23rd DGRA Annual Congress, WCCB, 14 Sept 2021

Medical Device Regulation EU – an Update

Dr. Rainer Edelhäuser
c/o Zentralstelle der Länder für Gesundheitsschutz
bei Arzneimitteln und Medizinprodukten
Heinrich-Böll-Ring 10, D-53119 Bonn

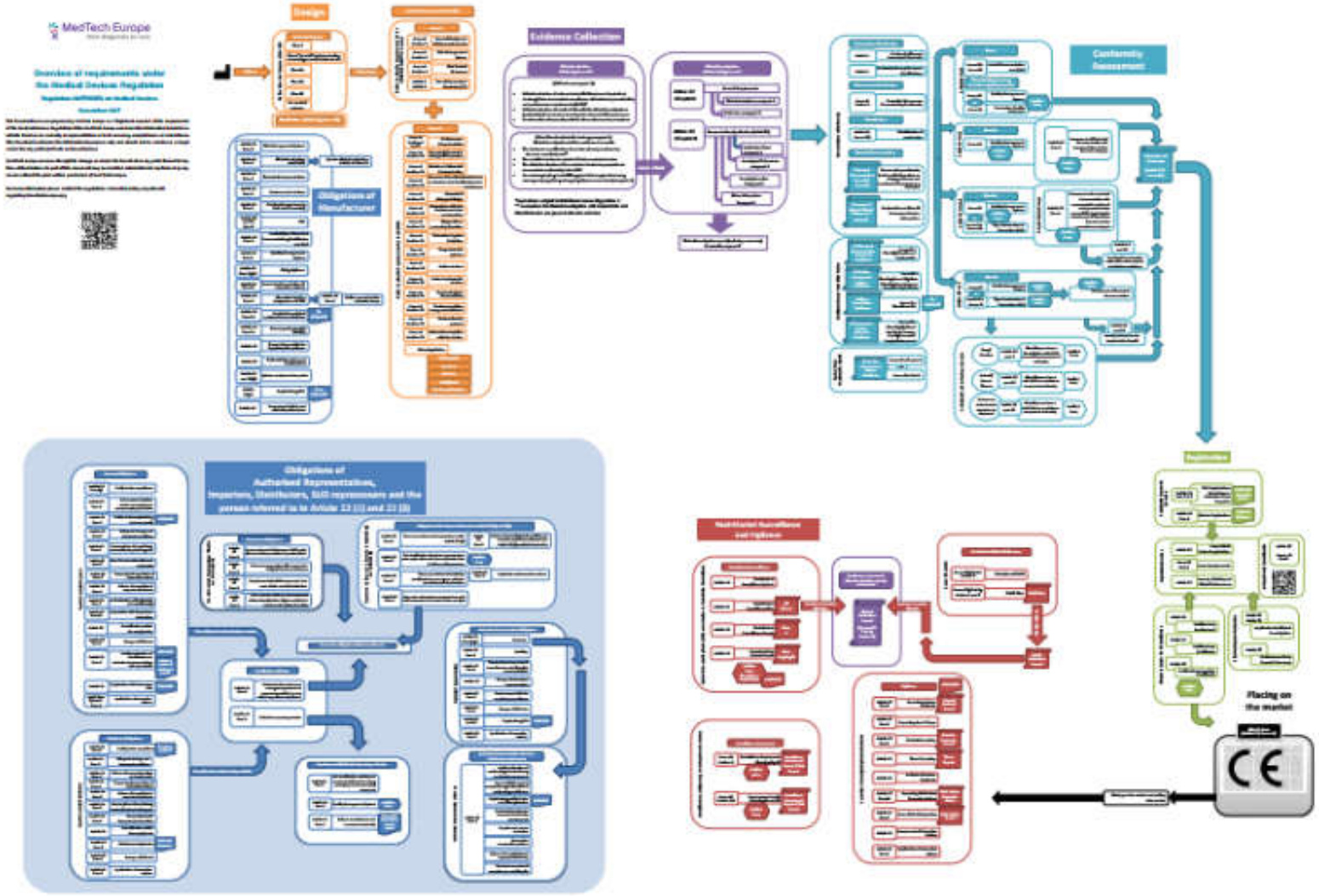
The Medical Device Regulation (MDR)

https://eur-lex.europa.eu/procedure/EN/2012_266

A long way which started already 2008

… The Medical Device Regulation (MDR)

https://www.medtecheurope.org/wp-content/uploads/2018/01/EN_MTE_MDR_Flowchart_Dec2017.pdf



… Medical Device Regulation

- Adopted 5 April 2017
- Publication OJ L 117/1 5 May 2017
- Entry into force 26 May 2017
- Application (designation) 26 Nov 2017
- **Application** ~~26 May 2020~~
- Postponed to **26 May 2021**

- Implemented **?**

MDR date of application

First the positive: 26 May passed – and our globe didn‘t stop turning

But is the system ready?

Let‘s focus on some special aspects

- status of implementing acts
- guidance documents
- harmonised standards
- new designations & notifications of notified bodies
- notified body capacity
- transitional provisions
- scientific bodies – expert panels
- backbone EUDAMED – state of play

Implementing Acts

- work has started already before the adoption of the Regulations
- some had been identified to have priority
- but drafts disapeared from the agenda
- **priorities changed** more than once
- mandatory ones with legally fixed dates (e.g. for products acc. to Annex XVI) are still outstanding
- …

