2 March 2026
EMA/32158/2026
Committees and Quality Assurance (H-QA)

Highlight report – Combination Products Operational Group (COMBO)

In vitro Diagnostics

Held on 9 February 2026, Virtual (10:00 – 12:00 CEST)

Chairperson: Alberto Gañán Jiménez (EMA)

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

Item	Title	Highlights
1.	Presentation of topic under discussion	A brief introduction was provided to recap that the priority topic under discussion concerned the scope of the CDx consultation procedure. It was also highlighted that, in order to progress the work between COMBO meetings, a dedicated drafting group—comprising notified bodies and medicines competent authorities—had been established.
2.	Experience of the medicines regulators and notified bodies regarding the scope of the CDX consultation procedure	Discussion was held on the challenges and requirements of the consultation procedure for companion diagnostics, focusing on the roles and responsibilities of notified bodies and medicines competent authorities, enabling a better understanding of their respective approach. Clearer delineation of roles to foster complementary assessments, elaboration on the missing information/need to improve the documentation available for the consultation, and potential for guidance to avoid redundancy were discussed.

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Item	Title	Highlights
3.	Wrap up and follow-up actions	A problem statement as well as proposals for possible solutions are work in progress. Next meeting will be held on 11 May 2026.