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Guidance for applicants on Simultaneous National Scientific Advice (SNSA) Briefing book format and content

Introduction

This document is intended to provide applicants general guidance on the type of documentation and the format of information to be provided in the context of a SNSA request. Applicants are being recommended to take this guidance into account when preparing for an SNSA request in order to ensure that the information to provide advice on is appropriate and allows the NCAs taking part in the SNSA pilots to effectively handle all incoming requests. The quality and format in which SNSA requests are submitted is critical to allow NCA's not only to guarantee predictive procedural timelines but also to facilitate scientific and regulatory advice of high quality. Therefore, applicants are being recommended to provide the following documentation in the context of their SNSA request:

1. At the time of initiating the SNSA submission request

- Application form
- Draft List of Questions for which SNSA is being requested to allow the involved NCAs to start designating the most appropriate experts for addressing the SNSA request
- Brief outline of the scope of the SNSA request (e.g. including short description of the drug product characteristics, manufacturing process for e.g. ATMP, background of the intended (pre) clinical development project, etc.

2. At the time of the formal start of the procedure

- Cover letter:
 - A clear description + rationale for demanding SNSA
 - If the SNSA request is related to specific, planned or ongoing applications (e.g. other national advice requests, CTAs, MAAs, SAWP advices, PIPs etc.), explicitly refer to these applications
 - If applying for any kind of fee exemption or reduction of the standard fee charged by the NCAs for national or simultaneous national scientific advice requests (see details on the NCAs webpages), please state

- Detailed list of questions & clear position statement of the applicant for each question⁽¹⁾,
i.e. questions related to quality, preclinical, clinical, regulatory or other issues. This information is critical to allow the involved NCAs to designate the most appropriate experts.
- Briefing Document containing all detailed scientific and regulatory information regarding the dossier:

e.g. scientific background information on the drug product, regulatory status of the product, planned clinical trials, the development status of the drug product (e.g. exploratory phase, Phase I - III, etc...), target indication / patient population, etc.

Applicants are strongly recommended to apply the CTD format in their briefing document.
- Additional supportive documentation⁽²⁾:

Any relevant, supporting documentation that might be available at the time of submitting a formal SNSA request and as far as applicable in the early stage of product development: e.g.
 - Product information
 - Investigator Brochure
 - Relevant study protocols or draft protocols / study synopsis
 - Relevant draft IMPD(s)
 - Bibliographic info (references)
 - Content of previously received or pending scientific advices (eg. from other NCA(s), EMA, FDA, ETF, ITF, CTEG, etc.)Relevant guidelines (e.g. different from CHMP/CVMP guidelines), including national guidelines
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 - Other relevant documentation

⁽¹⁾ When submitting the detailed list of questions, applicants should avoid including new questions or subquestions that were not previously included in the draft list of questions at the time of initiating the SNSA request. The same holds true for introducing question modifications (as compared to the draft list of questions) that would require additional expert designations from the involved NCA's as this could trigger significant delays in the planification of the formal SNSA meeting.

⁽²⁾ Additional supportive documentation can be provided in the SNSA request either as an annex in the briefing document or as separate documents provided that clear cross-reference is made by the applicant between e.g. the briefing document and the additionally provided documentation.