swissmedic

Guidance document
Time limits for authorisation applications

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List of contents

1 Terms, definitions, abbreviations

1.1 Terms and definitions

- ***Additional time (see also "Applicant time")***
  The submission of additional documentation (requested by Swissmedic or unsolicited) during the processing of an application, or the submission of an application for a variation during an ongoing new authorisation procedure, can result in additional time being necessary, if the resources and scheduling need to be adjusted by Swissmedic as a result of these additional submissions (for exceptions, see the section "Implementation of the time limits").
  Each additional time period is debited to the applicant, i.e. the additional time taken will not be recorded against Swissmedic time. The provisions of the FeeO-Swissmedic referring to any associated fee surcharge must be taken into consideration.
- ***Administrative time limits***
  Periods of time set by Swissmedic that must be observed by the applicant (e.g. the applicant time for answering the List of Questions, the applicant time for additional questions raised by Swissmedic, etc.).
- ***Applicant time***
  The total time available to the applicant in the ongoing process of handling the application (e.g. for responding to the List of Questions). The applicant time is made up of all the phases assigned to the applicant.
- ***Milestone (MS)***
  The breakpoints between the phases are termed milestones, e.g. "Documentation formally OK", "List of Questions", "Preliminary decision" and "Official decision".
- ***Phase***
  A phase refers to the period between two milestones of a process, e.g. the phases of "Formal control", "Evaluation I", "Evaluation II", "Labelling".
- ***Phase period***
  The total time available from the starting point of a particular phase until its end.
- ***Procedure period***
  The total time that can elapse from the date that the application is received until the completion of the application, i.e. the sum of Swissmedic time and applicant time. The procedure periods are divided into different time limit categories (see Annex 1).
- ***Swissmedic time***
  The total time available to Swissmedic to process the application, from receipt of the application until the official decision. The Swissmedic time is made up of all the phases assigned to Swissmedic.
- ***Target time***
  The point in time at the end of a phase, calculated from a starting point and a phase period.
- ***Time limit category***
  Group of application types that are processed according to the same time frame (see Annex 1).

1.2 Abbreviations

AAA	Accelerated Application Hearing
AI	Additional indications
Ann.	Annex
App.	Applicant
CD	Calendar days
CM	Complementary medicine
Doc. OK	Formal aspects of documentation OK
eCTD	Electronic submission in CTD format
EMA	European Medicines Agency
EoI	Expression of Interest
Eval. I and II	Evaluation phase I and II
FDA	Food and Drug Administration (USA)
FTP	Fast-track authorisation procedure
HMP	Human Medicinal Products
IR	Information Request
KAS	Medicinal product with known active substance
LoQ	List of Questions
MP	Medicinal product
MPI	Medicinal product information
MS	Milestone
MUMS	Minor Use Minor Species
n.a.	not applicable
NAS	New Active Substance
OMCL	Official Medicines Control Laboratory
PD	Preliminary decision
PIP	Paediatric Investigation Plan
Rep.	Reply
SMC	Swissmedic
TPO	Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance, TPO) (SR 812.212.21)
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Authorisation of Therapeutic Products by the Notification Procedure (SR 812.212.23)
VMP	Veterinary medicinal products
WL	*Wegleitung* = guidance document

2 Introduction

This document describes the timetable for authorisation procedures and defines the time limits observed by Swissmedic (SMC) in connection with submitted authorisation applications. Legal provisions are in existence for certain time limits (e.g. appeal deadlines).

Where comparable expertise and processes exist, the processes and application time limits are based on those of the European Medicines Agency (EMA) for the Centralised Procedure. Since certain provisions of Swiss law concerning the administrative process differ from European law, the EMA requirements cannot be directly transferred to the procedures at SMC.

3 Objective

This guidance document (WL) stipulates the time limits to be respected by SMC and the applicant in connection with the administrative procedure. It also describes the procedure to be followed for applications that are incomplete in terms of formal requirements and content. This information is designed to improve the planning certainty for SMC and the applicant.

