20th DGRA Annual Congress, WCCB, 15. June 2018

Medical Device Regulation EU – Challenges for Notified Bodies and Manufactures

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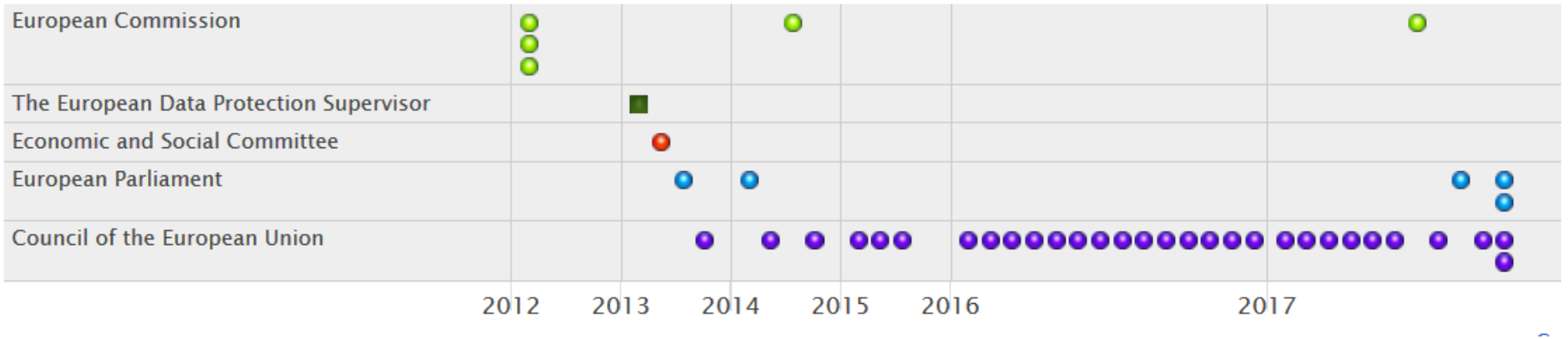
Medical Device Regulation

Procedure 2012/0266/COD

COM (2012) 542: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, and amending 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Adopted



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

A long way with a – even longer – history …

Content

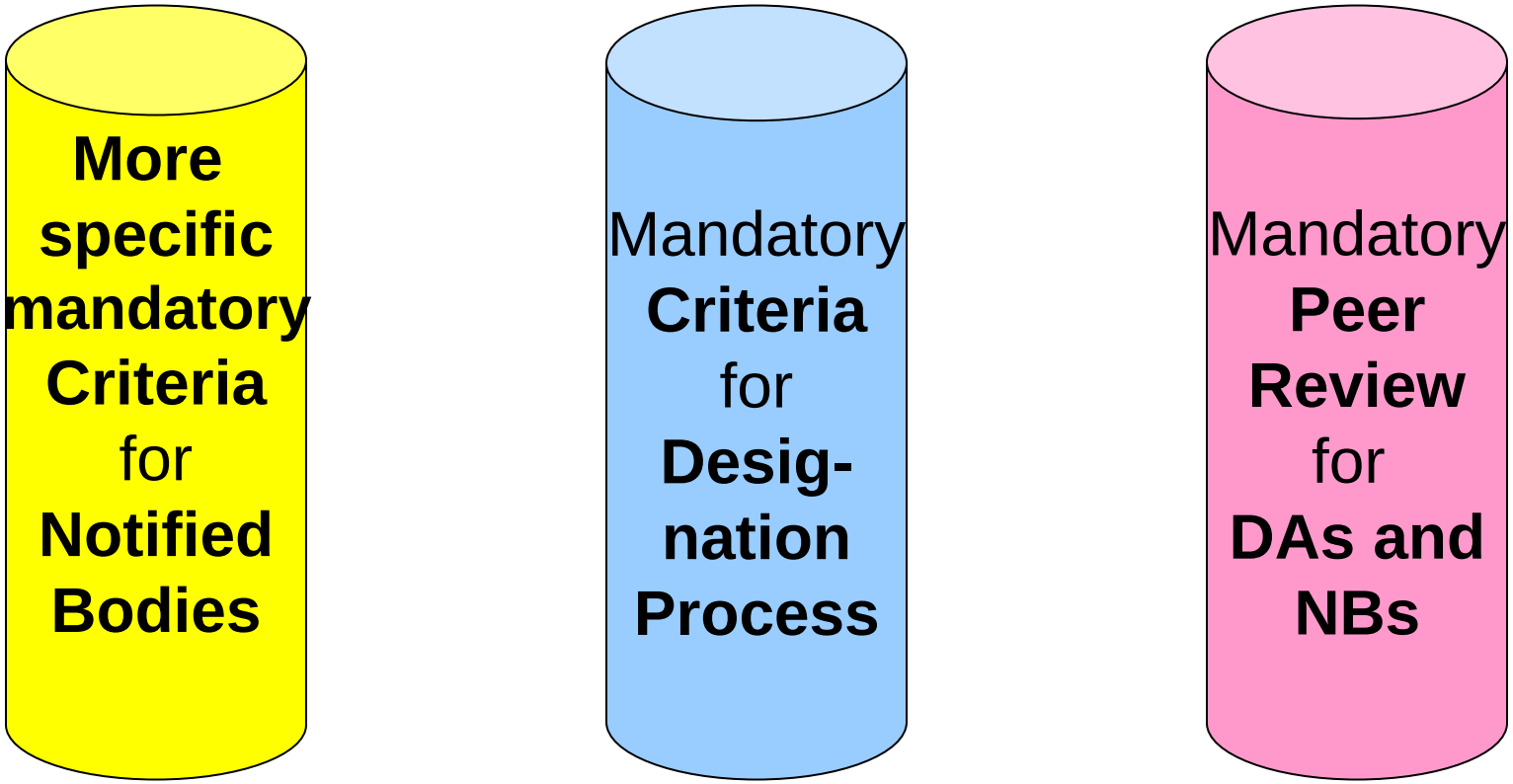
- Brief look back – some history
- The Medical Device Regulation (MDR)
  - Brief overview
  - Some facts and structural elements
  - Activities of Commission and Member States
- New designation process and new requirements for notified bodies
- New monitoring requirements
- Summary and discussion

Directive 2007/47/EG

- Increased requirements for conformity assessment activities of notified bodies = **assessment of technical documentations** of class IIa / IIb devices
- **Despite knowing the need for improvement** in the area of designation and monitoring of notified bodies **no changes** of the **requirements** have been included
- but a **provision for an implementing act** to ensure consistent application of designation criteria (see MDD Art. 16)

Member State‘s Working Group discussions

Following Directive 2007/47/EC, for the Designation and Monitoring of Notified Bodies **three areas** needing an update or to be introduced have been identified



