

EMA update on Combination Products Operational Group

17th Industry Standing Group

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Committees and Quality Assurance Department



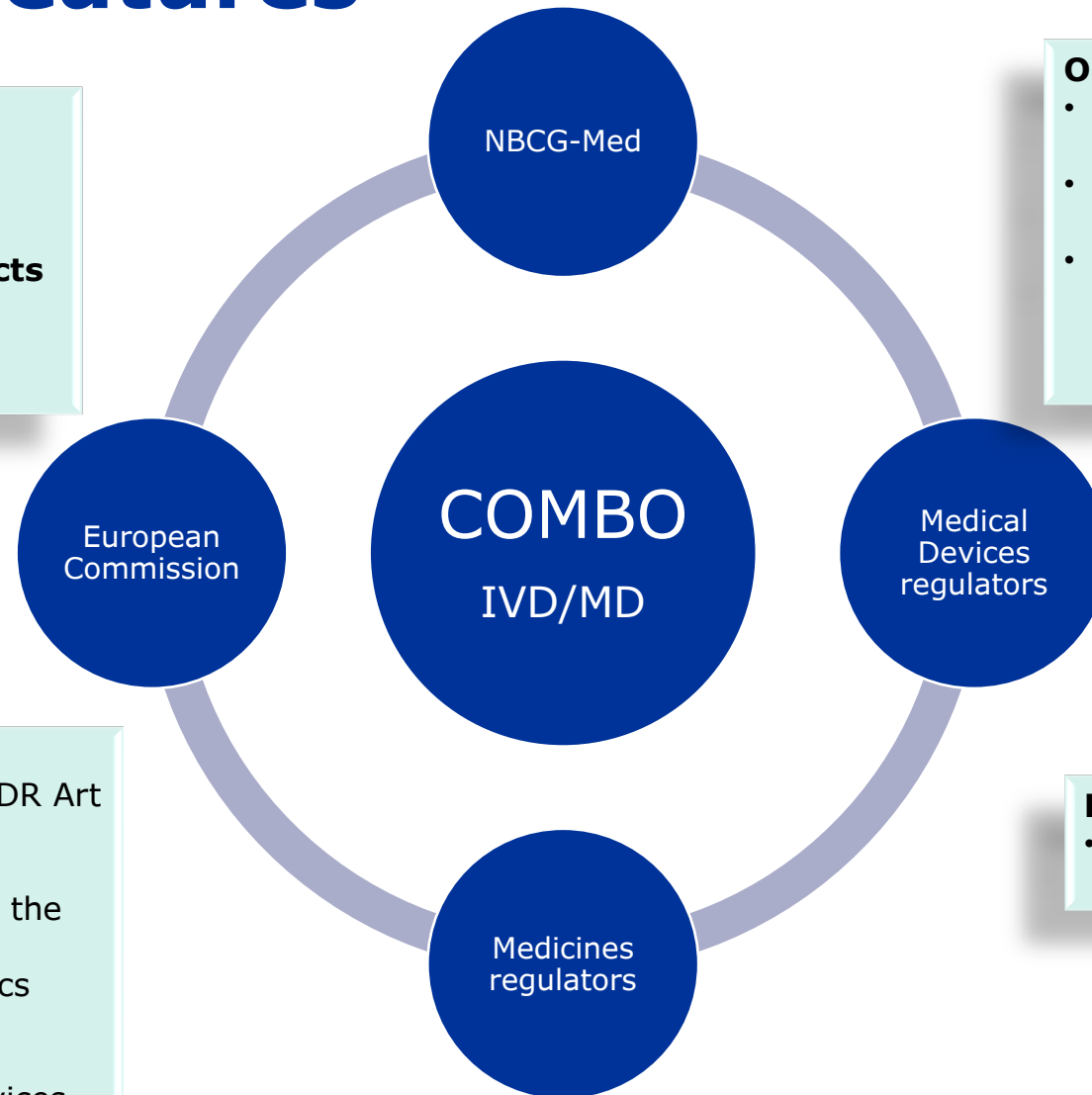
Combination Products Operational Group – Key features

Scope:

- Focus on MDR/IVDR related requirements and processes at the interface with medicinal product framework i.e. **combination products and consultation procedures** by Notified Bodies with medicines regulators

Procedures/products in scope:

- Medicines with an integral device (MDR Art 117)
- Medicines with a co-packaged device
- Medicines with a device referenced in the PI and supplied separately
- Consultation for companion diagnostics
- Consultation for ancillary medicinal substances (into a device)
- Consultation for substance-based devices



