famhp
federal agency for medicines and health products

Detailed guidance for National Scientific-Technical Advice (STA) requests

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1. Introduction

The Directorate General PRE authorisation of 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 medicines for human or veterinary use in view of potential clinical trial applications (CTA's), marketing authorisation applications (MAA's), introduction of variations to marketed medicines or extensions of a range of medicines. The FAMHP's main objective in providing STA to applicants at a national level is to promote and facilitate the development of new medicines as much as possible from a regulatory perspective in order to increase the availability of innovative medicines 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, for example through its interface with the Scientific Advice Working Party (SAWP) and Scientific Advice Working Party - Veterinary Products (SAWP-V) at the European Medicines Agency (EMA) in order to guarantee the quality and consistency of the national STA's issued by the FAMHP.

The national STA can be issued to sponsors of clinical trials, pharmaceutical/biotech companies (for example 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 (e.g. CTA's), 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. After an 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. CTA's, MAA's, SAWP advices, Paediatric Investigation Plan (PIP's). Nevertheless, applicants are strongly recommended to seek the FAMHP's advice well in advance of an upcoming application. However, 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 relating to an upcoming application (e.g. CTA, MAA ...) which the applicant plans to submit in the near future should not be considered as a preliminary assessment or approval of the planned 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 the advice requests throughout the procedure. In particular, this guidance provides information on conditions, timelines and rules of procedure as well as the scope for requesting national scientific-technical advice to the FAMHP.

2. Legal basis

The FAMHP provides scientific or technical advice on research and development of medicines for future CTA's, MAA's or introduction of variations to marketed medicines under the conditions and rules of article 6sexies of the Belgian Medicines Law of 25 March 1964. In addition, article 4 of the Law of 20 July 2006 on the establishment and functioning of the FAMHP clearly states that scientific advice to applicants falls within the competence of the agency.

In addition, article 13bis of the Belgian Medicines Law of 25 March 1964 and the Royal Decree of 31 March 2009 form the legal basis for the fees charged by the FAMHP to applicants submitting a request for STA.

The Royal Decree of 31 March 2009, in execution of article 6sexies of the Belgian Medicines Law of 25 March 1964, defines the legal scope, procedures, timelines and fees that are applicable to requests for national STA that are submitted to the FAMHP.

The Royal Decree of 16 July 2012, modifying the Royal Decree of 31 March 2009, defines the new definitions, procedures and fees that are legally applicable to requests for national STA that are submitted to the FAMHP as of 18 October 2012 (cf. section 3 and 6).

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

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

- scientific issues related to research and development;
- technical-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 the raised question for an STA request type I.

Given the general, simple nature of this type of advice request, only expertise in one specific field is normally required and the request would therefore be addressed in writing. However, on exceptional basis, an individual question may also concern a complex matter that would require 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, III STA requests (cf. section 6.3).

3.2 STA request Type II and III

A national STA request type II and III is an advice request for a set of multiple, specific questions regarding:

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

Multidisciplinary expertise is normally required to address the raised question(s).

In general, type II and type III STA requests would typically cover several types of questions (e.g. related to quality, non-clinical, clinical issues, regulatory) requiring multidisciplinary expertise.

A detailed list of the different types of STA requests that can be submitted to the FAMHP is available in Annex 1.
More information on the maximum legal deadlines for the FAMHP to provide a formal advice to the applicant after validation of the STA request can be found in section 6.

3.3 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 these advice request/questions 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 being 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-regulatory subjects for which there are differences in the current legislation.

Frequently asked questions (FAQ's)
Frequently asked questions on, for example, submission procedures (e.g. CTA's, MAA's, MRP's) or general dossier requirements, as described in current national and European guidelines, legislation …

Dossier-related questions
Questions from applicants which are submitted to the FAMHP within the context of an application submitted in Belgium (e.g. CTA) fall within the procedure for that particular application and are normally addressed by the involved file manager(s). Subsequently, dossier-related questions fall 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.

Requests for presubmission meetings related to marketing authorisation (MA)
Currently, requests for a presubmission meeting related to new MA applications, line extensions or variations are only being accepted when Belgium acts as reference member state (RMS) in the MRP

(Mutual Recognition Procedure)/DCP (decentralised procedure) or when Belgian acts as rapporteur/co-rapporteur in the centralised procedure (CP). Such meetings fall outside the scope of the national STA procedures as they are being addressed in a separate procedure. However, when Belgium acts as concerned member state (CMS) in the MRP/DCP, the FAMHP offers applicants the opportunity to use the national STA procedures to raise scientific-technical (e.g. regulatory) questions in preparation of the MRP/DCP (as long as the questions fall within the legal scope of a national STA request).

