



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 January 2026
EMA/357562/2025

Highlight report – Combination Products Operational Group (COMBO)

Medical Devices stream

Meeting held on 7 November 2025

Chairperson: Alberto Gañán Jiménez (EMA)

Topic lead(s): Christelle Bouygues (EMA)

Item	Title	Highlights
1.	Establishment and launch of the COMBination products Operational group - Introduction of COMBO MD stream and tour de table	<p>The COMBination products Operational group (COMBO) was established with the view to bring together stakeholders across medicine, medical device, and in vitro diagnostic sectors to facilitate dialogue, enhance mutual understanding and reflect on potential solutions within the current framework, regarding regulatory challenges at the interplay of pharmaceutical and medical device frameworks for combination products and consultations procedures.</p> <p>It was noted that the establishment of the COMBO group is highly valued by all participating stakeholders, namely the medicines and devices competent authorities and the notified bodies.</p> <p>The COMBO group is organised into two distinct streams: In-Vitro Diagnostics (IVD) and Medical Devices (MD). Each stream comprises different experts representing the respective stakeholder groups.</p> <p>The kick-off meeting began with a <i>tour de table</i>, where each core member and alternate introduced themselves and shared their area of expertise.</p>

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Item	Title	Highlights
2.	Discussion and agreement on the ToRs	<p>EMA has presented the draft Terms of Reference outlining the scope, objectives, composition, and organisational aspects for operating the group.</p> <p>The group's primary objectives are to establish a shared understanding of technical and procedural challenges related to combination products and consultation processes, and to collaboratively explore potential solutions within the existing framework, with the aim of developing and updating relevant guidance.</p> <p>Follow-up: Once reviewed and endorsed by both streams, the final terms of reference will be published on the EMA website by end of 2025.</p>
3.	Collection and prioritisation of topics	<p>Several topics have been identified for further development and discussion in the upcoming COMBO meetings. Key areas of focus include:</p> <ul style="list-style-type: none"> • Consultation procedure for ancillary medicinal substances: Reflection on harmonisation and scope of assessment by competent authorities, as well as clarification of dossier requirements and structure. • Notified body opinion for integral devices: Review of current experience and clarification/harmonisation of elements covered in notified body opinions, along with streamlining the scope of review between the notified body opinion and the marketing authorisation application. Subsequently, it is foreseen to touch upon 'platform approach' regarding a device with the 're-use' of notified body opinion. • Co-packaged devices: Particular attention to labelling aspects. <p>Follow-up: The COMBO will start working on the problem statement for the identified top priority topics.</p>

Item	Title	Highlights
4.	Wrap up and planning of next meeting	For follow-up actions, please refer above. Next meeting is planned to take place in February 2026.