The New Medical Devices Regulation

clinicians participation

Paul Piscoi

Brussels

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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

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

Regulation on *in vitro* diagnostic medical devices

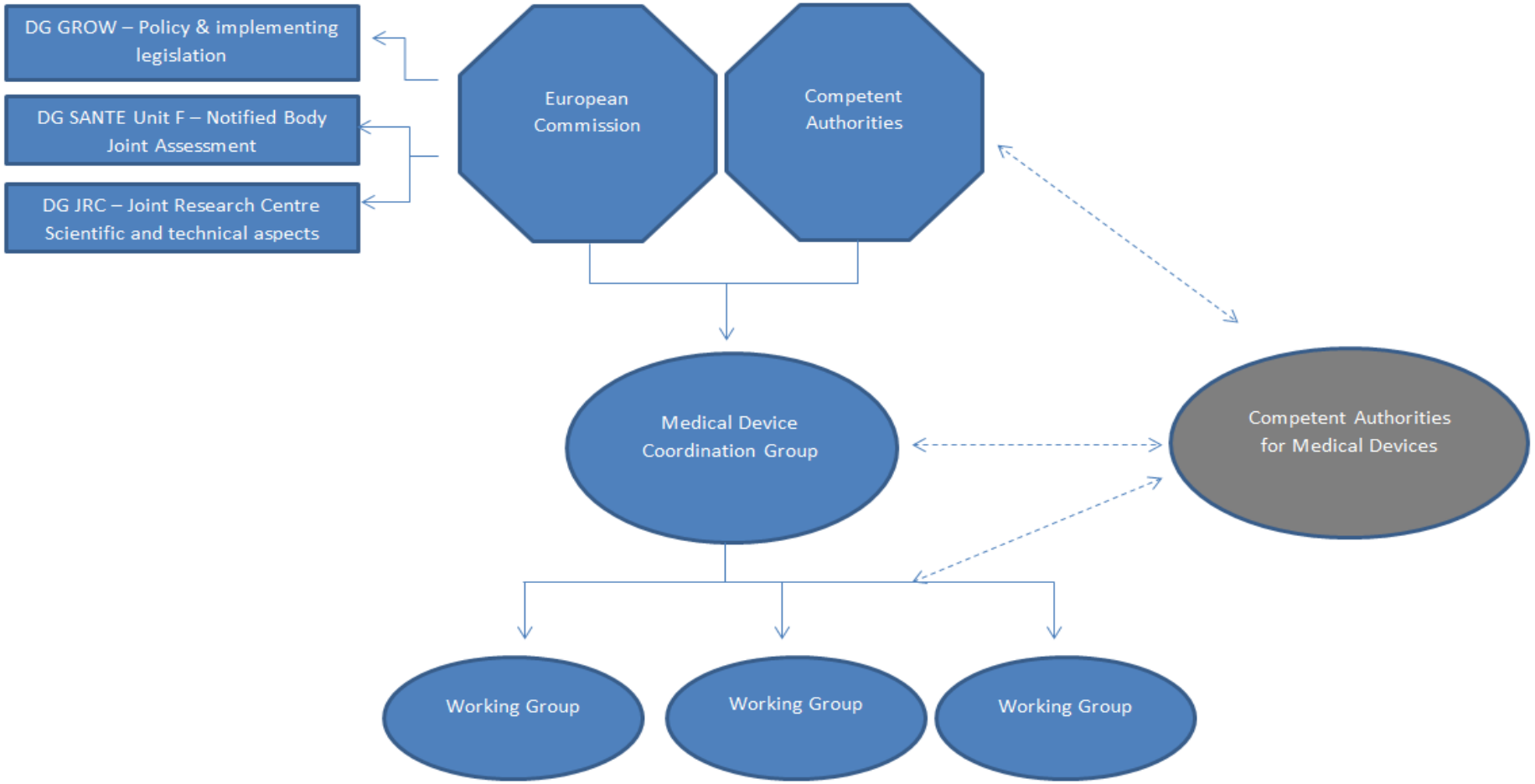
European Commission

Transitional period

Other relevant compliance timelines

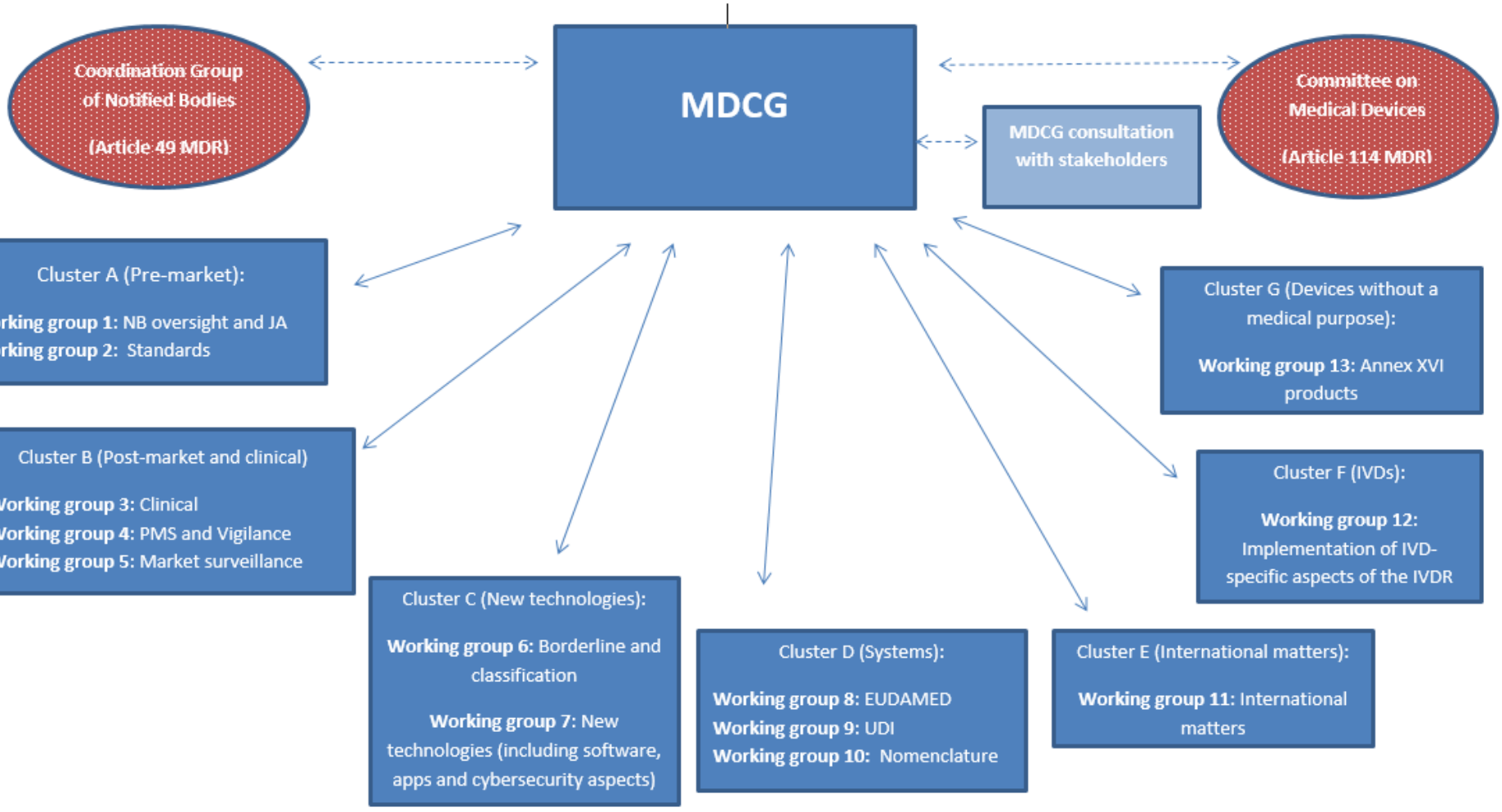
- 26 November 2021/2023 (or 24 months after Eudamed becomes available): Registration of devices (including UDI)
- 26 May 2021-2023-2025(MD)/2023-2025-2027 (IVD): UDI labelling
- 26 May 2024: Maximum period of validity of certificates issued under current Directives
- 26 May 2025: Making available of devices placed on the market pursuant to current Directives
- 26 May 2027: Coordinated procedure for clinical investigations