In December 2011 “PIP happend“

… the so called **“breast-implant scandal“**

- exceptional case, **fraud**
- European Commission (DG SANCO) switched to **“crisis mode”**
- Announcement of **short-term activities**
  https://ec.europa.eu/growth/sectors/medical-devices/pip-action-plan_en
  -> 2012 **Dalli-Plan** for immediate actions … incl.
  -> **Implementing Regulation** (EU) 920/2013 up to
  -> 2017 **MDR**

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The Medical Device Regulation (MDR)

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

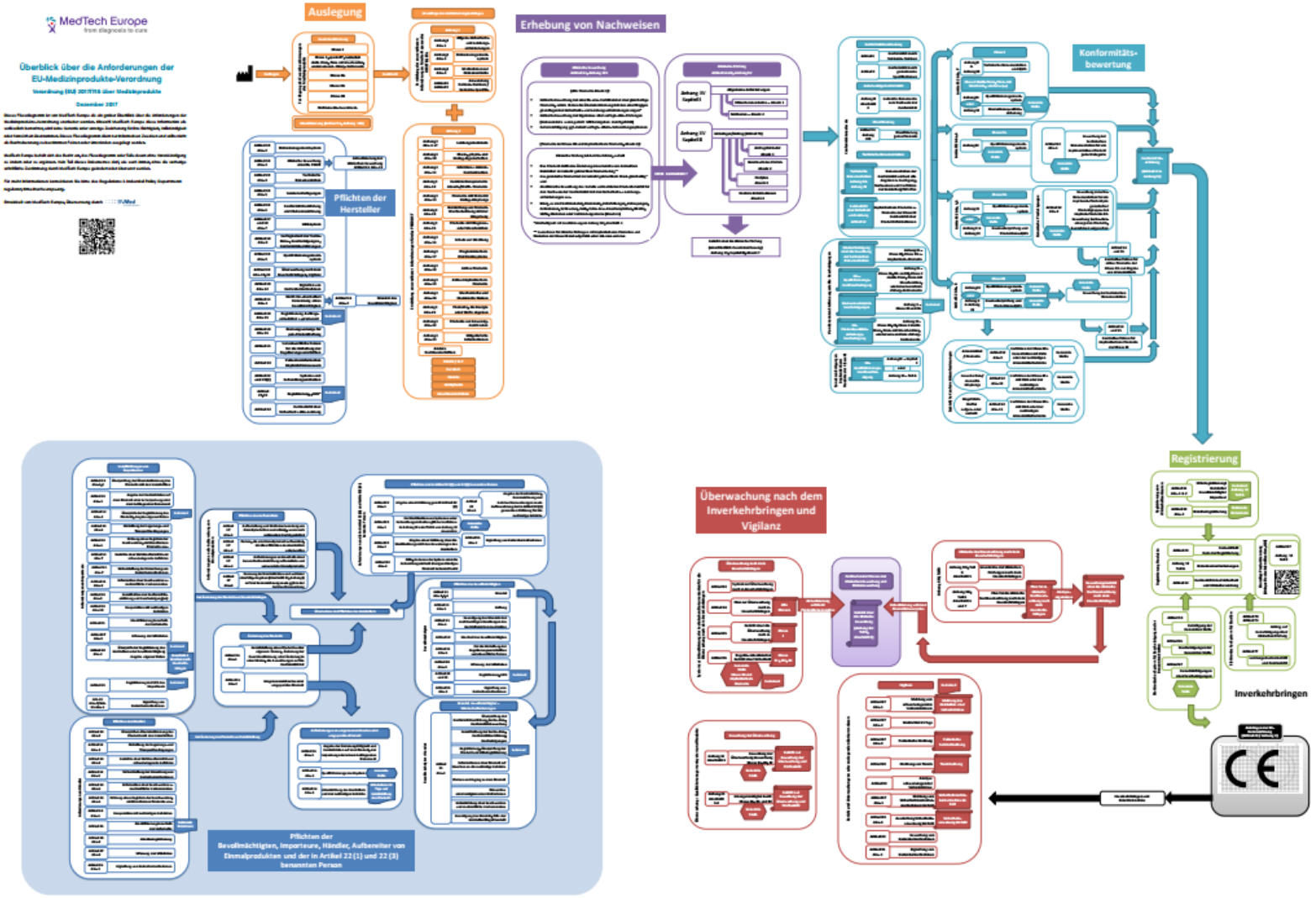
- OJ L 117/1 5.5.2017
- will **replace directives 90/385/EEC** (AIMDD) and **93/42/EEC** (MDD)
- (in principle) **direct applicable law**
- national adaptations e.g. for assignment of competences required

… The Medical Device Regulation (MDR)

- 175 pages, 10 Chapters, 123 Articles (in MDD 23), XVI (XVII) Annexes
- date of application = 26 May 2020
- **expanded scope** covering e.g. also listed **devices without an intended medical purpose** (Ann. XVI)
- increased **registration, identification (UDI), documentation and information requirements**
- central element will be a database = **new Eudamed**
- new **governance structure**
- complex **transitional provisions**

… The Medical Device Regulation (MDR)

https://www.bvmed.de/de/recht/rechtsrahmen/eu-medizinprodukte-verordnung/poster-uebersicht-mdr-flowchart-2017



Transitional provisions

[added after discussion]

- see MDR Article 120
- date of application = 26 May 2020; earlier application (partially) possible – details p. 20 & NAKI FAQ zur MDR
- immediate need for certificates according to new classifications?
  Only in case where the current law does not require a certificate, e.g. **for reusable surgical instruments (new class I r)** or in case of change from class I to IIa or higher
- use of this option is limited until 2024, for devices lawfully placed on the market bevor 2020 to 2015 (MDR Art. 120 (4) and definitions in Art. 2)

… Transitional provisions

[added after discussion]

