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General Secretariat

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Medical Devices)
Subject:	Regulation to simplify rules on medical and in vitro diagnostic devices - Commission presentation on cluster 2 - Support to the regulatory system

Delegations will find in annex the presentation by the Commission services at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 21 April 2026.

MDR/IVDR revision
Commission Proposal



DG SANTE Unit D3, Medical devices

European Commission

#HealthUnion

Agenda

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1. Support to the regulatory system

- Medical Device Coordination Group (MDCG), cooperation between competent authorities and support by the European Medicines Agency (EMA)
- expert panels, expert laboratories and EU reference laboratories
- conflict of interest, device registers, data protection, digital submission of information and documents, levying of fees

2. Borderline and classification

European Commission

Support to regulatory system

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Stronger support by EMA for coordination between national authorities

European Commission

Problem statement

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The current medical devices regulatory system **lacks sufficiently strong, integrated, and operational support at Union level**, resulting in fragmented oversight, inconsistent implementation, and underuse of scientific expertise.

Challenges in:

A. Coordination and oversight of notified bodies (e.g. inconsistent application of the Regulations)

B. Coordination as regards oversight of devices (e.g. market surveillance & vigilance activities)

C. Use of scientific/technical expertise (e.g. expert panels)

D. Support for innovative, breakthrough, and orphan devices

Results in:

- Inconsistent regulatory outcomes
- Delays in access to devices in particular BTx and orphans
- Increased burden and uncertainty for the sector
- Monitoring of safety of devices may be affected

Sources (non-exhaustive): *targeted evaluation, CAMD statements and joint workshop calling for stronger coordination, MDCG workshops, EPSCO joint paper.*

Medical Devices Coordination Group

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Streamlining of its role
(Art. 103 and 105 MDR)

- Continues to be central body to support implementation of the Regulations (e.g. definition of priorities, policy discussions, guidance documents etc.)
- Enlarge MDCG composition to include Designating Authorities (DA)
- Formalise the Notified Body Oversight (NBO) subgroup
- Bring also NBCG-Med under MDCG umbrella (Art. 49 MDR)

Tasks

- Consultative role regarding specific topics (e.g. Common Specifications, NB fees, classification, derogations and other implementing acts, Art. 10a, Eudamed, oversight of NBs, etc.)
- Recommendation regarding designation of NBs
- Development/maintenance of European market surveillance programme
- MDCG NBO: key role to harmonise DA and NB practices

European Medicines Agency

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Scientific, technical and administrative support to CA cooperation and coordination on behalf of the Commission	Secretariat for the expert panels Art. 106 MDR, Art. 30 Reg. (EU) 2022/123 (as it is today)	Additional tasks
- regulatory status & classification - derogations - clinical evaluation / performance evaluation - vigilance & market surveillance - other thematic areas (such as new technologies, technical IVD matters, standards)	- select and appoint experts - provide administrative and technical support to the expert panels - ensure independent work of expert panels and prevent conflicts of interests - ensure transparency regarding expert panels' work (dedicated webpage; publication of scientific opinions, etc.) - provide annual reports to COM and MDCG - pay experts and recommend fees for expert panel opinions or advice	- set up SME support scheme (Art. 106b(3)) - support COM in establishing Union level sandboxes (Art. 106b(2)) - draw up methodology for and list of devices covered by Art. 10a reporting, in collaboration with MDSSG (Art. 10a(5))

↓

Organisation, preparation and follow up of meetings, regular coordination calls, consultation of stakeholders

EMA's scientific, technical and administrative support to CA cooperation and coordination
Key principles

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Provides secretariat functions to facilitate the organisation of work of MSs in the relevant thematic areas through **standing working groups** or Task Forces (no **decision-making/voting role** for EMA).

All MSs represented, elect the Chairs of working groups and adopt their Rules of Procedure.

EC participates in working groups as member/observer as necessary; EMA will act as secretariat with no co-chairing role.

MDCG to define the work items necessary to support the system also for the thematic areas supported by EMA; **decisions and ownership of the output remain with Member States/MDCG** (e.g. guidance documents, market surveillance measures).

