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.

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Guidance on meetings with Applicants on the responses to questions received from EMA Scientific Committees during the evaluation within the centralised procedure

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Introduction

In the context of applications for initial marketing authorisation, the value of clarifications meetings between Rapporteurs, the Applicant and the EMA, after the adoption of the Committee for Medicinal Products for Human Use (CHMP) Day 120 List of Questions (LoQ) or the CHMP Day 180 List of Outstanding Issues (LoOI) has been acknowledged over the years. These meetings are intended to discuss with the Applicants their response strategy and the potential need to adjust the response timelines, ahead of the formal responses submission within the legal timeframe.

Clarifications and transparent guidance to the Applicant on the rationale for the Major Objections and/or other issues as well as exchanges on the Applicant's proposed strategy and timelines for the responses may prevent the submission of inadequate, incomplete or premature responses leading potentially to prolongation of the procedure.

1. Scope of the guidance

This guidance describes the planning, organisation, conduct, communication and record tracking of the clarification meetings involving Committee (Co-) Rapporteurs (CHMP, PRAC and/or CAT, as relevant), the Applicant and the EMA Product Lead (EPL). These meetings will be convened as required, particularly in those procedures where major concerns are identified in the adopted CHMP LoQ or LoOI. To be most efficient and productive, these meetings are envisaged to be convened at an early time point during the said procedure and upon justified requests being accepted by the (Co-) Rapporteurs.

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.

2. Particularities of the meetings

a. Objectives of the meetings

- For the Committee (Co-)Rapporteurs, and based on the committee discussions, to clarify if necessary, the scientific rationale of the Major Objections and/or other issues adopted within the LoQ/LoOI which may not be unequivocally understood by the Applicant and clarify the appropriate EMA's Committees expectations on the responses.
- To discuss the Applicant's proposed responses strategy taking into account the regulatory context under which the Marketing Authorisation Application has been submitted, its dossier content and the Applicant's claim.
- Discuss the timelines' implications in the light of the planned responses' submission by the Applicant.

It should be emphasised that these meetings are not intended to provide a pre-assessment of the Applicant's intended responses.

b. Request and organisation of the meetings

- After the **receipt of the adopted CHMP LoQ/LoOI** and prior to the formal submission of the responses, the Applicant can request a meeting with the (Co-)Rapporteurs and the EMA (EPL and other relevant team members as appropriate).
- A **justification** for such meetings explaining the scope and the reason for them should be **sent within two weeks after receipt of the adopted CHMP LoQ/LoIOs** in order to be assessed by the (Co-) Rapporteurs. It is reminded that Applicants should carefully consider the appropriate reasons to request such meetings, having carefully reviewed and considered the LoQ/LoOIs. The detailed instructions on how to request, organise and prepare for the meeting will be sent to the Applicant by the EMA at the time of sending of the adopted CHMP D120 LoQ. Upon receipt of these instructions, the Applicant would be expected to send to the EPL the following, keeping the Procedure Manager (PM) in copy of all the correspondence:
    - proposed dates for the meeting,
    - list of applicant's participants,
    - an agenda indicating points to be discussed,
- Once agreed upon by the (Co-)Rapporteurs, the meeting should normally take place within a month after receipt of such acceptance.
- **At the latest one week in advance of the confirmed meeting date**, the applicant should send to the (Co-)Rapporteurs and EPL the following documents:
    - a briefing document explaining the Applicant's response strategy to address the questions identified by the Applicant for clarifications; In this document the applicant should explain the point(s) for discussion/clarification and its position and rationale,
    - a slide presentation to guide the discussion;

The meeting will usually happen *via* teleconference; in exceptional cases and depending on the availability of participants, a face-to-face meeting can be arranged. The meeting is expected to last a maximum of two hours.

c. Conduct of the meeting and participants

The Rapporteur will chair the meeting.

In addition to CHMP Rapporteur and Co-Rapporteur, their assessors may also participate as required, together with other committee Rapporteurs (as relevant and needed), the EMA Product Lead (EPL) and other relevant staff from the EMA as appropriate.

The Applicant should focus their presentation on the response strategy to address the points agreed to be discussed that require clarifications.

The (Co-) Rapporteurs should endeavour to represent the Committees' views/position on the issues discussed and the Committees' expectations, as appropriate. They will be supported by the EPL and relevant product team members.

The points discussed during the meeting and the conclusions on each of the points will be summarised by the Rapporteur. It is emphasized that while the (Co-)Rapporteurs will endeavour to present in the best possible way the Committees' position, this position cannot be taken as to pre-empt the outcome of the assessment, and cannot be regarded as binding to the CHMP and relevant Committees.

d. Records of the meeting

The Applicant will prepare the minutes of the meeting within one-week and send it to the Rapporteurs and EPL for comments. The EPL will co-ordinate the comments from the attendees and send to the Applicant the final version within 2 weeks.

The Applicant is required to submit the final minutes as an attachment to the cover letter accompanying the responses submission.

The (Co-) Rapporteurs may decide to put the minutes in the Agenda of the respective Committees, as appropriate, in case discussion is needed on specific scientific aspects or timelines consideration.