4 Scope

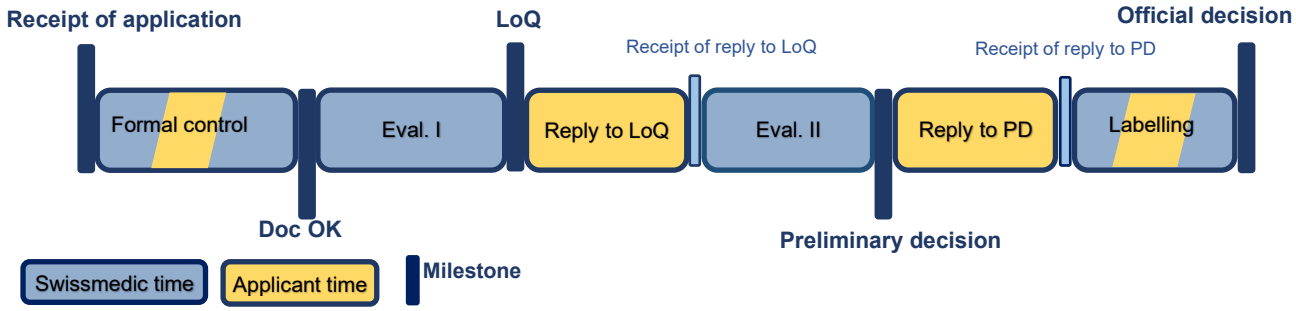
This WL is valid for the authorisation procedures for medicinal products (MP).

5 Description

5.1 Procedure period

5.1.1 Phases and milestones

Applications for new authorisations usually include the following phases and milestones (MS).



Key: Rep. = Reply; Eval. I or II = Evaluation Phase I or II; Doc. OK = Documentation formally OK; LoQ = List of Questions; PD = Preliminary Decision

Figure 1: *Possible milestones and phases in the authorisation procedure*

- ***MS "Receipt of application "***
  SMC receives and dates the application.
- ***Phase "Formal control and technical validation"***
  On receipt, the formal aspects of the application are checked. If the documentation for the application is complete and formally correct, the application is formally accepted as valid. If there are formal shortcomings in the application, however, a formal objection is sent to the applicant.
  On receipt, the technical aspects of electronic applications submitted in the CTD format (eCTD) are validated prior to the formal control (technical validation). Any technical shortcomings must be corrected by the applicant before the formal control can begin. The formal control is carried out in the same way as that for the paper process.
- ***MS "Doc OK"***
  SMC accepts the application as being in order from a formal perspective. The applicant is informed only if a formal objection was raised beforehand.
- ***Phase "Evaluation Phase I"***
  After the "Doc OK" MS, the application is evaluated. Based on Evaluation Phase I (Eval. I), a *List of Questions* (LoQ) is drawn up and sent to the applicant.
- ***MS "List of Questions"***
  Questions relating to the content of the application, as well as initial feedback on the medicinal product information (MPI) are sent to the applicant.
- ***Phase "Evaluation Phase II"***
  The replies to the LoQ are evaluated within the context of Evaluation Phase II (Eval. II). Eval. II ends with the preliminary decision (PD), which can be positive or negative.
- ***MS "Preliminary Decision"***
  The PD is sent to the applicant and constitutes a right to a hearing. The decision does not cover the MPI texts, which are finalised during the phase between the PD and the official decision.
- ***Phase "Labelling"***
  In response to a positive PD the applicant submits the revised medicinal product information texts (MPI texts) and packaging texts. The texts must be revised by the applicant in a way that permits their approval. After a successful revision of the MPI texts and packaging texts, and once any other requirements that have been communicated to the applicant are met, SMC makes its official decision.
  If the evaluation of the applicant's response to the PD reveals that further revisions are necessary in order correct the MPI texts and/or packaging texts, these can be sent to the applicant with a text correction communication. The time needed to complete such additional text correction rounds is debited to the applicant. If a second text correction round is necessary, the applicants are also invoiced for the processing costs involved, in addition to the procedure-related flat fee.
- ***MS "Official decision"***
  The official decision marks the completion of the application and will be sent to the applicant.

Not all types of application undergo all the phases and MS. If, for example, there are no questions arising from Eval. I, the MS LoQ is skipped.