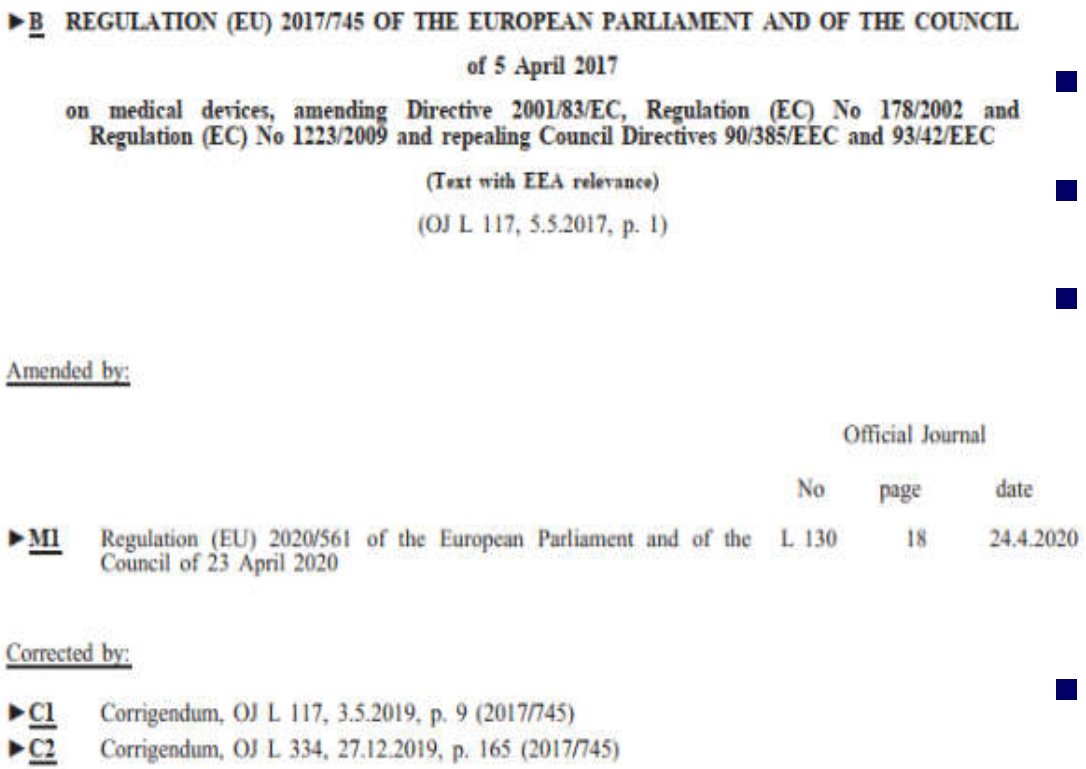
Current Commission activities

[Fig. DG GROW, May 2018]

Implementing acts

- Reprocessing of single-use medical devices (CS) ✓
- Designation of issuing entities for UDI ✓
- Funding of activities related to designation and monitoring of Notified Bodies —
- Common specifications for IVDs —
- Designation of: Expert panels / (Expert laboratories) / EU reference laboratories ✓/ —
- Fees for Expert panel / (Expert laboratories) / EU Reference laboratories —
- Devices without a medical purpose (CS) —
- Chapter VI and Chapter VII (to be decided – based on priorities/needs): Clinical evaluation and clinical investigations (MDR) / Clinical evidence, performance evaluation and performance studies (IVDR) / Vigilance —

… Medical Device Regulation



►B 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

(Text with EEA relevance)

(OJ L 117, 5.5.2017, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020	L 130	18	24.4.2020

Corrected by:

►C1 Corrigendum, OJ L 117, 3.5.2019, p. 9 (2017/745)

►C2 Corrigendum, OJ L 334, 27.12.2019, p. 165 (2017/745)

- **228 Pages**
- **2 Corrigenda**
- **1 Amendment**
- a lot of **changes would be necessary** (available in Brussels since Dec. 2017)

- **4 Implementing Acts**
- **plus …**

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424

Let‘s focus on some special aspects

- status of implementing acts
- **guidance documents**
- harmonised standards
- new designations & notifications of notified bodies
- notified body capacity
- transitional provisions
- scientific bodies – expert panels
- backbone EUDAMED – state of play

… (too) many guidance documents

https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

Guidance - MDCG endorsed documents and other guidance

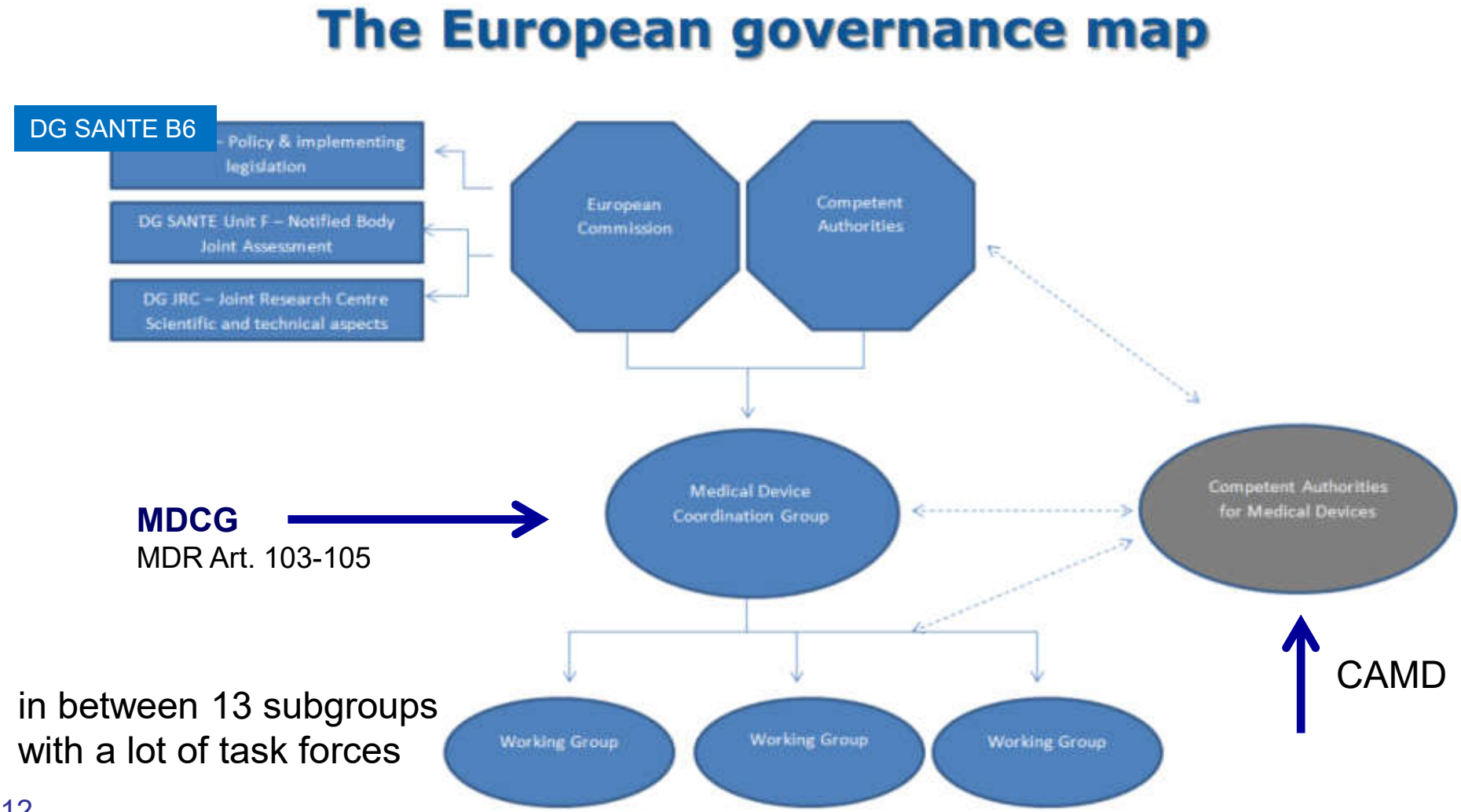
The European Commission provides a range of guidance documents to assist stakeholders in implementing the medical devices regulations, including documents endorsed by the Medical Device Coordination Group (MDCG) and other informative texts.