- For interpretation of "**placing on the market**" [current law] see

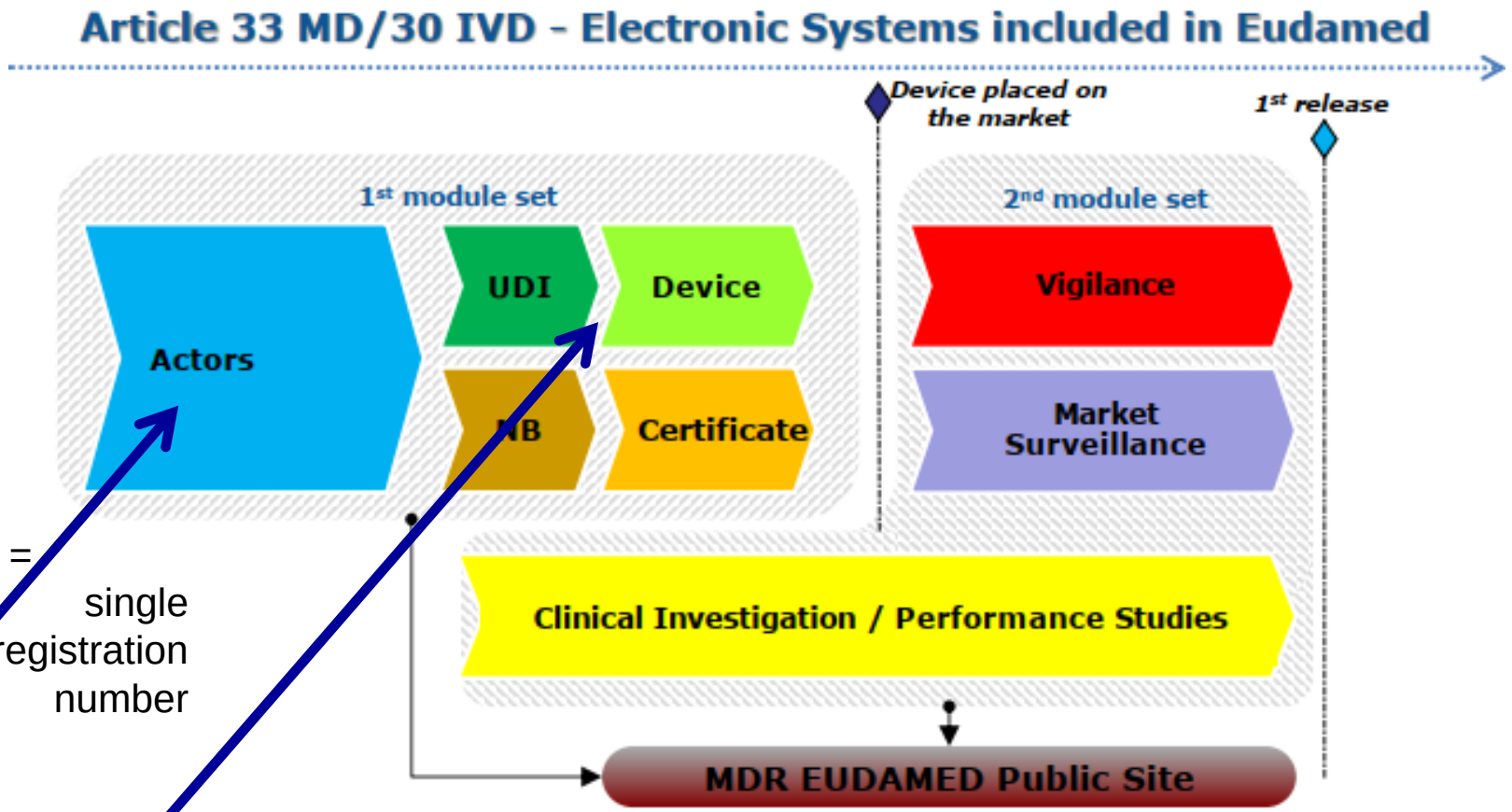
  Informative document of the Commission's services on placing on the market of medical devices
  https://ec.europa.eu/docsroom/documents/10265/attachments/1/translations/en/renditions/native

  from 16 November 2010

- **refers to the individual product**, not the type!

New Eudamed

[Fig. from DG GROW, May 2018]