5.1.2 Time limits for authorisation applications

In order to effectively plan resources and prevent the unnecessary lengthy processing of applications,

SMC sets administrative time limits for applicants. These are not legally stipulated time limits. Procedural time limits are established by an interim order, and the applicant is informed of these in writing; the same applies to any threatened consequences resulting from the failure to comply with the time limits. Upon request, procedural time limits may, in principle, be extended once only; a second time limit extension is granted only in justified exceptional cases.
The time limits are measured in calendar days (CD). The total processing time for an authorisation procedure (procedure period) is calculated as the sum of the total of SMC and applicant times.
A complete list of procedure periods can be found in Annex (Ann.) 1.

5.1.3 International procedures

SMC refers to international procedures as those procedures in which it actively exchanges information with one or more foreign partner authorities during the evaluation. This may involve the exchange of information on scientific issues (e.g. Project Orbis) and/or work sharing (e.g. Access Consortium).
So that the partner authorities involved are able to meet their national legal obligations and performance standards, special time limits apply to international procedures (see Ann. 1).
Further details on the implementation of international procedures for human medicinal products (HMP) can be found in the WL *Project Orbis* as well as the *Operational Procedures Access Consortium New Active Substance Work-Sharing Initiative* and *Operational Procedures Access Consortium Generic Medicines Work-Sharing Initiative*.
For veterinary medicinal products (VMP), the option of Simultaneous Review by Swissmedic and the UK Veterinary Medicines Directorate has been available since May 2023. Since this procedure is currently in the pilot phase, it is not yet included in this WL. Further details on this international procedure can be found in the WL *Switzerland-United Kingdom Regulatory Cooperation: Guidance on Veterinary Medicines Simultaneous Reviews.*

5.2 Implementation of the time limits

5.2.1 Technical validation

For applications in eCTD format, a technical validation takes place prior to the formal control. SMC informs the applicant of its findings with regard to the technical validation. If the electronic data do not satisfy the requirements, the applicant must make the necessary corrections and resubmit the data, usually within 30 CD. The time needed for such technical corrections are deducted from the time available to the applicant for correcting formal shortcomings.
Technical objections can be made more than once. Exceptions to this are applications for variations of types IA, IA_{IN} and IB for HMP and variations without assessment (or with assessment but with “reduced” time limit) for VMP, for which technical objections may only be made once.

5.2.2 Formal control / Formal objection

In the case of a formal objection, the time needed by the applicant to correct and complete the documentation and the time needed by SMC for the formal control thereof is then debited to the applicant. The time specified in Ann. 1 is again available to SMC. A "Doc OK" notification is usually issued only if a formal objection has previously been raised.
Formal objections are usually issued only once. If the applicant is unable to resolve the formal shortcomings after the objection is issued, SMC will not process the application. For minor variations of types IA, IA_{IN} and IB for HMP or variations without assessment and variations with assessment but with time limit “reduced” for VMP, a corresponding interim order is issued instead of a formal objection.

5.2.3 Evaluation phase I

- Eval. I begins after the successful completion of the formal control and when the processing of the application begins (MS "Doc. OK").
- If the scientific documentation proves to be incomplete during Eval. I, and if the applicant is required in the LoQ process to send additional documentation, additional time may be added to the process.
- The unsolicited submission of new evaluation documentation (e.g. applications for variations during ongoing new authorisation procedures) during Eval. I can lead to the time limit being reset to the point "Doc OK". This is implemented as additional time and debited to the applicant. Exceptions to this rule are the subsequent submission of long-term stability data, validation reports on the manufacturing process for the active substance/finished product and documents that, during a pre-submission meeting or on request by the applicant, Swissmedic agreed to accept at a later date.

5.2.4 List of questions

The tables in Ann. 1 show the cases in which an LoQ is anticipated in the standard process. SMC reserves the right, for every type of application, to issue an LoQ when it is necessary to obtain additional information from the applicant in order to make an informed decision. If there is no need to send questions, SMC dispenses with an LoQ.

5.2.5 Replies to the List of Questions

- SMC begins the evaluation of the replies to the LoQ at the latest once the specified time limit for the "Reply to the LoQ" procedure expires, as long as the answers to all aspects of the LoQ content have been received, and are both complete and correspond to the formal requirements. It may be possible to begin Evaluation II earlier than scheduled, provided the answers are received before the specified time limit expires and SMC has the necessary resources to begin the evaluation early.