Legally non-binding guidance documents, adopted by the MDCG in accordance with Article 105 of Regulation 745/2017, pursue the objective of ensuring uniform application of the relevant provisions of the regulations within the EU.

- In the beginning, Commission **rejected to produce guidance** in case of empowerments for implementing or delegated acts – **even in cases where the MDR explicitly refers to MDG guidance** (e.g. MDR Annex IX, 2.3., 3rd paragraph)
- In between they changed their mind and **seem to be a publishing house** …

New Committee structure

[Fig. from DG GROW, May 2018]



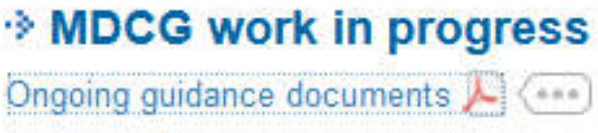
MDCG
MDR Art. 103-105

CAMD

in between 13 subgroups
with a lot of task forces

… (too) many guidance documents

- more than **80 MDCG** documents endorsed
- plus > 10 additional Commission documents
- **in addition ca. 40** MDCG documents in progress or **planned**



https://ec.europa.eu/health/sites/health/files/md_sector/docs/mdcg_ongoing_guidancedocs_en.pdf

- as well as many documents for **EUDAMED**
- documents contain partially contradictory content

- **Who is able to keep the overview?**

Guidance documents – examples

- MDCG 2019-6 v2 **Questions and answers**: Requirements relating to notified bodies
  IV. 1 … *As no exceptions were established under the regulations for the migration or transfer of MDD/AIMDD/ IVDD certificates to the MDR / IVDR the general provisions should apply. Therefore,* ***all devices to be certified under the MDR / IVDR should be subject to an initial certification*** *according to the applicable annex. The notified body should ensure* ***that all requirements under the MDR / IVDR are fulfilled****. …*
- when the Commission has realised the consequences, they pushed the endorsement of
- MDCG 2019-3 Rev. 1 **Interpretation of article 54(2)b**

… Guidance documents – examples

- MDCG 2019-3 Rev. 1 **Interpretation of article 54(2)b**
- its spirit contradicts the approach in
- MDCG 2020-12 **Guidance on transitional provisions for consultations of authorities** on **devices incorporating a** substance which may be considered a **medicinal product** and which has action ancillary to that of the device, as well as on devices manufactured using **TSE susceptible animal tissues**
- because in this case there is **no** (real) **exemption for already consulted (directive) devices**!

Guidance documents

- also their **status** is interesting
- on the one hand, they are **not legally binding**
- on the other hand they are used to **define new requirements**
- manufacturers and notified bodies are expected that they follow them, e.g. in case of CECP (clinical evaluation consultation procedure)
- …

Example CECP

- JRC instruction for notified bodies requires use of
  - MDCG 2020-13 template for **CEAR** (NB)
  - MDCG 2020-7 template for **PMCF plan** and
  - MDCG 2020-8 template for **PMCF evaluation report** (mfg)

Let‘s focus on some special aspects

- status of implementing acts
- guidance documents
- **harmonised standards**
- new designations & notifications of notified bodies
- notified body capacity
- transitional provisions
- scientific bodies – expert panels
- backbone EUDAMED – state of play

Harmonised standards

- a lot of long lasting discussions and attempts
- mandate accepted by CEN/CENELEC in May 2021
- Commission Implementing Decision (EU) 2021/1182 of 16 July 2021
- **How many?**

  Only …

- And the others?
- Until 2024

No	Reference of the standard
1.	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
2.	EN ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014) EN ISO 11135:2014/A1:2019
3.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019
4.	EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
5.	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)

