famhp
federal agency for medicines and health products

STA procedure for Health Products – Guidance for applicants

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1. Introduction

The Federal Agency for Medicines and Health Products (FAMHP) in Belgium offers applicants the possibility to request national scientific and/or technical advice (STA). The advice relates to the research and development aspects of medical devices (MD), in vitro diagnostics (IVD), substances of human origin (SoHO) and raw materials for human use in view of potential clinical investigation applications, performance study applications, conformity assessments, introduction of post-market product changes or post-market clinical follow-ups (PMCF). The FAMHP's main objective in providing STA to applicants at a national level is to promote and facilitate the development of new medical devices, IVD's, SoHO's and raw materials as much as possible from a regulatory perspective in order to increase the availability of innovative products to patients, particularly in therapeutic areas with unmet medical needs.

Therefore, the National Innovation Office and Scientific Technical Advice Unit of the Directorate General PRE authorisation offers a centralised and transparent service within the agency to ensure the timely processing of national STA requests while assuring full confidentiality and management of potential conflict of interest of the experts involved. The FAMHP also aims to provide a consistent follow-up to previous national and European advice, in order to guarantee the quality and consistency of the national STAs issued by the FAMHP.

The national STA can be issued to sponsors of clinical investigations and performance studies, pharmaceutical/biotech companies (e.g. small biotech spin-offs, global companies), research centres, etc.

Given that science and subsequently the scientific/regulatory guidelines are constantly evolving over time, the national STA issued by the FAMHP is to be considered as not legally binding with regard to any future, related application, neither towards the FAMHP, nor to the applicant. The advice given by the FAMHP is based on the questions and information submitted by the applicant at the time of the STA request and cannot take into account any future changes in science and the scientific/regulatory guidelines. When the initial STA request has been processed by the FAMHP, applicants are free to submit a follow-up STA request at any time (e.g. when they feel the need to obtain advice on new development data that have been obtained, changes in scientific/regulatory guidelines, etc).

National STA applications may be submitted to the FAMHP at any time, independently from other ongoing or planned applications, e.g. clinical investigation (CI), performance study (PS), PMCF, post-market performance follow-up (PMPF), SoHO authorisations. Applicants are strongly recommended to seek the FAMHP's advice well in advance of an upcoming application. Nevertheless, the FAMHP maintains the right to refuse STA requests in case of ongoing legal procedures which are related to the STA request and which may involve FAMHP experts. In this case, the STA request cannot be treated by the FAMHP as long as the legal procedure has not been closed.

A national STA request related to an upcoming application (e.g. CI, PS ...), which the applicant plans to submit in the near future should not be considered as a preliminary assessment or approval of that upcoming application.

The objective of this guidance is to provide applicants with information regarding the planning and submission of national STA requests to ensure an effective and efficient handling of all advice requests throughout the procedure. In particular, this guidance provides information on the conditions, timelines, and procedure, as well as the scope for requesting national scientific and/or technical advice from the FAMHP.

2. Legal basis

2.1 National legislation

- Law of 20 July 2006 on the establishment and operation of the Federal Agency for Medicines and Health Products, Article 4/2, §§ 1 and 2;
- Royal Decree of 12 May 2024 relating to scientific and technical advice on health products and advice relating to the status and classification of a product.

2.2 European legislation

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Annex IX, Sections 5.2, 5.3.1, 5.4;
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, Annex IX, Section 5.2.

3. Types of requests

As defined in the Royal Decree of 16 July 2012, the following types of advice fall within the legal scope of a national STA request submitted to the FAMHP: STA request type I, II and III.

3.1 STA request type I

A STA request type I is a request for advice on one specific question regarding:

- scientific issues related to research and development;
- technical and/or regulatory issues for which no (national or European) legislation or guidelines exist or the current legislation or guidelines are insufficient.

No multidisciplinary expertise would normally be required to address type I STA request questions.

Given the general and straightforward nature of this type of advice request, only expertise in a specific field is required. As a result, the request will be addressed in writing. However, on an exceptional basis, an individual question may concern a complex matter that requires in-depth expertise. In that case the request might be considered by the FAMHP as a type II or type III STA request (i.e. depending on the complexity of the STA request), since it represents a heavy workload. In this case, the STA request will follow the procedure for type II or type III STA requests (cf. section 6.3).