EMA role in the Decentralised System (CMD) (1)

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- **Technical/scientific coordination**
  - Support to the Chair (organising preparatory meetings, discussing Agenda, flagging potential complicated cases, coordinating direct interventions from the Commission as necessary, etc)
  - Ensures coordination between groups and input from relevant experts
  - Organises of stakeholder engagement activities, as needed
  - Records outcomes and prepares of meeting minutes
  - Functions as institutional and regulatory memory to achieve consistency of the group's outcomes
  - Ensures adequate record management of meeting documents and adequate access to experts and the EMA secretariat;

(!) Decision-making remains with **Member States.**

EMA role in the Decentralised System (CMD) (2)

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- **Technical/scientific coordination**
  - Establishment of Rules of Procedure (RoP) of the group together with the CMD
  - Ensures best practices for the group's activities and provides advice on the application of the RoP, practices and precedents
  - Manages and coordinates the preparation of work plan and monitors and reports on its implementation
  - Manages of Conflict of Interest in accordance with the Agency's policy, incl. restricting participation of group members according to agenda, as necessary
  - Ensures application of transparency policy (publication of agendas, minutes etc.)
  - Supports in coordination of expert input (e.g. working parties or ad-hoc experts)

(!) Decision-making remains with **Member States.**

EMA role in the Decentralised System (CMD) (3)

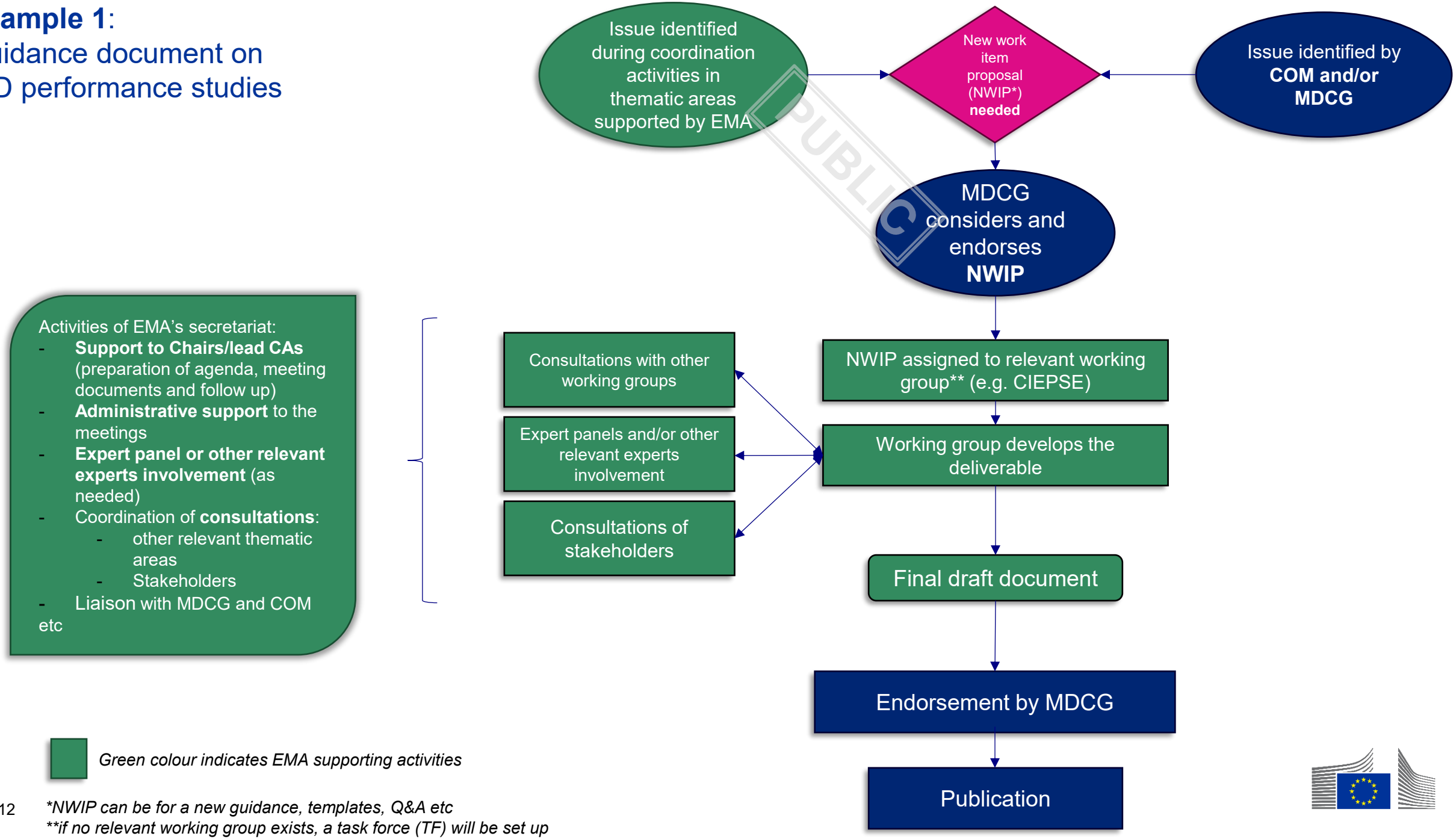
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Administrative support

