment/Submission of UDI data/UDI carrier

- Before placing a device on the market, the manufacturer shall **assign** to the device and – if applicable – to all higher levels of packaging a UDI.
- The **UDI carrier** shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.
- Before a device is placed on the market the manufacturer or his authorised representative shall ensure that the **information** referred to in Part B of Annex V of the device in question is correctly **submitted and transferred** to the UDI database
- In some cases, the manufacturer is required to assign a UDI to the device before the conformity assessment.

Main deadlines

- **UDI assignment and submission of UDI core data elements to the database**: date of application of the new Regulations (unless EUDAMED is not functional by that date).

- **UDI carrier**:

- Implantable devices and Class III devices (and Class D IVDs): 1 year after the date of application.
- Class IIa and Class IIb devices (Class C and B IVDs): 3 years after the date of application;
- Class I devices (Class A IVDs): 5 years after the date of application;
- Reusable devices that shall bear the UDI Carrier on the device itself: 2 years after the date applicable for its respective class of devices.

Requirements for Eudamed/UDI database

Article 24 (22 IVDR) - Unique Device Identification system

Article 24a (22a IVDR) - Electronic system on UDI ('UDI database')

Article 24b (22b IVDR)- Process for registration of devices (Basic UDI-DI):

Annex V - Part B - Core data to be provided to the UDI database

Annex V - Part C - The European Unique Device Identification System (guidance)

Traceability-related obligations

Traceability obligations

- Identification of economic operators up and down the supply chain.
- Introduction of the Single Registration Number for manufacturers, authorised representatives and importers.
- Obligation of **UDI storage for all economic operators** (preferably by electronic means) for Class III implantable devices (scope might be expanded through an implementing act).
- Obligation of **UDI storage for health institutions** for Class III implantable devices.

Towards implementation

Towards implementation: delegated/implementing acts

Implementing acts	COM Proposal total	...of which compulsory	Final total	...of which compulsory
MD	26	6	32	8
IVD	24	5	32	6
Delegated acts	**COM Proposal total**	**...of which compulsory**	**Final total**	**...of which compulsory**
MD	17	2	11	0
IVD	15	2	5	0
Total	**82**	**13**	**80**	**14**

Implementation: priorities

- Notified bodies
- Common specification on Annex-XV-devices (devices without a medical purpose) and reprocessing of single-use devices
- UDI and EUDAMED
- Governance: Setting up of the Medical Device Coordination Group (MDCG)* and Expert Panels

*The MDCG is the main body supporting the Commission in implementing the future Regulations. It comprises representatives from National Competent Authorities and is chaired by the Commission

THANK YOU
FOR YOUR ATTENTION