3.2 STA requests Type II and III

A type II STA request is an advice request for multiple questions within one domain of expertise (e.g. related to quality, non-clinical or clinical, regulatory issues).

A type III STA request is an advice request for a set of specific questions across multiple domains of expertise. Multidisciplinary expertise is required to address these questions. Another Belgian health authority (e.g. Sciensano, FPS Public Health, Federal Agency for Nuclear Control, etc.) may also be involved in the advice, classifying it as a type IIIb request (otherwise it is a type IIIa). This type of joint advice can be requested, but its necessity must be duly justified and is subject to acceptance by the other authority.

Given the broader nature of type II and III requests, they are usually addressed during a meeting and accompanied by a written report. This procedure is detailed in section 6. More information on the maximum legal deadlines for the FAMHP to provide formal advice to the applicant after validation of the STA request can also be found in section 6.

A list of examples of questions for the different types of STA requests that can be submitted to the FAMHP is available in Annex 1.

4. Scope

In general, a national STA request submitted to the FAMHP may cover multiple questions related to a wide range of areas in research and development products.

Non-exhaustive list of examples:

MD, IVD

- quality aspects;
- non-clinical aspects;
- clinical aspects;
- technical and regulatory issues;
- clinical investigations;
- clinical evaluation and post-market clinical follow-up (PMCF);
- performance studies (PS);
- performance evaluation and post-market performance follow-up (PMPF);
- physico-chemical characterisation;
- microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing.

SoHO

- donation;
- procurement;
- testing;
- processing;
- preservation;
- handling;
- SoHO authorization.

National STA requests may be related to:
- the research and development of specific medical devices, IVD's, SoHO and raw materials;
- more general, non-product related aspects (e.g. platform technologies).

National STA requests may cover different types of products:
- medical devices: class I, class IIa (short and long term use), class IIb (short and long term use), class III;
- IVD: class A, class B, class C, class D;
- SoHO: cells, tissue, blood, SoHO preparations.

4.1 Out of scope

Depending on their nature and purpose, several type of advice requests/questions fall outside the legal scope of the national STA procedure as they are being addressed by the FAMHP in a different way, according to different procedures, timelines, ... Addressing such advice requests/questions normally falls within the informative tasks of the FAMHP, for which no additional fees are charged.

The following types of advice requests/questions are considered 'out of scope' (this list is non-exhaustive):

- **Advice requests related to current legislation**

Advice requests representing one or multiple specific questions regarding technical and/or regulatory subjects for which there are differences in the current legislation.

- **Frequently asked questions (FAQ's)**

Frequently asked questions on, for example, submission procedures or general dossier requirements, as described in current national and European guidelines, legislation …

- **Dossier-related questions**

Questions from applicants submitted to the FAMHP within the context of an application (e.g. CI, PS, PMCF, PMPF, SoHO authorisations) in Belgium fall within the procedure for that specific application and are normally handled by the assigned file manager(s). Consequently, dossier-related questions are outside the scope of the national STA procedure.

- **Legal advice**

Requests for legal advice should be sent directly to the legal department of the FAMHP and fall outside the scope of national STA requests.

- **Portfolio meetings**

Applicants can request a portfolio meeting with the agency. This informal and informative meeting typically gives pharmaceutical companies the opportunity to present an overview of one or several development programmes, therapeutics areas in which the company is actively involved, different products (or classes of products) which are in the development phase. In addition, the portfolio meetings allow the agency to clarify its role in a forthcoming European procedure for specific medicinal or health products. This information forms an important basis for the long-term planning. This type of meeting is considered to fall outside the scope of a national STA request and therefore no fee will be charged to the applicant for a portfolio meeting. Detailed information on how to apply for a portfolio meeting can be found on our website.

However, if the applicant seeks advice on specific scientific, technical and/or regulatory aspects (e.g. related to an individual development program), this advice is considered to fall within the scope of a national STA request as this would rather be discussed in a specific advice meeting. The need for a subsequent specific STA meeting may result from a portfolio meeting; this advice must be requested separately.

- **Project info meetings**

For small and medium enterprises, academic research centres, spin-offs and academic hospitals, the National Innovation Office provides the possibility to informally present a specific clinical research project in a very early stage of development.

Project info meetings give innovators with initial high-level guidance on general regulatory requirements, scientific guidelines and key development aspects relevant to the initiation of a development project for a medicinal or health product. These meetings are intended to help identify potential future scientific, technical and regulatory challenges that may impact the project.

