EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 July 2011
EMA/CHMP/551508/2010
Committee for Medicinal Products for Human Use (CHMP)

Procedural Advice for CHMP on the need to convene a Scientific Advisory Group (SAG) or *Ad Hoc* Expert Meeting

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Table of contents

Executive summary

It is necessary to identify the need for a SAG as early as possible in order to allow adequate planning and preparation of the meetings. The objective of this document is to provide procedural advice to Rapporteurs and CHMP members on timelines and factors for CHMP to consider when proposing whether to refer certain questions to a SAG or an Ad Hoc Expert Group.

1. Introduction (background)

SAGs have been established to provide an independent recommendation on scientific/technical matters related to products under evaluation through centralised regulatory procedures and Referrals by the CHMP or any other scientific issue relevant to the work of the Committee.

As per current regulation it is up to the discretion of the CHMP to convene a SAG meeting. The SAG can also be consulted through the CHMP on scientific questions by other EMA's Committees related to human medicines, by the Commission (e.g. in collaboration with the WHO) and by the Scientific Advice Working Party (see the SAG mandate and rules of procedure).

The Rapporteur, Co-Rapporteur or any CHMP member may suggest to the Committee the need for a SAG/ad-hoc Expert Group meeting to be scheduled in order to clarify the issues raised at any stage during the evaluation procedures (during the initial MAA evaluation, a re-examination procedure, a referral or during any type of post-authorisation procedure). The applicant/MAH may also request a SAG in the context of a re-examination.

The SAG can also be consulted through the CHMP by the CHMP Temporary Working Parties and Drafting Groups to address topics related typically to production of guidelines. The SAG itself can also propose general topics to CHMP for SAG discussion.

2. Scope

The objective of this document is to provide procedural advice to Rapporteurs and CHMP members on timelines and factors for CHMP to consider if and when proposing to refer certain questions to a SAG or an Ad Hoc Expert Group. The aim is to further develop a consistent approach when deciding in favour or against the need for a SAG meeting.

3. Legal basis

Regulation (EC) No. 726/2004. This document has to be read in conjunction with the SAG mandate and rules of procedure.

4. Situations for considering the need for a SAG meeting

- Expected major public health interest where public controversy might be expected (e.g.: first-in-class medical product for human use; medical product for a significant new indication).
- Substantial disagreement between rapporteurs and/or CHMP members on issues of clinical judgment and expertise (e.g.: where there is a clearly split CHMP on clinical relevance of beneficial effects or toxicity).
- Controversial issues of such nature that it would be highly beneficial for CHMP to seek the advice as part of the regulatory process (e.g.: high impact on health care professionals, the public and other stakeholders).

- Complex technical aspects, rare disease, need for specialist clinical expertise where CHMP feels it could be beneficial to seek external advice via a SAG (e.g.: novel product or use of new technology; intersection of several scientific disciplines; expertise on scientific techniques or research).
- Questions about risk minimisation measures affecting the clinical practice, where the advice of those currently working in that practice area would be helpful.
- Questions about the design and feasibility of a clinical trial (e.g.: scientific advice, post authorisation commitments) where the requisite expertise is not available within the regulatory system.
- Major post-authorisation safety issues on products such that the risk benefit is questioned.

5. Timing of The Request for a SAG meeting

5.1. General considerations

The need for a SAG should be identified as early as possible in order to allow adequate planning and preparation of the meetings, including the nomination of additional SAG experts if necessary.

The optimal timing of a SAG meeting will depend on a number of issues including type of input requested, urgency of the matter, procedural timing, experts' availability.

For practical reasons and to maximise expert availability it may be appropriate to group different SAG requests into a single meeting.

A SAG should also be considered in case of previous involvement of SAG for similar issue/procedure (in case the previous recommendations cannot be applied to the product under assessment).

5.2. Product and MAA related assessment

Very short procedures pose bigger challenges in terms of expert selection and timely preparation of the meeting. Early identification for a meeting should generally be considered for the following procedures:

- Procedures undergoing accelerated scientific assessment
- Article 20 procedures
- Non centrally authorised product referrals
- Non centrally authorised product issues raised by PhVWP to the CHMP
- Re-examination following request by the company

In case a potential need for a SAG is identified at the pre-submission stage for very short procedure, the date for the SAG will be tentatively identified and CHMP will be asked to put forward tentative nominations for additional experts for formal appointment to participate in the meeting.

The timing of the meeting should be chosen so as to allow the maximum benefit from the SAG advice during the assessment procedure. This will vary depending on a number of factors, in particular, the type of input requested, urgency of the matter and procedural timing.

In general, the need for a SAG will be identified by the Rapporteurs following the Rapporteurs' assessment of the data and circulation of assessment reports and before finalisation of the procedure. Typically, this will occur after assessment of the responses to the list of outstanding issues by the applicant/MAH and before an oral explanation/Opinion.

In certain cases, identification of the SAG could occur earlier in the process, for instance to assess complex technical aspects, rare disease, need for specialist clinical expertise, i.e., situations where the SAG could be asked to contribute to the primary assessment of the data or responses submitted in parallel to the Rapporteur's assessment.

5.3. Preparation, review and update of guidelines/concept papers, specific positions / Q&As

The timing of the interaction(s) with the SAG will vary depending in particular in particular on the type of input requested.

The timing of a SAG and type of input requested may also be discussed between the relevant Working Party and SAG chairpersons.

References

Mandate, objectives and rules of procedure for the scientific advisory groups (SAGs) and ad-hoc experts groups

(http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CHMP/people_listing_000031.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028dd2&jsenabled=true).

Procedural Advice to CHMP Members

(http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004020.pdf)