4 November 2026
EMA/32677/2026
Committees and Quality Assurance (H-QA)

Highlight report – Combination Products Operational Group (COMBO)

Medical devices

Held on 08 October 2026, Virtual (15:30 – 16:30 CEST)

Chairperson: Alberto Ganan Jimenez (EMA)

Topic lead(s): Christelle Bouygues (EMA)

Item	Title	Highlights
1.	Discussion of comments on proposed output about the NBOp sharing of experience and way forward to enhance harmonisation	The COMBO MD group discussed the proposed scope and format for an output taking into account the respective experience by notified bodies and medicines regulators with NBOps, with the aim to strengthen the complementarity of the NBOp with the quality assessment and enhance harmonisation of NBOps. The discussions supported clarification and harmonization efforts regarding both sides' expectations and remits on applicant data to be assessed by underlining the areas of potential overlaps and the different scopes of evaluation between the devices and medicines frameworks.
2.	Wrap up and follow-up actions	The COMBO MD will continue to progress their work based on a joint review of the NBOp template from TeamNB.

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