2 March 2026
EMA/32693/2026
Committees and Quality Assurance (H-QA)

Highlight report – Combination Products Operational Group (COMBO)

Medical devices

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

Chairperson: Alberto Gañán Jiménez (EMA)

Topic lead(s): Christelle Bouygues (EMA)

Item	Title	Highlights
1.	Presentation of outcome priorities	A brief recap highlighted the potential topics of interest and confirmed the decision to prioritise work on the ancillary substance consultation and the notified body opinion.
2.	Ancillary substance consultation. Experience from medicines regulators and Notified Bodies	Medicines competent authorities and notified bodies shared their respective experience with the ancillary medicinal substance consultation highlighting challenges and proposed improvements. A group of medicines competent authorities (CAs), initiated in September 2025, has mapped challenges and identified proposed actions with prioritisation. Their survey identified major issues such as inconsistent dossier structures, unclear roles between CAs and notified bodies (NBs) on scope of assessment considering the interplay between the device and the ancillary substance, and difficulties managing products with multiple ancillary substances.

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		Notified bodies highlighted long timelines, limited availability of CAs, unclear boundaries of responsibility, inconsistent documentation expectations, and unclarity on submission expectations for post-consultation changes, in particular minor amendments. Overall, both NCAs and NBs recognise similar issues and are aligned on the need for clearer and harmonised procedures. Priority actions include developing harmonised guidance on dossier structure and content. **Follow-up action:** To initiate work to update procedural guidance on the dossier structure and content.
3.	Notified Body opinion (Art. 117) • Experience from medicines regulators Experience from Notified Bodies	Regulators shared their observations on the notified body opinions (NBOps) and noted that NBOps varied widely in structure and length, and it could be difficult to understand what had been assessed. Significant duplication was observed between NBOps and marketing authorisation dossiers, and highlighted the value of the NBOp around device performance parameters and complex technical devices such as software. Notified bodies, presenting their perspective, outlined their assessment approach, covering manufacturing, risk management, and sterility. They reported practical challenges such as incomplete data from applicants, limitations in obtaining supplier information due to confidentiality, and residual risks not being fully addressed in submissions. Overlaps with regulatory assessment—particularly in design, usability, and stability—were also acknowledged, compounded by the timing of NBOps, which are often issued before complete data are available. Overall, both regulators and notified bodies recognise duplication and a need for clearer, harmonised expectations regarding NBOp. **Follow-up action:** To draft a position paper summarising identified gaps, areas of duplication, and expectations for notified body opinions, in particular clarifying aspects of the NBOp which should complement the MAA evaluation.
4.	Wrap up and follow-up actions	**Next COMBO MD:** will be planned Q2-Q3 2026 subject to progress on the work by the respective drafting groups on ancillary substance consultation and notify body opinion. **Interaction with Industry:** Plan to invite in Q2 2026 Industry Associations representatives involved on these topics to share their experiences and challenges in a dedicated meeting.