




Recast Medical Device directives Impacts on materiovigilance

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Revision of the EU Medical Devices Legislation

- 
- Directive 90/385/EEC on active implantable medical devices
 - Directive 93/42/EEC on medical devices

Regulation on medical devices

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

Regulation on in vitro diagnostic medical devices



State of play and next steps



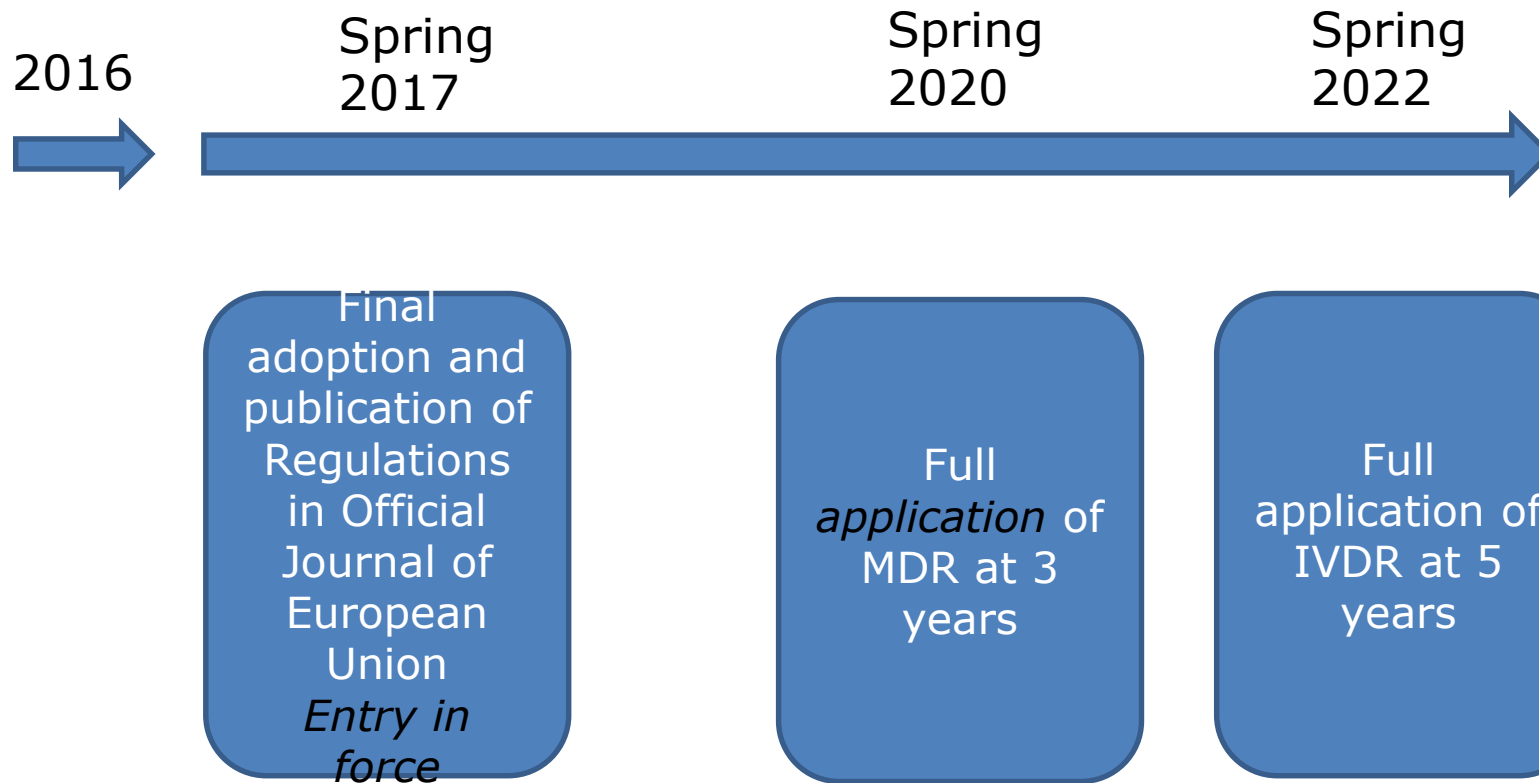
- ✓ 26 September 2012: adoption of the two Commission proposals on medical devices and IVDs
- ✓ 15 June 2016: Council and Parliament reached agreement on the final text
- ✓ 20 September 2016: Council's political agreement

Early 2017 (expected): Adoption of the Council's first reading position

Spring 2017 (expected): EP second-reading vote



Transition period



Key derogations (1)

6 months after entry in force

From November 2017

- Requirements on Notified Bodies
- Designation of Competent Authority
- Establishment of the MDCG

12 months after entry in force

From April 2018

- Cooperation among Competent Authorities (including Commission to provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly)

6 months before the date of application (IVD)

From November 2021

- Designation of reference laboratories for IVDs

Key derogations (2)

0-18 months after the date of application

(from April 2020 to end 2021)

- Registration of devices

0-7 years after the date of application

(From Q1 2020 and to 2027)

- Coordinated procedure for clinical investigation

2-4 years after the date of application

(From 2022 to 2024)

- Certificates issued under old Directives: maximum period of validity of 4 years (MD) and 2 years (IVD) after entry into application

Key derogations (3)

1-5 years after the date of application

From 2021 to 2025

- Placement of the UDI career

2 - 4 years after the date of application

From 2022 to 2024

- Max validity of certificates for devices placed on the market pursuant to old Directives

The new regulatory framework in the field of medical devices is expected to ensure



Better protection of public health and patient safety



Legal certainty and innovation-friendly environment



More transparency and patient empowerment



A more European approach



Better protection of public health and patient safety



- ✓ **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**.
- ✓ Reinforcement of the rules on **clinical evaluation** (and performance evaluation) and **clinical investigation** (and performance studies)
- ✓ **Stricter rules for "substance-based" devices**
- ✓ **New classification system for IVDs** based on international guidance (80% of IVDs to be assessed by a Notified Body)
- ✓ Stricter requirements related to the **use of hazardous substances** for certain devices
- ✓ Introduction of a **UDI system**



Legal certainty and innovation-friendly environment



- ✓ Use of **EU regulations** as a regulatory tool.
- ✓ **Clarification of the scope** for both MD and IVDs.
- ✓ Stronger role for the Commission in the context of decisions on the **regulatory status of products**.
- ✓ Clarification of the specific regime applicable to **devices manufactured and used in the same health institution**.
- ✓ Clarification of the **role and responsibilities of economic operators**.
- ✓ New dedicated rules for **medical software and medical apps**.



