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Quo vadis MDR

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Content

- Current status – where do we stand?
- Why do we stand where we are?
- What currently happens
- What are the next steps?

MDR – a story of success?

Knowing that **after only eight years** the MDR isn‘t fully implemented but

please indicate if you – agree to the question above, i.e. would say yes

– don‘t agree, i.e. would say no

MDR – a story of success?

MEMO | Apr 5, 2017 | Brussels | Lesedauer: 11 Min

New EU rules to ensure safety of medical devices

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Related topics

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Ranging from simple contact lenses and sticking plasters to sophisticated pacemakers and hip replacements, medical devices and in vitro diagnostic medical devices are important to our health and quality of life.

People rely on these devices every day and expect them to be safe and incorporate the latest progress in science and innovation. The current rules on the safety and performance of medical devices in the EU were harmonised in the 1990s. To reflect the substantial technological and scientific progress in this sector over the last 20 years, the Commission proposed to update the rules to improve the safety of medical devices for EU citizens, create the conditions to modernise the sector and to consolidate its role as a global leader.

Why do we need new regulations on medical devices?

Problems with diverging interpretation of the existing rules as well as certain incidents - e.g. with breast implants and metal hips - highlighted the weaknesses of the current legal system and damaged the confidence of patients, consumers and healthcare professionals in the safety of medical devices.

https://ec.europa.eu/commission/presscorner/detail/en/memo_17_848

… MDR – a story of success?

Will the transition to the new rules create any disruptions to the availability of medical devices? What are the arrangements?

It is crucial to ensure that the new rules enter into force without any unreasonable delays and they do not create any serious disruption of the medical devices supply. The Commission, competent Authorities, Notified Bodies and all other stakeholders will work together to ensure that the transition to the new regime is smooth and successful. The Regulations foresee that certificates issued under the current Directives can remain valid for a certain additional period after the general application date of the two Regulations (3 years after the entry into force for medical devices and 5 years for the *in vitro* diagnostic medical devices). Moreover, a set of exemptions from clinical investigation requirements

https://ec.europa.eu/commission/presscorner/detail/en/memo_17_848

Transition timelines have been extended twice, now until end of 2027 (class III / IIb n.e.) / 2028 (others)

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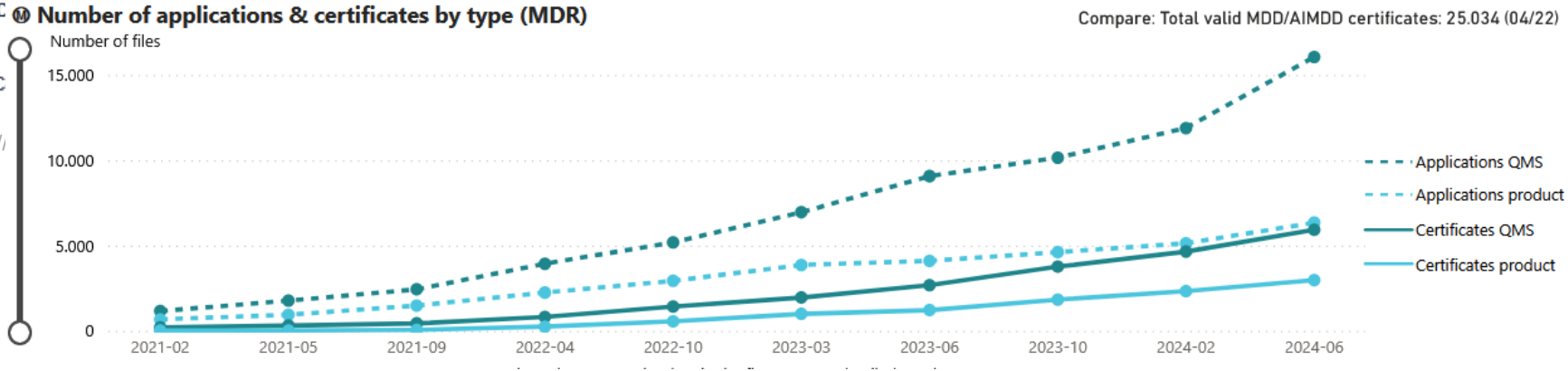