The European governance map for MD



European Commission

MDCG: Organisational structure



European Commission

Implementation - achieved

(1) Governance and transitional provisions

- ✓ Setting up of Medical Device Coordination Group (MDCG) - as of 26/11/2017)
- ✓ Establishment of the new technical Expert Groups (MDCG subgroups) - as of 1st March 2019
- ✓ + 2 new subgroups: Annex XVI (May 2019) and Nomenclature (September 2019)

(2) Increasing monitoring and transparency in the planning of activities

- ✓ Rolling plan listing Commission's essential actions during the transitional period: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en
- ✓ New documents on completed and ongoing work of MDCG Subgroups https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

(3) Notified Bodies

- ✓ Infrastructure and codes for the designation procedure – as of 26 November 2017
- ✓ All applications managed by the Commission within the requested timelines
- ✓ Designation of 9 Notified Bodies completed (including 2 under IVDR)
- ✓ Estimated 20 designations to be completed in the course of Q1 2020

(4) Setting up of scientific structures (expert panels, expert laboratories, reference laboratories)

- ✓ Implementing Act establishing expert panels adopted on 10 September 2019
- ✓ Call for expression of interest for expert panels finalized on 24 November 2019 https://ec.europa.eu/growth/content/call-expression-interest-expert-panels-medical-devices-and-vitro-diagnostic-medical-devices_en

Implementation - achieved

(5) Design and establishment of EUDAMED/UDI

- ✓ Plan for implementation of functional specifications completed in May 2018 and release of high-level functional specifications in March 2019
- ✓ Designation of UDI issuing entities on 6 June 2019 and many UDI guidelines and Q/A published; decision on nomenclature in March 2019

(6) IVD

- ✓ Publication of CTS on combined test adopted in July 2019

(7) Communication campaign

- ✓ New dedicated website and first updated library are live; Factsheets https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/getting-ready-new-regulations_en

(8) SCHEER's opinion on phthalates

- ✓ Published on 10 September 2019

(9) Guidelines (31) released on many crucial aspects

- ✓ Notified Bodies, UDI, Registration procedure and timelines (including legacy products), Application of Article 54(2), Incident reporting form, Implant card, PRRC, Qualification and classification of software, SSCP

(10) Corrigendums to the MDRs published in May & December 2019

- ✓ Important clarifications on sampling plans for auditing

and employment of certain types of Notified Body staff; transition for some class I devices

Implementation – next steps

1) Continuing the designation of Notified Bodies

2) EUDAMED: go-live in 2022; possible release of voluntary actor registration module by May 2020

3) Standards: Mandate to European Standardisation Organisations

4) Common specifications on Annex XVI products

5) Common specifications on reprocessing

6) Establishment of reference laboratories

7) Establishment of UDI system:
   Issuing of additional guidelines, implementation of nomenclature, establishment of UDI helpdesk

8) MDCG Guidance documents in crucial areas, notably on borderline and new classification rules, clinical evaluation, vigilance, medical software/apps

9) Communication campaign

Specific topics of interest

- Medical devices registries
- Expectations for PMS including PMCF
- Transparency – SSCP, IC, IFUs & labelling, CI report and summary
- Expert Panels and planning for Common Specifications and Harmonized Standards

Registers

Article 108 Device registers and databanks

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices setting common principles to collect comparable information. Such registers and databanks shall contribute to the independent evaluation of the long-term safety and performance of devices, or the traceability of implantable devices, or all of such characteristics.