More transparency and patient empowerment



- ✓ Establishment of a comprehensive EU database on medical devices (**EUDAMED**) with large part of information to be made publicly available.
- ✓ Introduction of an EU-wide requirement for an '**implant card**' to be provided to patients containing information about implanted medical devices.
- ✓ **Summary of safety and clinical performance** for all Class III and implantable devices available in EUDAMED.
- ✓ New obligations for manufacturers and authorised representatives, aimed at **protecting damaged consumers/patients**.



A more European approach



- ✓ **Registration of devices and economic operators** at the EU level.
- ✓ **Improved coordination between Member States** in the fields of **vigilance and market surveillance**.
- ✓ Confirmation and strengthening of the **EU joint assessment** procedure for notified bodies.
- ✓ Introduction of a **coordinated assessment of clinical investigations** conducted in more than one Member State.



Towards implementation



MDR	may	Shall	may & Shall	Grand Total
Delegated Acts	11	1		12
Implementing Acts	23	6	3	32
Common Specifications		1		1
Grand Total	34	8	3	45



Notified Bodies (IA on scope of designation, application, fees and reimbursements related to joins assessment)



Governance : setting up of the Medical Device Coordination Group (MDCG) and setting of Expert Panels and reference laboratories



Common specifications on Annex XVI devices (devices without a medical purpose) and reprocessing of single use device



Eudamed and UDI system

IVDR	may	May/ Shall	Shall	Grand Total
Delegated Acts	6			6
Implementing Acts	25	2	5	32
Grand Total	31	2	5	38



Traceability, Post-market surveillance, vigilance and market surveillance





Traceability, Post-market surveillance, vigilance and market surveillance

Background

Chapter III of the MDR :

- Identification and traceability of devices

Chapter VII of the MDR

-3 sections:

- Post market surveillance (Art. 83-86) affects the manufacturer
- Vigilance (Art. 87-92)
- Market surveillance (Art. 93-100) affects the competent authority

“Key elements of the existing regulatory approach, such as ... vigilance and market surveillance should be significantly reinforced ...”!





Post-market surveillance and traceability

Actual issues

- No clear overview of medical devices placed on the market in European Union
- No (clear) harmonized procedures to register medical devices or economic operators
- No unique identification means
- No clear overview of parties participating in a supply chain
- Some Member States impose traceability requirements, others do not
- Difficult to intervene or coordinate corrective actions, withdrawals or recalls throughout the EU
- PIP Scandal: evidenced the need for a reinforced system for post-market safety.
- No harmonized post-market safety without harmonized traceability



Traceability : UDI System



Purpose: to allow identification and facilitate traceability of medical devices

Means: Registration of devices and economic operators

Requirements:

- Internationally recognised Nomenclature
- IT infrastructure, the European Databank on Medical Devices (Eudamed) and UDI data base
- Cooperation throughout the distribution and sales channels
- Obligations to all economic operators to provide information on medical devices in their control
- International cooperation in particular US FDA

Use of UDI

- In relation to applying for certification to a notified body
- To include in the summary of safety and clinical performance
- For reporting serious adverse incidents
- For field safety or corrective actions
- To appear on the EU declaration of conformity
- For Class III and implantable medical devices:
 - For economic operators and health institutions to store and keep, preferably by electronic means the UDI supplied by or to them
- Health care institutes and health care professionals shall be encouraged and may be required by Member States to store and keep more devices



Post market surveillance system



“manufacturers shall plan, establish, ..., a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device...” (and see Art. 83.1)

General duty

- Plan, establish, document, implement, maintain and update a surveillance system
- System has to be appropriate to the risk class and type of device
- Plan shall be an integral part of manufacturer’s QMS Scope
- Actively gathering, recording and analysing relevant data on quality, performance and safety throughout the device’s whole lifetime
- Drawing the necessary conclusions
- Determining, implementing and monitoring any preventive and correctives actions



Vigilance (Art. 87 – 92)



- Aim to incorporate MEDDEV GUIDELINES 2.12 Rev. 8, including definitions such 'incident' plus 'serious incident' and 'withdrawal'.
- New prescriptive rules for the manufacturer's vigilance, including reporting (Art 87) and trend reporting (Art 88):
- Vigilance reporting via an EU portal that is part of the overall European Databank on Medical Devices EUDAMED system
- High participation by competent authorities, Member States and the Commission (Art 90)
- Expect further Implementing Acts by the Commission (Art 91)



Market surveillance (Art. 93 – 100)



- A coordinating authority will evaluate the same or similar incidents that have occurred, or where a corrective action has to be taken, in more than one member state
 - Harmonisation across Member States
- Member states will be obliged to coordinate their enforcement activities; the Commission may recommend changes to the plans.
 - Closer collaboration between Member states and the European Commission
- A binding procedure for dealing with non-compliant and compliant devices, both in national and cross-border situations
 - The European Commission's role as an 'arbitrator' between Member States





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