famhp
federal agency for medicines and health products

Guide to accelerated scientific-technical advice for medicines against COVID-19

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1. Introduction

Since the start of the COVID-19 health crisis, the FAMHP has given the highest priority to requests for national scientific-technical advice (STA) on medicines against COVID-19. The National Innovation Office and Scientific-Technical Advice Unit therefore applies an accelerated procedure for requests on clinical trials for medicines against COVID-19, including vaccines.

For national STA requests with regard to the research and development aspects of medicines for human use for prophylactic (preventive) or therapeutic treatment of COVID-19 infections, a formal request for accelerated STA can be submitted according to the provisions set forth in article 4 of the Law of 8 February 2022 amending the Law of 20 July 2006.

1.1 Type of product

National STA requests on the research and development aspects of medicines for human use for prophylactic (preventive) or therapeutic treatment of COVID-19 infections, including combination products (medicine + medical device) that fall under the category of medicinal products.

STA requests on medical devices including in-vitro diagnostics (IVDs), human body material or borderline products (products whose status are not clearly defined) fall outside the scope.

1.2 Stage of development

In order to accelerate clinical development of COVID-19 treatments and accelerate its access for patients and healthcare professionals, requests for accelerated STA should focus first on the pre-marketing authorisation phase (up to the first marketing authorisation) with a particular focus on requests for clinical trials and early stage of development.

Accelerated STA requests with regard to post-marketing authorisation phases (such as changes to the production site) or requests to repurpose existing molecules being developed for a potential COVID-19 indication as well as compassionate use programs may also fall within the scope, when justified and within the temporary nature of the COVID-19 health crisis.

1.3 Scope of the accelerated STA request

As is the case for standard STA requests, the scope of an accelerated STA request may include the following fields of expertise (non-exhaustive list): chemical-pharmaceutical, non-clinical, clinical, clinical trial design, statistics, aspects of good practice (GXP aspects), genetically modified organisms (GMOs).

1.4 Type of STA procedure

The accelerated STA procedure is set up to address the following STA requests:

- STA type I requests for which the advice is given in writing (such as STA for GMOs and STA related to a specific question in one particular field of expertise);
- STA requests types II and III for which a consultation meeting with the applicant will normally be organised, followed by a report of that consultation (to be drawn up by the applicant) and a formal written advice from the FAMHP;
- initial and follow-up requests.

The accelerated STA procedure can, if justified, also be applied to the pilot procedure for simultaneous national scientific advice (SNSA). This is done in cooperation with a second medicines authority, provided the latter can manage the same accelerated timelines.

1.5 Applicants
All applicants (non-commercial sponsors, academic research centres, SMEs, pharmaceutical companies, etc.) may resort to the accelerated STA procedures.

1.6 Temporary nature of the accelerated STA procedures
The FAMHP limits the possibility of accelerated STA procedures as described in this guide to the duration of the COVID-19 health crisis.

1.7 Urgent nature of the accelerated STA request
The FAMHP applies the basic principle for granting an accelerated STA procedure in the context of a situation involving a serious threat to public health such as the COVID-19 health crisis: the applicant must demonstrate a clear urgency or pressing reason to be able to resort to such a procedure. After all, the intended purpose of the accelerated STA concept is to fully support and accelerate the access to innovative medicines needed to treat and prevent COVID-19.

The justification of the urgency can be clarified by the applicant in the letter accompanying the STA request. The FAMHP checks the justification when validating the STA request (eligibility check). In the absence of a justification, the request will be processed in accordance with the usual deadlines for standard STA requests (see table 1).

2. Procedures and timelines
Requests for written technical-regulatory national STA (STA type I) are processed in writing within a **maximum of fifteen calendar days**, counting from the day the STA request can be declared admissible. This is done according to the procedure described in article 3 of the Law of 7 April 2019, which inserts article 4/2 into the Law of 20 July 2006. If the FAMHP needs to receive additional information in order to declare the STA request admissible, the FAMHP will forward the validation questions to the applicant within two working days of receiving the initial STA request.

Those who request an accelerated STA are expected to send an intent to submit letter to the FAMHP at least one week prior to the formal submission in order to proactively make their request known, while including, amongst other things, the planned submission date, brief background information on the nature of the COVID-19 medicine, the nature of the questions raised and submitted for advice and the specific context of the accelerated STA request (see table 1).