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 medicines. 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 and/or technical-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 initial high-level guidance on general regulatory requirements, scientific guidelines and development aspects to be considered when initiating a medicine development project and help identify any future scientific, technical and regulatory obstacles that may impact the project.

Project info meetings can also create early awareness about particular uncertainties, potential criticalities or the feasibility of the project which can facilitate further 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.

Regulatory planning meetings
For example meeting requests from applicants who plan to submit multiple applications at once (MAA's, variations, etc.).

Questions/advice requests concerning healthcare products
For example questions/advice requests concerning:

- medical devices;
- blood, cells and tissues;
- borderline products (e.g. food supplements, cosmetics, biocides ...).

Questions concerning other aspects
All questions on medicines 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 medicines, publicity issues, counterfeit …

4. Scope

In general, a national STA request submitted to the FAMHP may cover multiple questions related to a broad range of areas in research and development products. STA requests can also be submitted for medical devices that are used in combination with a medicinal product and in case such combination product falls under the legal status of a medicinal product.

A non-exhaustive list of examples.

- Quality aspects
- Non-clinical aspects
- Clinical aspects
- Unmet medical needs
- Early market access
- Switch from prescription to over-the-counter status
- Technical-Regulatory issues: e.g. regulatory status of borderline products
- Regulatory strategy: e.g. for CTA, SAWP advice, PIP, MAA, Committee for Medicinal Products for Human Use (CHMP) re-examination, World Health Organisation (WHO) pre-qualification)
- Aspects related to good practices: e.g. Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), Good Laboratory Practices (GLP)
- Designing and conducting clinical trials/clinical development programs (e.g. integrated protocol designs)
- Pharmacovigilance aspects: e.g. post-authorisation safety studies (PASS)/post-authorisation efficacy studies (PAES), referrals
- Risk-management aspects: (e.g. risk management plan (RMP), environmental risk assessment (ERA)
- Benefit/risk aspects
- Genetically modified organisms (GMO) and biosafety related aspects of investigational medicinal product (IMP)
- Combination packages
- Combination products consisting of medicines and devices
- New (platform)technologies and concepts: e.g. on-site formulation
- …

National STA requests may be related to:

- the research and development of specific medicinal products (i.e. products falling within the legal definition of a medicinal product) or a class of medicinal products;
- more general, non-product related aspects (e.g. genotoxic impurity testing).

National STA requests on a specific medicinal product or class of medicinal products may cover different types of medicinal products: chemical, radiochemical, bio(techno)logical, genetically modified organisms, paediatric medicines, geriatric medicines, advanced therapy medicinal products (ATMP's), nanomedicines …

5. Timing of requests

5.1 Introduction

Scientific-technical advice can be requested during any stage of the initial development of the medicinal product (e.g. before submission of a CTA, MAA, variation, line-extension).
Meetings with the FAMHP can also be held to discuss pharmacovigilance issues, proposals for changes to labelling or package leaflets, etc.

In conclusion, the following STA requests can be submitted to the FAMHP throughout the complete lifecycle of the product:

- Before or during phase 1 (first in man, exploratory CTA's)
- Before or during phase 2
- Before or during phase 3
- During phase 4: post marketing authorisation (MA)

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/regulatory guidelines have taken place, etc).

Irrespective of the procedure applied during 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. Subsequently, the same fees apply for a follow-up STA request as for an initial STA request submitted to the FAMHP.

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. The requests for further clarifications should be submitted within fourteen calendar days after the 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 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 or 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 a 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 e-mailbox: sta@fagg-afmps.be.

Alternatively, for example if large electronic files would be submitted, electronic STA requests can also be sent via the Eudralink system or via an online data sharing platform of your choice.

6.2 Payment information

From 1 October 2021, the FAMHP uses a new invoicing method for national STA applications of types I, II and III treated by the National Innovation Office and Scientific-Technical Advice Unit.

Applicants no longer pay a fee when submitting the application for advice, but must pay the invoice sent by the FAMHP's Budget and Management Control Division after validation of the STA 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, we will consider the invoice as unpaid.

About 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 fee.
- Costs related to bank charges for payments from abroad cannot be charged to the FAMHP, they will be covered by the payer.
- 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

In general, national STA requests submitted under the type I, II or III advice procedure will follow the procedure below consisting of three steps.