Post-market surveillance

Post-market surveillance system of the manufacturer (Article 83)

- for each device a post-market surveillance system will be established and continuously maintained, in a manner that is proportionate to the risk class

- actively and systematically gather, record and analyse relevant data on the quality, performance and safety so as to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions;

- the data will be used in particular for […] (8 mentioned fields);

- should a need for preventive or corrective action or both be identified they will be implemented and reported; same if a serious incident is identified or a FSCA.

Post-market surveillance plan

(Article 84)

- section 1.1 of Annex III (Technical documentation on post-market surveillance);

- shall be part of the technical documentation specified in Annex II (other than custom made devices).

Post-market surveillance report

(Article 85)

For class I devices, class A and B IVDs

- summarise results and conclusions of the analyses of the post-market surveillance data;
- shall provide a rationale and description of any preventive and corrective actions taken;
- updated when necessary and made available to the competent authority upon request.

Periodic safety update report

(Article 86)

For class IIa, class IIb and class III devices, Class C and D IVDs

- for each device / for each category / or group of devices;
- summarising the results and conclusions of the analyses of the post-market surveillance data;
- rationale and description of any preventive and corrective actions taken;
- updated annually for IIb & III, class C & D IVDs when necessary for IIa devices;
- class III devices or implantable devices and class D IVDs submitted through Eudamed to the NB in charge → CAs;
- for other classes submitted to the NB in charge (CAs on request).

Clinical evaluation and PMCF

" 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following: […]

– clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;" (Article 2(48))

"The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84." (Article 62(11))

Clinical work has to be continued after the product has been placed on the market – it becomes a continuous task like post-market surveillance.

Annex XIV Clinical evaluation and post-market clinical follow-up

Part B: Post-Market Clinical Follow-Up

- a continuous process that updates the clinical evaluation (Part A);
- shall be addressed in the manufacturer's post-market surveillance plan;
- shall collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking;
- confirming the safety and performance throughout the expected lifetime of the device; ensuring the continued acceptability of identified risks; detecting emerging risks.

Vigilance (Article 87)

- Reportable events;
- FSCA & FSN;
- Under-reporting.

