Scientific advice and protocol assistance meeting requests at Afssaps

Aim

To help development of new medicinal products by taking into account the current knowledge of a given condition, targeted patient population, existing treatment modalities and specificities of the product being developed. In addition, regulatory requirements and existing guidelines are systematically integrated in the advice. The aim of the advice is not to substitute a company's responsibility in the development of its product.

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 Afssaps 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. Therefore, advice is not binding with regard to product developed, neither for the Company nor for Afssaps; however, major changes in the product development should be justified.

Scope

Scientific advice and protocol assistance meetings at Afssaps are organized in order to provide responses to specific questions pertaining to the quality, safety and efficacy of medicinal products in development in all fields of medicine. For protocol assistance, questions related to the demonstration of significant benefit within the scope of the orphan drug designation are also discussed.

Scientific advice and protocol assistance meetings are of particular interest where there are no available EU guidance documents and/or when a company chooses to deviate in their development program from the available guidance.

A national scientific advice may be useful in identifying the most important points to discuss at the EMEA if an EMEA advice is planned by a company.

It is not in the scope of scientific advice to provide a pre-assessment of data; however, the appropriateness and completeness of MA file before submission may be discussed. The advice will not be given :

- If a company has already obtained the EMEA advice
- When rapporteur and co-rapporteur for MA request have already been designated by the CHMP
- For concerns raised during assessment of MA request

When may a company request for a scientific advice?

During medicinal product development

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

Before submission

To discuss completeness of marketing authorization file before legal submission

During post authorization phase

eg. new indications.

Content of the request

Questions may address specific scientific issues such as:

- Specific issues concerning the pre-clinical development,
- Specific issues on the clinical development (e.g. endpoints, trial duration, target population, comparator, study design, safety)
- Quality aspects (e.g. specific tests to be performed during the development of biotechnological products)

The questions asked by a Company should be as clear as possible and Company's position justified.

Structure of the request

Cover letter

Includes the description of the product, the intended indication, the scope and the justification of the request and proposals of dates (several dates to be proposed by the Company within the two months following the request)

Briefing document

It includes:
- Background information
- Disease/targeted population/Indication
- Specific problems pertaining to this request
- Questions : company's position and justification for each question
- Investigator's brochure

Participants

In-house and external experts invited by Afssaps

Minutes of the meeting

Should be sent by the Company within 3 weeks after the meeting.
The minutes have the same structure as a Briefing document :

- Background
- Disease/targeted population/indication
- Specific problems pertaining to this request
- Questions : for each question
  a) company's proposal and justification
  b) agency's response

- Conclusion

Minutes are approved and officially validated by Afssaps and sent to the Company shortly upon approval.

Fees

free of charge

Timetable

The delay will depend on the availability of experts needed; in most cases, meetings are organized within 2 months after the receipt of the request. This delay may be longer. The relevant documentation should be sent at least 3 weeks before the meeting.

Contact

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