Contents

Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
2.1	13.05.19	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	**05.02.19**	**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	**01.01.19**	**Implementation of TPO4**	**dts**

1 Terms, definitions, abbreviations

1.1 Terms and definitions

- ***Applicant time***
  The total time available to the applicant during the ongoing process of handling the application (e.g. for responding to the List of Questions). This time will be debited to the applicant.
- ***Time limit category***
  Group of application types that are processed according to the same time frame (see Annex 1).

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- ***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).
- ***Procedure section (PS)***
  The procedure section is the period of time between two milestones of a process, e.g. the procedure sections "Formal control", "Evaluation I", "Evaluation II", "Labelling".
- ***Section period***
  The total time available to Swissmedic from the starting point of a particular phase until its end.
- ***Milestone (MS)***
  The breakpoints between the procedure sections are termed milestones, e.g. Doc OK, LoQ, preliminary decision and official decision.
- ***Swissmedic time***
  The total time available to Swissmedic to process the application, from receipt of the application until the official decision. It comprises the sum of the section periods.
- ***Target time***
  The point in time at the end of a procedure section, calculated from a starting point and a section period.
- ***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.).
- ***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.

1.2 Abbreviations

Ann.	Annex
AP	Application phase
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
Eval. I and II	Evaluation phase I and II
FC	Formal control (incl. technical validation)
FO	Formal objection
FTP	Fast-track authorisation procedure
HMP	Human Medicinal Products
LoQ	List of Questions
MP	Medicinal product
MPI	Medicinal product information

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MS	Milestone
MUMS	Minor Use Minor Species
NAS	New Active Substance
OMCL	Official Medicines Control Laboratory
PD	Preliminary decision
PIP	Paediatric Investigation Plan
PS	Procedure section
SMC	Swissmedic
TCM	Traditional Chinese medicine
TC-comm.	Text correction communication
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)
TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)
VMP	Veterinary medicinal products

2 Introduction and objective

This document describes the timetable for authorisation procedures and defines the time limits observed by Swissmedic 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 Swissmedic.

This guidance document pursues three primary objectives: (1) Make all parties aware of the time limits to be respected by Swissmedic and by the applicant. (2) Explain the procedure to be followed for applications that are incomplete in terms of formal requirements and content. (3) By specifying procedure periods, help the applicant with its planning and enable key data to be recorded on the duration of procedures overall and on individual procedure sections.

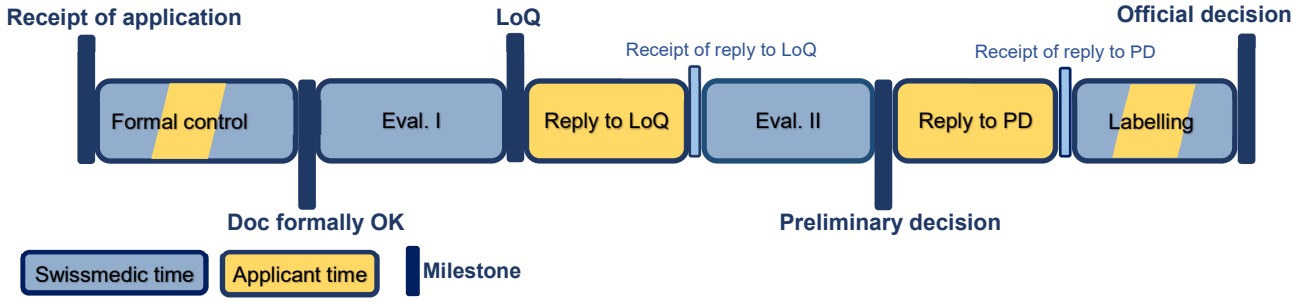
3 Scope

This guidance document is valid for the Authorisations sector.

4 Procedure period

4.1 Procedure sections and milestones

Applications for new authorisations usually include the following procedure sections (PS) and milestones (MS).



Key: Eval. = Evaluation; LoQ = List of Questions; PD = Preliminary Decision

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

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- ***MS "Application received"***
  Swissmedic receives and dates the application.
- ***AP "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 eCTD applications 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 formally OK"***
  Swissmedic accepts the application as being in order from a formal perspective. The applicant is informed only if a formal objection was raised beforehand.
- ***PS "Evaluation I"***
  After the "Doc formally OK" MS, the application is evaluated. Based on Evaluation I, a *List of Questions* is drawn up and sent to the applicant.
- ***MS "List of Questions"***
  The questions relating to the content of the application are sent to the applicant.
- ***PS "Evaluation II"***
  The replies to the List of Questions are evaluated within the context of Evaluation II. Evaluation II ends with the preliminary decision, which can be positive or negative.
- ***MS "Preliminary Decision"***
  The preliminary decision is sent to the applicant and constitutes a right to a hearing. The decision does not cover the medicinal product information texts, which are finalised during the phase between the preliminary decision and the official decision.
- ***PS "Labelling"***
  In response to a positive preliminary decision the applicant submits the revised medicinal product information texts and packaging elements. The texts must be revised by the applicant in a way that permits their approval. After a successful revision of the medicinal product information texts (MPI texts), and once any other requirements that have been communicated to the applicant are met, Swissmedic makes its official decision.
  If the evaluation of the applicant's response to the preliminary decision reveals that further revisions are necessary in order correct the medicinal product information texts and/or packaging elements, these are 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 procedure sections and milestones. If, for example, there are no questions arising from Evaluation I, the List of Questions milestone is skipped.