https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en

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medical devices). More

https://ec.europa.eu/com

The situation

There are over 35,000 medical technology companies in Europe – 92% of them small and medium-sized enterprises (SMEs) – currently providing around 500,000 medical technologies to European patients.[2] At least 17% of today's IVDs[3] and 20% of the MD product portfolios[4] are expected to be discontinued in Europe due to the expectation that costs of the transition to the IVDR or MDR outweigh product revenue, particularly among SMEs. 28% of IVD manufacturers[5] and 48% of medical device manufacturers[6] are deprioritising the EU market (or plan to do so) as the geography of choice for first regulatory clearance of their new devices due to the unpredictability (time, cost, changes) of the IVDR and MDR.

https://www.medtecheurope.org/wp-content/uploads/2023/11/medtech-europe_future-of-medical-technology-regulations_position-paper_2023.pdf

… MDR – a story of success?

What are the main benefits for patients and consumers?

The new Regulations pave the way to a more patient-friendly environment, where transparency and patients' information and choice are a priority; where patients can benefit from innovative, highly performing devices and new therapies become possible. The new rules introduce:

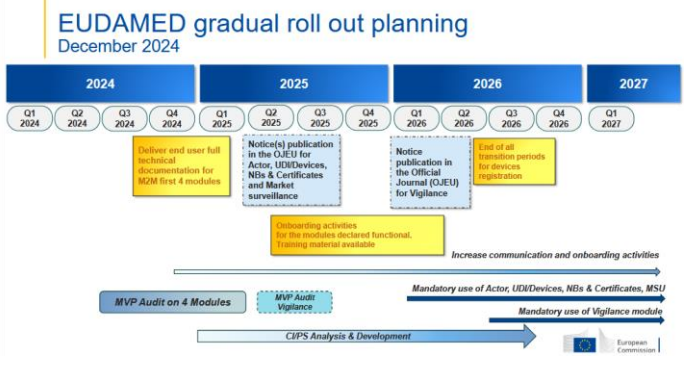
- **better protection of public health and patient safety**. In particular high-risk devices are going to be subject to stricter pre-market control. Certain aesthetic devices (such as coloured contact lenses or equipment for liposuction) presenting high-risk to consumers and practices such as reprocessing of single-use devices are included in the scope of the new Regulations and made subject to a stricter and more harmonised regime. Rules on clinical evaluation and clinical investigation (and, for *in-vitro* diagnostic medical devices, performance studies) are generally strengthened and stricter requirements on the use of hazardous substances are introduced.
- a comprehensive **EU database** on medical devices (EUDAMED) that will contain a living picture of the lifecycle of all products being available on the EU market. A large part of the information will be made publicly available, including a newly introduced summary of safety and performance for all Class III and implantable devices. The Commission is required to set up the database by spring 2020 and to maintain it thereafter.

Biomedical Alliance in Europe

Press release

27 June 2023

Press release calls on the Commission to address limited availability of medical devices, particularly for children



https://ec.europa.eu/commission/presscorner/detail/en/memo_17_848

… MDR – a story of success?

Will the new rules be able to keep up with the future progress?

The final Regulations contain very important changes to the current system to enable the sector to produce safer and more innovative devices and help address future challenges. The new Regulations contain many provisions to increase security and regulatory certainty (harmonised rules on drug-device combination products, tissue engineering, nanoscience, personalised medicine, substance based devices and genetic tests) and take into account the latest developments in the sector (medical software, apps, cybersecurity).

To help boost innovation in the sector, the EU-wide database on medical devices (EUDAMED), supported by a new device identification system based on a unique device identifier (UDI), will make big sets of data in the field of medical devices available within the EU. By producing more innovative devices, medical device manufacturers will also be able to offer solutions for disease prevention or early diagnosis that will in turn make the healthcare sector more affordable, by for example helping to prevent or reduce hospitalisation.

https://ec.europa.eu/commission/presscorner/detail/en/memo_17_848

Many complaints about **unpredictability** and **significantly increased costs**

R&D employees needed **to compile technical documen-tations** instead of developing new devices

Where do we stand?