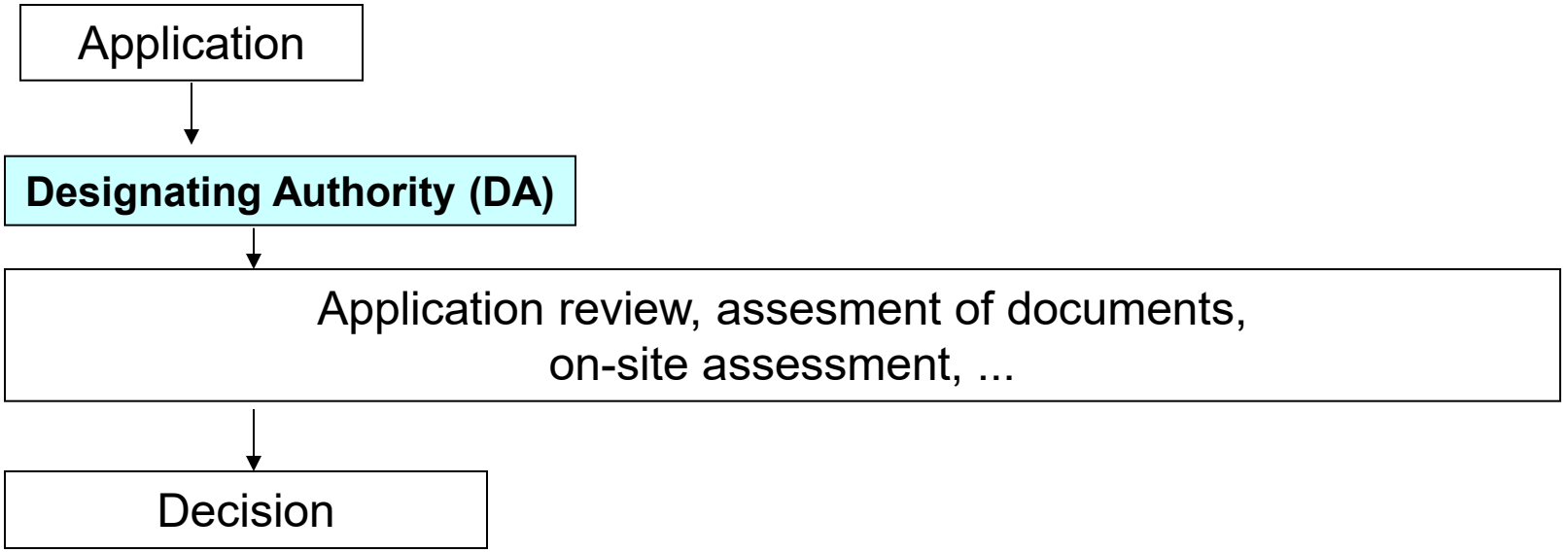
Let‘s focus on some special aspects

- status of implementing acts
- guidance documents
- harmonised standards
- **new designations & notifications of notified bodies**
- **notified body capacity**
- transitional provisions
- scientific bodies – expert panels
- backbone EUDAMED – state of play

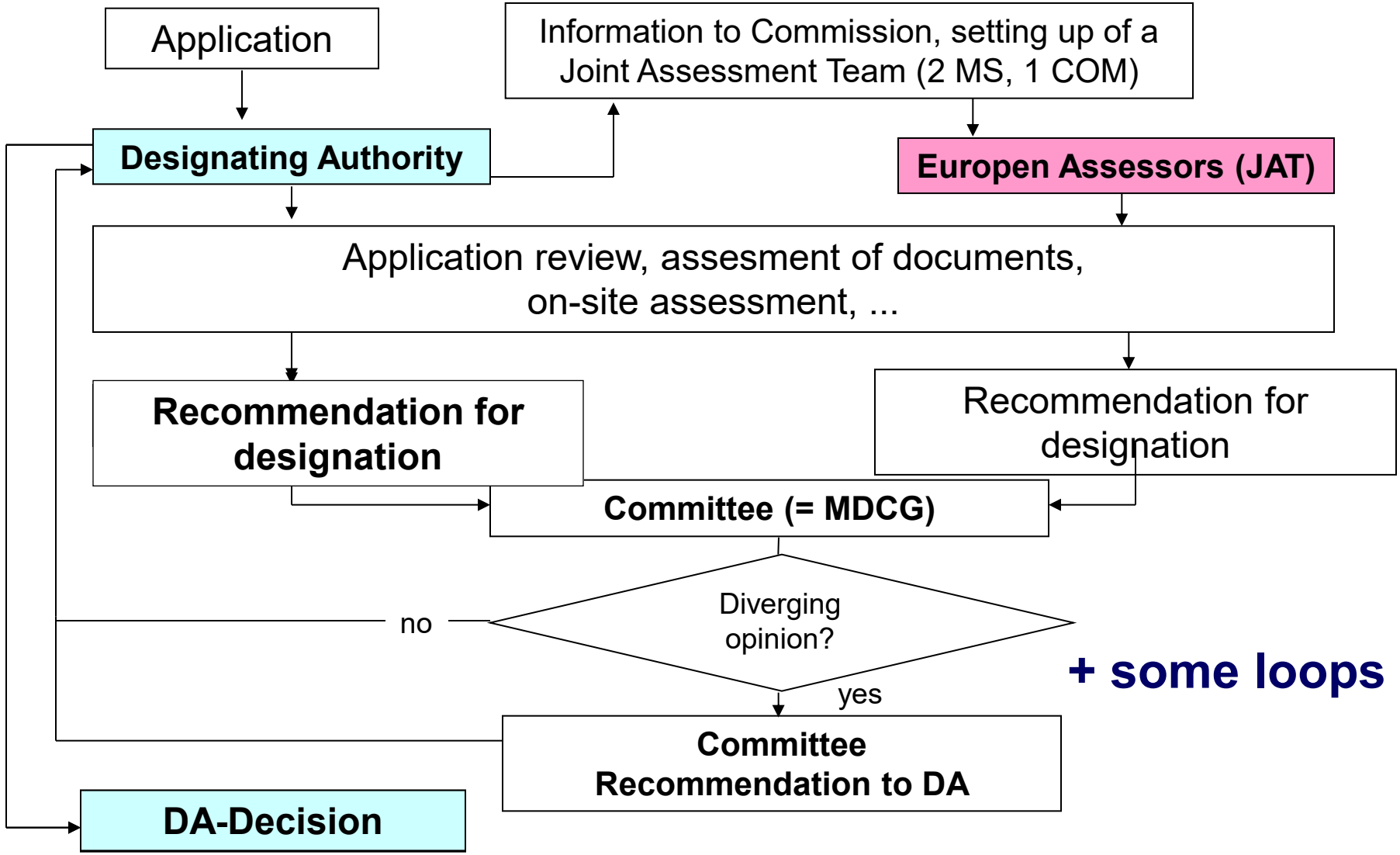
New designations & notifications

- Regulation requires complete new designations
- now much **more detailed requirements** for
  - notifed bodies as well as for
  - designating authorities
- **complex process** with the **involvement of a joint assessment team**: two national experts from other Member States plus Commission representative(s)
- time from application to notification ca. **1 ½ years**
- see Best Practice Guide NBOG BPG 2017-1

Previous process of designation (schematical)



New process of designation (schematical)



… New designations & notifications

- in total **52 applications** under the **MDR** [IVDR 14]

  overview in State of play of joint assessments of Notified Bodies in the medical device sector

