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Change history

Version	Valid and binding as of:	Modified without version change	Description, comments (by author)	Author's initials
		18.07.18.	More detailed instructions regarding chapter 6.7 "Labelling": Deletion of the text approval of the product information texts.	dts
3.0	**01.07.18**		**More detailed instructions regarding subsequent submission of evaluation documentation owing to the scientific documentation being incomplete, please see section 6.3, point 2.**	**dts**
2.0	**01.10.17**		**Table in chapter 5.2 "Time limits for authorisation applications":** • **Harmonisation of time limits for FTP with time limits for temporary authorisation** • **New footnote 4 with reference to the pilot phase of the "Optimisation of labelling phases" package of measures** • **Various applications without LoQ: Swissmedic review time limits now presented in Rev I instead of Rev II**	**dts**
1.0	**30.05.17**		**Formal adaptation to Swissmedic's requirements management: Administrative ordinance converted into Guidance document; content unchanged**	**fua**

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1 Terms, definitions, abbreviations

1.1 Terms and definitions

- ***Additional time (see also "applicant time")***
  The submission of unsolicited additional documentation during the processing of an application, or the submission of an application for a variation during an ongoing first authorisation procedure, can result in additional time being necessary, if the resources and scheduling need to be adjusted by Swissmedic (for exceptions, see the section "Implementation of the time limits"). Each additional time period is considered to be applicant time and a surcharge will be made to the applicant i.e. the additional time taken will not recorded against Swissmedic time. The provisions in the regulations referring to fees must be taken into consideration with regard to the additional fees to be charged.
- ***Administrative time limits***
  Periods of time set by Swissmedic and attributable to the applicant (e.g. the applicant time for answering the List of Questions, the applicant time in the case of additional questions raised by Swissmedic etc.).
- ***Application phase (AP)***
  An application phase is the period of time between two milestones of a process, e.g. the application phases formal control, evaluation I, evaluation II, labelling.
- ***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 charged to the applicant. Applicant time also includes the mailing time (time from dispatch until entry at Swissmedic) and any additional time limits stipulated by Swissmedic.
- ***Application time limit***
  The total time that can elapse from the date that the application is submitted until the completion of the application, i.e. the sum of Swissmedic time and applicant time. The application time limit is divided in different /several time limit categories (See Section 6.2).
- ***Milestone (MS)***
  A milestone is a breakpoint between the application phases, 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 consists of the sum of time limits for the applications phases.
- ***Target time***
  The point in time at the end of an application phase, calculated from a starting point and the allocated period for a phase of the application.
- ***Time limit category***
  Group of application types that are processed according to the same time frame (see Section 6.2).
- ***Time limit for the application phase***
  The total time available to Swissmedic from the starting point of this phase until its end.

1.2 Abbreviations

AP	Application phase
CD	Calendar days
Doc. OK	Formal aspects of documentation OK
eCTD	Electronic CTD document
EMA	European Medicines Agency
Eval. I and II	Evaluation phase I and II
FC	Formal control (incl. technical validation)
LoQ	List of Questions
MS	Milestone

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New API	New Active Pharmaceutical Ingredient
OMCL	Official Medicines Control Laboratory
Prel. dec. rec'd.	Preliminary decision received
SMC	Swissmedic

2 Introduction and objective

The present document defines the rules relating to time limits and the procedures that must be observed in the context of the submission of an authorisation application to Swissmedic. The information applies to Swissmedic's internal activities related to regulatory submissions. Legal provisions are in existence for certain time limits (e.g. appeal deadlines).

Where comparable processes and expertise exist, the processes and application time limits are based on those of the European Medicines Agency (EMA) for the Centralised Procedure.

For the administrative process in accordance with Swiss law, specific provisions are applicable. Among other aspects, this means that the EMA requirements cannot be directly transferred to Swissmedic.

The establishment of time limits for applications has three primary objectives: (1) the time limits to be respected by Swissmedic and by the applicant are known to all parties, (2) an explanation of the procedure used with regard to applications that are incomplete in terms of formal requirements and content is provided, (3) Specification of application time limits enables measurement of the evaluation process.

3 Scope

This guidance document is valid for the Authorisations sector.

4 Other valid documents

Document ID
OF000_21_001d_GF_Rules_relating_to_the_levying_of_fees (only available in German and French)
ZL000_00_001e_VZ_Time_limits_for_authorisation_applications

5 Time limits for applications

5.1 Application phases and milestones

Applications for first authorisation generally include the application phases (AP) and milestones (MS) described below.