Project info meetings can also create early awareness about particular uncertainties, potential criticalities or the feasibility of the project. This can in turn facilitate project planning, thereby increasing the chances for success. If necessary, the applicants will be advised during such informal project info meeting to request a formal national or European scientific advice on key issues that were identified in a next phase.

Since project info meetings are informal of nature, no fee will be charged to the applicant for such meeting request.

Detailed information on how to apply for a project info meeting can be found on the website.

- **Qualification/classification of medical devices**

Any questions about qualification/classification of medical devices are handled via the STA Borderline procedure at FAMHP. You can consult the corresponding webpage for more information.

- **Questions concerning other aspects**

All questions on medicinal products and medical devices (not related to research and development) used in combination with a medicinal product and falling under the legal statute of a medicinal product.
For example, questions concerning the proper use of medicinal products, publicity issues, counterfeit …
You can consult the corresponding webpage for more information.

5. Timing of requests

5.1 Introduction

Scientific and/or technical advice can be requested during any stage of the product's life cycle of medical devices, in vitro diagnostics (IVD), substances of human origin (SoHO) or raw materials.

5.2 Initial/follow-up STA requests

As previously mentioned, after an initial STA request has been addressed by the FAMHP, applicants are free to submit a follow-up STA request at any time (e.g. whenever there would be a need to seek advice on new development data that have been obtained, when changes in scientific and/or regulatory guidelines have taken place, etc).

Regardless of the procedure followed for the initial STA request, any follow-up STA request may be treated by the FAMHP either as a type I, II or III national advice request depending on the scope of the follow-up STA request. The applicable fees for a follow-up request are the same as those for an initial STA request.

5.3 Clarification requests

In some cases it is possible that the applicant requests a clarification of the formal advice issued by the FAMHP of an initial or follow-up STA request. Requests for further clarifications should be submitted within 14 calendar days following receipt of the final scientific advice (see section 6.3). In such cases, no additional fee will be charged for the clarification given by the FAMHP.

The request for clarification may be addressed by the FAMHP either in writing (i.e. standard approach) or on an exceptional basis through a meeting with the applicant. However, such clarification is strictly limited to the questions and issues that were addressed during the formal STA procedure (i.e. either in a face-to-face meeting, a teleconference meeting, or in writing). Any new questions that have arisen from the initially issued FAMHP advice should be addressed in a follow-up advice request.

6. Procedure and timelines

6.1 Introduction

Applicants who intend to seek scientific and/or technical (regulatory) advice from the FAMHP, are requested to strictly follow the procedures described below. This will allow the FAMHP to provide targeted advice within the stipulated timelines.

Each official request for national STA that falls within the legal scope of a type I, II or III STA request should be submitted to the Directorate General PRE authorisation of the FAMHP. Requests should be sent electronically to our central email inbox: sta.meddev@fagg-afmps.be.

Alternatively, to submit large electronic files, electronic STA requests can also be sent via the Eudralink system or via an online data sharing platform of your choice. If you encounter any problems with the form, you can contact us via sta.meddev@fagg-afmps.be or at the following address:

Federal Agency for Medicines and Health Products
Directorate General PRE authorisation
National Innovation Office and Scientific Technical Advice Unit
Galileelaan – Avenue Galilee 5/03
1210 Brussels
BELGIUM

6.2 Payment information

Please find all the information on the fees applicable in the current year on our website.

Applicants do not pay a fee when submitting the application for advice but will receive an invoice sent by the FAMHP's Budget and Management Control Division following formal validation of the request. Each payment should be accompanied by the structured reference on the invoice, so that the payment can be linked to the correct invoice, even if the payment is made by a third party. Without the structured reference the invoice will be considered as unpaid.

The procedure:

- The company receives a quarterly invoice for all national STA applications submitted during the previous quarter.
- The invoice lists the references of the files.
- The fact that the FAMHP does not work with Purchase Order (PO) numbers is not a valid reason for not paying an invoice.
- You will always receive the invoice at the invoicing address. Please state your email address for invoicing purposes in the 'cover letter' when submitting the request for advice.
- Have you already paid a fee for a recent request for advice? Send an email to refund@fagg-afmps.be to request a refund of the paid fee.
- Bank fees for payments from outside Belgium are at the payer's expense and may not be charged to the FAMHP.
- If the applicant withdraws a STA application after validation of the application, the fee will still have to be paid.
- If a formally submitted STA application is declared invalid by the FAMHP at the end of the validation phase of the procedure, no fee will have to be paid by the applicant.