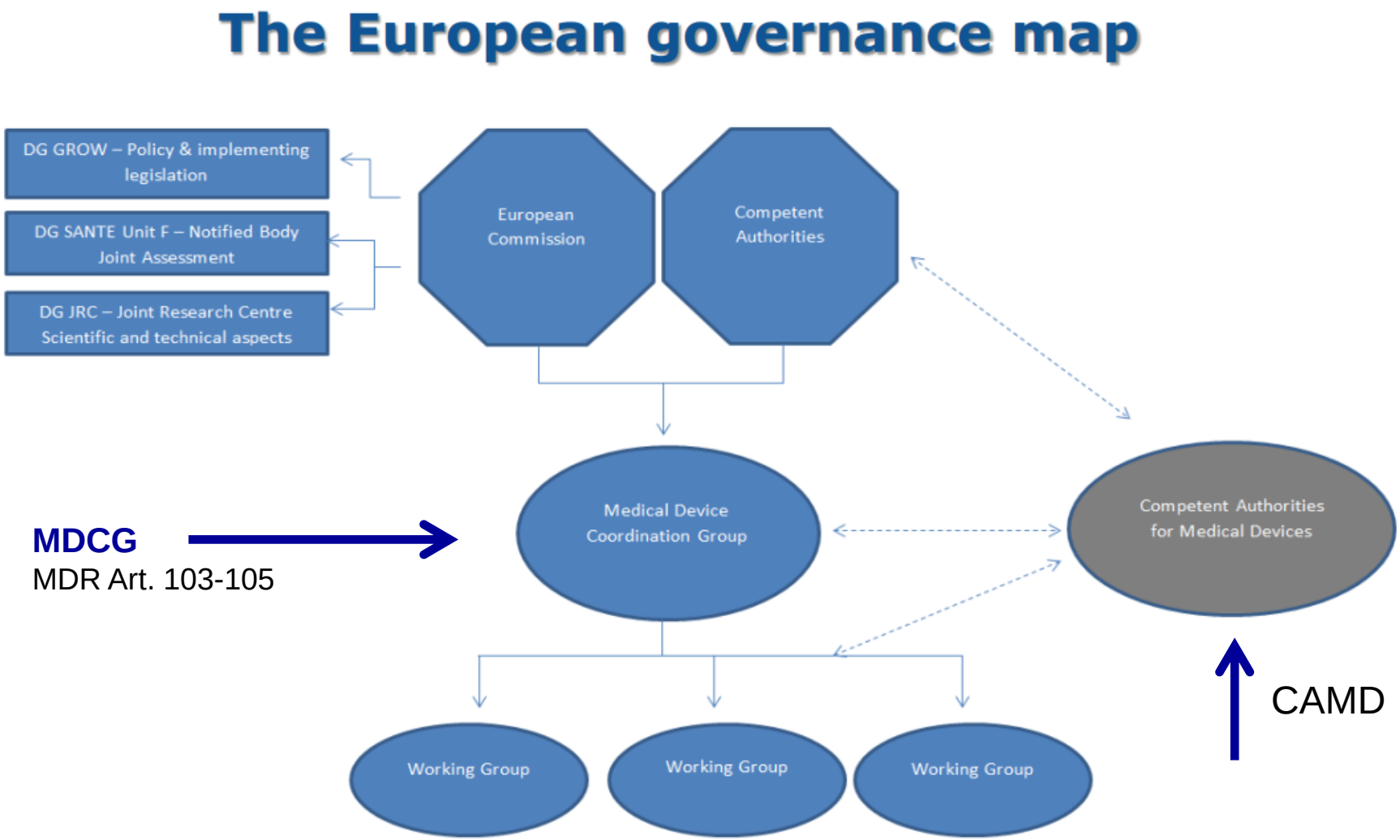


SRN = single registration number

Basic UDI-DI

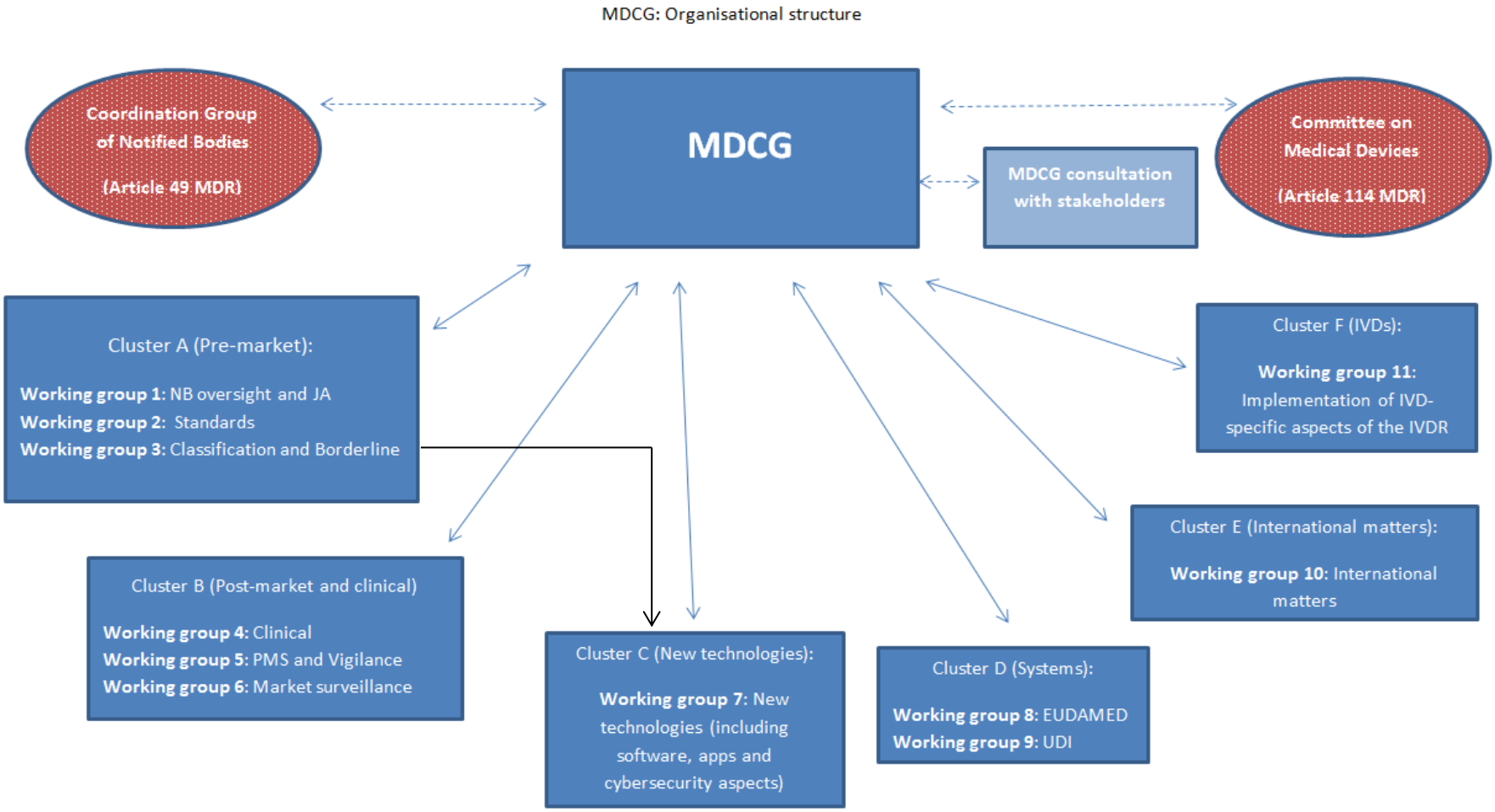
New Committee structure

[Fig. from DG GROW, May 2018]