- Organisation of meetings (invitations, mailings, ad-hoc events, etc)
- Document circulation
- Facilities
- IT support

(!) Decision-making remains with **Member States.**

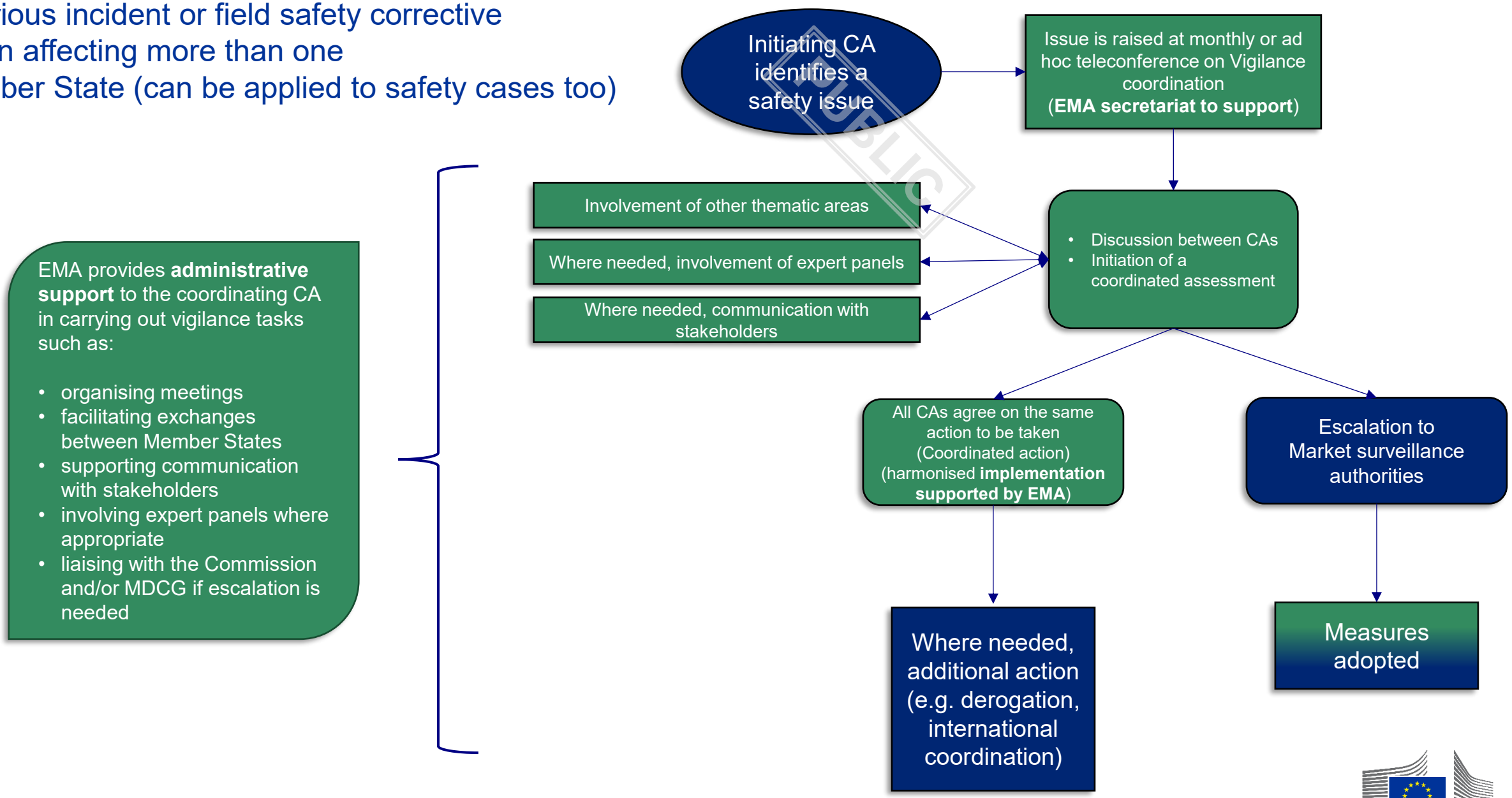
Example 1:
Guidance document on IVD performance studies