6.3 Procedures and timelines

National STA requests generally follow the three-step procedure outlined below.

6.3.1 Step 1: validation phase

The FAMHP will verify for each request if the following criteria are met:

- the submitted STA request falls within the legal scope of a national STA request;
- the submitted STA request has been correctly submitted by the applicant under the correct type of STA request;
- all supporting documentation is included in the submitted STA request (cf. section 7);
- the applicant provides a clear and solid motivation for seeking national scientific and/or technical advice.

The validation phase will only start when the Directorate General PRE authorisation of the FAMHP has received the formal STA request (including all supporting documents).

Based on the received documents and depending on the complexity and nature of the raised questions, the FAMHP will assess whether the submitted STA request meets the definition of a type I, II or III STA request and whether a meeting at the agency would be necessary (i.e. for type II and type III), or if a written advice will be given (i.e. type I STA advice). Nevertheless, it is the applicant's responsibility to submit the STA request under the appropriate procedure.

The applicant will be informed about the validation of the STA request. Any refusal to validate the STA request will be communicated to the applicant as soon as possible.

Grounds for refusing validation of the STA request may include:

- insufficient or missing motivation of the STA request;
- insufficient or missing supportive documentation;
- the requested STA falling outside the legal scope of a national STA.

Deficiencies that cannot be resolved by the applicant will automatically lead to an invalid application. In contrast, when all deficiencies can been resolved by the applicant during validation phase, the STA request will be declared valid (= day 0). As soon as all validation criteria are met, the valid STA request will enter the evaluation phase of the STA procedure (cf. step 2).

Each STA request will be validated within 7 days after receipt, unless some clarifications are necessary. In that case, any questions sent to the applicant will pause the 7-day period until a response is received.

6.3.2 Step 2: evaluation phase

During the evaluation phase of a valid STA request, the appropriate internal and/or external experts of the FAMHP are being selected and designated by the STA coordinator. Subsequently, the content of the STA request is being evaluated by the designated experts in view of addressing the questions raised by the applicant. The questions in the STA request will be formally processed by the FAMHP as described below.

- **Type I STA requests**

Generally, a valid STA request that falls within the definition of a type I STA request will be addressed by the FAMHP in writing, within maximum 30 calendar days[1]. The validated final scientific advice will be accompanied by a qualitative feedback questionnaire (cf. section 8), which the applicant may complete voluntarily.

This type of advice request will usually be addressed in writing due to its straightforward nature and the minimal workload involved in the STA request. However, on an exceptional basis, a national STA request submitted by the applicant as a type I STA request might represent a very complex question that would require in-depth expertise from the FAMHP. Taking into account the complexity and heavy workload, such dossier could be considered by the FAMHP as a type II or type III STA request rather than a type I STA request. In that case, the STA request may be classified as a type II or III STA request, depending on the FAMHP's decision during the validation phase.

- **Type II and III STA requests**

Generally, a valid STA request that falls within the definition of a type II or type III STA request will be addressed by the FAMHP in a face-to-face meeting or via a teleconference meeting with the applicant. Depending on the nature and complexity of the STA request, the applicant is free to propose which type of meeting they prefer. However, the FAMHP generally prefers online meetings to discuss these types of STA requests.

Type II and type III STA requests will be addressed by the FAMHP in a teleconference meeting within maximum 70 calendar days[1]. A face-to-face meeting can be organised if specifically requested by the applicant, and depending on the availability of all the involved assessors.

The FAMHP generally foresees one and a half hours (maximum two hours) for advice meetings with applicants. The applicant is strongly encouraged to provide a brief presentation (more or less fifteen minutes) during the meeting with the FAMHP. The presentation can cover for example an overview of the issues to be discussed or background information on the development of the product, relevant to the meeting. The presentation and the attendance list should be electronically sent to the Scientific Technical Advice Unit 14 calendar days prior to the meeting.

The meetings are chaired by the FAMHP and the discussions are usually held in English. The applicant is free to bring experts to attend the meeting as long as this is properly communicated well in advance (i.e. through the attendance list). Nevertheless, it is the responsibility of the FAMHP to select and designate the internal and/or external experts who will provide the formal advice on behalf of the FAMHP.