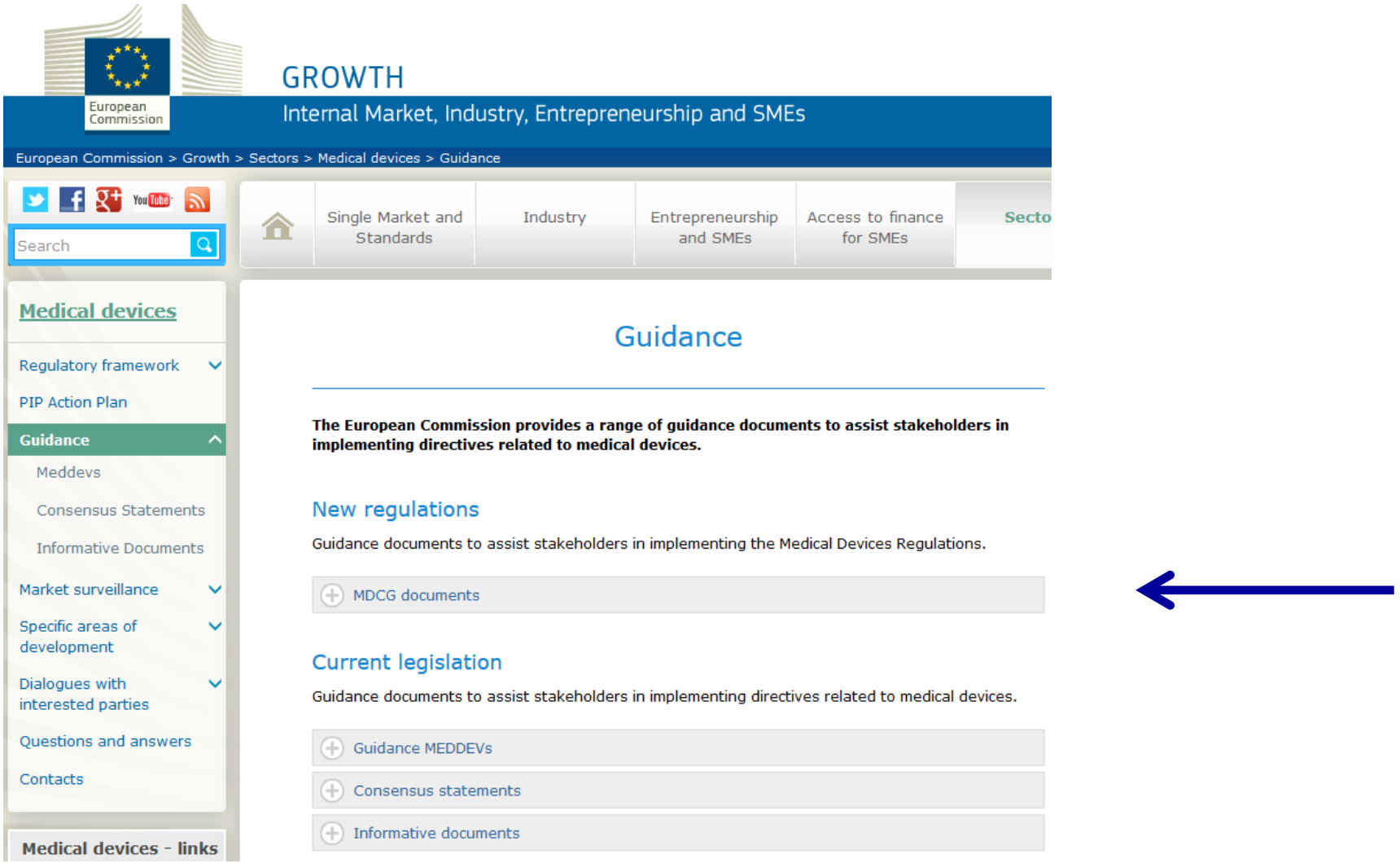
… New Committee structure

[Fig. from DG GROW, May 2018]



MDCG output on Commission‘s website

https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

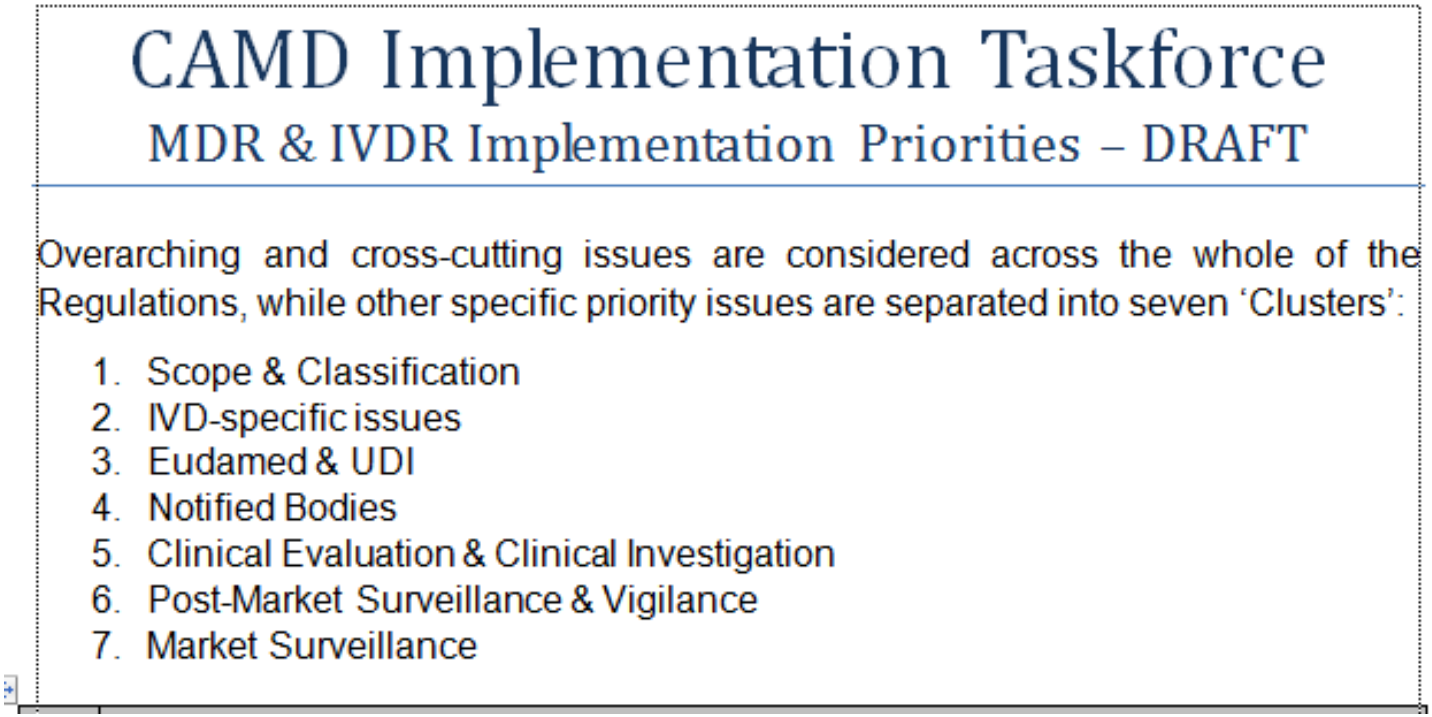


Current Commission activities

- **Short term** e.g.
  - **setting up of MDCG subgroups**
  - communication campaign and
  - plan for implementation of **functional specifications for Eudamed**
- **Medium-long term** e.g.
  - **implementing acts** (e.g. for Art. 17, Annex XVI devices)
  - guidance documents
  - establishment of **expert panels,** expert laboratories and **EU reference laboratories**

CAMD Executive Group
Task Force on Implementation

- Two **Stakeholder Meetings** in 2017
- Identification of priority issues



CAMD Implementation Taskforce

MDR & IVDR Implementation Priorities – DRAFT

Overarching and cross-cutting issues are considered across the whole of the Regulations, while other specific priority issues are separated into seven 'Clusters':

1. Scope & Classification
2. IVD-specific issues
3. Eudamed & UDI
4. Notified Bodies
5. Clinical Evaluation & Clinical Investigation
6. Post-Market Surveillance & Vigilance
7. Market Surveillance

- https://www.camd-europe.eu/

… CAMD Executive Group
Task Force on Implementation

- **Roadmap** published November last year

Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap

By Andrew Queen / On November 7th, 2017 / In Regulatory

Download the Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap from the CAMD Implementation Taskforce.

https://www.camd-europe.eu/news/

… CAMD Executive Group Task Force on Implementation

The CAMD network publishes FAQ documents covering the transitional provisions of the MDR and IVDR.

These documents were developed by the CAMD Transition Subgroup (TSG) which was tasked with agreeing and providing greater clarity on the transition-related provisions in the new Regulations.