- If there are shortcomings with regard to the quality of the documents submitted in the reply to the LoQ, SMC may return those texts affected to the applicant to be corrected or completed.
- For new applications and applications for variations, SMC may request the submission of MP samples for analysis, which the applicant must send to the Official Medicines Control Laboratory (OMCL). In such cases, the submission of the MP samples is a prerequisite for Eval. II to begin.
- If, in order to answer the LoQ, the applicant submits new evaluation documentation in addition to that required to respond to the questions, SMC decides – on a case-by-case basis – whether it will carry out a second Eval. I with a related second LoQ. The time available in this case is debited to the applicant and usually corresponds to the time limits for Eval. I. In individual cases, additional time can also be debited to the applicant in Eval. II; in this case a PD is issued without a second LoQ.
  Exceptions to this rule are the subsequent submission of long-term stability data, validation reports on the manufacturing process for the active substance/finished product and documents that SMC has agreed, on request, to accept at a later date.
- Regarding subsequent submission of evaluation documentation owing to the scientific documentation being incomplete, please see section 5.3, point 2.

5.2.6 Evaluation phase II

- The submission of new documents during Eval. II (or of applications for variations during ongoing new authorisation processes) leads to the procedure being reset to the beginning of Eval. II. If the documentation concerned is extensive, a decision is taken on a case-by-case basis whether to reset the procedure to Eval. I back to "Doc OK". In these cases, corresponding additional time is debited to the applicant. Exceptions to this rule are the subsequent submission of long-term stability data, validation reports on the manufacturing process for the active substance/finished product and documents that SMC has agreed, on request, to accept at a later date.
- In order to streamline the process and largely avoid repeated rounds of the process, an LoQ is not usually sent after Eval. II. Instead, the corresponding PD is issued directly. A second LoQ may, if necessary, be sent in exceptional cases as mentioned under "Replies to the LoQ".
- The scheduled official decision, as determined by SMC, is communicated to the applicant at the MS "PD". The following so-called "Labelling phase" is primarily intended for revising the MPI texts and the packaging texts.

5.2.7 Labelling

- Following the issue of a positive PD, SMC expects evidence that any additional conditions for granting authorisation have been fulfilled.
- The corrections to the text elements (MPI, labels, cartons, etc.) requested by SMC must be included as revisions in the draft texts and submitted to the Agency for approval. If SMC is able to approve the text elements and if all authorisation conditions are fulfilled, the approved texts are returned to the applicant with the official decision.
- If it is not possible to approve the MPI texts and packaging texts that the applicant has corrected and completed, the texts are returned to the applicant within the pre-defined time limit for correction. The time available to SMC for reviewing and approving MPI texts and packaging texts in accordance with Ann. 1 is only calculated for the evaluation of the MPI texts and packaging texts that are submitted with the reply to the PD.

- For the processing of subsequent text review rounds, the same times are available to SMC as those for the application phase "Evaluation of the reply to the PD". The time taken for these additional text review rounds is debited to the applicant.

5.2.8 Review of applicant’s input within the framework of the right to a legal hearing and official decision

Prior to taking a decision, SMC reviews the applicant's input within the framework of the right to a legal hearing and examines the intended decision in the light of this input. SMC then takes its official decision.

5.2.9 Right of appeal

An appeal may be lodged against the official decision within 30 days of issue of the decision.

6 Annex - Overview of time limits

Unless otherwise defined, the time limits shown in the table apply to HMP and VMP**.** These refer to maximum time limits in CD.

6.1 Meetings

Scientific Advice Meeting and Presubmission Meeting	
Review of the application by SMC	Usually within 2 to 4 weeks of receipt of submission
Scheduling Meeting	Usually within 4 to 8 weeks of receipt of submission
Review of the protocol submitted by the applicant	Usually within 2 weeks of receipt of the protocol

Clarification Meeting	
Submission of the meeting request	Within 2 weeks of receipt of the LoQ
Review of the application by SMC	Usually within 1 to 2 weeks of receipt of the meeting request
Scheduling Meeting	Usually within 3 to 6 weeks of receipt of the meeting request
Review of the protocol submitted by the applicant	Usually within 2 weeks of receipt of the protocol