After the STA meeting, the applicant should send an electronic copy of the company's meeting minutes to the FAMHP within maximum 5 working days following the STA meeting. The meeting minutes should reflect the topics that were discussed/clarified during the STA meeting and should complement the supportive documentation provided by the applicant in the briefing package of the STA request prior to the meeting. The company's meeting minutes will not be formally reviewed or endorsed by the FAMHP but will be used as additional supportive information by the involved FAMHP experts in order to draft the final scientific advice. The validated final scientific advice will be sent in writing to the applicant within maximum 21 calendar days following the formal STA meeting or 14 days after having received the company's meeting minutes.

A qualitative feedback questionnaire will be sent to the applicant (cf. section 8), which can be completed by the applicant on a voluntary basis.

6.3.3 Step 3: administrative phase

If the FAMHP does not receive any further clarification request from the applicant within 14 calendar days after sending out the validated final scientific advice, the procedure will officially be closed.

[1] Date from the day on which the STA request is formally declared valid by the FAMHP (= day 0). The timelines represent the maximum period during which the FAMHP commits to deliver robust advice to the applicant. Evidently, the FAMHP aims to address all advice requests from applicants as soon as practically possible after validation.

7. Content and format

7.1 Introduction
Detailed information on the content and format of national STA requests submitted to the FAMHP is available on the website.

7.2 Application form
As part of the required content of a national STA request, applicants are requested to download and complete the electronic application form available on the FAMHP website and to include the completed electronic document in the STA request.

The electronic application form contains all essential information related to the national STA request as the FAMHP needs complete and precise data in order to deliver robust advice.

8. Feedback questionnaire for applicants
As a federal authority, the FAMHP highly values the quality of the national STAs it provides and the satisfaction of the applicants. In order to improve its national STA service on a continuous basis, applicants can fill out a feedback questionnaire after receiving the final scientific advice from the FAMHP.

The qualitative feedback questionnaire aims to get the applicant's opinion on the following three aspects related to the received national STA:
- quality of the provided national STA;
- quality of the service provided during the STA procedure;
- consistency of the provided national STA with previous advice(s).

Applicants are invited to send the completed voluntary feedback questionnaire to the FAMHP. An electronic version of the questionnaire, along with instructions for its completion and return, is available on the FAMHP website.

9. Fees
Please find all the information on the fees applicable in the current year on our website.

10. Contact for further information
All questions from applicants regarding the national scientific and/or technical (regulatory) advice of the FAMHP can be sent to sta.meddev@fagg-afmps.be.

11. Frequently asked questions
A list of frequently asked questions is under construction and will be published on the website of the FAMHP in due time.

12. Abbreviations

CI	Clinical investigation
FAMHP	Federal Agency For Medicines And Health Products
IVD	In vitro diagnostic medical devices
MD	Medical devices
NCA	National competent authority
PMCF	Post-market clinical follow-up
PMPF	Post-market performance follow-up
PO	Purchase order
PS	Performance study
SoHO	Substances of human origin
STA	Scientific and/or technical advice

13. Annex 1: Types of national scientific and/or technical advice

<table>
<tr><td colspan="4">TYPE I: maximum one question</td></tr>
<tr><td colspan="4">Written advice
Maximum 30 calendar days</td></tr>
<tr><td colspan="4">TYPE II: multiple questions on one domain of expertise</td></tr>
<tr><td colspan="4">Through a scientific advice meeting or in writing upon request of the applicant
Maximum 70 calendar days</td></tr>
<tr><td colspan="4">TYPE III: multiple questions on multiple domains of expertise</td></tr>
<tr><td colspan="4">Through a scientific advice meeting or in writing upon request of the applicant
Maximum 70 calendar days</td></tr>
<tr><td colspan="2">TYPE IIIa
• Advice concerning multiple expertise domains (see below)</td><td colspan="2">TYPE IIIb
• Joint advice with other Belgian health authorities (e.g. Sciensano, FPS Public Health, Federal Agency for Nuclear Control, etc.) or other NCA’s</td></tr>
<tr><td colspan="4">Expertise Domains</td></tr>
<tr><td>Expertise domain 1: advice concerning technical/mechanical aspects</td><td>Expertise domain 2: advice concerning non-clinical aspects</td><td>Expertise domain 3: advice concerning clinical aspects</td><td>Expertise domain 4: advice on regulatory aspects</td></tr>
</table>

*For more detailed information, see point 3.