The TSG has answered around 20 initial questions on the following topics:

- Placing on the market of MDR/IVDR compliant devices until 26 May 2020/2022
- Placing on the market of AIMDD/MDD/IVDD compliant devices after 26 May 2020/2022
- The so called "sell off" provision of Art. 120 para 4 MDR / Art. 110 para 4 IVDR
- EUDAMED and its relevance for the application of certain provisions of the MDR/IVDR.

These FAQs will evolve and expand as the TSG continues to address the key issues, and will act as an aid to the consistent interpretation of the transition articles.

= European transposition of output from **BMG NAKI** transition subgroup (UG 1)

https://www.bundesgesundheitsministerium.de/naki.html

Download the **MDR Transition Provisions FAQ** and **IVDR Transition Provisions FAQ** from the CAMD Transition Subgroup.

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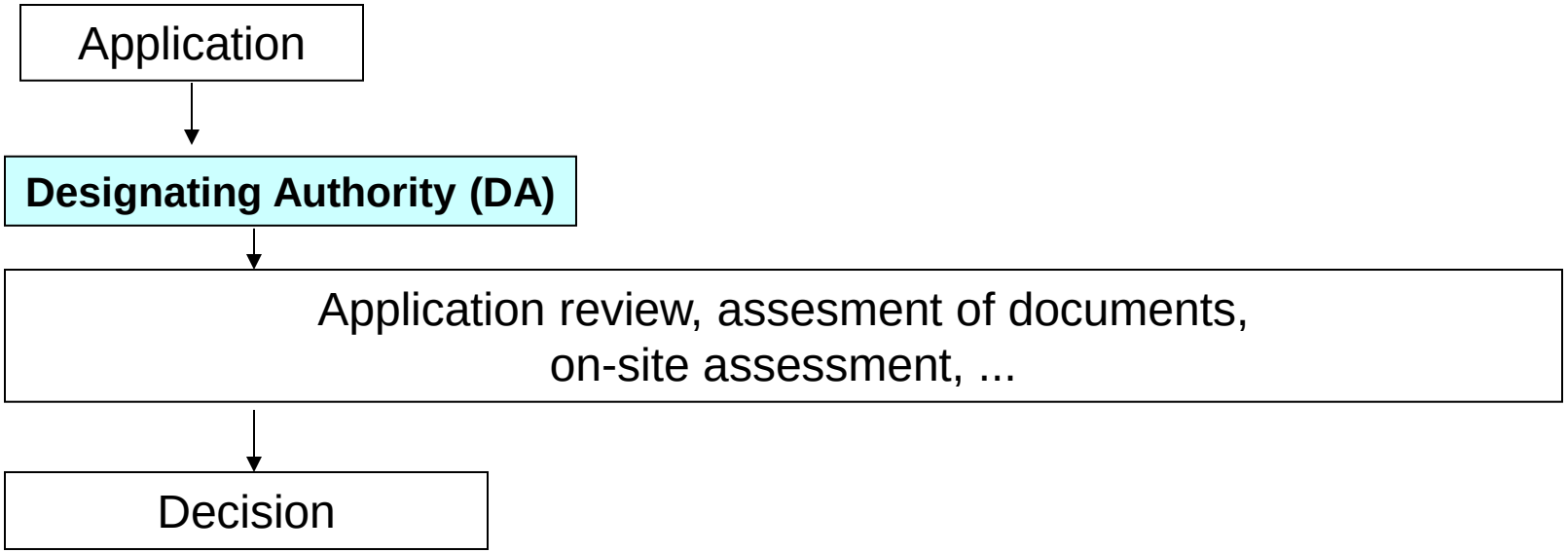
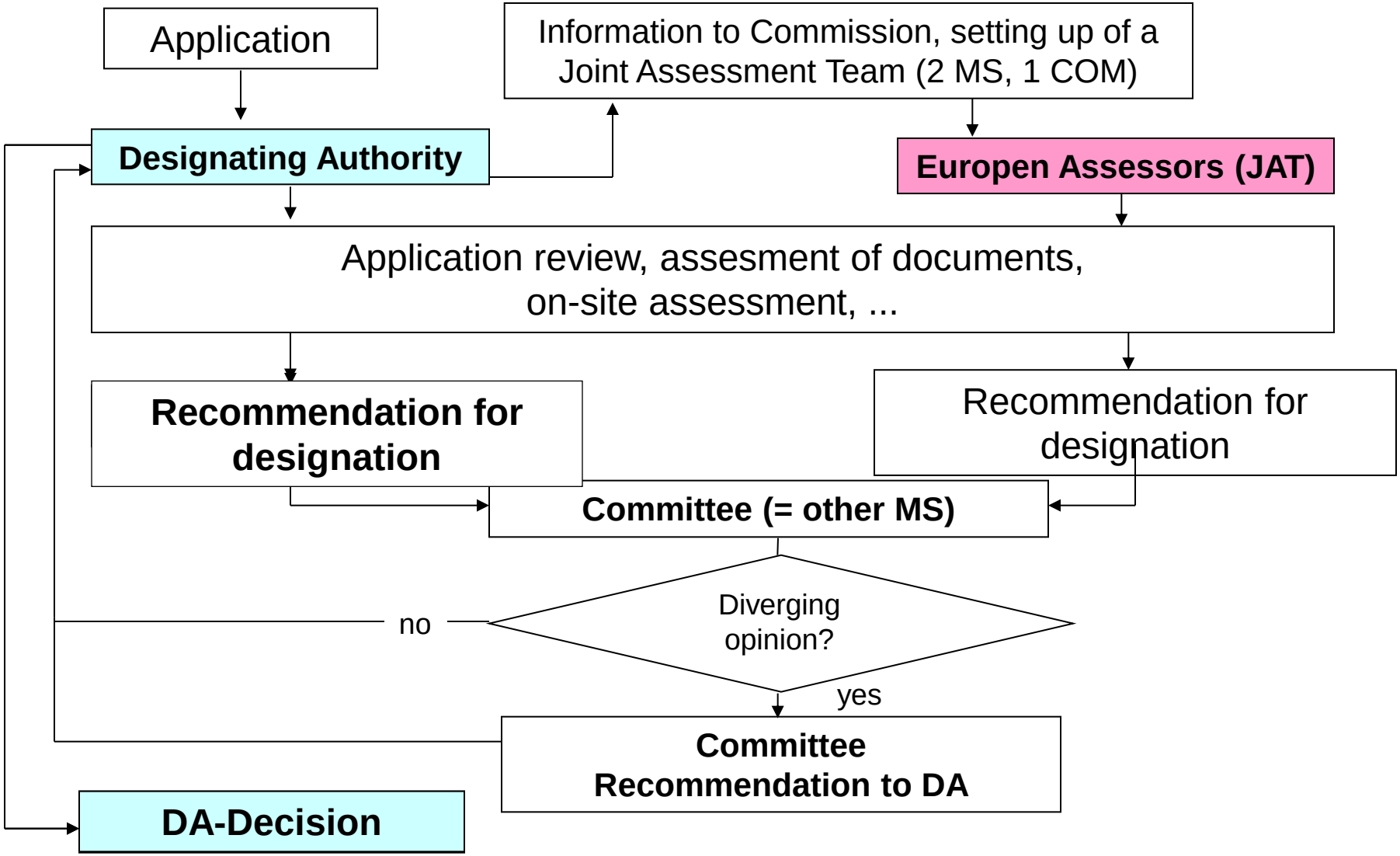
Previous process of designation (schematical)