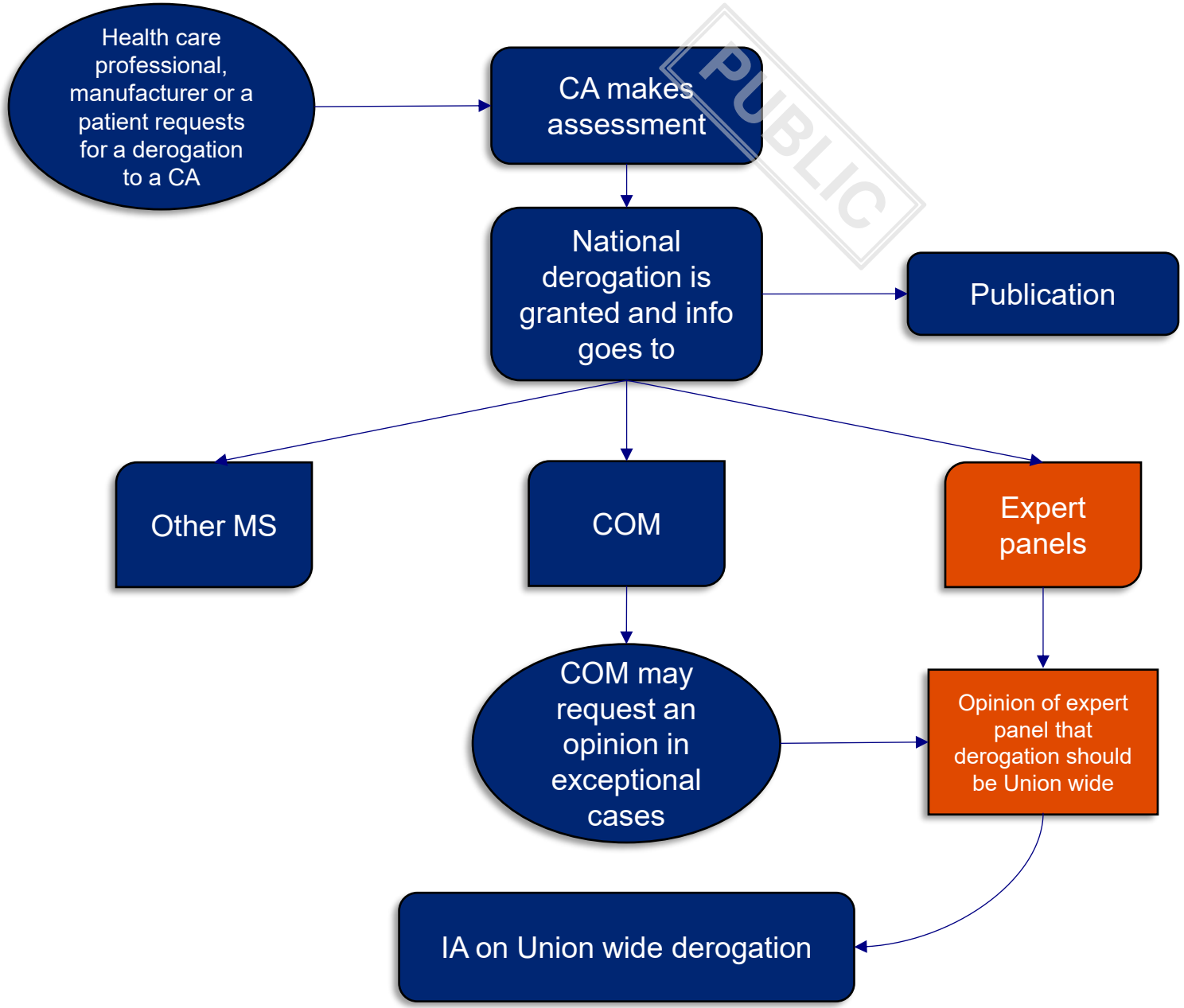
Green colour indicates EMA supporting activities