- In the middle of an **interesting process**
- Why do we stand where we are?
- What should / needs to be done?
- What is / will be done?

… Where do we stand?

The MDR

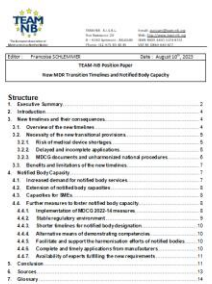
- contains **inconsistencies** and **“multiple controls“** with partially **contradictory requirements** and insufficient / mismatching processes,
- requires a **multitude of guidance documents …**
- which have been / are written by different groups with various objectives and **often without considerations about their impact** …
- and partially establishing new requirements

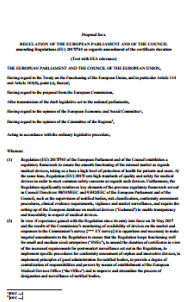
- There was / is a **delayed implementation of essential elements** – in particular EUDAMED, expert panels, harmonised standards, Common Specifications (CS)
- Also the **multiple amendments** of the Regulations require(d) extra work
- and **prohibid**(ed) the application of **stable processes**

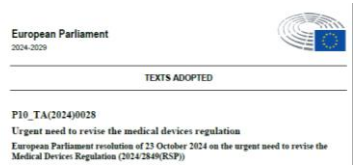
… Where do we stand?

Many groups have issued position papers, e.g.


BVMed and VDGH White Paper on the Future Development of the MDR and IVDR




REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL



A lot of ideas – but is there any “valid analysis“ why we are where we are?

Why we are where we are?

- Procedural aspect(s)
- Clear objectives?
- Sound impact assessment(s), especially for changes brought in by Council and European Parliament?

Objectives – significant changes over the last years

patient safety

innovation friendliness

Affordability

Availability

One “output“ of this should be the need to define a **common understanding** in respect of the direction to be taken, i.e. what is a **balanced approach?**

… Why we are where we are?

Do the Regulations meet the objectives of the **Interinstitutional Agreement … on Better Law-Making**, OJ. L 123/1 of 12 May 2016?

> I. 3. The three Institutions agree that **Union legislation should be comprehensible and clear**, allow citizens, administrations and businesses to **easily understand their rights and obligations**, include appropriate reporting, monitoring and evaluation requirements, **avoid overregulation and administrative burdens**, and **be practical to implement.**

In case they would, we **wouldn‘t need thousand(s) of pages of guidance documents!**

Hope: “targeted evaluation“

Announced by Commissioner Kyriakides 7 March 2023 could / should be used

European Commission

Home > Law > Law-making process > Pl

The Commission, together with Member States, notified bodies and the medical industry will continue to work on additional measures to address the structural problems and identify medium and long-term solutions. Ensuring the transition to the new Regulations must be our collective priority to safeguard patient safety and foster innovation in Europe.”

Better Regulation: why and how

The Better Regulation agenda ensures evidence-based, transparent EU law-making based on the views of those impacted. The Commission evaluates and improves EU laws, focusing on delivering where it matters the most.

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Objectives of the Better Regulation agenda

What the Commission is doing

Have Your Say: Public Consultations and Feedback –

Objectives of the Better Regulation agenda

– Ensure EU policymaking is based on evidence

– MakingEU laws simpler and better, and avoiding unnecessary burdens

– Involving citizens, businesses and stakeholders in the decision-making process

- public consultation ended 21 March 2025
- more than 500 contributions
- plus separate data collections

… Hope: “targeted evaluation“

Our overall timeline

Fig. DG SANTE D3, Apr. 2025

… Hope: “targeted evaluation“

- Complex activity
- Defined content
- Five areas
  - **Effectiveness**
  - **Efficiency**
  - **Relevance**
  - **Coherence**
  - **EU added value**

