DG Pre Marketing Authorisation

Federal agency for medicines and health products
Eurostation II - Place Victor Horta 40/40
1060 Bruxelles
www.afmps.be

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

Guidance for Applicants (Version 1.2)

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:

- **Proof of payment (eg. bank statement)**
  Applicants should clearly mention on the bank statement if the application concerns a Type I, Type II or Type III STA request and if it concerns an initial or follow-up STA request; followed by the name of the applicant. The topic of the submitted STA request (eg. product name) should also be clearly mentioned.
- **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.)

- **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.

- 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 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.