**NWIP can be for a new guidance, templates, Q&A etc*
***if no relevant working group exists, a task force (TF) will be set up*

Example 2: vigilance issue related to a serious incident or field safety corrective action affecting more than one Member State (can be applied to safety cases too)



Example 3: derogation for unmet clinical need

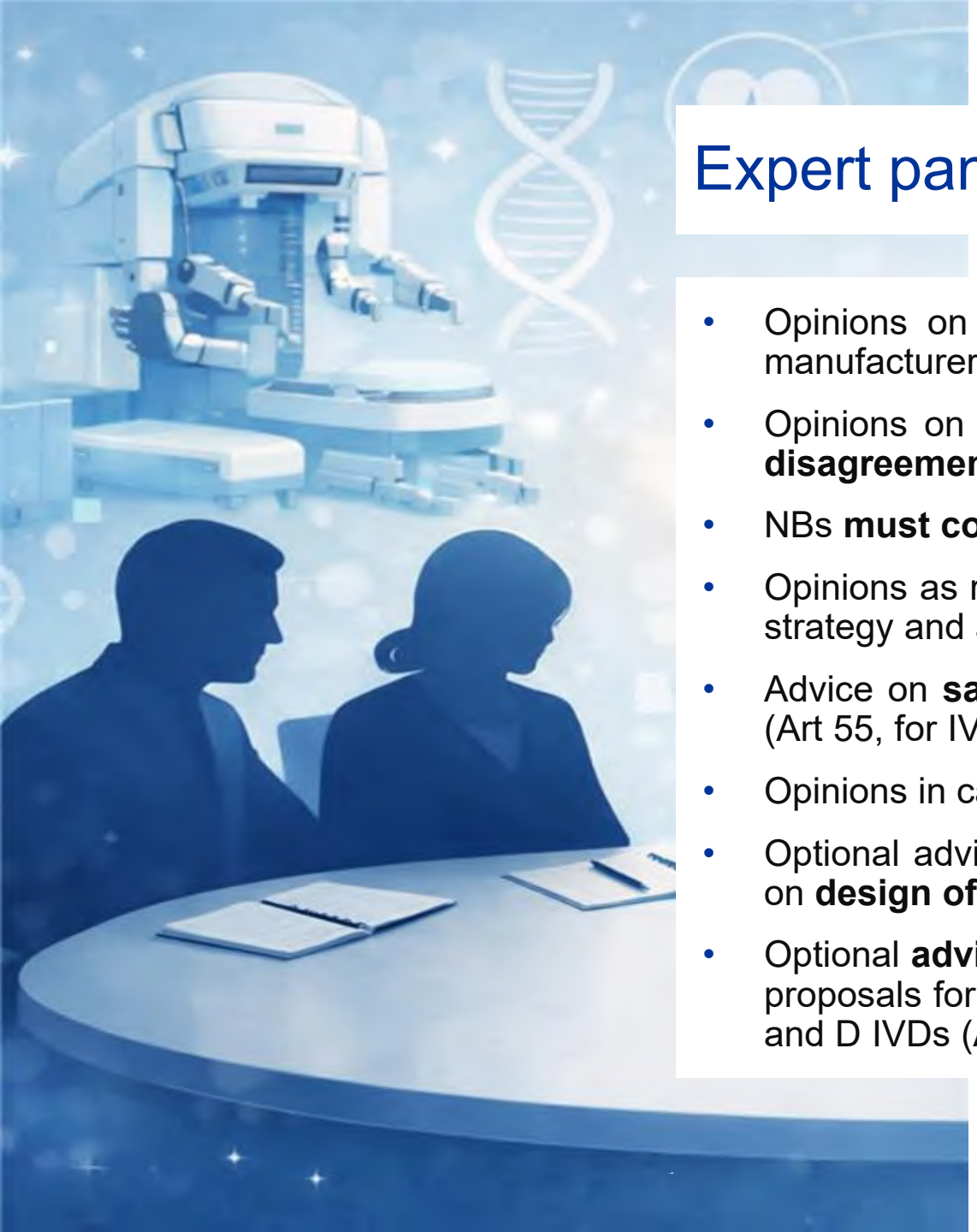


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More scientific expertise at EU level (expert panels, expert labs, EURLs)

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Expert panels - new tasks

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- Opinions on **qualification of product** as MD or not on request from CA, NB, manufacturer, developer or COM
- Opinions on **qualification** (Art 4) **or classification** (Art 51a and 51b) in case of **disagreement between CAs** (Art 49)
- NBs **must cooperate** with, among other actors, the expert panels (Art 49)
- Opinions as regards **breakthrough** and **orphan** status and on clinical development strategy and appropriate (pre)clinical data (Art 52a and 120)
- Advice on **safety and performance of any device** on request of MDCG or COM (Art 55, for IVDs also EURLs – IVDR proposal Art 50)
- Opinions in cases of **Union-wide derogations** (Art 59)
- Optional advice on draft **national sandbox plans** (Art 59b) and mandatory advice on **design of Union sandbox** (Art 59c)
- Optional **advice to manufacturers** on clinical development/performance strategy or proposals for CI/ PS for class IIb and III devices (Art 61 MDR proposal) and class C and D IVDs (Art 56a IVDR proposal)



Expert laboratories – MDR Art. 106a and Art. 55(2)

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- **Dedicated Article** – showcase that purpose of expert laboratories is to provide expertise through testing of medical devices – complementary to expert panel
- Add criterion of acting **in the public interest and in an independent manner**
- Clarify tasks to better distinguish from expert panels