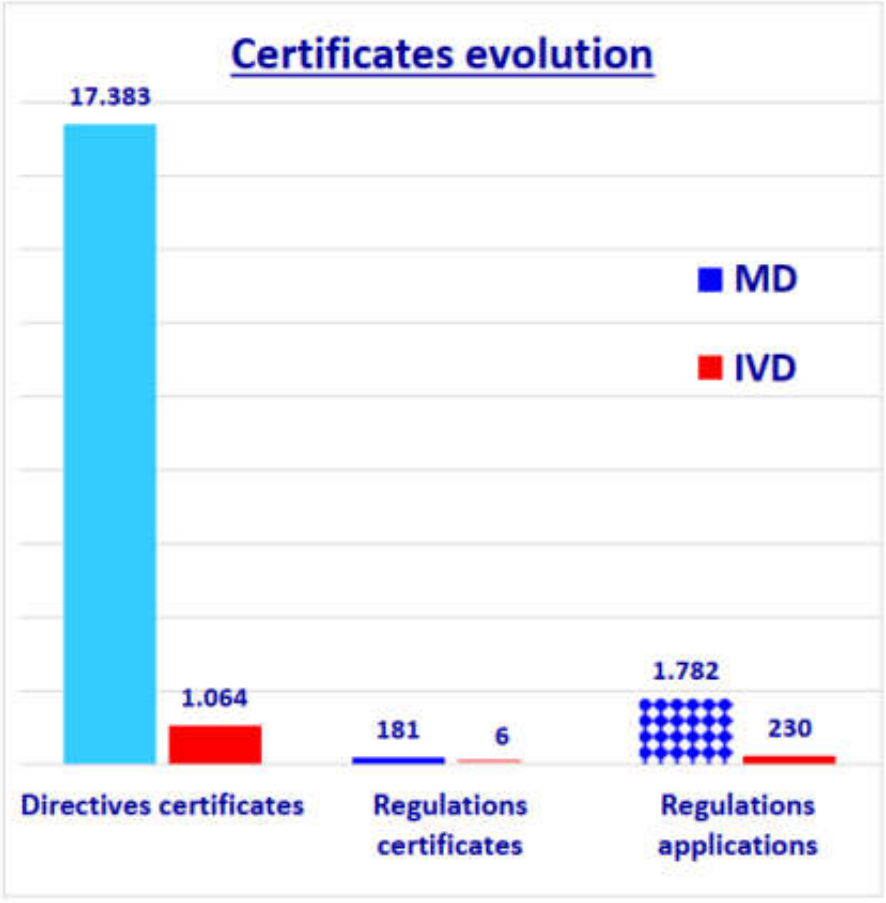
- **23 notifications** under the **MDR** [IVDR 6]

Body type ▲	Name ▲	Country
NB 2696	UDEM Adriatic d.o.o.	Croatia
NB 0537	Eurofins Expert Services Oy	Finland
NB 0598 (ex-0403)	SGS FIMKO OY	Finland
NB 0459	GMED SAS	France
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany
NB 0124	DEKRA Certification GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0297	DQS Medizinprodukte GmbH	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0373	ISTITUTO SUPERIORE DI SANITA'	Italy
NB 0476	KIWA CERMET ITALIA S.P.A.	Italy
NB 0477	Eurofins Product Testing Italy S.r.l.	Italy
NB 1936	TUV Rheinland Italia SRL	Italy
NB 0344	DEKRA Certification B.V.	Netherlands
NB 1912	DARE!! Services B.V.	Netherlands
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2460	DNV Product Assurance AS	Norway
NB 2265	3EC International a.s.	Slovakia
NB 2862	Intertek Medical Notified Body AB	Sweden

Notified Body capacity

Team NB survey press release mid April 2021

- **Transition process form directives to regulations**



… Notified Body capacity

information from DG SANTE, 27 May 2021

The big part (ca. 70 %) of existing certificates is covered by NBs designated under the MDR but …

… Notified Body capacity

- is a **serious issue**
- **23 notifications** under the **MDR** [IVDR 6]
- manufacturers wait for certifications

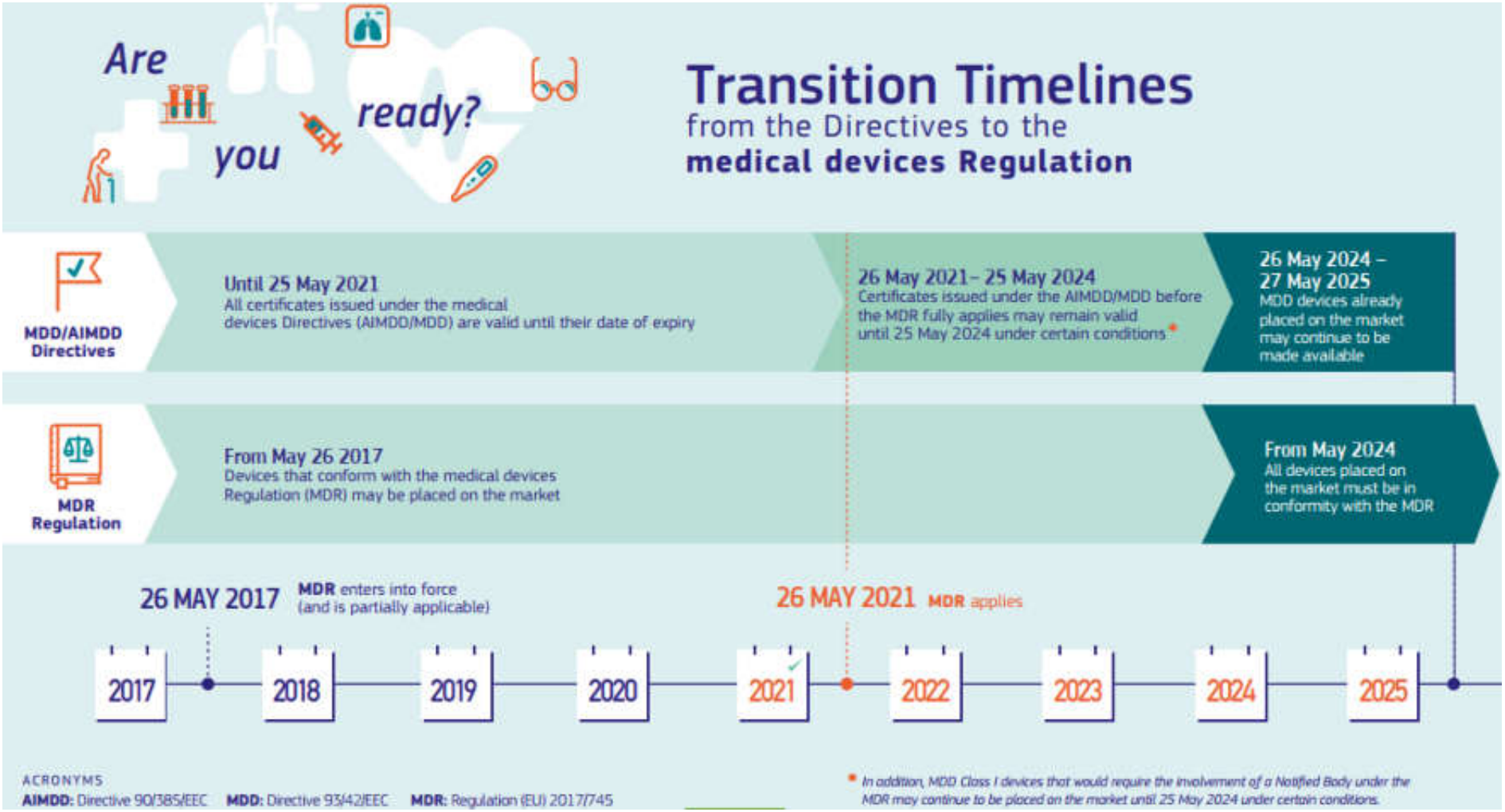
- Consequences?

