



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scientific Committees organisational aspects post EMA business continuity plan (BCP)

10th meeting of the industry stakeholder platform on the operation of the
centralised procedure for human medicines
27 June 2023





Background

- As of 5 May 2023, COVID-19 no longer a public health emergency of international concern (PHEIC) and as of 11 May 2023 Mpox no longer a PHEIC
- As of 10 May 2023, EMA and European medicines regulatory network lifted COVID-19 business continuity status
- Scientific Committees Rules of procedure foresee possibility of in-person or virtual meetings
- Regular F2F Scientific Committee meetings re-instated in May 2022 in an alternating format with virtual Committee meetings (1 year experience)
- Scientific Committee meetings format for 2023 -> alternating F2F/virtual meetings
- Oral explanations in front of Scientific Committees fully remote since COVID-19



Experience acquired with alternating F2F/virtual Committee meetings

- ✓ Positive experience -> builds on benefits of both remote and F2F meetings & experience acquired with remote meetings during COVID-19
- ✓ From a technical aspect, remote Committee meetings run smoothly and enabled an agile way of working (e.g. extraordinary committee meetings at short notice)
- ✓ Good balance between F2F and virtual meetings, i.e. ensures group cohesion through regular F2F meetings whilst offering flexibility with remote working
- ✓ Builds on EMA environmental policy & EMA commitment to environmental aspects
- ✓ Allows flexibility in meeting organisation & consideration of 'black-out' dates in AMS for hotel bookings



Experience acquired with remote oral explanations

- ✓ Oral explanations (OE) for human scientific committees held fully remote via telephone since COVID-19
- ✓ Feedback received from Applicants that format of OE was sub-optimal, as Applicants could not see the slides or the Committee members
- ✓ Format of oral explanation enhanced to Webex for OEs in front of CHMP/PDCO as of May 23 and being rolled out in June/July 23 to all Scientific Committees
- ✓ New format enables an experience as close as possible to a F2F setting -> Applicants can see the slides and the Committee Chairs/Members asking questions
- ✓ A review of the new format for remote oral explanations to take place after some experience acquired
- ✓ EMA acknowledges willingness of Applicants to resume F2F oral explanations -> concerns on how this could work on an alternating F2F/virtual format



Any questions?

Thank you for your attention

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

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