4.2 Time limits for authorisation applications

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

Swissmedic 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.
The time limits are measured in calendar days and include weekends and public holidays. The total processing time for an authorisation procedure (procedure period) is calculated as the sum of the total of Swissmedic and applicant times.
A complete list of procedure periods can be found in Ann. 1.

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5 Implementation of the time limits

5.1 Technical validation

For applications in eCTD format, a technical validation takes place prior to the formal control. Swissmedic 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 type IA, IA_{IN} and IB variations, for which technical objections may only be made once.

5.2 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 Swissmedic for the formal control thereof is then debited to the applicant. The time specified in Ann. 1 is again available to Swissmedic. 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, Swissmedic will not process the application. For minor variations of types IA, IA_{IN} and IB, a corresponding interim order is issued instead of a formal objection.

5.3 Evaluation phase I

- Evaluation phase I begins after the successful completion of the formal control and when the processing of the application begins (milestone "Doc. OK").
- If the scientific documentation proves to be incomplete during Evaluation phase 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 Evaluation phase 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.

5.4 List of questions

The table in Ann. 1 shows the cases in which a List of Questions is anticipated in the standard process. Swissmedic reserves the right, for every type of application, to issue a list of questions 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 to the applicant within the framework of an application, it is possible to omit the list of questions.

5.5 Replies to the List of Questions

- Swissmedic begins the evaluation of the replies to the list of questions once the specified time limit for the "Answer to the LoQ" procedure expires, as long as the answers to all aspects of the 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 at least 30 days before the specified time limit expires and Swissmedic 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, Swissmedic may return those texts affected to the applicant to be corrected or completed.
- For new applications and applications for variations, Swissmedic may request the submission of samples of the medicinal product for analysis, which the applicant must send to the Official

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Medicines Control Laboratory (OMCL). In such cases, the submission of the samples of the medicinal product is a prerequisite for Evaluation phase II to begin.

- If, in order to answer the List of Questions, the applicant submits new evaluation documentation in addition to that required to respond to the questions, Swissmedic decides – on a case-by-case basis – whether it will carry out a second Evaluation phase I with a related second List of Questions. The time available in this case is debited to the applicant and usually corresponds to the time limits for Evaluation phase I. In individual cases, additional time can also be debited to the applicant in Evaluation phase II; in this case a preliminary decision is issued without a second list of questions.
  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 Swissmedic 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.

5.6 Evaluation phase II

- The submission of new documents during Evaluation phase II (or of applications for variations during ongoing new authorisation processes) leads to the procedure being reset to the beginning of Evaluation phase II. If the documentation concerned is extensive, a decision is taken on a case-by-case basis whether to reset the procedure to Evaluation Phase I back to "Doc formally 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 Swissmedic has agreed, on request, to accept at a later date.
- In order to streamline the process and largely avoid repeated rounds of the process, a list of questions is not usually sent after Evaluation phase II. Instead, the corresponding preliminary decision is issued directly. A second list of questions may, if necessary, be sent in exceptional cases as mentioned under "Replies to the LoQ".
- The scheduled official decision, as determined by Swissmedic, is communicated to the applicant at the milestone "Preliminary decision". The following so-called "Labelling phase" is primarily intended for revising the medicinal product information texts and the packaging elements.

5.7 Labelling

- Following the issue of a positive preliminary decision, Swissmedic expects evidence that any additional conditions for granting authorisation have been fulfilled. Swissmedic then begins the evaluation of the replies to the preliminary decision once the specified time limit for the applicant's "Reply to the preliminary decision" expires, provided the documents requested are complete and comply with the formal requirements.
  If the applicant has requested an extension of the time limit to provide its answers to the preliminary decision, the evaluation may begin, on a case-by-case basis, only after the extended time limit has expired.
- The corrections to the text elements (medicinal product information, labels, cartons, etc.) requested by Swissmedic must be included as revisions in the draft texts and submitted to the Agency for approval. If Swissmedic 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 elements 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 Swissmedic for reviewing and approving MPI texts and packaging elements in accordance with Ann. 1 is only calculated for the evaluation of the MPI texts and packaging elements that are submitted with the reply to the preliminary decision.
- For the processing of subsequent text review rounds, the same times are available to Swissmedic as those for the application phase "Evaluation of the reply to the preliminary decision". The time taken for these additional text review rounds is debited to the applicant.

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

Prior to taking a decision, Swissmedic 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. Swissmedic then takes its official decision.