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-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 subsequently if 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 be: insufficient or missing motivation of the STA request, insufficient or missing supportive documentation, inappropriate payment of the fee, the requested STA may fall outside the legal scope of national STA, etc.

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).

Currently, no legal timelines apply to the validation of STA requests as the validation of each STA dossier depends on the completeness and acceptability of the submitted data. Evidently, the FAMHP tries to validate all incoming STA requests as soon as practically possible (i.e. usually the validation of each STA request is initiated within one week upon receipt of the formal STA request).

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 thirty calendar days[1]. Together with the validated final scientific advice, a qualitative feedback questionnaire will be sent to the applicant (cf. section 8) which can be completed by the applicant on a voluntary basis.

This type of advice request will usually be addressed in writing due to its simple nature and the minimal workload involved in the STA request. However, on exceptional basis, a national STA request submitted by the applicant as an 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 particular case, the STA request will follow the procedure of a type II or III STA request based 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 a face-to-face meeting to discuss these types of STA requests.

Type II and type III STA requests will be addressed by the FAMHP in a face-to-face meeting or teleconference meeting within maximum seventy calendar days[1].

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 during the meeting with the FAMHP, it should be limited (more or less fifteen minutes). The presentation can cover for example an overview of the issues to be discussed or background information on the development of the medicinal product which is relevant to the meeting. The presentation and the attendance list should be electronically sent to the Scientific Technical Advice Unit fourteen 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 five working days following the STA meeting. The meeting minutes should reflect the topics that were orally 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

[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 provide a robust advice to the applicant. Evidently, the FAMHP aims to address all advice requests from applicants as soon as practically possible after validation.

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 as a pdf file to the applicant within maximum twenty-one calendar days following the formal STA meeting or fourteen days after the reception of 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 no further clarification request from the applicant is received by the FAMHP within fourteen calendar days after sending out the validated final scientific advice, the procedure will officially be closed.

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 (in Word format which is 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 concise data in order to provide a robust advice.

8. Feedback questionnaire for applicants
As federal authority, the FAMHP attaches great importance to the quality of the provided national STAs 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 asked to complete the feedback questionnaire on a voluntary basis and send it to the FAMHP. An electronic version of the document can be found on the FAMHP website along with the instructions for completing and returning the document to the FAMHP.

9. Fees

The detailed fees can be found on our website:
https://www.famhp.be/en/human_use/medicines/medicines/scientific_technical_advice/fees

A reduction of 75 % of the STA fee is possible for small and medium enterprises (SME's), universities, certified hospitals, public utility foundations and statutory administrations requesting national scientific and/or technical regulatory advice (i.e. STA type I, II or III) on all aspects related to research and development of a medicinal product for example for a potential future application for marketing authorisation, a registration of a medicinal product, a request for a variation or line extension or a request for a CUP/MNP. In order to qualify for the 75 % fee reduction the following conditions must be met.

- For SME's applying for national STA according with the 75 % reduced fee, 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, public utility foundations and statutory administrations should be formally recognized by the FAMHP as sponsor of non-commercial studies as defined by article 31 of the Law of 7 May 2004 in order to be eligible for the 75 % reduced STA fee. The recognition should be in place prior to applying for a formal STA request according to the reduced STA fee concept or should at the latest be initiated by the applicant in parallel with the national STA request submission. In the latter case, the applicant should be aware that in case the FAMHP would not recognise the applicant as a sponsor of non-commercial studies, the standard fee will be charged to the applicant or its legal representative for the STA request.

Fees for STA requests on upcoming clinical trials:

An exemption from the standard fee "zero fee" for national STA requests (i.e. STA type I, II and III) relating to a planned clinical trial is applicable if the applicant commits himself (i.e. at the time of STA request) to submit an admissible request for approval of the clinical trial that is subject of the preceding STA request, within two years after receipt of the formal national STA issued by the FAMHP. This commitment should be clearly stated in the cover letter of the national STA request at time of STA submission to the FAMHP.

- The subsequent CTA application should be submitted according to the Law of 7 May 2017 regarding clinical trials with medicines for human use.
- If the commitment made by the applicant at the time of STA submission cannot be fulfilled, the fee for the STA will retrospectively be charged by the FAMHP to the applicant (or it's legal representative). In this case, an indexed fee will be charged for the specific STA request of the applicant that is applicable at the time that an admissible request for CTA approval should have been submitted to the FAMHP.