Table 1 - STA type I

Different stages of the STA procedure	Timelines of the accelerated STA procedure	Timelines of the standard STA procedure
Letter of intent (Applicant)	At least one week prior to the STA submission[1]	Not mandatory
Validation phase	≤ two working days to send out questions for validation[2]	≤ five working days to send out questions for validation
Evaluation phase : final written STA	≤ fifteen calendar days after validation	≤ thirty calendar days after validation

1 Processing the accelerated STA request in a timely manner, within the shortened timelines, is only possible on the strict condition that the applicant sticks to the date announced in advance for formal STA submission. If this is not the case, the FAMHP will apply the standard STA timelines.

2 Including eligibility check for whether or not to grant the accelerated STA procedure.

Requests for scientific national STA (STA type II) and mixed scientific and technical-regulatory advice (STA type III) are handled within a **maximum of twenty calendar days** by consulting with the applicant, counting from the day the STA request can be declared admissible. This is done according to the procedure described in article 3 of the Law of 7 April 2019, which inserts article 4/2 into the Law of 20 July 2006. If the FAMHP needs to receive additional information in order to declare the STA request admissible, the FAMHP will forward the validation questions to the applicant within two working days of receiving the initial STA request.

Those who request an accelerated STA are expected to send a letter of intent to the FAMHP at least two weeks prior to the formal submission in order to proactively make their request known, while including, amongst other things, the planned submission date, brief background information on the nature of the COVID-19 medicine, the nature of the questions raised and submitted for advice and the specific context of the accelerated STA request (see table 2).

Table 2 - STA types II and III

Different stages of the STA procedure	**Timelines of the accelerated STA procedure**	**Timelines of the standard STA procedure**
Letter of intent (Applicant)	At least two weeks prior to the STA submission[1]	Not mandatory
Validation phase	≤ two working days to send out questions for validation[2]	≤ five working days to send out questions for validation
Evaluation phase (up to and including consultation)	≤ twenty calendar days after validation	≤ seventy calendar days after validation
Final written STA	≤ two weeks after receiving the consultation report[4]	≤ two weeks after receiving the consultation report

1 Processing the accelerated STA request in a timely manner, within the shortened timelines, is only possible on the strict condition that the applicant sticks to the date announced in advance for formal STA submission. If this is not the case, the FAMHP applies the standard STA timelines.
2 Including eligibility check for whether or not to grant the accelerated STA procedure.
3 If the applicant opts for a purely written advice without any STA consultation with the FAMHP, the deadline for sending out the final written advice will be the same as the deadline on which the consultation was normally scheduled (see options below).
4 The applicant submits the report of the meeting to the FAMHP within seven calendar days of the STA consultation.

Two options are available for the accelerated STA procedure for requests types II and III.

- **Option 1**
  The accelerated STA procedure includes a consultation with the FAMHP in the same way as for a standard STA procedure.
- **Option 2**
  Given the urgent nature of the accelerated request for advice, in the context of the COVID-19 health crisis, the applicant may choose to follow the accelerated STA procedure without any consultation with the FAMHP and may request a written advice only. In this case, the written advice is given to the applicant within a maximum of twenty calendar days.

3. Fees for accelerated STA requests

In principle, STA requests types I, II and III submitted under the accelerated STA procedure, are subject to the same fees and conditions allowing a reduced fee as those laid down for national requests for advice submitted under the standard STA procedures. The applicable STA fees and conditions for granting fee reductions are laid down in the Law of 7 April 2019.

Exceptionally, for accelerated STA requests for a planned clinical trial submitted after the STA was issued in accordance with European Clinical Trial Regulation (CTR) 536/2014, the two-year deadline set forth in annex V and annex VII of the Law of 20 July 2006, is reduced to a period of twelve months after issuing the STA.

More information is available in the FAMHP guidelines: Detailed guidance for National Scientific-Technical Advice (STA) requests.

The fee is to be paid on the basis of the invoice sent by the FAMHP's Budget and Management Control Division in the month following the quarter in which the STA request is submitted.

4. Other provisions with regard to accelerated STA requests

In addition, the same general principles and procedural provisions apply for standard STA requests as established in the "Detailed guidance for National Scientific-Technical Advice (STA) requests" and "Simultaneous National Scientific Advice (SNSA) guidance document", both drawn up by the FAMHP.