6.2 Applications

Application types/ Procedure variants	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	SMC + applicant
	Formal control	Correction of documents subject to formal objection	Eval. I	Reply to LoQ	Eval. II	Reply to PD	Eval. of reply to PD	Total	Total	Total
Clarification of FTP application (AAA)	5	30	30[1]	n.a.	n.a.	n.a	n.a	30	40 - 50[2]	70 - 80[2]
Clarification of application for temporary authorisation procedure HMP (AAA)	5	30	30[3]	n.a.	n.a.	n.a.	n.a.	30	40 – 50[2]	70 - 80[2]
Clarification of application for temporary authorisation VMP	5	30	25	n.a.	n.a.	30	20	60	50	110
Clarification of application for Minor Use Minor Species (MUMS) status	30	60	30	n.a.	n.a.	90	30	150	90	240
Clarification of application for Orphan Drug Status	30	60	90	90	60	90	30	240	210	450

[1] 6 – 8 weeks after receipt of the application for a Fast-Track Procedure (FTP), the Accelerated Application Hearing (AAA) takes place. SMC takes the binding decision at the AAA. The official decision is communicated to the applicant after the AAA. Provided the SMC has no objections to the temporary authorisation application and no further clarifications are required, the official approval decision for the temporary authorisation application is issued directly after the "Eval. I" phase.

[2] Depends on timing of AAA

[3] 6 – 8 weeks after receipt of the temporary authorisation application, the AAA takes place. SMC takes the binding decision at the AAA. The official decision is communicated to the applicant after the AAA. Provided the SMC has no objections to the temporary authorisation application and no further clarifications are required, the official approval decision for the temporary authorisation application is issued directly after the "Eval. I" phase.

6.3 New authorisations and extensions

In principle, the standard time limits also apply to applications in the procedures according to Art. 13 TPA and Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA, to parallel import according to Art. 14 paras. 2 and 3 TPA, and to MP with orphan drug status or MUMS status, unless these qualify for one of the fast-track procedures.

6.3.1 National procedures in standard time limits

Application types/ Procedure variants	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	SMC + applicant
	Formal control	Correction of documents subject to formal objection	Eval. I	Reply to LoQ	Eval. II	Reply to PD	Eval. of reply to PD	Total	Total	Total
- New application (NA) new active substance (NAS) - NA known active substance - NA MP (Art. 12 para. 5 TPLO) - NA biosimilar - NA parallel-imported MP (Art. 14 paras. 2 and 3 TPA) - Authorisation extensions (Art. 24 TPO) - Evaluation of conditions **Complementary and herbal medicines** - NA herbal medicinal product in the simplified procedure - NA complementary medicine (CM) with/without indication - NA reduced dossier - NA basic applicant dossier - NA sample quality doc. - NA Asian MP	30	60	120	90	90	60[4]	90	210	330	540
Co-Marketing	30	60	30	30	30	30	30	120	120	240

[4] In the event of a PD rejection, companies have 30 CD to respond to the PD.

Notification procedure (Art. 15 TPA)	30	60	60	n.a.	n.a.	60[4]	90	120	180	300
Notification procedure for VMP (Art. 39 TPLO)	30	60	60	n.a.	n.a.	60[4]	30	120	120	240

6.3.2 International procedures in standard time limits

Application types/ Procedure variants	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	SMC + applicant
	Formal control	Correction of documents subject to formal objection	Eval. I	Reply to LoQ	Eval. II	Reply to PD	Eval. of reply to PD	Total	Total	Total
Projekt Orbis[5]										
NA NAS – Orbis type C and type B[6] possible	30	60	120	90	90	60[4]	90	210	330	540

6.3.3 Fast-track national procedures

Application types/ Procedure variants	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	SMC + applicant
	Formal control	Correction of documents subject to formal objection	Eval. I	Reply to LoQ	Eval. II	Reply to PD	Eval. of reply to PD	Total	Total	Total
FTP (Art. 7 TPO)	5	60	65	90[7]	50	60[4]	20	210	140	350
Temporary authorisation (Art. 9a TPA)	5	60	65	90[7]	50	60[4]	20	210	140	350
NA under the procedure with prior notification (Ann. 1 no. I no. 1. FeeO-SMC)	10	10	100	90	90	60[4]	64	160	264	424

[5] In exceptional cases, deviations from these time limits may be required in order to guarantee the exchange of scientific information with the partner authorities.