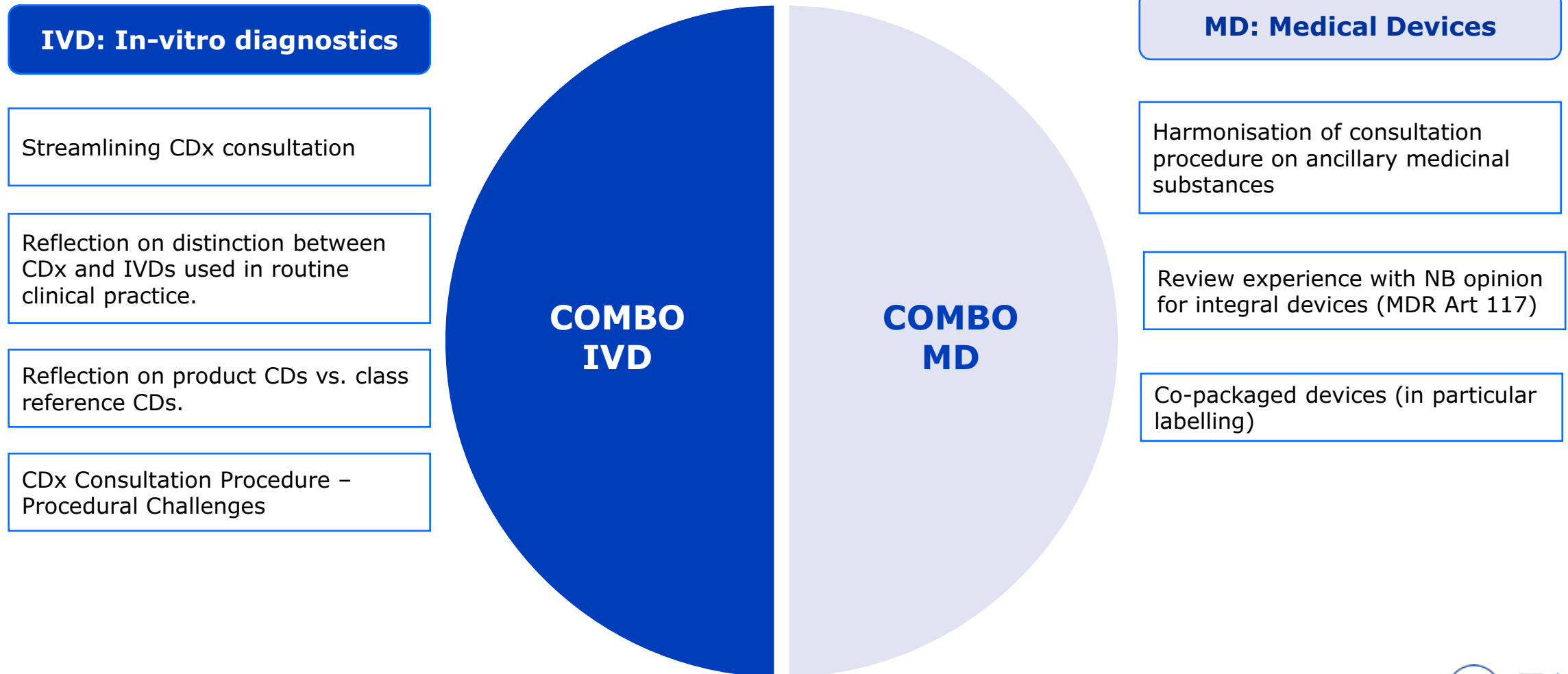
Objectives:

- To exchange on technical matters (policy matters are out of scope)
- To share mutual experience, enhance mutual understanding
- To facilitate streamlining of processes and requirements concerning combination products and NBs' consultation procedures

Deliverables:

- Guidance (new/update) and others

Outline of identified topics



Status update



Established in October 2025 - So far 3 COMBO IVD meetings; 2 COMBO MD meetings (3rd scheduled in July)



IVD: Prioritised topics – CDx consultation procedure (scope and procedural aspects)



MD: Prioritised topics – consultation for ancillary substance; integral devices and NB opinions



Work in progress: started with respective experience and challenges from NBs and medicines regulators in operating those procedures, ongoing reflection on aspects for alignment and better complementarity



Plan ad-hoc interactions with Industry – Q4 2026



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