6 January 2026
EMA/353484/2025

Highlight report – Combination Products Operational Group (COMBO)

In Vitro Diagnostics stream

Meeting held on 4 November 2025

Chairperson: Alberto Gañán Jiménez (EMA)
Topic lead(s): Ana Trullas; Antonella Baron (EMA)

Item	Title	Highlights
1.	**Establishment and launch of the COMBination products Operational group** - Introduction of COMBO IVD stream and tour de table	The **COMBination products Operational group** (COMBO) was established with the view to bring together stakeholders across **medicine**, **medical device**, and in **vitro diagnostic sectors** to facilitate dialogue, enhance mutual understanding and reflect on potential solutions within the current framework, regarding regulatory challenges at the interplay of pharmaceutical and medical device frameworks for combination products and consultations procedures. It was noted that the establishment of the COMBO group is highly valued by all participating stakeholders, namely the medicines and devices competent authorities and the notified bodies. The COMBO group is organised into two distinct streams: **In-Vitro Diagnostics (IVD)** and **Medical Devices (MD)**. Each stream comprises different experts representing the respective stakeholder groups. The kick-off meeting began with a *tour de table*, where each core member and alternate introduced themselves and shared their area of expertise.

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2.	Discussion and agreement on the **ToRs**	EMA has presented the draft Terms of Reference outlining the scope, objectives, composition, and organisational aspects of the group. The group's primary objectives are to establish a shared understanding of technical and procedural challenges related to combination products and consultation processes, and to collaboratively explore potential solutions within the existing framework, with the aim of developing and updating relevant guidance. **Follow-up:** Once reviewed and endorsed by both streams, the final terms of reference will be published on the EMA website by end of 2025.
3.	Collection and prioritisation of **topics**	Several topics have been identified for further development and discussion in the upcoming COMBO meetings. Key area of focus include: • The **distinction between companion diagnostics (CDx) and in vitro diagnostics (IVD)** used in routine clinical practice. • **CDx Consultation Procedure** – Procedural Challenges • Clarification on the **scope of the CDx consultation** procedure. • Reflection on Medicinal products **Class reference for companion diagnostics** as a topic for further development. **Follow-up:** The COMBO will start working on the problem statement for the identified top priority topics.

Item	Title	Highlights
4.	Wrap up and planning of next meeting	For follow-up actions, please refer above. Next meeting is planned to take place in February 2026.