[6] SMC may handle Orbis type B applications differently depending in each case on the period between the submission to the Food and Drug Administration (FDA) or SMC and resulting differences in the status of the review process. The details apply to those Orbis type B applications for which SMC decides to apply the standard time limits.

[7] A six-day submission window before the published HMEC date must be factored in for the submission of answers to the LoQ for fast-track and temporary authorisation procedures.

6.3.4 Fast-track international procedures

Application types/ Procedure variants	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	SMC + applicant
	Formal control	Correction of documents subject to formal objection	Eval. I	Reply to LoQ	Eval. II	Reply to PD	Eval. of reply to PD	Total	Total	Total
Access Consortium[8]										
NA NAS, NA biosimilars	30[9]		120	30 or 60[10]	45	15	50	n.a.	n.a.	290 or 320
Medicinal product with known active substance (KAS) without innovation	15		90	30 or 60[10]	50	15	50	n.a.	n.a.	250 or 280
Project Orbis[5]										
NA NAS – Orbis type A and type B[11] possible (with rolling questions, IRs)	5	10	255[12]			30	50	n.a.	n.a.	350

[8] In exceptional cases, deviations from these time limits may be required in order to guarantee the work sharing with the partner authorities.

[9] Overall, the formal control, including any correction of formal shortcomings, must be completed within 30 CD. The applicant has 10 CD in which to resolve any objection, and SMC then has 10 CD in which to check the reply.

[10] According to preference and the applicant's corresponding binding entry in the Expression of Interest (EoI) form.

[11] SMC may handle Orbis type B applications differently depending in each case on the period between the submission to the FDA or SMC and resulting differences in the status of the review process. The details apply to those Orbis type B applications for which SMC decides to issue Information Requests (IRs) as part of a rolling questioning process.

[12] Eval. I and II are combined. IRs are processed with a rolling questioning process, and the response deadline is usually 10 CD.

6.4 Variation applications

6.4.1 National procedures in standard time limits

Application types/ Procedure variants	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	SMC + applicant
	Formal control	Correction of documents subject to formal objection	Eval. I	Reply to LoQ	Eval. II	Reply to PD	Eval. of reply to PD	Total	Total	Total
Type IA / IA$_{IN}$ (Art. 21 TPO)	n.a.	n.a.	30[13] (time to interim order / official decision)	n.a.	n.a.	n.a.	n.a.	n.a.	30	30
Variations without assessment VMP (Art. 25a TPO)	n.a.	n.a.	30**Fehler! Textmarke nicht definiert.** (time to interim order / official decision)	n.a.	n.a.	n.a.	n.a.	n.a.	30	30
Type IB (Art. 22 TPO)	10	30	60[14] (time to interim order / official decision)	n.a.	n.a.	n.a.	n.a.	30	70	100
Variation with assessment VMP "shortened" time limit (Art. 25b TPO)	10	30	60[14] (time to interim order / official decision)	n.a.	n.a.	n.a.	n.a.	30	70	100
Type II (Art. 23 TPO)	30	60	120	60	70	60[4]	50	180	270	450
Variations with assessment VMP "Standard" time limit (Art. 25b TPO)	30	60	120	60	70	60[4]	50	180	270	450

[13] Unless informed otherwise by SMC, the variation is considered to be accepted 30 CD after receipt of the application. In the case of an interim order, the applicant has 30 CD to correct the shortcomings.

[14] Unless informed otherwise by SMC, the variation is considered to be accepted 70 CD (10+60 CD) after receipt of the application. In the case of an interim order, the applicant has 30 CD to correct the shortcomings.

