

Re-start of F2F oral explanations for in-person Committee meetings – 1 year Pilot

14th Meeting of the industry stakeholder
platform on the operation of the
centralised procedure for human
medicines, 23 June 2025

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Background

- Oral explanations (OEs) from Applicants have been held fully remotely since the start of the COVID-19 pandemic in early 2020;
- EMA has improved the format and overall experience of OEs in 2023 by allowing video connection via WEBEX/TEAMS;
- Feedback received from Industry on the high value of in-person interactions and request to EMA not to exclude the possibility of F2F oral explanations;

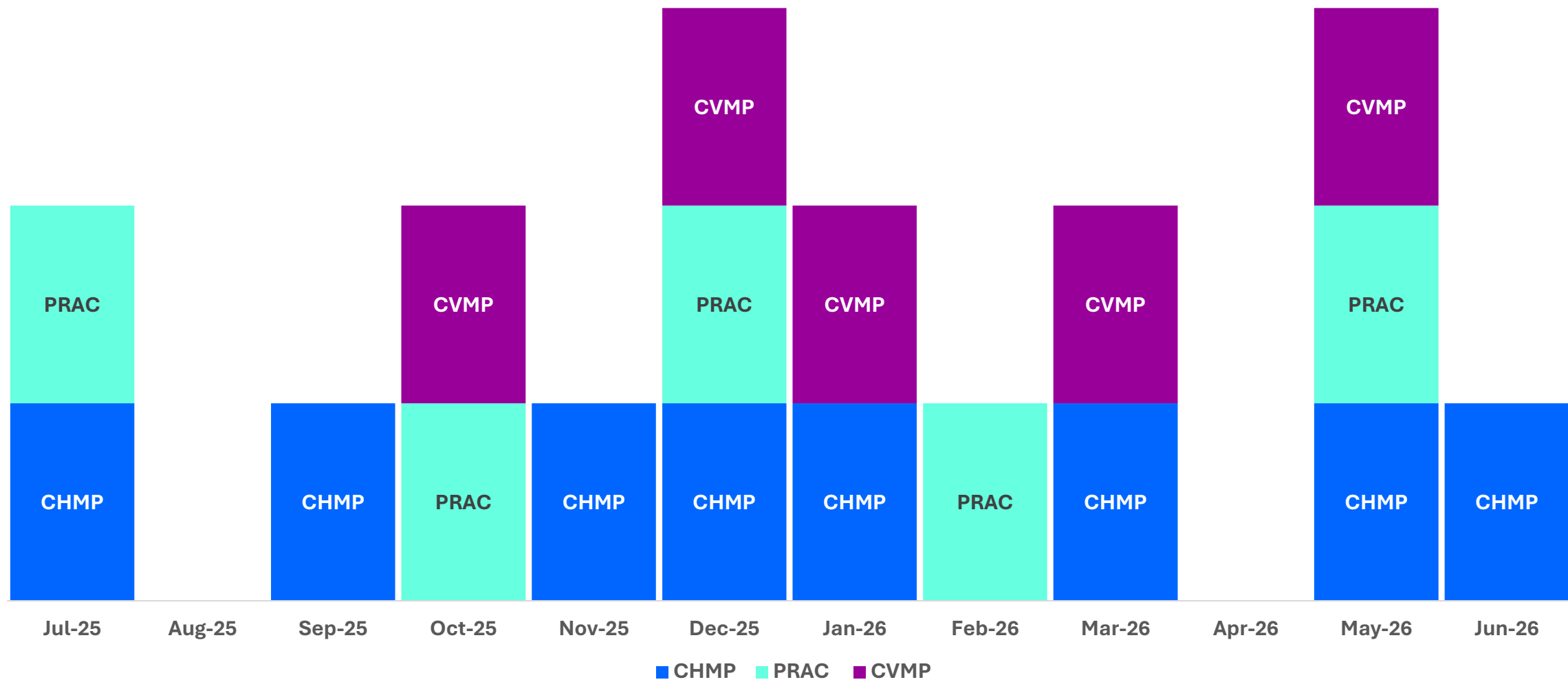
Principles for the pilot

- EMA will pilot the re-introduction of in-person OEs in the current setting (F2F/remote) for a 1-year period starting as of July 2025;
- The scope of the pilot will cover CHMP, CVMP and PRAC;
- For F2F plenary meetings, oral explanations can take place remotely or in-person;
- If Applicant decides to participate in-person, all participants should attend in-person;
- For remote plenary meetings, all OEs will continue to take place remotely;
- Same rules apply to in-person or remote OEs (e.g. number of participants);
- The Agency will not accept requests for changes to timetable of procedures to accommodate in-person OEs;
- Applicants to be aware of possibility of cancellation of OEs at short notice, if no longer required during preparatory Committee discussions

Next steps

- Applicants with OEs as of July 2025 in F2F plenary meetings will be given the possibility to have their OE held in person or remotely;
- EMA will issue targeted communication informing Industry associations;
- EMA will review, in Q3, 2026 experience acquired with the pilot and present the outcome, including any recommendations, at a future Industry platform meeting.

CHMP-PRAC-CVMP F2F SCHEDULE July 2025 – June 2026



Updated in January 2026 to include June 2026 CHMP as an F2F meeting



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Thank you

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