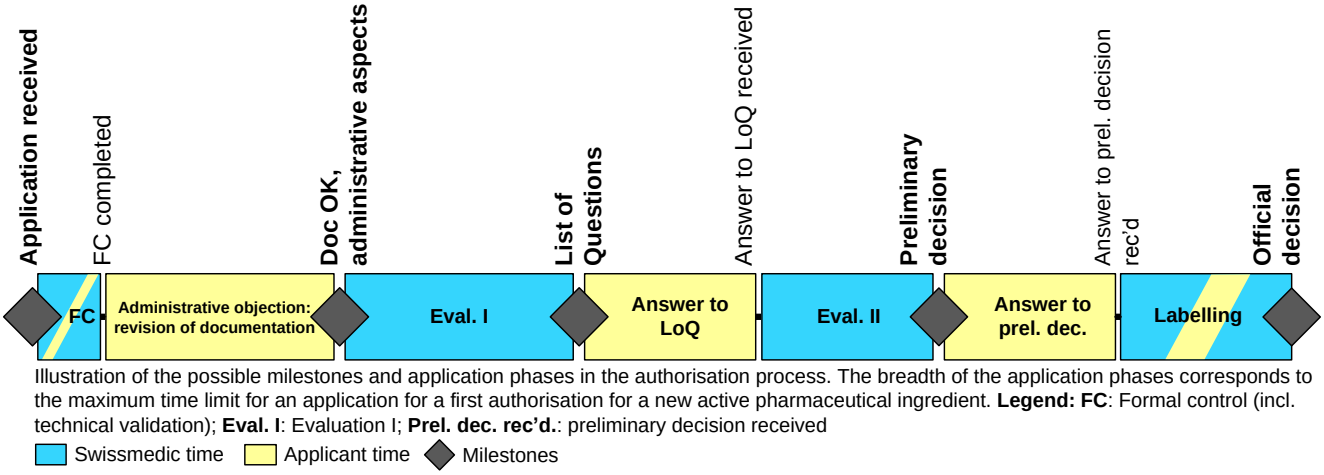

Illustration of the possible milestones and application phases in the authorisation process. The breadth of the application phases corresponds to the maximum time limit for an application for a first authorisation for a new active pharmaceutical ingredient. **Legend: FC**: Formal control (incl. technical validation); **Eval. I**: Evaluation I; **Prel. dec. rec'd.**: preliminary decision received

- ***MS "Application received"***
  Swissmedic receives and dates the application.
- ***AP "Formal control and technical validation"***

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Paper submissions:
On receipt, the formal aspects of the application are checked. If the documentation for the application is complete and there are no shortcomings in the formal aspects of the submission, the application is formally accepted as valid. If there are shortcomings in the application documents a formal objection is sent to the applicant.
eCTD submissions:
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. This control is carried out in the same way as that for the paper process.

- ***MS "Doc OK, formal aspects"***
  Swissmedic accepts the application as being in order from a formal perspective, and (for applications for first authorisations) informs the applicant accordingly.
- ***AP "Evaluation I"***
  After the "Doc OK, formal aspects", the application is evaluated by case managers and reviewers. 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.
- ***AP "Evaluation II"***
  The responses 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 constitutes a right to a hearing, and is sent to the applicant in writing. After the preliminary decision milestone, the applicant has normally no further opportunity to clarify questions relating to content, with exception to the texts of the product information. The product information may be finalised during the phase between the preliminary decision and the official decision.
- ***AP "Labelling"***
  The applicant submits the revised product information and packaging element texts in response to a positive preliminary decision. The texts must be revised by the applicant in a way that permits their approval (Text approval). After a successful revision of the product information texts (, and once any other requirements that have been communicated to the applicant are met, Swissmedic takes its official decision.
  If the evaluation of the answer to the preliminary decision reveals that further revisions are necessary in order correct the product information texts, these are sent to the applicant with a text checking letter. The time needed to complete such additional rounds of text checking is imputed to the applicant. If a second round of text checking is necessary, the applicants are also invoiced for the processing costs involved.
- ***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 application phases and milestones. If, for example, there are no questions arising from Evaluation I, the List of Questions milestone is omitted.

5.2 Time limits for authorisation applications

In order to effectively plan resources and prevent the unnecessary lengthy processing of applications, Swissmedic establishes administrative time limits. These are not legally defined time limits. Administrative time limits and any sanctions imposed for failure to comply with the time limits are communicated in writing. Upon request administrative time limits may, in principle, be extended once only.
A selection of key application time limits, allocated to various time limit categories, is shown in the table below. The corresponding maximum time limits are specified for each category. A full breakdown of all application time limits and the related administrative time limits can be found on the Swissmedic website.

