EMA
EUROPEAN MEDICINES AGENCY

# EMA update on combination products

14th Industry Standing Group

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# How EMA supports combination products?

**Operational activities**

- Regular guidance updates, in particular, regarding application of Art 117, co-packaged combined products, CDx consultation procedure
- Engagement with stakeholders through existing and ad-hoc channels (ad-hoc interaction with NBCG-Med about Art 117 and CDx; Industry Platform meetings; participation to external fora)
- Focus group to reflect on multi-stakeholder scientific advice

**EU initiatives**

- COMBINE programme: Participation of EMA in all cross-sectoral projects
- MDR/IVDR revision: EMA contribution to the EC targeted evaluation, participation in MDCG meetings and workshops and ad-hoc collaboration on any referred matter

# Looking forward

## Regulatory Science Strategy to 2025

Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products

- **Create a process to consult medical device authorities and/or notified bodies** (as applicable) for device-related aspects throughout the product lifecycle, including post-authorisation safety related events

## The European Medicines Agencies network strategy to 2028 (EMANS) -> Seizing opportunities in a changing medicines landscape

Theme 3. Regulatory science, innovation and competitiveness

- **For both medicines and medical devices, taking steps to deepen and foster communication and collaboration with stakeholders**, such as clinicians, academics, medical devices experts, notified bodies, ethics committees and patients organisations, small and medium-sized enterprises (SMEs), research groups, industry and incubators can help harness expertise and talents across the EU.
  - **Increase collaboration with medical device experts, notified bodies**, ethics committees and patient communities, HTA bodies and the Substances of Human Origin network in conjunction with the European Commission to support development and authorisation of combination products

# Coming soon

EMA to set up a new multistakeholder operational group (endorsed by MDCG in June 2025)

**Composition:**

- NBCG-Med, DA/NCA medical devices (from MDCG), NCA medicinal products (CMDh, QWP, BWP), EMA, EC
- **2 sub-groups** : Medical Devices and *In-vitro* Diagnostic Devices

**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

**Objective**:

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

**Ad-hoc interactions**:

- Plan for ad-interactions with Industry (e.g. through Interested Parties meeting model, Industry Stakeholder Platforms)

**Establishment of a Combination Products Operational Group**

# Plan to launch this initiative

- Ongoing nominations by respective stakeholders
- Kick-off meeting – Q4 2025
- Collection of topics and prioritisation
- Plan approx. quarterly meetings
- Plan ad-hoc interactions with Industry

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# Thank you

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