- Add task to provide scientific and technical assistance to Member States and the Commission **in vigilance and market surveillance activities**
- Art 55(2) – add that MDCG or COM, based on reasonable concerns, may request **advice** from expert laboratories, on the basis of **laboratory testing**, in relation to the **safety and performance of any device**



EU reference laboratories – IVDR Art. 100 and 50(2)

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- Clarifications to tasks:
  - Task on advice on **state of the art**: **remove duplication** and align text between Art 100(2)(d) and 100(5)(j), clarify it is **on request** and on the basis of lab **testing**
  - Remove the task to set up and manage a **network of national reference laboratories**
  - Remove duplicative task to provide opinions in response to consultations by notified bodies
  - Add **empowerment to modify tasks** of EURLs
- Remove possibility for **one MS** to request EURLs on **class C** devices
- More flexibility for fees: still cost-recovery basis but for tasks in general rather than the individual requested task
- New task in Art 50(2) - add that MDCG or COM, based on reasonable concerns, may request **advice** from EURL, on the basis of **laboratory testing**, in relation to the **safety and performance of any device**



Conflict of interest, device registers, data protection, digital submission of information and documents, levying of fees

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Other provisions

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Competent authorities and cooperation (Art. 101, 102 MDR & 96, 97 IVDR)

- Reinforced resourcing of CAs; international cooperation moved to separate section

Conflict of interests (Art. 107 MDR)

- Declarations of interest of MDCG members, experts and expert labs to be publicly available – not necessarily on the Commission website

Device registers and databanks (Art. 108 MDR, Art. 101 IVDR)

- Addition of EMA among actors to encourage establishment of registers and databanks
- Integration of IVD into Art. 108 MDR and deletion of Art. 101 IVDR

