24 June 2026
EMA/32394/2026
Committees and Quality Assurance (H-QA)

Highlight report – Combination Products Operational Group (COMBO)

In vitro Diagnostics

Held on 12 June 2026, Virtual (14:00 – 16:00 CEST)

Chairperson: Alberto Ganan Jimenez (EMA)

Topic lead(s): Ana Trullas; Antonella Baron (EMA)

Item	Title	Highlights
1.	Presentation of topics under discussion	A brief introduction was provided to introduce the topics under discussion.
2.	Topic: Clarifying the Scope of the Companion Diagnostics Consultation Procedure.	Participants discussed the scope and process of suitability assessment in the Medicines Competent Authorities consultation for companion diagnostics, focusing on the roles of the Medicines Product Authority, notified bodies, and the need for alignment on information requirements. ◦ Overall aim of the consultation on suitability should be to confirm, on the basis of the information available to the MPA (draft SSP/IFU), that the medicinal product is effective in the patient group identified by the CDx candidate. It was suggested incorporating the clarified definition of suitability into EMA guidance documents and updating the SSP template or its instructions to better address companion diagnostic requirements. The group agreed to draft a proposal for the MDCG (Medical Device Coordination Group) outlining the information needed in the SSP for companion diagnostics.

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Item	Title	Highlights
		Actions and Next Steps: The group agreed to collect key points from the discussions taken place for inclusion in EMA guidance, prepare a proposal for the MDCG regarding SSP content, and coordinate further actions via written procedure and future meetings, aiming for a proposal to be ready in Q4. The group will prepare a proposal for SSP template changes, with expected delivery around Q4 2026.
3.	Consideration of CDx procedural aspects	Participants discussed the timeline for the CDx consultation procedure as defined under the IVDR, including whether there may be flexibility in how the rules are applied. The topic will be further developed to clarify the degree of flexibility.
4.	Not companion diagnostic specific	Participants explored the regulatory and practical challenges of assays that do not fully meet the definition of companion diagnostics but are used in clinical decision-making, focusing on intended use, oversight, and the distinction between IVDs and CDx. Members presented cases where biomarkers are mentioned in the SmPC but are not part of the formal indication, raising questions about how such assays can be legally marketed and whether they require certification as IVDs or CDx. Intended Use and Regulatory Oversight: members clarified that most IVDs support clinical decision-making without being strictly defined as CDx, and their intended use is determined by the manufacturer and verified by notified bodies. CDx are strictly defined under IVDR, while other assays with a medical purpose are regulated as IVDs. The link between intended purpose and clinical evidence is addressed in ongoing projects, emphasising that clinical evidence for one medicinal product cannot automatically be used for another, and performance studies may still be required depending on the intended use.