Scientific Advice for medicinal products in ANSM

Eligibility Criteria

Scientific advices/Protocol Assistances are free of fees in ANSM, because aiming at helping timely access of patients to innovative products or products corresponding to an unmet medical need, especially as regards rare diseases and paediatric developments.

The ANSM would only answer to questions where related answers are not included in existing EMA or ICH guidelines, or if the Applicant seeks feedback on justified reasons to deviate from these guidelines.

Consequently, a scientific advice request would not necessarily be accepted, depending of the product and of the nature of the questions raised.
In all cases, a Scientific Advice request will be refused:

- If a company has already obtained the EMEA advice (or has already submitted such a request)
- When rapporteur and co-rapporteur for MA request have already been designated by the CHMP
- For concerns raised by the ANSM during the assessment of a CTA or MAA. In that case, the Applicant will need to contact directly the Product Division in charge of the assessment of the request, and having issued the concerns.

Regulatory frame

Scientific Advice meetings are optional and relay on Company's and Regulator's free choice. A Company is free to request or not for a meeting; the ANSM is free to accept or to refuse a request.

In general, the advice is given based on the documentation provided by the Company, in the light of the current scientific knowledge and without prejudice to evolution and developments in the state of the art. Advice will be given in good faith but circumstances could change and an alternative approach to that advised may become appropriate.
Also, the scope of a Scientific Advice being to seeks Agency feed-back on specific issues not covered by available Guidance documents (see below), the recommendations given during the meeting will reflect personal opinions from internal or external experts invited to the meeting. Consequently, the advice will not be considered as binding, neither for the Applicant nor for the ANSM; however, major changes in the product development when compared to the recommendations given will need to be discussed and justified at the time of submitting e.g. a Clinical Trial Application or a marketing Authorization Request.

Objectives

Scientific Advice and Protocol Assistance (for orphan drugs) meetings at ANSM are organized in order to provide responses to specific questions raised by the Applicant related to quality, safety and/or efficacy of medicinal products in development in all fields of medicine and whatever the area of expertise concerned: pharmacokinetics, toxicology, pharmacology, methodology, statistics, benefit, risk…. For protocol assistance, questions related to the demonstration of significant benefit within the scope of the orphan drug designation are also discussed. Regulatory questions are out of the scope of Scientific Advices.

Request may be submitted at any stage of product development, however, the availability of at least preliminary non-clinical efficacy data ("proof of Principle") will make the advice more profitable for the Company.

The scope of Scientific Advices is not pre-assessment of data, and the appropriateness or completeness of a CTA or MAA does not enter the scope of Scientific Advices, and are meant to be discussed directly at the level of the Product Division where the dossier will be assessed, and at their discretion.
However, general recommendations on the development strategy, or the nature or details of studies to be completed before filing a CTA or a MAA may be discussed.

Given the Innovative nature of products falling into the scope of Scientific advice meetings in ANSM (see below Eligibility Criteria), it is likely that the MA will be assessed through a centralised procedure, and that an EMA scientific advice will be useful before finalising the development program. A national scientific advice at ANSM may however be useful in identifying the key issues to be discussed at the EMA level, and the head of the Scientific Advice Unit who chairs the Scientific Advice meeting in ANSM often thereafter candidate to be one of the coordinators of the EMA scientific Advice within the Scientific Advice Working party.

Procedural details

All exchanges with the Applicant will be by email at:
caroline.auriche@ansm.sante.fr
Voluminous documentation can be sent using Eudralink.

Applicants are received in ANSM for scientific advices two days per month, generally the third Tuesday and Thursday of each month, with exceptions linked to specificities of the agendas or working groups in ANSM or EMA, that we manage on a case by case basis, always 1-2 months in advance.

In order to be in a position to offer a slot for the organisation of a scientific advice meeting, the Scientific Advice Unit needs to receive first both a Request Letter and a Briefing Book.

The Request Letter will need to mention:

- the name of the product (Company product code, active substance and brand name when applicable), specifying if it is a chemical or a biological compound, the therapeutic indication,
- the number of questions and
- the areas of the development covered by the questions (Quality, Non clinical, Efficacy and Safety (specifying if PK or statistics are covered).

The Briefing Book will need to summarise, as shortly as possible,

- background information on the disease,
- background information on the product including steps of quality, non-clinical and clinical development, as often as possible as tables summarizing the studies completed, on-going and planned with outlines on the results,
- questions and Applicant's proposed argumented position on each question.
  A maximum 6 questions needs to be thoroughly selected based on their relevance and key role as regards the development, since an overall one-hour and a half meeting duration is allocated for both the Applicant's presentation and discussion/answer to questions. The ANSM may reject any question considered too general or for which an answer may be found through analysis of existing European or ICH guidance documents.

Corresponding templates for Request letter and Briefing Book are the same as the ones on EMA website for European scientific advices.
Authorised languages for documentation, correspondence and discussion meeting are English and French.

Upon reception of these documents, and after analysis of the fulfilment of eligibility criteria and identification of relevant participants to the meeting along with verification of their availability, the next available slot for the meeting will be proposed by email, with details on the time-frame.
The meeting will take place in the ANSM building. A further email will be sent specifying the exact location within ANSM.

Two weeks before the meeting, we are expecting receiving from the Applicant the list of participants and the slides of its presentation as powerpoint

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The day of the meeting, when arriving in ANSM, the Applicant's team will present at the Reception Desk and a representative from the Scientific Advice Unit will be called and will take them to the meeting room.

A proposal for meeting minutes should be sent by the Company within 2 weeks after the meeting.
The minutes should have the same structure as the Briefing document, with the draft ANSM answer located below the Applicant's proposal and justification for each question.
Minutes are reviewed by ANSM and sent to the Company for approval of any modification before officially validated and signed by the Scientific Advice Referent.
The signed copy is normally scanned and sent by email. The original may be sent by post-mail upon request.