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

FAQ's - national scientific-technical advice requests

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Payment of fees

1. **The published guidance states that the fees should be paid before submission and that proof of payment should be included in the submission. What would normally be done in these circumstances? Should an applicant wire-transfer the fee direct to the Agency, without any invoice being issued, and then include in the submission a copy of a statement of confirmation from the bank that the funds have been transferred? Alternative, does the Agency issue an invoice for STA against which the fee can be paid?**

   As mentioned in the published guidance document on national scientific advice requests, the fees for a STA request should be paid before submission and a proof of payment should be included in the formally submitted dossier. This payment procedure implies that the applicant should wire-transfer the fee directly to the bank account nr of the Agency (mentioned in the guidance document and on the website), without any invoice being issued, and then include in the formal submission a proof of payment (eg. a copy of a statement of confirmation from the bank that the funds have been transferred). Thus, our agency does NOT issue an invoice towards the applicant for national STA requests.

2. **Could you advise whether the Agency now provides any additional incentives / discounts over those offered by the EMA? For example, does the agency offer any fee reduction for National Scientific Advice requests from SME's, academic centres, etc.?**

   No, the Agency doesn't provide any additional incentives over those offered by the EMA .
   At current, the Agency doesn't offer an fee reduction for national scientific advice related to eg. orphan drugs or advice requests from SME's, academic research centres, etc.

3. **What should the applicant do in case the originally submitted Type I STA is considered by the FAMHP as a Type II or Type III STA during the validation of the dossier?**

   In that case, the applicant should deposit the missing part of the corresponding Type II / III STA fee during the validation of the dossier (i.e. clearly referring to the company and product name etc. when making the bank transfer).

4. **Can the payment for a national STA request be performed by credit card? On the website it is only mentioned that payments can be made through a remittance?**

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The modality of payment is free of choice for the applicant. The information regarding the payment must be correct (i.e. correct fee on the correct FAMHP bank account number; with a clear mentioning of the applicant name en the name of the STA dossier) so it could be easily traced back by the departments of the FAMHP.
In any case, the applicant must include a proof of payment (eg. a copy of the remittance) in the STA dossier so the verification of appropriate fee payment could be performed.

Application form

1. **Is it possible that the application form is not entirely accessible; in particular it seems that the name of the applicant can not be introduced and that the sections 'CONTACT', 'PRODUCT' and 'DOCUMENTS' can not be correctly used?**

   The (pink) data field for the applicant name on the front screen of the electronic application form is automatically completed when you first create a field for the applicant name under the section 'CONTACT' and on the right side of the field fill in the data (name, address, etc). Subsequently, when you return to the front screen of the application form, the applicant name should automatically appear in the corresponding pink data field.
   Concerning the access to the section 'CONTACT', 'PRODUCT' and 'DOCUMENTS': Normally, a screen would automatically appear when clicking on these sections in which the alongoing data fields can be completed. Tthe data fields can be completed when selecting them with the cursor.
   It is recommended to save the MS Acces document on your computer after opening the zip format of the application form.

2. **Does the FAMHP provides a WORD-format of the electronic application form in case the applicant does not have MS Acces software?**

   Yes, this is possible if necessary.

3. **How can the electronic application form (available on the FAMHP website) be uploaded by the applicant into the D-base of the FAMHP?**

   The electronic upload of the application form can only be performed by the FAMHP. There is no web-based portal at current to allow applicants to upload the completed form into the FAMHP internal D-base. After downloading and completing the Access form template, the applicant can send this form (eg. directly in access-format or indirectly in zip-format) to the FAMHP via e-mail or via post with CDrom/USB key.

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4. **Can applicants, in a first step, only submit some supportive documents (eg. application form) and provide others (especially the briefing package) in a second step of the submission a few weeks later (4 weeks ahead of the meeting)?**

   No, all relevant information regarding the STA application has to be provided in one submission step with exception of the meeting slides for the scientific advice meeting. In the open text fields of the application form you can clarify if such specific documents will be sent in a later phase.

Timelines

1. **Phase de validation : combien de temps prend l'étape de validation de notre dossier?**

   The validation phase normally takes 1 week (i.e. if the dossier is complete). The validation starts when the dossier and the fee have been received by the FAMHP. The duration of the validation phase depends on the quality of the dossier. If the dossier contains all documents that are requested by agency (cfr. note on the website), the validation can be performed within normally 1 week. However, if the dossier contains shortcomings, the validation phase could take longer.

2. **In which timeframe organizes the FAMHP the scientific advice meeting counting from the day that the Type II /III advice request has been declared valid?**

   Normally our agency aims to organize a scientific advice meeting within 6 weeks after validation of the scientific advice request. The legal delay is maximum 70 calender days after time of validation of the advice request.

3. **Evaluation phase : A face-to-face meeting or a teleconference meeting is normally forseen within a timeframe of max. 70 calender days for Type II / III STA requests after validation of the dossier. Is this delay valid independent of the calender period in which the dossier is submitted (during vacation periods)?**

   Yes, the maximum delay of 70 days for the evaluation phase is being maintained independent of the calender period in which the dossier is submitted although it is less evident to bring together all involved parties during holiday periods.

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Supportive documentation / briefing document

1. **"Detailed information regarding the dossier. Eg. background of the drug product, planned clinical trials, the development status of the drug product".**

   The list of required supportive documents which can be found in the « Guidance for Applicants : National STA dossier content and format » is a non-exhaustive list that provides examples of the type of documents that can be included in an advice request. If the Investigator Brochure, study protocol and IMPD contain all necessary information to allow the adequate treatment of the STA request, the STA dossier could be validated as such.