https://www.daserste.de/information/wirtschaft-boerse/plusminus/sendung/swr/medizinprodukte-106.html

Let‘s focus on some special aspects

- status of implementing acts
- guidance documents
- harmonised standards
- new designations & notifications of notified bodies
- notified body capacity
- **transitional provisions**
- scientific bodies – expert panels
- backbone EUDAMED – state of play

Transition provisions



https://ec.europa.eu/health/sites/health/files/md_newregulations/docs/timeline_mdr_en.pdf

How to understand Article 120 (3) MDR?

- also with the one year postponement there were / are still controversial dicussions
- necessary guidance for the surveillance to be done by the (old) notified bodies is still not there

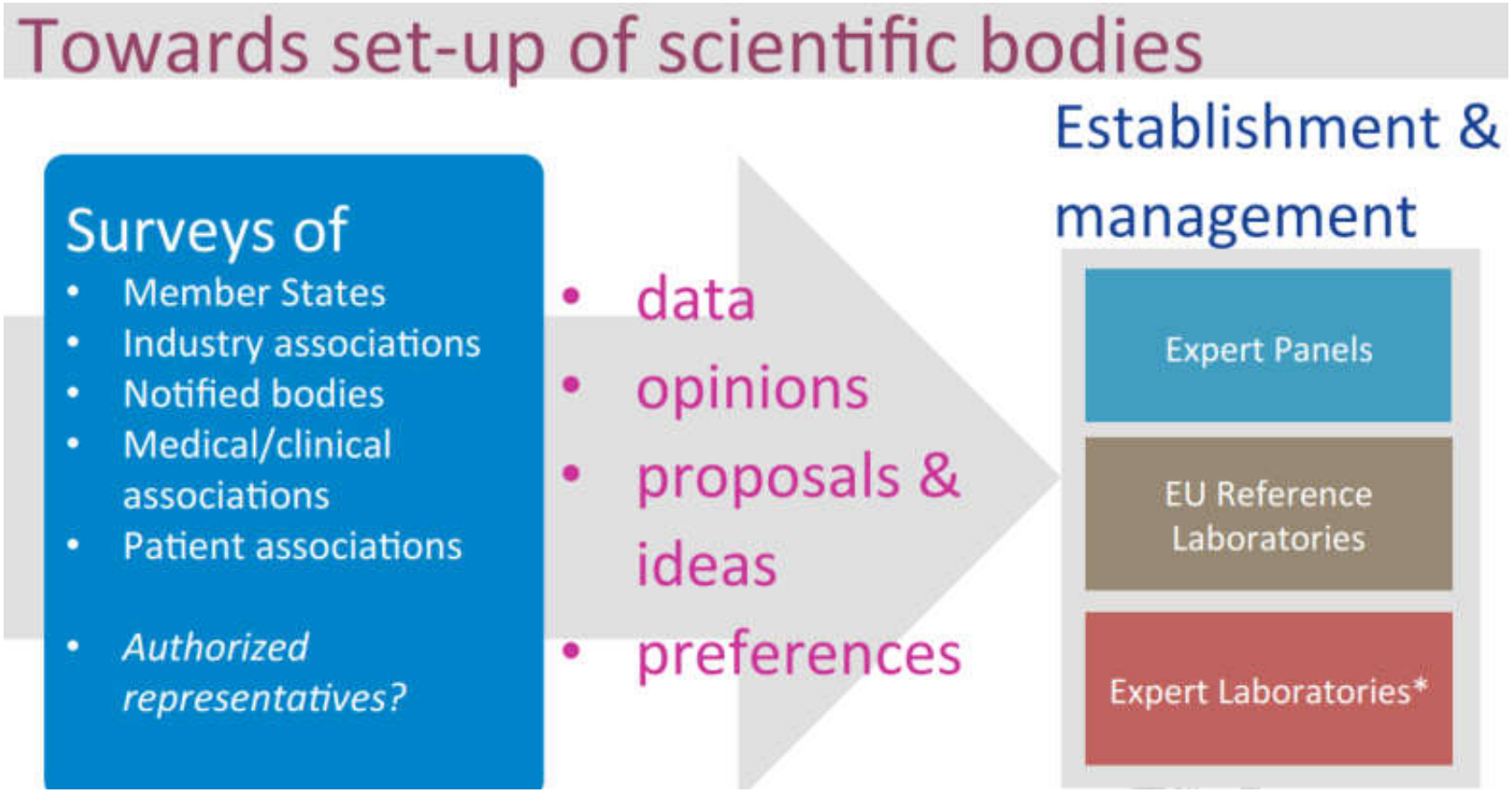
- What is with **PSURs**, the **periodic safety update reports?**
- Does **Article 86** (and others) apply for the so called **legacy devices?**
- **agreement expected this week**

Let‘s focus on some special aspects

- status of implementing acts
- guidance documents
- harmonised standards
- new designations & notifications of notified bodies
- notified body capacity
- transitional provisions
- **scientific bodies – expert panels**
- backbone EUDAMED – state of play

Current Commission activities

[Fig. DG GROW, May 2018]



Rolling Plan of Commission: expected 3rd quarter 2019

Expert panels

- See MDR Art. 106
- Commission Implementing Decision (EU) 2019/1396 of 10 September 2019
- expert panels **operational since Q2 2021**
- only for **CECP**
- advice according to MDR Art. 61 (2) not yet available