New process of designation (schematical)



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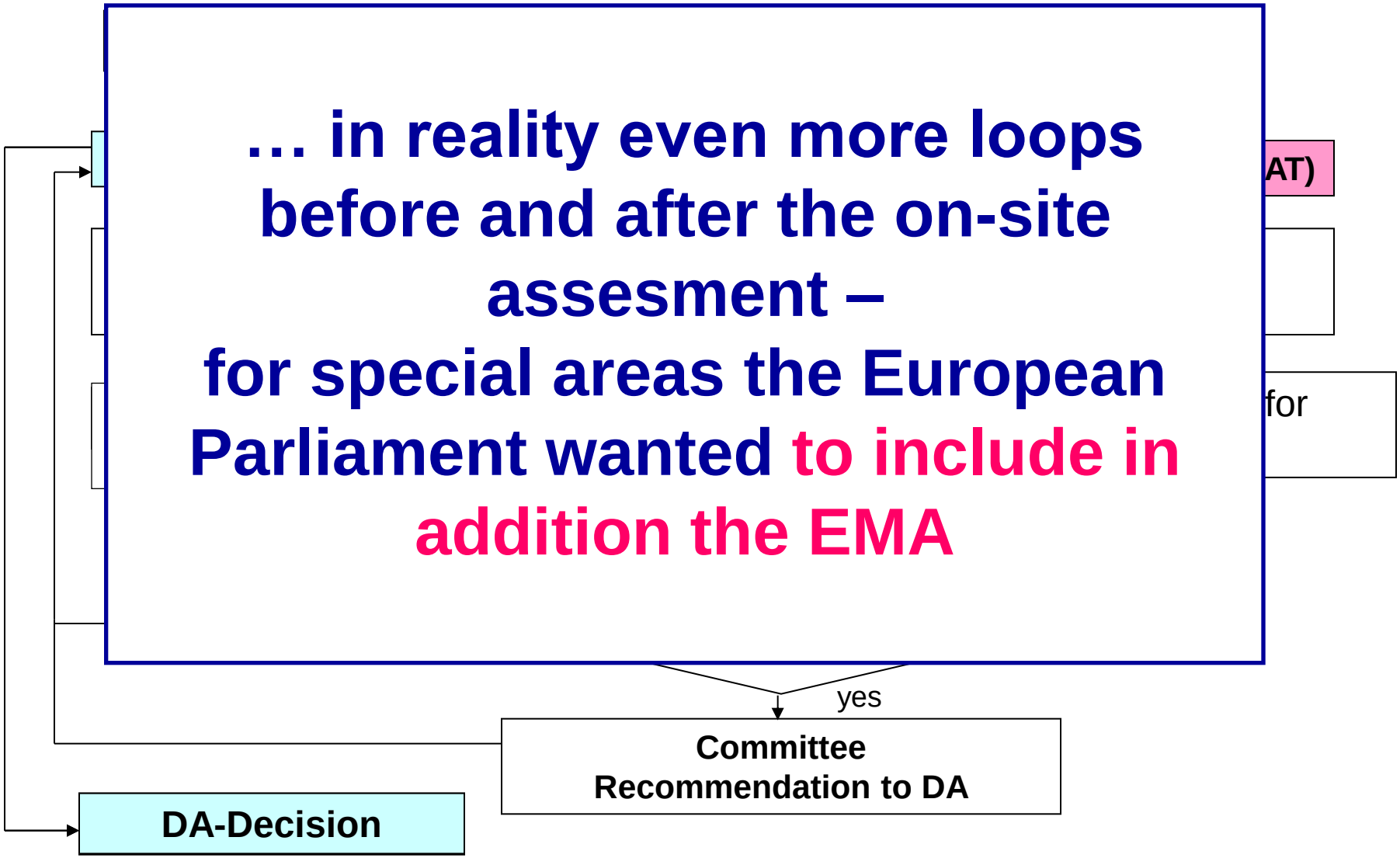


Annex VII Requirements to be met by NBs

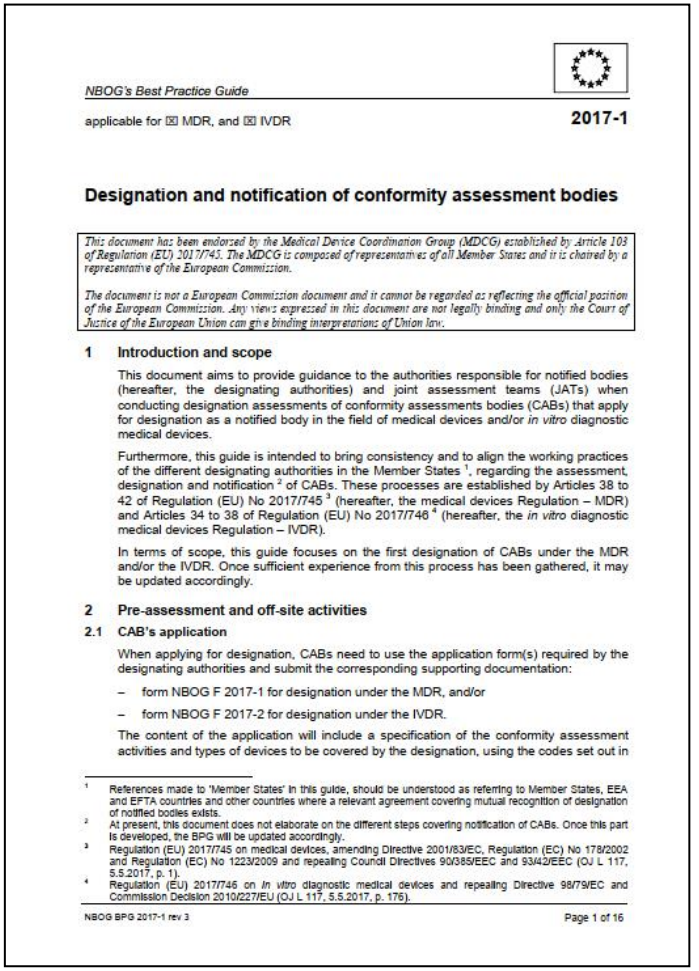
- **Organisational and general requirements**
  legal status and organisational structure, independence and impartiality, confidentiality, liability, financial requirements, participation in coordination activities
- **Quality management requirements**
- **Resource requirements**
  qualification criteria in relation to personnel, …, subcontractors and external experts, …
- **Process requirements**
  Application review / contract, allocation of resources, conformity assessment activities, decisions, certifications, surveillance, changes