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The time limits are measured in calendar days (CD), and include weekends and public holidays. The total processing time of an application (application time limit) is calculated as the sum of the total of Swissmedic *and* applicant times.

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Time limit category	SMC: Tech. val. & FC -> Doc OK or formal objection	Applicant: Correction of documents	SMC: Eval. I -> LoQ or prelim. decision	Applicant: Answer to LoQ	SMC: Eval. II -> Prelim. decision	Applicant: Answer to prelim. Decision[4]	SMC: Eval. answer to prelim. decision -> Text checking letter or official decision	Total applicant time	Total SMC time
First authorisation and major variations[1]	30	120	120	90	90	90	90	300	330
New application: new API / additional indication w. prior notification	10	10	100	90	90	90	64	190	264
Fast-track authorisation procedure	5	120	65	90	50	90	20	300	140
Authorisation with time limit[2]	5	120	65	90	50	90	20	300	140
Co-marketing	30	120	30	30	30	30	30	180	120
Variations requiring approval[3]	30	120	120	60	60	90	60	270	270
Safety-relevant variations	n.a.	n.a.	n.a.	n.a.	40	30	20	30	60
Variations requiring notification	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	30 (time to preliminary . decision / official decision)	n.a.	30
Extensions	30	10	60.	n.a.	n.a.	30	60	40	150

Legend: Eval. I and II: Evaluation phase I and II; **Doc. OK**: Formal aspects of documentation OK; **FC**: Formal control; **LoQ**: List of Questions; **New API**; New Active Pharmaceutical Ingredient; **SMC**, Swissmedic.

1 Applications for medicinal products with Orphan Drug/MUMS status are not shown as separate application types, and no specific time limit category is attributed to them. Applications for the authorisation of a medicinal product with Orphan Drug/MUMS status are, if possible, given priority with regard to their processing.

2 Time limit applies only to the medicinal product for which a first authorisation application is submitted.

3 For variations requiring approval without scientific assessment, no LoQ is expected. The evaluation time limit is therefore that for Eval. II i.e. 60 calendar days.

4 During the pilot phase of the "Optimisation of labelling phases" package of measures (Swissmedic Journal 07/2017), a time limit of 60 CD will apply to new applications and major variations for the evaluation phase of "Replying to a preliminary decision".

6 Implementation of the time limits

6.1 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 does not meet with 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 requiring notification, for which technical objections may only be made once.

6.2 Formal control

A formal control resulting in the applicant being given "Doc OK" notification usually occurs only for first applications for authorisation (e.g. new application for a new active pharmaceutical ingredient) and major variations. For other applications (e.g. applications for variations, for extensions, etc.), Swissmedic also carries out a formal control, with the applicant only being informed if the application has shortcomings (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 deducted

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from that attributed to the applicant. The time specified in the *Time limits for authorisation applications* for the Agency to carry out the formal control is again available to Swissmedic.
Formal objections are only issued once. If the applicant is unable to resolve the shortcomings after the objection is issued, Swissmedic will not process the application. For applications requiring notification, a preliminary decision is issued instead of a formal objection.

6.3 Evaluation phase I

- Evaluation phase I begins after the successful completion of the formal control (for eCTD applications, this includes the technical validation) 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 spontaneous submission of new evaluation documentation (e.g. applications for variations during ongoing first authorisation processes) during Evaluation phase I can lead to the time limit being reset to the point "Doc OK". This is implemented as additional time, attributed to that available 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 pharmaceutical ingredient / finished product and documents that, during a pre-submission meeting or on request by the applicant, Swissmedic agreed to accept at a later date.

6.4 List of questions

In general, a list of questions can be drawn up during any processes and all authorisation applications. The table in Section 6.2 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.

6.5 Answers to the list of questions

- Swissmedic begins the evaluation of the answers to the list of questions once the time limit specified for the applicant for the "Answer to the LoQ" 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. In exceptional cases, it may be possible to begin the Evaluation phase II early, if the answers are received at least 30 days before the specified time limit expires, and if Swissmedic has the necessary resources available to begin the evaluation early.
  If the applicant has requested an extension of the time limit in which to respond to the LoQ, Swissmedic will only begin Evaluation phase II after the extended time limit has expired.
- If there are shortcomings with regard to the quality of the documents, Swissmedic may return those texts affected to the applicant to be corrected or completed.
- For first 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 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 new evaluation documentation is submitted in order to answer the list of questions which is additional to that required to respond to the questions, Swissmedic decides – on a case-to-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 attributed to that available to the applicant and corresponds to the time limits for Evaluation phase I. In exceptional cases, additional time can also be attributed to that available 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 pharmaceutical ingredient / finished product

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and documents that Swissmedic previously agreed could be sent at a later date, on request by the applicant.