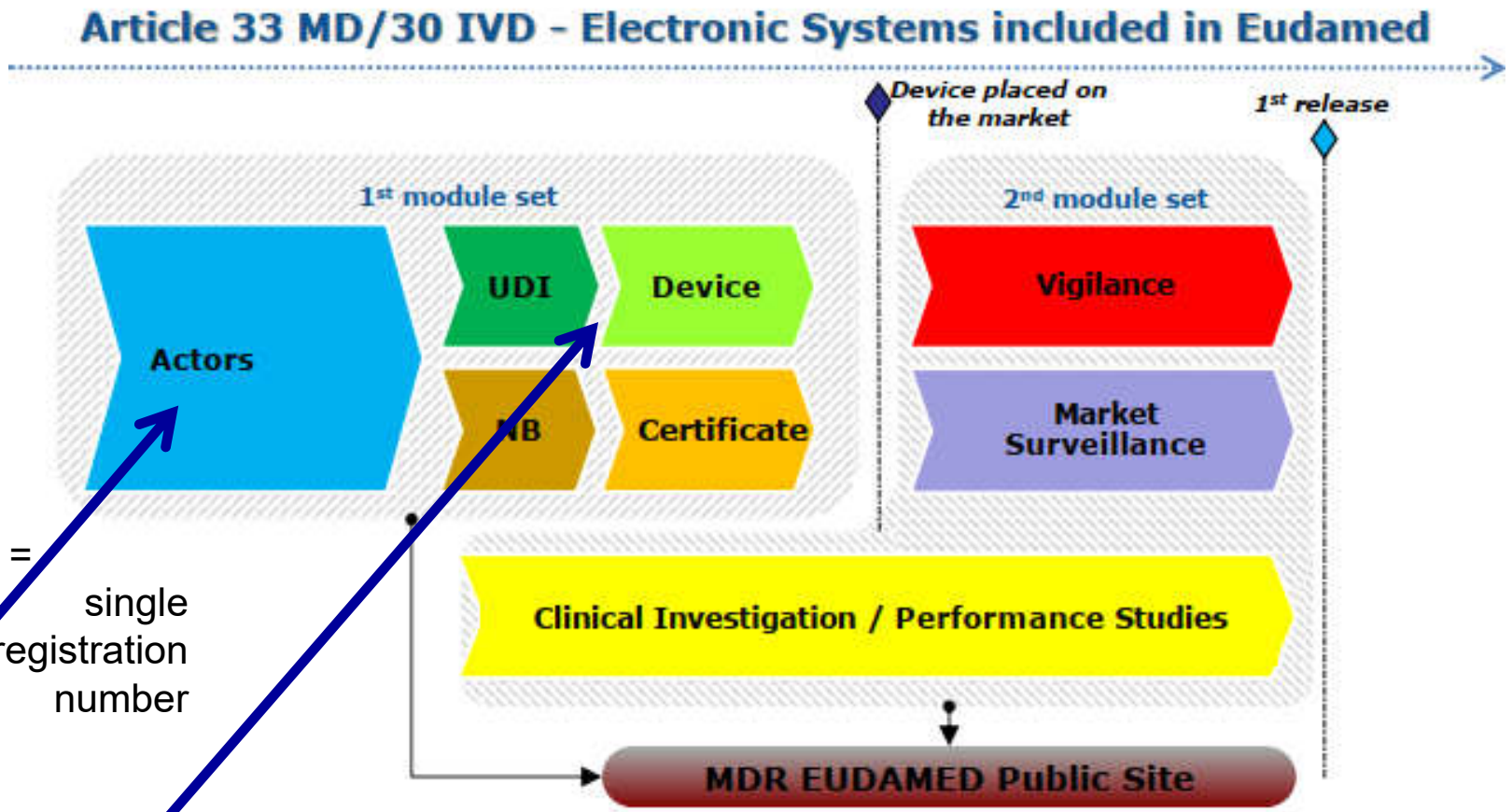
https://ec.europa.eu/health/md_expertpanels/overview_en

Let‘s focus on some special aspects

- status of implementing acts
- guidance documents
- harmonised standards
- new designations & notifications of notified bodies
- notified body capacity
- transitional provisions
- scientific bodies – expert panels
- **backbone EUDAMED – state of play**

New EUDAMED

[Fig. from DG GROW, May 2018]