Electronic submission of information or documents (Art. 110a MDR, Art. 103a IVDR)

- New

Levying of fees by Member States (Art. 111 MDR, Art. 104 IVDR)

- Addition of Commission

Funding of designation/monitoring of notified bodies (Art. 112 MDR, Art. 105 IVDR)

- Replaced by new Art. 40a MDR



Borderline and classification

European Commission

Problem statement – borderline and classification

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The EU medical devices regulatory system currently **lacks efficient and decisive** borderline and classification coordination mechanisms **grounded in scientific expertise**, resulting in inconsistent application, fragmentation of the internal market and delays to innovation and patient access to devices.

Challenges in:

A. Efficiency in Member State coordination processes for borderline and classification

B. Use of scientific/technical expertise (e.g. expert panels)

C. Respect of decisions across the EU

D. Providing timely and consistent information to developers, manufacturers and notified bodies

Result in:

- Inconsistent regulatory outcomes
- Delays in development of and access to devices
- Fragmentation of the internal market
- Increased burden and uncertainty for the sector

Sources (non-exhaustive): *targeted evaluation, consultations and workshops.*

The future – borderline and classification

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- **Well-defined** and **streamlined** procedure for Articles 4-4a MDR / 3-3a IVDR and 51-51a-51b MDR / 47-47a-47b IVDR with more secretariat resources for support
- Strengthened **scientific input from expert panel** for faster and more evidence-based equivalent of Helsinki procedure
- The scientific, technical and administrative **support** is within the **same entity** (the EMA)
- Possibility for **direct advice** from expert panel on qualification for developers, manufacturers, NBs, CAs and COM
- Results of CA coordination and expert panel opinions to be made **publicly available**
- More possibilities for **implementing acts**



More efficient use of resources, greater alignment at EU level, smoothly functioning internal market and faster patient access to devices

Regulatory status of products

Art 24 MDR – free movement of compliant devices

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Art. 4 MDR / 3 IVDR

A CA considers CE marked product to not fall under MDR

Consultation of other CAs

No disagreement by CA(s) of other MS

Final decision by CA

CA(s) of other MS raises substantiated disagreement

Referral to Expert Panel

Expert Panel opinion to the CA(s)

Opinion published

Final decision by CA

EMA provides, on behalf of the COM, scientific, technical and administrative support to the CAs

Art. 4a MDR / 3a IVDR

CA, NB, manufacturer, developer of a product or COM may submit a substantiated request to Expert Panel

Expert Panel opinion

MS may submit substantiated request to COM

Expert Panel opinion to be taken into consideration by requester

COM may request Expert Panel clarifications

COM Implementing act

Classification

Art 24 MDR – free movement of compliant devices

Art. 51a MDR / 47a IVDR

Dispute between manufacturer and NB referred to CA of manufacturer

Art. 51b MDR / 47b IVDR

A CA considers that a CE marked device is not correctly classified

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30 days

Consultation of other CAs

30 days

No disagreement by CA(s) of other MS

(for dispute within 90 days of referral)

Final decision by CA

CA(s) of other MS raises substantiated disagreement

Referral to Expert Panel

30 days

Expert Panel opinion to the CA(s)

Opinion published

(for dispute 30 days)

Final decision by CA

EMA provides, on behalf of the COM, scientific, technical and administrative support to the CAs



What does this all bring?

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- **Stronger coordination among MS with a focus in thematic areas** where coordination and consistent implementation is essential.
- **No change to decision making powers or institutional responsibilities**: national decisions remain at national level and the Commission retains its institutional responsibilities, however the proposal will streamline and strengthen support functions to facilitate alignment.
- **A more efficient system**, building on existing structures rather than creating a new operational model.
- **Better use of scientific and technical expertise at EU level** leading to more evidence based regulatory outcomes.
- **A more strategic MDCG**, with allocation of support tasks to EMA and stronger focus on steering the system and on policy and regulatory issues.
- **Freed-up capacity for the Commission** to work on Implementing Acts and Delegated Acts securing greater harmonisation and alignment

Thank you!

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