Transparency

SSCP, IFU & labelling, IC, CI report and summary

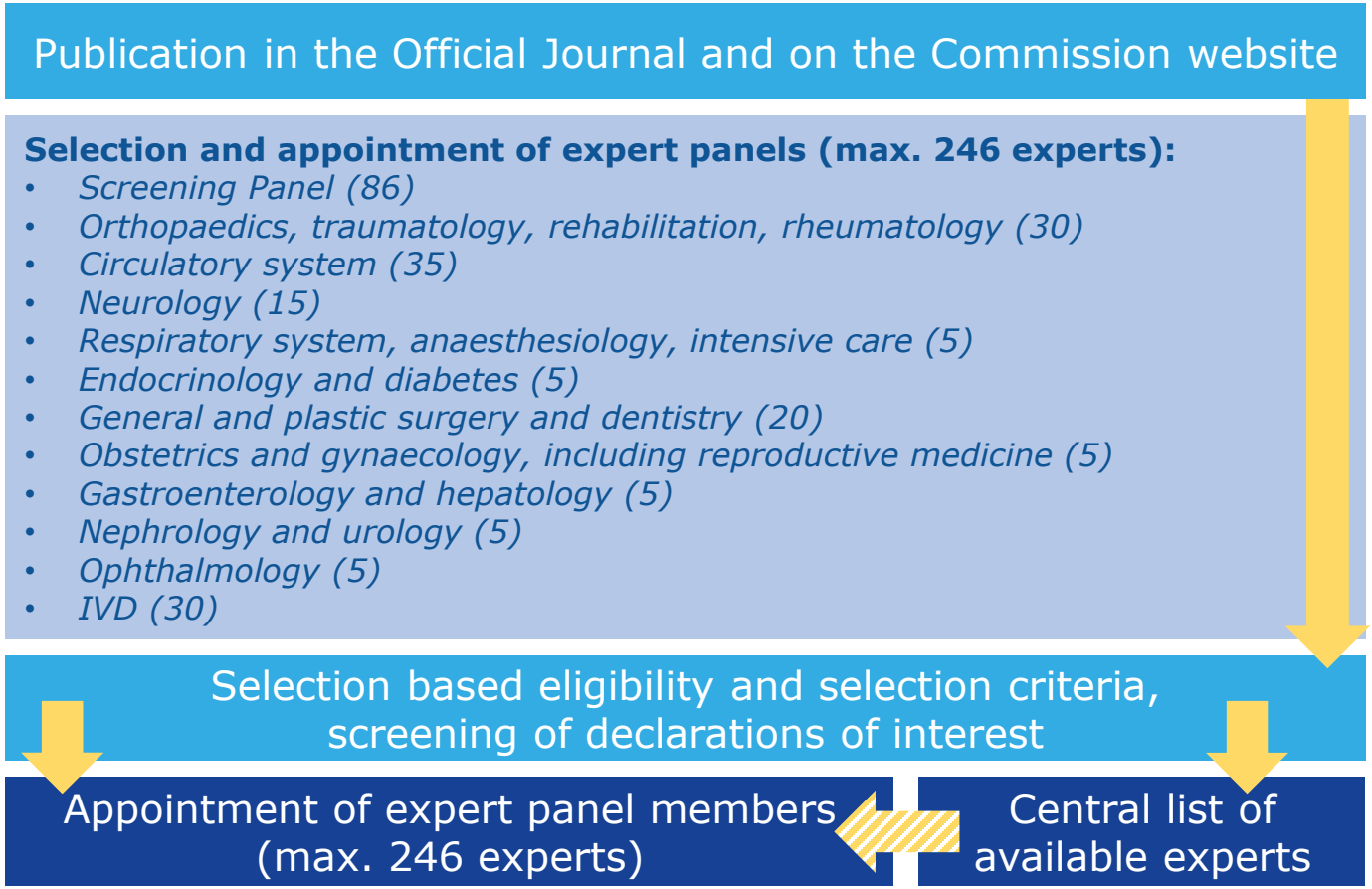
- For class III and implantable devices
- To be validated by the Notified Body & uploaded in Eudamed
- Accessible to the intended readers & languages
- Guidance available: https://ec.europa.eu/docsroom/documents/37323

- Clinical Investigation report and summary
- Implant card https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

- IFU & labelling

Expert panels

Call for expression of interest and selection procedure



Main steps of the Selection Procedure

1. Checking of the applications against the **eligibility criteria** (by JRC with support of the Selection Board)

2. **Evaluation of candidates** with the aim to establish a ranked list of eligible and apt candidates for each panel and the central list (by the Selection Board with support by JRC)
   - **2a.** Evaluation and scoring of the applicants against the **selection criteria** (Selection Board)
   - **2b.** Evaluation of candidates' **declarations of interest** (JRC)

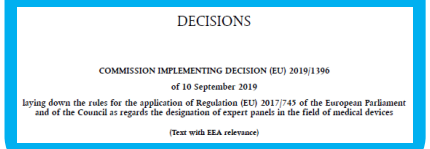
3. **Appointment** of suitable candidates to expert panels and the central list of available experts (in consultation with the MDCG)

Overall timelines for call and selection procedure

Legal Basis

10 September 2019

Implementing Act (EU) 2019/1396



DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2019/1396

of 10 September 2019

laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices

(Text with EEA relevance)

Call for experts

27 Sept – 24 Nov 2019

- Publication in OJ and dissemination
- Collection of applications, CVs and supporting documents

Selection Procedure

Dec 2019 – Feb 2020

- Selection Board composed by Commission Services and Agencies
- Eligibility check and scoring of selection criteria
- DOI assessment
- Proposal for appointment to expert panels or central list of available experts

Appointment

By 26 May 2020

- Endorsement of candidates in consultation with the MDCG
- Appointment of expert panels at the appropriate Commission level
- Full application of the MDR

Call for expression of interest for expert panels on medical devices and in vitro diagnostic medical devices (2019/C 323/05)

https://ec.europa.eu/growth/content/call-expression-interest-expert-panels-medical-devices-and-vitro-diagnostic-medical-devices_en

European Commission

Thank you!