29 July 2026
EMA/32685/2026
Committees and Quality Assurance (H-QA)

Highlight report – Combination Products Operational Group (COMBO)

Medical devices

Held on 7 July 2026, Virtual (14:00 – 16:00 CEST)

Chairperson: Alberto Ganan Jimenez (EMA)

Topic lead(s): Christelle Bouygues (EMA)

Item	Title	Highlights
1.	Update on ancillary substances. Guidance revision	The COMBO MD group discussed the scope of the proposed update of the guidance for ancillary substances, outlining the current roadmap, timelines, and key discussion points such as dossier content, GMP requirements, to provide further clarity in the dossier expectations and to foster harmonisation across regulators.
2.	Update on the NB opinion reflections	The COMBO MD discussed findings from the medicines regulators and notified body experience on the application of notified body opinions, highlighting differences in format and content across NBs, inconsistencies and overlap with the quality module assessment by the medicines competent authorities. Hence the COMBO MD discussed possible way forward to enhance harmonisation of the NBOp, clarity, and complementarity with Module 3 assessments.

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3.	Industry proposal on MDR Art. 117	The industry position paper proposing a risk-based approach to notified body opinions, was shared to raise awareness to all parties involved in the COMBO MD. However, it was clarified that policy decisions are outside the group's remit, and the work of the COMBO MD focuses on the current medical devices and pharma framework. Finally, possible future interactions with industry through an interested party meeting was discussed and supported to be hold at an appropriate timepoint to update on the COMBO MD activities rather foreseen Q4 2026.
4.	Discussions and follow-up actions	COMBO MD to continue progressing outputs on revision of the ancillary substance consultation guidance and NBOp application.