Advantages and Shortcoming of the EU MDR – And its impact on patient safety

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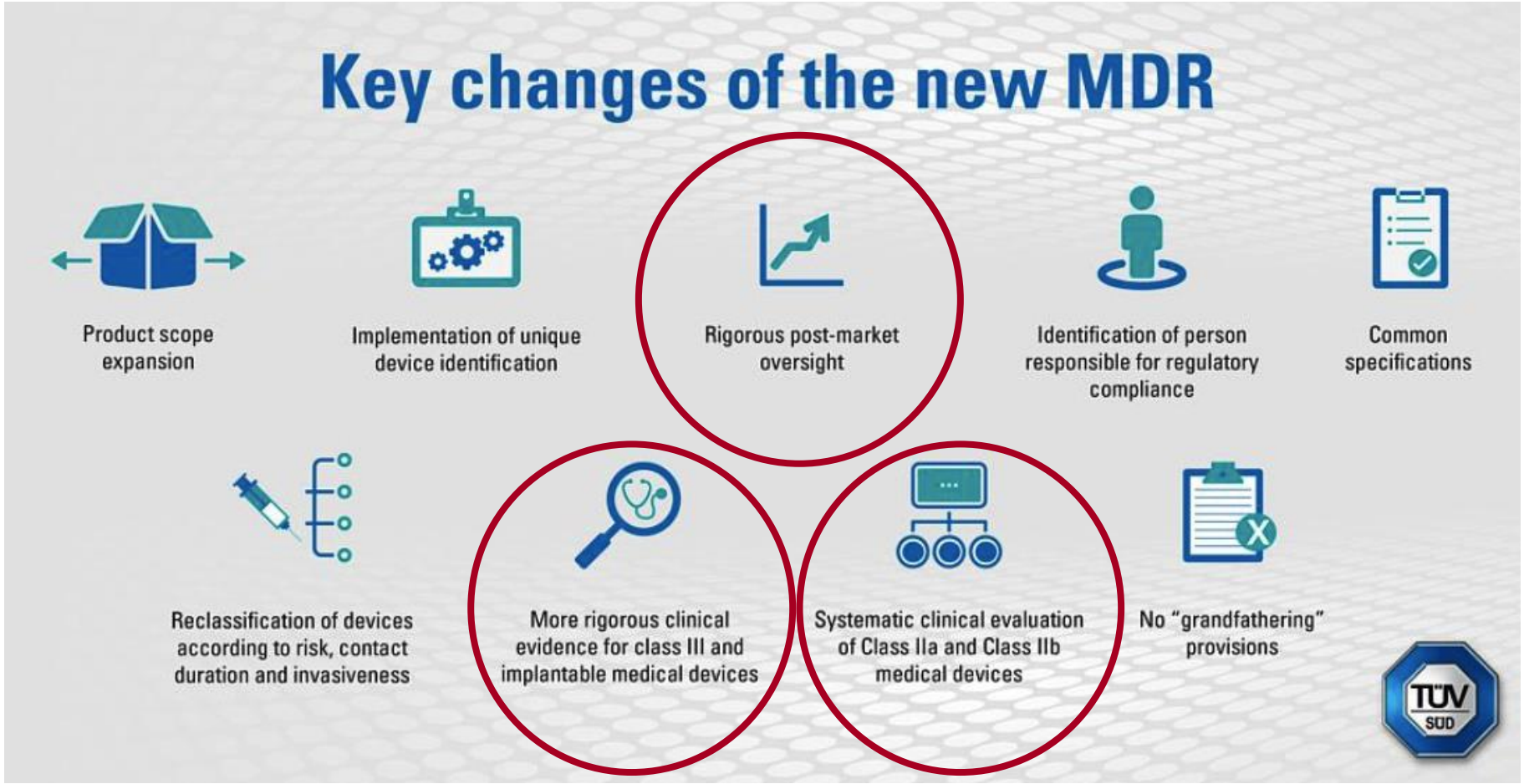
Benefits and Drawbacks of MDR



More clinical data

Perceived Benefit:
Higher product safety

Drawback:
Higher cost:
€10B for TD Update MDD to MDR –
without product changes

Introduction of MDR

"… a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation."