5.9 Right of appeal

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

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6 Annex 1 - Overview of time limits

Unless otherwise defined, the time limits shown in the table apply to human and veterinary medicinal products

Meetings

Scientific Advice Meeting and Presubmission Meeting

Review of the application by Swissmedic	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 List of Questions
Review of the application by Swissmedic	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

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Applications

Time limit categories / Application types	Swissmedic: Formal control	Applicant: Correction of documents subject to formal objection	Swissmedic: Eval I	Applicant: Reply to LoQ	Swissmedic: Eval II	Applicant: Reply to PD	Swissmedic: Eval. of reply to PD	Total App. time	Total SMC time
Clarification of FTP application	5	30	25	n.a.	n.a.	30	20 - 90[1]	60	50 - 120[1]
Clarification of application for temporary authorisation	5	30	25	n.a.	n.a.	30	20	60	50
Clarification of application for MUMS status	30	60	30	n.a.	n.a.	90	30	150	90
Clarification of application for Orphan Drug status	30	60	90	90	60	90	30	240	210

[1] Depending on the respective review workload and the volume of the submitted documentation, a time limit of 20–90 CD is required for reviewing the statement in response to the preliminary decision.

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New authorisations and extensions

Time limit categories / Application types	Swissmedic: Formal control	Applicant: Correction of documents subject to formal objection	Swissmedic: Eval I	Applicant: Reply to LoQ	Swissmedic: Eval II	Applicant: Reply to PD	Swissmedic: Eval. of reply to PD	Total App. time	Total SMC time
New authorisations	30	60	120	90	90	60	90	210	330
NAS, known active substances, MP as per Art. 12 para. 5 TPLO / Biosimilar									
Parallel import									
Herbal medicinal products, CM with/without indication, reduced dossier									
CM: Basic company dossier, master dossier, sample quality doc. Asian MP									
Procedure with prior notification New authorisations according to Ann. 1 no. 1 FeeO-Swissmedic	10	10	100	90	90	60	64	160	264
Authorisation extensions (Art. 24 TPO)	30	60	120	90	90	60	90	210	330
Temporary authorisation	5	60	65	90[2]	50	60	20	210	140
Fast-track authorisation procedure	5	60	65	90[2]	50	60	20	210	140
FTP for NAS / known active substances (incl. MP as per Art. 12 para. 5 TPLO) / Biosimilar and authorisation extensions as per Art. 24 TPO									
Co-Marketing	30	60	30	30	30	30	30	120	120
Evaluation of conditions	30	60	120	90	90	60	90	210	330
Notification procedure as per Art. 15 TPA	30	60	60	n.a.		60	90	120	180
Notification procedure for veterinary medicinal products	30	60	60	n.a.		60	30	120	120

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

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Variations

Time limit categories / Application types	Swissmedic: Formal control	Applicant: Correction of documents subject to formal objection	Swissmedic: Eval I	Applicant: Reply to LoQ	Swissmedic: Eval II	Applicant: Reply to PD	Swissmedic: Eval. of reply to PD	Total App. time	Total SMC time
Type IA / IA$_{IN}$ (Art. 21 TPO)	n.a.	n.a.	30[3] (time to interim order / official decision)	n.a.	n.a.	n.a.	n.a.	n.a.	30
Type IB (Art. 22 TPO)	10	30	60[4] (time to interim order / official decision)	n.a.	n.a.	n.a.	n.a.	30	70
Type II (Art. 23 TPO)	30	60	120	60	70	60	50	180	270
Type II - Procedure with prior notification Additional indication according to Ann. 1 no. 5.1 FeeO-Swissmedic	10	10	100	60	70	60	36	130	216
Type II - Fast-track authorisation procedure Additional indication according to Ann. 1 no. 5.1 FeeO-Swissmedic	5	60	65	60	50	60	20	180	140
Type II Safety-related variations (Art. 23 TPO)	5	10	35	n.a.	n.a.	30	20	40	60

[3] 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.

[4] 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.

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Other application types

Time limit categories / Application types	Swissmedic: Formal check	Applicant: Correction of documents subject to formal objection	Swissmedic: Eval I	Applicant: Reply to LoQ	Swissmedic: Eval II	Applicant: Reply to PD	Swissmedic: Eval. of reply to PD	Total App. time	Total SMC time
Renewal of the authorisation	30	10	60	n.a.		30	60	40	150
Extension of temporary authorisation, conversion of temporary to regular authorisation	10	10	20	n.a.		10	20	20	50
Renewed authorisation	30	60	60	n.a.		60	60	120	150
Waiver of authorisation of a preparation	10	10	20	n.a.		10	20	20	50
Notification according to Art. 8a TPO (No marketing / Interruption of distribution)	n.a.	n.a.	30	n.a.	n.a.	n.a.		0	30
Confirmation of complete fulfilment of the PIP[5]	10	10	20	n.a.		10	20	20	50

[5] In the case of a Swissmedic confirmation, an official decision is made directly after Evaluation phase I.

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