Requirements – Designation

- for **MDR** a **new Designation** is mandatory
- Applications are possible since 26 November 2017
- Implementing regulation for **scope of designation** (Art. 42 (13)) -> (EU) **2017/2185** from 23 Nov 2017
- **Joint assessment process** (joint assessments) in principle comparable to those defined in the Commission implementing regulation (EU) No. 920/2013, but **more detailled requirements** prior and after the on-site assessment
- complete **re-assessment** first after **3 years**, then every four years (MDR Art. 44 (10))

Process description

- **NBOG Best Practice Guide 2017-1**
- and application forms (scope, documents to be delivered)
- detailled description of the process
- will be amended based on experience
- others in preperation



NBOG's Best Practice Guide

applicable for ☒ MDR, and ☒ IVDR

2017-1

Designation and notification of conformity assessment bodies

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

1 Introduction and scope

This document aims to provide guidance to the authorities responsible for notified bodies (hereafter, the designating authorities) and joint assessment teams (JATs) when conducting designation assessments of conformity assessments bodies (CABs) that apply for designation as a notified body in the field of medical devices and/or *in vitro* diagnostic medical devices.

Furthermore, this guide is intended to bring consistency and to align the working practices of the different designating authorities in the Member States [1], regarding the assessment, designation and notification [2] of CABs. These processes are established by Articles 38 to 42 of Regulation (EU) No 2017/745 [3] (hereafter, the medical devices Regulation – MDR) and Articles 34 to 38 of Regulation (EU) No 2017/746 [4] (hereafter, the *in vitro* diagnostic medical devices Regulation – IVDR).

In terms of scope, this guide focuses on the first designation of CABs under the MDR and/or the IVDR. Once sufficient experience from this process has been gathered, it may be updated accordingly.

2 Pre-assessment and off-site activities

2.1 CAB's application

When applying for designation, CABs need to use the application form(s) required by the designating authorities and submit the corresponding supporting documentation:

– form NBOG F 2017-1 for designation under the MDR, and/or

– form NBOG F 2017-2 for designation under the IVDR.

The content of the application will include a specification of the conformity assessment activities and types of devices to be covered by the designation, using the codes set out in

[1] References made to 'Member States' in this guide, should be understood as referring to Member States, EEA and EFTA countries and other countries where a relevant agreement covering mutual recognition of designation of notified bodies exists.

[2] At present, this document does not elaborate on the different steps covering notification of CABs. Once this part is developed, the BPG will be updated accordingly.

[3] Regulation (EU) 2017/745 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 (OJ L 117, 5.5.2017, p. 1).

[4] Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

NBOG BPG 2017-1 rev 3 Page 1 of 16

… Requirements – Area of Notified Bodies

- **93/42/EEC**
  one Article (Art. 16), Annex XI (3/4 p.)
- **Implementing regulation** (EU) No. 920/2013
  10 Articles, 2 Annexes, 12 pages in total
- **MDR** Chapter IV (9 pages, ca. 15 Articles), Annex VII (16 pages, with > 50 % description of the process)

?

Yes, in principle, but …

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New (monitoring) requirements

Medical Device Regulation MDR =
Too much focus on clinical aspects?

- Tasks of Notified Bodies in this area **increased again**
- focus of the technical documentation assessments is on clinical aspects
- separate reports for the clinical evaluation assessments are required
- Notified Bodies need to review **periodic safety update reports** (**PSURs**) for class III and implantable devices annulally (see MDR Art. 86)

Requirements – for Designating Authorities

(New) **focus of assessments** (Art. 45)

- **… shall review an appropriate number of notified body assessments**
  - of manufacturers' technical documentation
  - in particular the **clinical evaluation documentation**
  - shall be conducted both **off-site and on-site**
  - recommendation on sample size (devices, numbers) can be established by the Medical Device Coordination Group (MDCG)

Requirements – for Designating Authorities

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  - in particular the **clinical evaluation documentation**
  -
  -

… this includes the manufacturer‘s documentation

… new monitoring requirements

Article 54 Clinical evaluation consultation procedure for certain class III and class IIb devices

- for implantable class III devices and active class IIb devices intended to administer and / or remove a medicinal product … (Rule 12) to / from the human body
- not in case of renewals (under the MDR!), …
- notification obligation via Eudamed
- notification shall be accompanied by the **clinical evaluation assessment report**

Specific additional procedures (Anh. IX, 5.1)

- For those devices … the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 61(12), prepare **a clinical evaluation assessment report** which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan referred to in Article 10(3) and Part B of Annex XIV

  … **shall transmit** its report … **to the Commission**.

Specific additional procedures (Anh. IX, 5.1)

- The **Commission** shall immediately **transmit** those documents **to the relevant expert panel referred** to in Article 106.
- **expert panel** decides on the basis of defined criteria …
- whether to provide a scientific opinion on the clinical evaluation assessment report
- scientific opinion shall be provided within a period of 60 days
- notified body shall give due consideration to the views expressed in the scientific opinion of the expert panel
- full justification by the notifed body required in case it has not followed the advice of the expert panel

… new monitoring requirements

Article 55 Mechanism for scrutiny of conformity assessments of certain devices

- all certificates granted for the aforementioned devices need to be notified **including**
- the **summary of safety and clinical performance (SSCP)** pursuant to Article 32
- the assessment report by the notified body
- instructions for use referred to in Sect. 23.4 of Annex I
- where applicable, the scientific opinion of the expert panels referred to in Section 5.1 of Annex IX
- In the case of divergent views between the notified body and the expert panels, a full justification

… new monitoring requirements

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- the assessment report by the notified body
-
-
-

A competent authority and … the Commission may, based on reasonable concerns apply further procedures…

Summary

- General increase of requirements, especially in respect to the **clinical evaluation**
- **Time and efforts for documentation** will significantly increase for all “players“
- Question if the **“multilayer monitoring requirements“** are adequate & justified
- **Transitional provisions** are “very ambitious“

When you read

the **Interinstitutional Agreement** of 13 April 2016 on **Better Law-Making**, OJ L 123/1 of 12 May 2016 with

> … ***Union legislation should be comprehensible and clear***, *allow ... 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***

You may ask how the MDR could have been adopted …

Thank you very much for your attention!

Contact

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