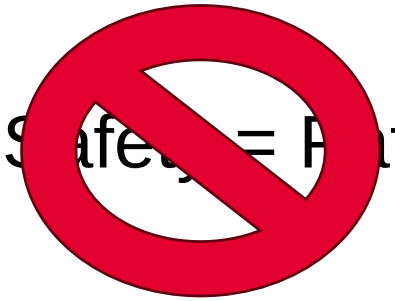
228 pages

?

+ 100 MDCG documents (Medical Device Coordination Group)
+ 2000 pages

→ Increased product safety
→ Fewer products (portfolio streamlining)
→ Less innovation & new products
→ Cost increase

Fundamental Equation

Product Safety  Patient Safety

Patient Safety =

f(Product Safety + Product Availability + Product Innovation)

Challenges caused by MDR/IVDR in EU

- Challenge 1: **Transition to MDR/IVDR** (2024 to 2028)
  Medtech EU survey (July 2022): High cost for transition
  → Potential supply shortage in EU & CH, min. 15% portfolio reduction

- Challenge 2: **Innovation** under MDR or FDA? (today)
  Medtech EU survey (July 2022): >50% of EU companies prefer FDA for 1st approval
  → New technologies not or 2-7 years later in EU & CH

→ Driving force for Parliamentary Motion 20.3211

Vision for a Future MDR/IVDR

Based on MedTech Europe & BVMed/VDGH White Paper

https://www.medtecheurope.org/resource-library/the-future-of-europes-medical-technology-regulations/

https://www.bvmed.de/de/bvmed/presse/pressemeldungen/whitepaper-zur-mdr-ivdr-weiterentwicklung-medtech-verbaende-bvmed-und-vdgh-fordern-abschaffung-der-re-zertifizierung-und-fast-track-verfahren-fuer-innovationen

Improvement of MDR/IVDR

3 requests:

1. Europe needs a more **efficient and fit-for-purpose CE marking system** (while guaranteeing safety and performance of medical devices)

2. Europe needs a regulatory system for medical devices and IVDs that embraces **innovation**

3. Europe needs a **single clear and accountable entity** (specific to medical technologies) governing the oversight of the regulatory framework

Three Pillars of Change

<u>Pilar 1:</u> More efficient and fit-for-purpose CE marking system

- Build greater efficiency and predictability into the system
- One fee for certifying and evaluating a device or the QMS system
- Eliminate the ‘every 5 years’ certification renewal obligations; base validity of certificate on PMS/EUDAMED

<u>Pilar 2:</u> Regulatory system that embraces innovation

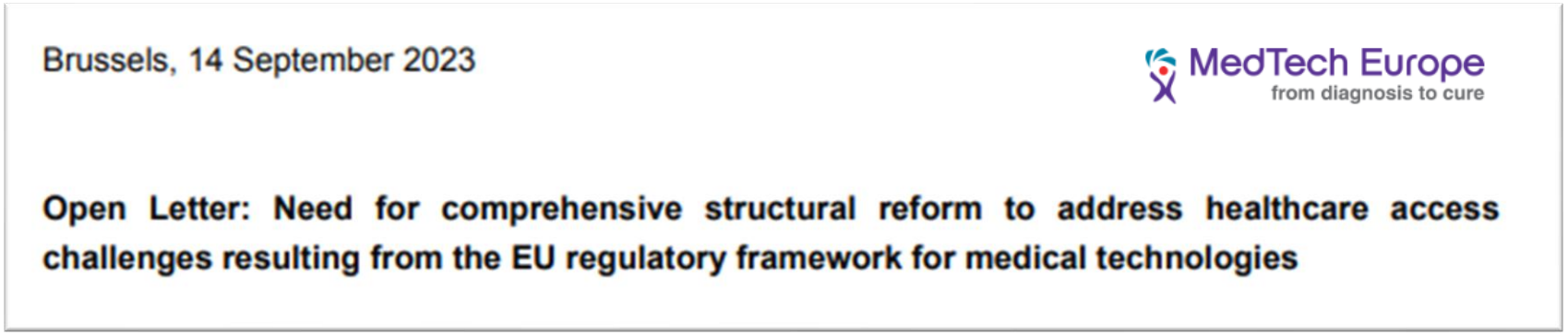
- Support of innovation with dedicated/accelerated pathways
- Early dialog with NB (“no surprises” principle)
- Revisit the use of “equivalent” evidence

