EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New practice for the management of clarification meetings

Presented by: Pavel Balabanov
Scientific and Regulatory Management Department

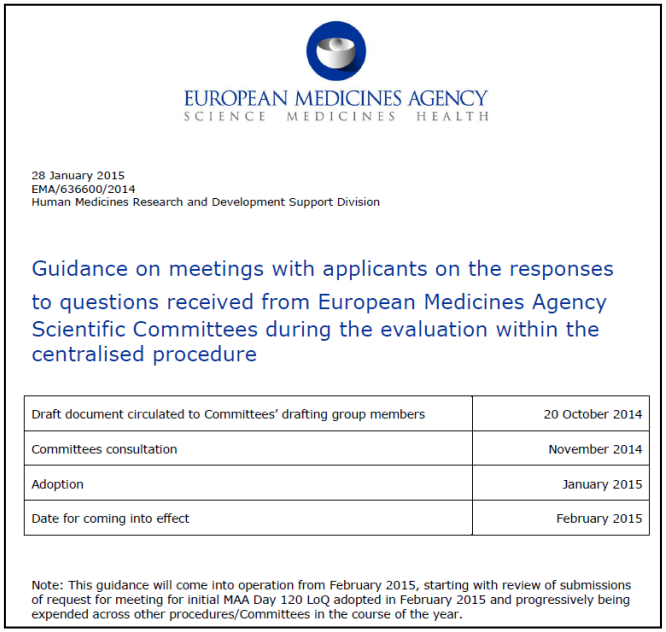
Objectives of clarification meetings

- To provide the applicant with an opportunity to better understand the considerations behind the questions and discuss/present their response strategy
- For the committee Rapporteurs to review the approach and provide a perspective how the Committee would see this approach addressing the concerns (strategy component)
- To clarify specific questions providing opportunity to applicant to better target their responses (clarification component)
- To prevent incomplete or premature responses leading to prolongation of the procedure
- To discuss the timelines and their implications in the light of the planned responses' submission by the applicant

Guideline revision coming into effect February 2015

Scope of the revision

- Meeting more focused on the strategy as opposed to focusing on the clarification component only
- Intended to provide a platform through which by means of communication with relevant EMA staff and the Rapporteurs, optimal results could be achieved during the sponsor's preparation for the meeting and throughout it
- New way of planning, organisation, conduct, communication and record tracking of the meeting



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2015
EMA/636600/2014
Human Medicines Research and Development Support Division

Guidance on meetings with applicants on the responses to questions received from European Medicines Agency Scientific Committees during the evaluation within the centralised procedure

Draft document circulated to Committees' drafting group members	20 October 2014
Committees consultation	November 2014
Adoption	January 2015
Date for coming into effect	February 2015

Note: This guidance will come into operation from February 2015, starting with review of submissions of request for meeting for initial MAA Day 120 LoQ adopted in February 2015 and progressively being expended across other procedures/Committees in the course of the year.

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005072.pdf

What has changed in practice for the Applicant? (1/2)

- Attached to the List of Questions produced at day 120 of the procedure the applicant will receive:
  - Details on what to provide in order to request a meeting i.e. agenda, briefing document, dial-in details, dates, time, list of participants, slides (2 weeks before the meeting)
  - Details of who to request the meeting to: EPL (with PM in cc) and Rapporteurs
- A justification will be needed for such meetings explaining the reason for them. This should be sent within two weeks after receipt of the adopted CHMP List of questions and will be assessed by the Rapporteurs.
- If agreed with it is expected to be scheduled within 1 month after CHMP List of questions' adoption

What has changed in practice for the Applicant? (2/2)

- The meeting should normally happen via teleconference and is expected to last up to a maximum of two hours when necessary
  - After the meeting: The Applicant prepares the minutes of the meeting within one week and send it to the Rapporteurs and the EPL for comments and is required to submit the final minutes as an attachment to the cover letter accompanying the responses
- These principles are also valid for responses to questions received during the evaluation of post-authorisation procedures, such as a Request for Supplementary Information (RSI) in the context of extensions of indications

Note: This guidance came into operation in February 2015, starting with review of submissions of request for meeting for initial MAA Day 120 LoQ adopted in February 2015 and progressively being expended across other procedures/Committees in the course of the year.