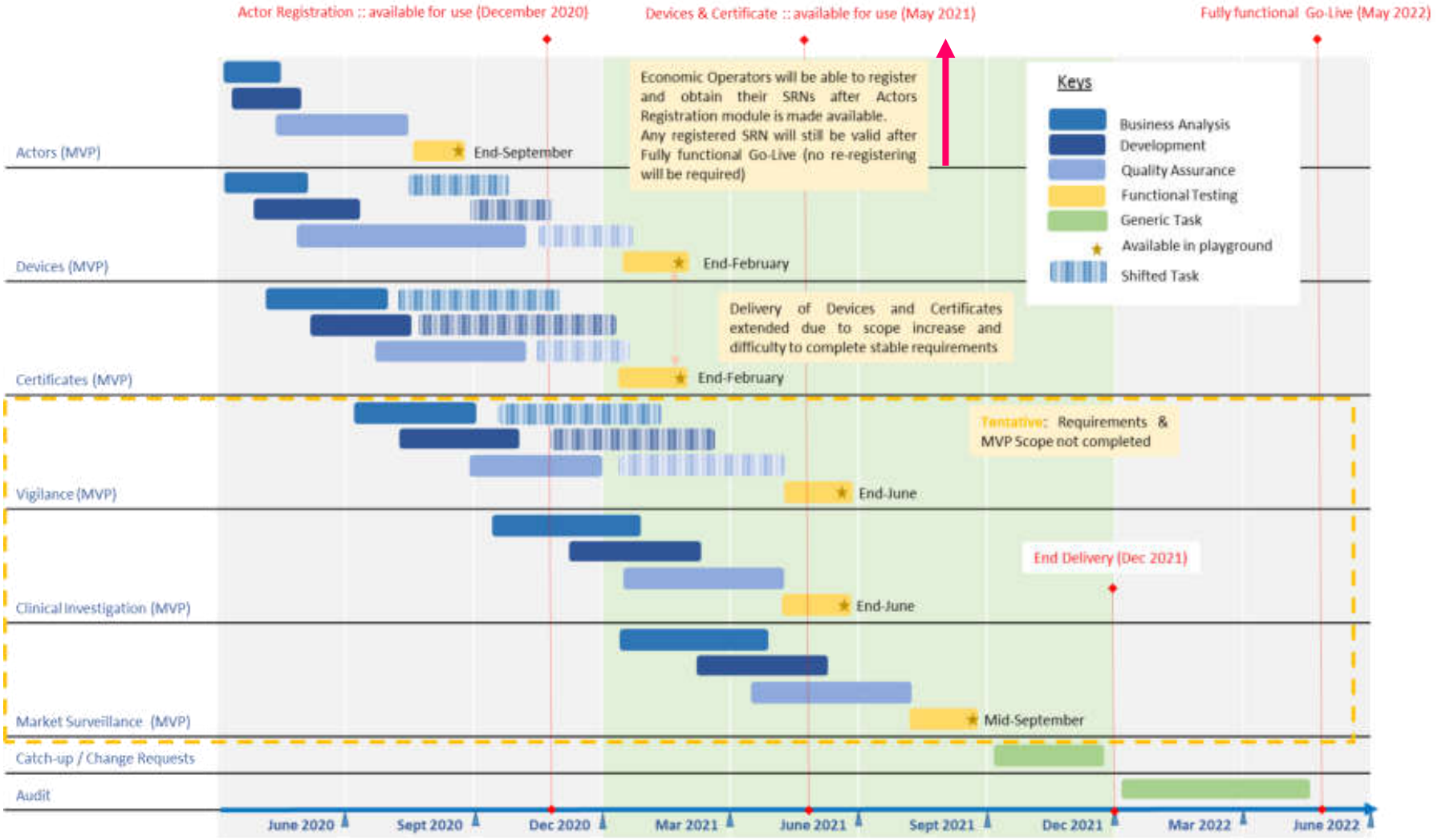


SRN = single registration number

Basic UDI-DI

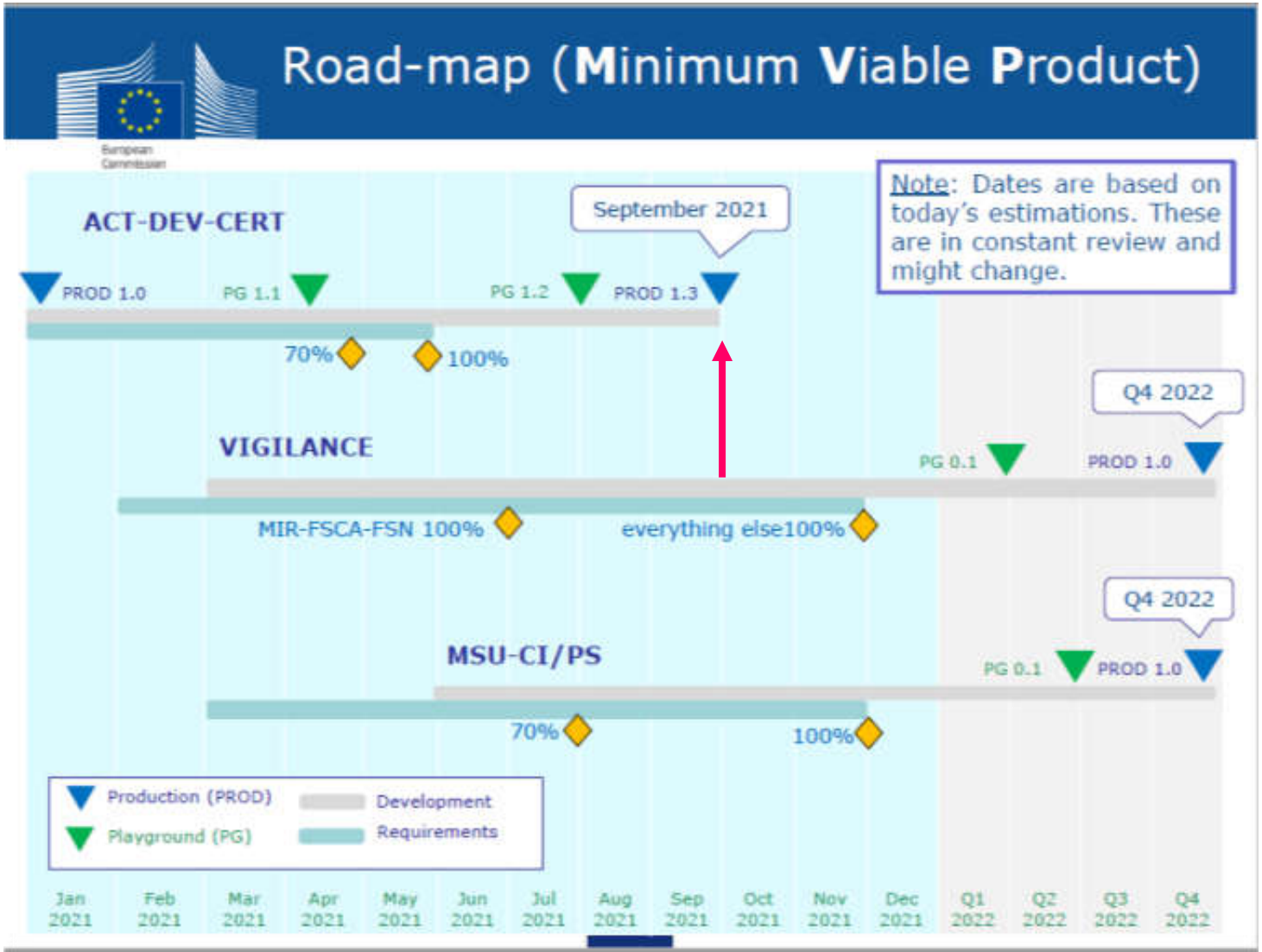
New EUDAMED

[Fig. DG SANTE, MDCG + Stakeholder, Okt 2020]



New EUDAMED

[Fig. DG SANTE, April 2021]



… New EUDAMED

- Where are we?
- **actor registration** module released end of 2020
- module on **UDI/device registration** and module on **Certificates and Notified Bodies** expected to be released in September
- currently playground
- all to be used first on a **voluntary basis**
- Will it be fit for purpose?

Summary

- significantly **increased requirements** for all "players"
- a lot of open questions and missing alignments
- **transitional provisions** are still not clearly defined
- **NB capacity** issue will have consequences
- implementation will take much more time

Thank you very much for your attention!

Contact

Dr. Rainer Edelhäuser
c/o Zentralstelle der Länder für Gesundheitsschutz
bei Arzneimitteln und Medizinprodukten
Heinrich-Böll-Ring 10
D-53119 Bonn