6.4.2 International procedures in standard time limits

Application types/ Procedure variants	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	SMC + applicant
	Formal control	Correction of documents subject to formal objection	Eval. I	Reply to LoQ	Eval. II	Reply to PD	Eval. of reply to PD	Total	Total	Total
Project Orbis[5]										
Additional indication (AI, type II variations) – Orbis type C and certain type B[6]	30	60	120	60	70	60[4]	50	180	270	450

6.4.3 Fast-track national procedures

Application types/ Procedure variants	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	SMC + applicant
	Formal control	Correction of documents subject to formal objection	Eval. I	Reply to LoQ	Eval. II	Reply to PD	Eval. of reply to PD	Total	Total	Total
Type II - Procedure with prior notification AI (Ann. 1 no. 5.1 FeeO-SMC)	10	10	100	60	70	60[4]	36	130	216	346
Type II - Temporary authorisation procedure AI (Ann. 1 no. 5.1 FeeO-SMC)	5	60	65	60	50	60[4]	20	180	140	320
Type II - Fast-track authorisation procedure AI (Ann. 1 no. 5.1 FeeO-SMC)	5	60	65	60	50	60[4]	20	180	140	320
Type II Safety-related variations (Art. 23 TPO)	5	10	35	n.a.	n.a.	30	20	40	60	100

Safety-relevant variations with assessment VMP (Art. 25b TPO)	5	10	35	n.a.	n.a.	30	20	40	60	100

6.4.4 Fast-track international procedures

Application types/ Procedure variants	**SMC**	**Applicant**	**SMC**	**Applicant**	**SMC**	**Applicant**	**SMC**	**Applicant**	**SMC**	**SMC + applicant**
	Formal control	**Correction of documents subject to formal objection**	**Eval. I**	**Reply to LoQ**	**Eval. II**	**Reply to PD**	**Eval. of reply to PD**	**Total**	**Total**	**Total**
Access Consortium[8]										
AI (type II variations)		30[9]	120	30 or 60[10]	45	15	50	n.a.	n.a.	290 or 320
Project Orbis[5]										
AI (type II variations) – Orbis type A and type B**Fehler! Textmarke nicht definiert.** possible (with rolling questions, Information Requests)	5	10	255[12]			30	50	n.a.	n.a.	350

6.5 Other application types

Application types/ Procedure variants	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	Applicant	SMC	SMC + applicant
	Formal control	Correction of documents subject to formal objection	Eval. I	Reply to LoQ	Eval. II	Reply to PD	Eval. of reply to PD	Total	Total	Total
Renewal of the authorisation	30	10	60	n.a.	n.a.	30	60	40	150	190
Extension of temporary authorisation	10	10	20	n.a.	n.a.	10	20	20	50	70
Renewed authorisation	30	60	60	n.a.	n.a.	60[4]	60	120	150	270
Waiver of authorisation of a preparation	10	10	20	n.a.	n.a.	10	20	20	50	70
Notification of no marketing / Interruption of distribution (Art. 11 TPO)	n.a.	n.a.	30	n.a.	n.a.	n.a.	n.a.	0	30	30
Confirmation of complete fulfilment of the Paediatric investigation plan (PIP)[15]	10	10	20	n.a.	n.a.	10	20	20	50	70

[15] In the case of an SMC confirmation, an official decision is made directly after Eval. I

Change history

Version	Change	sig
7.0	Revision of 5.1 Procedure period, with new subsection 5.1.3 International procedures. Annex 1: Restructuring of the procedures according to standard time limits versus fast-track time limits and national versus international procedures. Various editorial adaptations.	caw, fg, big, ate
6.1	New layout, no content adjustments to the previous version.	tsj
6.0	Due to expansion of scope of temporary authorisations: New inclusion of time limits for temporary additional indications in Annex 1	stb
5.0	Correction in Annex 1: Deletion of application type conversion of temporary to regular authorisation	stb/lm
4.0	Adaptation of guidance document due to new structure for VMP variations (early revision of VMP regulations) Details of FTP application procedure / temporary authorisation deadlines	fg/ps
3.2	Correction of the footnote in annex 1	stb
3.1	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
3.0	Annex 1 – Overview of time limits: Explanation that companies have 30 calendar days to respond if the PD is a rejection.	stb
2.1	Annex 1 – Overview of time limits: Explanation regarding the six-day submission window for responses to the LoQ in fast-track and temporary authorisation procedures.	dts
2.0	Correction of Time limit categories / Application types, Variation Type IB, Correction of documents subject to formal objection: 30 CD. Correction of the footnote 3 on page 11.	stb
1.0	Implementation of TPO4	dts