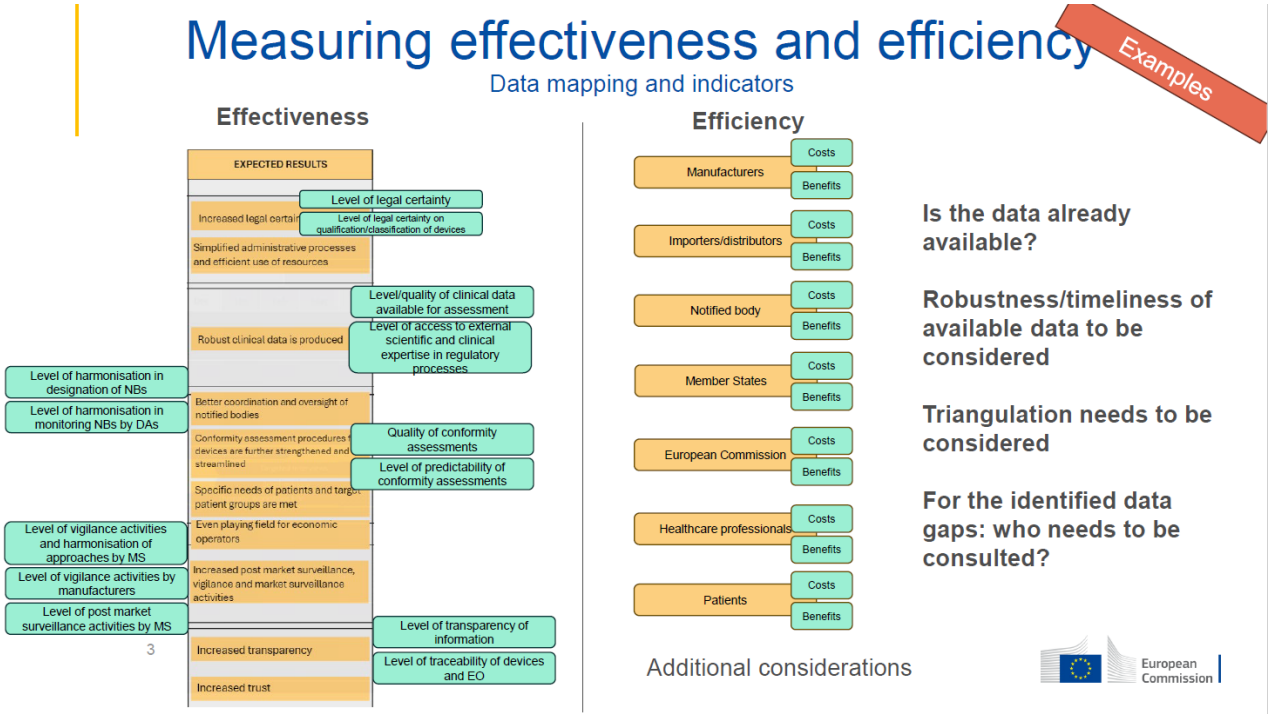

Fig. DG SANTE D3, Oct. 2024

- Will result in a 50page document

What should / needs to to be done?

Instead of new patchwork or “blind activism“ …

- … a **target-oriented** “thinning“ of the Regulations
- with a clear commitment to (**adapted**) **objectives**, i.e., “**one clear direction**“
- **Process analysis** and **adaptation**, i.e., which processes need to be adjusted in which way
- **What doesn‘t contribute** to an “added value“ to agreed objectives **should be deleted / omitted**
- Focus on “real“ issues and try to achieve a stable environment, i.e. without the need for permanent changes

Quo vadis MDR? – Outlook

- on the one hand, “problems are identified“
- on the other hand, (too) many **parallel activities & impacts** – e.g., planned implementing acts, environmental legislation, AI Act – requiring additional actions and **increase complexity**
- Will the targeted evaluation deliver a “**sound basis for a good revision**“ within **appropriate time**?
- Focus on **evidence based** changes in line with **better regulation principles** …

Many thanks for your attention!