<u>Pilar 3:</u> Single clear and accountable entity to govern the regulatory framework

- Oversee the de-centralised CE-marking system
- Harmonise management of the NB
- Limit the use of MDCG “guidance mechanism”

MDR/IVDR – Quo vadis?

→ MedTech Europe letter to EU Health Commissioner (signed by 34 national associations)



Brussels, 14 September 2023

MedTech Europe
from diagnosis to cure

Open Letter: Need for comprehensive structural reform to address healthcare access challenges resulting from the EU regulatory framework for medical technologies

https://www.medtecheurope.org/resource-library/open-letter-to-commissioner-for-health-stella-kyriakides-need-for-comprehensive-structural-reforms-of-the-medical-technology-regulatory-frameworks/

Next Steps

EU commission (Flora Giorgio at EAAR-Conference, Brussels, 31.01.2024):

- Recognises problems with MDR/IVDR → swift amendment (EU) 2023/607 and proposal (EU) 2024/0021 to give “breathing space”

→ Goal: Pragmatic application of extended transition provisions to **prevent potential shortages**

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R0607

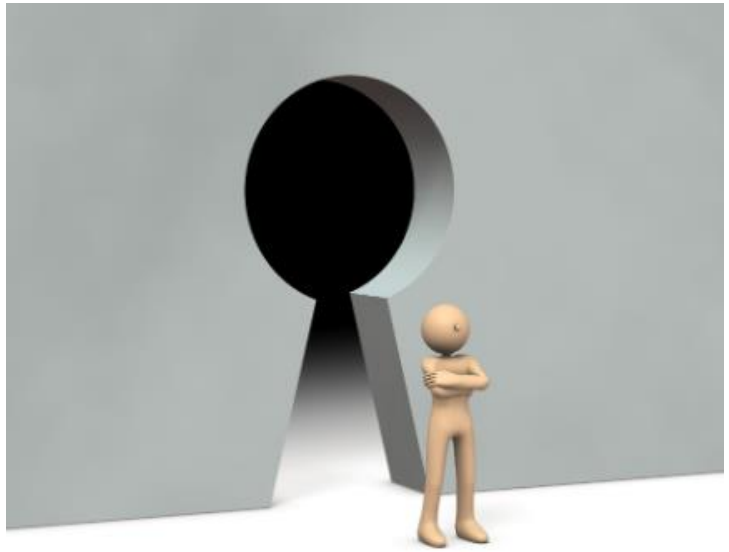
https://health.ec.europa.eu/system/files/2024-01/mdr_in-vitro-proposal.PDF

- Is carrying out studies on **governance, innovation, orphan devices and availability** of MD/IVD
- Promises to “look into MDR/IVDR earlier than originally planned” (2027)

What can companies and national associations do?

- Lead discussions with stakeholders on national and European level to maintain pressure
- In CH: Support parliamentary motion 20.3211

The Pivotal Role of the CH-REP



No access of medical devices to Switzerland without CH-REP

- CH-REP responsible for formal and safety-related aspects
- Jointly liable with foreign manufacturer for defective products

Duties of CH-REP:

- MedDO Art. 51 & IvDO Art. 44
- Equivalent to MDR Art. 11

«Swiss Finish»:

- CH-REP to ensure that technical documentation is submitted within 7 days from manufacturer to Swissmedic, on request
- PRRC does not need to be domiciled in Switzerland

https://www.swissmedic.ch/swissmedic/en/home/medical-devices/regulation-of-medical-devices/faq.html

The Prospects of CH-REP as Business Model