2. **« Supportive documentation : product info ».**
   Is this document applicable for any stage of product development? If yes,can you specify what info should be included in the Product Info section?

   The agency asks that all available information that is relevant to the product or the formulation should be provided at the time of STA submission. In addition, the « electronic application form » available on our website which the applicant needs to supply, contains several data fields that need to be completed. Depending on the development phase of your product, it is possible that you do not need to fill in all data fields available in the section « Product(s) » of the electronic application form. Only those data fields that apply to your specific situation need to be completed.

3. **« Table of content of the national STA request »**
   Can you clarify if this document is mandatory and if so, what information does it need to contain? In the cover letter, we intend to list the documents supplied in the STA dossier (i.e. proof of payment, electronic application form, list of questions, list of participant & agenda, Investigator Brochure, IMPD…..). Is this sufficient?

   The table of contents should mention all the supplied documentation of the STA request. This document is not strictly necessary if a list of all supplied documents is already listed in the cover letter.

4. **If available can the IMPD, clinical trial protocol (CTP) or Investigator Brochure (IB) be submitted in support of the scientific advice request?**

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Yes, all available documentation that is relevant to the questions for which the FAMHP's formal advice is being asked, should be included in the advice request. In the early phase, this can be eg. an IMPD or draft IMPD, CTP or protocol synopsis or draft protocol, IB, summary of the protocol design, etc.

5. **Content of previously received scientific advices**
   Does the applicant need to mention in the STA request all documentation that was included in the context of previously submitted STA requests (eg. Cover letter, Briefing book, Investigator Brochure) or only the issued scientific advices?

   It is not necessary to provide all documentation that was submitted in the context of previous scientific advice requests. In general, a copy of the issued advices should be sufficient.

6. **Does a formal FAMHP template exist regarding the content / structure of the briefing document in the STA dossier?**

   No, a formal template does not exist at current. However, the applicant is being recommended to use the CTD format as much as practically possible.

Scientific advice meeting (for Type II / III STA dossiers)

1. **When compiling the draft meeting minutes template, it is not clear if it is expected from the applicant to put already in the fields " FAMHP answer " what the applicant understood to be the answer of the FAMHP on the raised questions, or whether these fields are reserved for the comments of the FAMHP after sending back the draft meeting minutes to the agency.**

   Yes, during compilation of the draft meeting minutes, the applicant can already summarize in the fields " FAMHP answer " of the template what the applicant understood to be the answer of the FAMHP on the questions during the advice meeting. They are not specifically reserved for the FAMHP comments at this stage (cfr. this approach enables the FAMHP to check if the FAMHP position has been correctly understood by the applicant during the meeting).

2. **If a meeting is necessary, how many representatives from the FAMHP participate? Is this number usually balanced (eg. in function of the raised questions)? From the applicant's side is it also possible, if there is need for clarification in one discipline, that an additional expert needs could attend the meeting?**

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The number of FAMHP experts involved in an STA dossier largely depends on the nature of the questions raised by the applicant (which can vary a lot). The FAMHP makes sure that all necessary experts participate in the scientific advice meeting to address all questions. The applicant is free to bring one or more experts to the scientific advice meeting if needed (eg. in function of specific questions/disciplines, either via face-to-face meeting or via teleconference).

3. If a meeting was to occur is there a need to provide a presentation upfront and if yes how much in advance?

This is not strictly mandatory but it is strongly being recommended as it allows the applicant to clearly present their case and to summarize the key data and questions that are subject of the scientific advice meeting.
The FAMHP normally asks the applicant to provide the powerpoint presentation 1 – 2 weeks in advance of the meeting which is also sent to the FAMHP experts in preparation of the meeting with the applicant.

4. **In case the applicant should consider the written response issued under Type I STA request insufficient, is there a possibility - after the written advice has been issued by the FAMHP - to have a discussion meeting if deemed necessary from the applicant's side?**

After a formal scientific-technical advice has been issued (either in writing: cfr. Type I STA procedure) or orally + followed by the scientific advice meeting minutes (cfr. Type II / III STA procedure), the applicant can ask for clarifications (if needed) but only on the issues that were subject of the initial STA request. For other (new) issues that may arrive after the formal advice was given, a follow-up STA request can be submitted. According to the current procedures for national STA requests, only the Type II / III STA procedure foresees the possibility to have a discussion meeting between the FAMHP experts and the applicant. The Type I STA procedure only provides technical-regulatory advice in writing without any meeting.

5. Can the applicant propose target dates for a face-to-face meeting with the FAMHP (in case of a Type II / III STA) and if so how long beforehand does the applicant need to submit his STA in view of the proposed STA meeting date?

Yes, it is possible. i.e. Target dates can be proposed by the applicant when submitting his STA dossier to the FAMHP. In that case the proposed target dates should preferentially be mentioned in the cover letter of the formal STA request.

Normally the FAMHP tries to organize the face-to-face / TC meeting with the applicant within 6 weeks after the formal STA request has been declared valid.

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Electronic submission

1. Which format of electronic supportive documents is accepted by the FAMHP?

The supportive documentation can be submitted in pdf format (read and write) or in word format in order to allow the readers and experts to use the documents for editing (eg. to prepare an assessment report).

2. Can the Eudralink system be used for submitting STA requests to the FAMHP?

Yes. The Eudralink system can be used.