27 October 2026
EMA/32352/2026
Committees and Quality Assurance (H-QA)

Highlight report – Combination Products Operational Group (COMBO)

In vitro Diagnostics

Held on 21 October 2026, Virtual (10:00 – 12:00 CEST)

Chairperson: Alberto Ganan Jimenez (EMA)

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

Item	Title	Highlights
1.	Scope of the companion diagnostic consultation procedure. Proposal for Updating the Summary of Safety and Performance Template guidance	**SSP Template Companion Diagnostic update:** The group endorsed the proposal for a revised SSP template providing clearer requirements for companion diagnostics. The revision addresses identified information gaps and aims to clarify expectations, reduce follow-up questions and streamline consultation procedures. Following finalisation, the COMBO-endorsed document will be submitted to the European Commission for consideration by the appropriate MDCG forum.

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Item	Title	Highlights
2.	Alignment of marketing authorisation applications and related companion diagnostic consultation procedures	The group examined how Companion diagnostic consultation procedures should be managed when their timelines are not fully aligned to these from the medicinal product marketing authorization application and identified clock stops and structured communication as preferred areas warranting further consideration.
3.	Procedural issue: clock stop	The group discussed potential approaches to provide more flexibility in the timelines of companion diagnostic consultation procedures, particularly where additional information may be required. The topic will be further explored in the context of the broader work on improving procedural alignment.
4.	Class and Group Labelling of Companion Diagnostics	The group agreed to further explore class and group labelling of companion diagnostics, including the evidence criteria, boundaries and applicability.