Note
The STA fee reduction and STA fee exemption "zero fee" can by no means be cumulated. In case an STA request could be eligible for both concepts at the same time, the applicant should make a clear decision which fee reduction he wants to apply at the time of formal STA submission and will state this in his cover letter. No further changes can be made/proposed by the applicant once the STA request has been declared valid by the FAMHP.

Fees for national STA are subject to indexation on a yearly basis. Indexation of the fees takes place at the beginning of each calendar year. More information on the payment method can be found in section 6.2.

10. Contact for further information

All general or specific questions from applicants regarding the national scientific and/or technical (regulatory) advice of the FAMHP can be sent to sta@fagg-afmps.be.

11. Legal framework

11.1 Laws

- Law of 25 March 1964 on medicines: Dutch version – French version
- Law of 20 July 2006 on the establishment and functioning of the FAMHP: Dutch version – French version

11.2 Royal Decrees

- Royal decree of 31 March 2009 in execution of article 6sexies of the Medicines Law of 25 March 1964: Dutch version – French version
- Royal Decree of 16 July 2012 modifying the Royal Decree of 31 March 2009: Dutch version – French version

12. Frequently asked questions

A list of frequently asked questions is available on the website of the FAMHP.

13. Abbreviations

ATMP	Advanced therapy medicinal product
CHMP	Committee for Medicinal Products for Human Use
CMS	Concerned member state
CP	Centralised procedure
CTA	Clinical trial application
CTR	Clinical trial regulation
DCP	Decentralised procedure
EMA	European medicines agency
ERA	Environmental risk assessment
FAMHP	Federal Agency For Medicines And Health Products
FIM	First in man
GMO	Genetically modified organism
GMP	Good manufacturing practices
GCP	Good clinical practices
GLP	Good laboratory practices
HTA	Health technology assessment
IMP	Investigational medicinal product
MAA	Marketing authorisation application
MRP	Mutual recognition procedure
NCA	National competent authority
OTC	Over-the-counter
PAES	Post-authorisation efficacy studies
PASS	Post-authorisation safety studies
PIP	Paediatric investigation plan
RMP	Risk management plan
RMS	Reference member state
SAWP	Scientific Advice Working Party
SAWP-V	Scientific Advice Working Party – Veterinary Products
SNSA	Simultaneous national scientific advice
STA	Scientific-technical advice
WHO	World Health Organisation

14. Annex 1: types of national scientific-technical advice

<table>
<tr><td colspan="3">TYPE I: scientific technical-regulatory advice (maximum one question)</td></tr>
<tr><td colspan="3">Written advice
Maximum 30 calendar days</td></tr>
<tr><td colspan="3">Scientific/technical/regulatory advice concerning e.g. chemical, pharmaceutical or (pre)-clinical aspects, the statute of a medicinal product, investigational medicinal product (IMP) vs. non-investigational medicinal product (NIMP) statute, naming (umbrella brands), GMP aspects</td></tr>
<tr><td colspan="3">TYPE II: scientific advice (multiple questions on one domain of expertise)</td></tr>
<tr><td colspan="3">Through a scientific advice meeting or in writing upon request
Maximum 70 calendar days</td></tr>
<tr><td>Expertise domain 1: advice concerning chemical/pharmaceutical aspects of a medicinal product</td><td>Expertise domain 2: advice concerning the non-clinical or clinical aspects of a medicinal product (i.e. including protocol design, RMP’s, benefit/risk, CTA methodology)</td><td>Expertise domain 3: protocol assistance</td></tr>
<tr><td colspan="3">TYPE III: mixed advice (i.e. scientific and technical-regulatory advice, multiple questions possible)</td></tr>
<tr><td colspan="3">Through a scientific advice meeting (maximum 70 calendar days)</td></tr>
<tr><td colspan="2">TYPE IIIa
• Mixed advice concerning both technical/regulatory questions and scientific questions
• Scientific advice on multiple expertise domains mentioned above under STA type II: e.g. expertise domain 1 (chemical/pharmaceutical aspects) and expertise domain 2 (clinical, non-clinical aspects)
• Advice on early market access aspects of a medicinal product</td><td>TYPE IIIb – joint STA’s
• Joint advice with other Belgian health authorities (e.g. Sciensano, FPS Public Health, Federal Agency for Nuclear Control, etc.) or other NCA’s within the European Union (i.e. including simultaneous national scientific advice requests (SNSA).
• Joint advice with other health technology assessment (HTA) bodies within the EU (i.e. joint STA-HTA): advice concerning early market access and/or early reimbursement aspects in combination with STA aspects</td></tr>
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