DG Pre Marketing Authorisation

Federal agency for medicines and health products
Galileelaan 5/03
1210 Brussels
www.afmps.be

National Scientific-Technical Advice (STA) dossier content and format:

Guidance for Applicants (Version 1.3)

In order to provide national scientific and/or technical (regulatory) advice in an oral or written manner, applicants are requested to provide the FAMHP with the following documentation at the time of submitting the official STA request:

- **Electronic application form**
  Only those fields that are applicable to the specific STA request should be completed.

- **Table of content of the national STA request**

- **Cover letter:**
  The cover letter must include a clear description + motivation (rationale) for demanding national scientific-technical advice. In addition, if the STA request is related to specific, planned or ongoing applications (eg. other national advice requests, CTA's, MAA's, SAWP advices, PIP's, etc.), the applicant is asked to

explicitely refer to these applications in the cover letter (eg. by mentioning the designated dossier nr.).

The applicant should clearly mention its address and VAT number that is to be included on the invoice. In case the applicant is eligible and wishes to apply for an exemption of the standard fee (cfr. Detailed guidance for national STA requests – page 17), the applicant should explicitly indicate this in the cover letter.

- **Detailed list of questions & position statement of the applicant for each question:**
  (i.e. questions related to quality, preclinical, clinical, regulatory or other issues). This information is critical to allow the FAMHP to designate the most appropriate experts for addressing the STA request.

- **List of proposed participants (including their function/affiliation) and meeting agenda**:
  (cfr. In case a face-to-face meeting or teleconference meeting would be requested by the applicant)

- **Detailed information regarding the dossier:**
  eg. Background of the drug product, the intended clinical trial, the development status of the drug product (eg. exploratory phase, Phase I - III, etc…)

- **Supportive documentation:**
  Any relevant, supporting documentation that might be available at the time of submitting a national STA request and as far as applicable in the early stage of product development: e.g.

  - product info
  - Investigator Brochure
  - Relevant study protocols or draft protocols
  - Relevant draft IMPD's
  - Bibliographic info (references)
  - content of previously received or pending scientific advices (eg. from other EU member states, EMA, FDA, etc)
  - relevant guidelines (eg. different from CHMP/CVMP guidelines), including. national guidelines
  - other relevant documentation

Important remarks:

- In case the STA request is submitted to the FAMHP by a legal representative (eg. a consultant) of the applicant: In addition to the above mentioned documents, a letter of authorisation from the applicant should be included in the formal STA request. The authorization letter should clearly state that this particular legal representative is legally powered by the applicant to act on his behalf in this specific national STA request.

- For SME's applying for national STA according to the 75% reduced STA fee concept, a declaration of an external auditor must be attached to the STA request stating that the applicant is an SME as defined in annex IX of the Law of 7 APRIL 2019.

Universities, certified hospitals, foundations for the public good and statutory administrations should be formally recognized by the FAMHP as sponsor of non-commercial studies as defined by art. 31 of the Law of 7 May 2004 in order to be eligible for the 75% reduced STA fee. This recognition should normally be in place prior to applying for a formal STA request or should at the latest by initiated by the Applicant in parallel with the national STA request submission.

- Presentation material which may be presented by the applicant on a voluntary basis during a meeting at the FAMHP can be sent later on, at the latest 1 or 2 weeks prior to the meeting.

- For STA requests which are related to a clinical trial that the applicant plans to perform in Belgium: In case the STA request would contain specific questions regarding clinical issues, clinical statistics, the protocol design of the planned clinical trial, etc., please include details in the STA request on the involved ethical committee(s), in particular the leading EC. In case the (leading) EC has not been designated at the time of submitting the STA request at the FAMHP, please include details on the EC('s) that are likely to be involved in the clinical trial.