- Regarding subsequent submission of evaluation documentation owing to the scientific documentation being incomplete, please see section 6.3, point 2.
- In order to streamline the process and to exclude repeated rounds of the process to the greatest possible extent, no new list of questions is usually sent, but instead the corresponding preliminary decision is issued directly. A second list of questions can be issued if new questions arise from comprehensive documentation, which were received at a later date, and which were not possible to address in the first list of questions, and if answers to the additional questions are necessary for a considered assessment to be made with regard to the preliminary decision. In such a case the time limit is reset to the point "Doc OK, formal aspects".

6.6 Evaluation phase II

- The submission of new documents requiring assessment, during Evaluation phase II (or of applications for variations during ongoing first authorisation processes), leads to the time limit being reset to the beginning of Evaluation phase II. If the documentation concerned is extensive, a decision is taken on a case-to-case basis whether to reset the time limit to Evaluation Phase I or alternatively further back to "Doc OK, formal aspects". This possibility takes the form of additional time being attributed to that available 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 pharmaceutical ingredient / finished product and documents that Swissmedic previously agreed, following request by the applicant, could be sent at a later date.
- In order to streamline the process and to exclude additional steps to the greatest possible extent, no new list of questions is usually sent, but instead the corresponding preliminary decision is issued directly. A second list of questions may, if necessary, be sent for exceptional cases as mentioned under "Answers to the list of questions" above.
- The final decision, as determined by Swissmedic, is communicated to the applicant at the milestone "Preliminary decision". Under normal circumstances and unlike with the milestone "List of questions", the applicant generally no longer has the possibility of improving the application. The following so-called "Labelling phase" is primarily intended for revising the product information texts and the packaging elements.

6.7 Labelling

- Following the issue of a positive preliminary decision, Swissmedic expects evidence that any additional conditions for granting authorisation have been fulfilled. The Agency then begins the evaluation of the answers to the preliminary decision once the specified time limit for the applicant's "Answer to the preliminary decision" expires and as long as the documents requested are complete and comply with the formal requirements. In exceptional cases, it may be possible to begin the evaluation early, if the answers are received at least 30 days before the specified time limit expires, and if Swissmedic has the necessary resources available to begin the evaluation early.
  If the applicant has requested an extension of the time limit to provide its answers to the preliminary decision, Swissmedic will only begin the evaluation after the extended time limit has expired.
- For human medicinal products, the following rules apply:
  The corrections to the product information texts 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 product information texts without further corrections, the approved texts are returned to the applicant.
  The decision includes the request for the attached approved texts and the translations as required in accordance with the provisions of the legislation on therapeutic products to be uploaded electronically to the Swissmedic publication platform and released for publication.
- For veterinary medicinal products, the following rules apply:
  The corrections to the product information texts requested by Swissmedic (product information,

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labels, folding boxes, etc.) must be integrated into the drafts and submitted to the Agency for approval. If Swissmedic is able to approve the texts and if all the conditions for authorisation are met, the applicant receives the approved texts with the official decision. The publication in the electronic compendium of veterinary medicines is carried out by the Veterinary Medicines division immediately after the official decision is issued.

- If it is not possible to approve the product information texts that the applicant has revised and completed, the texts are returned to the applicant within the pre-defined time limit. The time attributed to Swissmedic for examining and approving product information texts in accordance with the list *Time limits, authorisation applications* is only calculated for the evaluation of the product information texts that are submitted with the answers to the preliminary decision.
- For the processing of subsequent rounds of examining the texts the same times are available to Swissmedic and to the applicant as those for the application phases "Evaluation of the answer to the preliminary decision" and "Answer to the preliminary decision". The time taken for this additional application phase is attributed to that available to the applicant.
- The applicant has 30 calendar days in which to respond to the preliminary decision. The conditions relating to the authorisation stated in the preliminary decision are to be fulfilled within the pre-defined time limit for "Answers to the preliminary decision" independently of the applicant's opinion.
- The submission of new documents at a later point (e.g. applications for variations during ongoing first authorisation processes) to support the applicant's opinion of the preliminary decision is not expected, and must be limited to justified, exceptional cases. Swissmedic decides whether a case is exceptional and decides at its discretion, whether the time limit is reset (additional time) to the milestones "Doc OK", "Evaluation phase I", or "Evaluation phase II. Such additional time will attributed to that available to the applicant.

6.8 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.

6.9 Applicant's appeal

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

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