

Guidance document

Temporary authorization of veterinary medicinal products

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1 Terms, definitions, abbreviations

1.1 Abbreviations

FeeO-Swissmedic	Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018 (SR 812.214.5)
LoQ	List of Questions
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)
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 Licensing 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)

2 Introduction

It is possible for temporary authorisation to be granted under certain defined conditions in order to make medicinal products for the treatment of life-threatening diseases available to animals as quickly as possible.

The requirements concerning the completeness of the documentation are reduced for temporary authorisation in comparison with a normal procedure. The applicant must submit the missing documentation while the temporary authorisation is in effect with the aim of ordinary authorisation being granted when the temporary authorisation expires.

2.1 Legal framework

The conditions for temporary authorisation are listed in Art. 9a TPA.

Temporary authorisation is possible as per Art. 18 TPLO.

Arts. 18–23 TPLO set out in detail the conditions for the granting of temporary authorisation.

3 Objective

Part 1 of this guidance document describes the conditions that must be met for a positive outcome from the **application** for temporary authorisation, as well as the procedure for an application of this type.

Formal and content requirements for an **application** for authorisation of a veterinary medicinal product by a temporary authorisation procedure, as well as the evaluation procedure itself, are described in part 2.

Swissmedic uses this guidance document first and foremost as a resource for applying the legal provisions in a uniform and equitable manner. For applicants, the document is intended to make clear the specific requirements that must be fulfilled so that corresponding applications can be processed by Swissmedic as quickly and efficiently as possible.

4 Scope

This guidance document is applicable to the authorisation of veterinary medicinal products and to additional indications and extensions.

5 Other valid documents

- *Meeting for applicants held with the Authorisation sector HMV4*
- *Time limits for authorisation applications HMV4*
- *Authorisation veterinary medicinal product under Art. 13 TPA HMV4*

6 Description

6.1 Part 1: Application for a procedure for temporary authorisation

6.1.1 Conditions for temporary authorisation

Art. 18 - 23 TPLO requires the following conditions to be fulfilled **cumulatively** to qualify a veterinary medicinal product for the temporary authorisation procedure:

- a) *The product must be used to identify, prevent or treat a disease that can lead to severe suffering possibly resulting in death or to the death of an animal in the short term*
- b) *There must be no alternative and equivalent medicinal product authorised or available in Switzerland*
- c) *The applicant will probably be in a position to submit the required data as per section 3 of the TPLO before the temporary authorisation expires with a view to achieving ordinary authorisation*
- d) *It would take so long to compile all the required data and to process and evaluate the data under letter d in an ordinary authorisation procedure as per Art. 11 TPA that irreversible damage would result or worsen or this would cause the affected animal severe suffering*

6.1.2 Application for a procedure for temporary authorisation

A procedure for temporary authorisation for a veterinary medicinal product must be requested from Swissmedic in advance.

The applicant should demonstrate in this application that the conditions for an application for temporary authorisation as per Art. 18 TPLO are fulfilled.

6.1.2.1 Scientific Advice

If required, the applicant can request a pre-submission meeting with Swissmedic in the form of a Scientific Advice Meeting to discuss the available data (see the guidance document *Meeting for applicants held with the Authorisation sector H MV4*).

6.1.2.2 Documentation to be supplied

The application must be made in writing by the authorisation holder or one of their legal representatives/companies to Swissmedic with the notice: "Application for a procedure for temporary authorisation".

The following documents should be submitted:

- a) Covering letter mentioning the indication(s) scheduled for Switzerland. The wording of the scheduled indication should be based on the populations / target animal species that have been or are being investigated and documented by the results of studies. If applicable, the covering letter must also refer to authorisation applications pending in other countries and the existence of questions or decisions from other authorities where these exist.
- b) Justification of why the applicant believes the conditions for temporary authorisation as per Art. 18 - 23 TPLO are fulfilled.
- c) An overview of the data package available for the application for temporary authorisation on submission. In addition, a table containing brief descriptions of the ongoing studies.
- d) Draft version of the Information for healthcare professionals or the Summary of Product Characteristics.

The process for applying for a procedure for temporary authorisation is shown in the [Annex 8.1](#).

6.1.2.3 Application fee

The assessment of the application for a procedure for temporary authorisation is charged on the basis of the work involved as per the Therapeutic Products Fees Ordinance.

6.1.3 Processing the application for a procedure for temporary authorisation

Swissmedic will decide within 30 days whether the criteria for temporary authorisation are met or not. The applicant will be informed of the decision in a preliminary notification or, in the case of an approval and if there is no need for clarification, directly with an official approval decision. If a preliminary notification is issued, the applicant has the option to submit a statement on the preliminary notification within 30 days. The corresponding official decision will subsequently be issued.

6.1.4 Presubmission Meeting (optional)

If the application for a procedure for temporary authorisation has been approved, a Presubmission Meeting can be held if required between one and two months before the application for temporary authorisation is submitted. The aim of the meeting is to establish whether all the documentation required to process the application is available. The following formal aspects of the authorisation application to be submitted, in particular, will be considered:

- Index of scientific and administrative documentation
- Any unresolved questions concerning incomplete clinical documentation and the times at which it will be submitted

The definitive submission date is established at the Presubmission Meeting.

The following information / documentation must be sent to Swissmedic, with an appropriate covering letter, at the latest 2 weeks before the Presubmission Meeting:

- List of questions: Presentation of the issues to be clarified during the Presubmission Meeting, usually in the form of a Briefing Book (see Chapter 3.2 List of questions/documentation in the guidance document *Company meetings in Authorisation H MV4*)
- Draft agenda with the points to be discussed
- Proposal for the type of meeting: in person, teleconference or videoconference
- List of participants and their functions

The guidance document *Meeting for applicants held with the Authorisation sector H MV4* also applies.

6.1.5 Planning the submission after approval of the application

If the application for temporary authorisation is approved, the authorisation application should be submitted no later than six months after the approval decision on the application for temporary authorisation has been issued.

6.2 Part 2: Submission of the application for temporary authorisation

6.2.1 Formal aspects and the documentation to be submitted

The applicant submits the application for temporary authorisation to Swissmedic with all the documents mentioned in the application for the procedure, incl. Part I of the CTD, no later than six months after the approval decision on the application for temporary authorisation has been issued.

6.2.1.1 Labelling of veterinary medicinal products with temporary authorisation

Art. 21 para. 2 TPLO requires the information about the medicinal product to show clearly that it has temporary authorisation.

The following note must also be included in the Information for healthcare professionals directly beneath the name of the veterinary medicinal product:

The medicinal product "NAME" has been granted temporary authorisation as the data was incomplete at the time the authorisation application was assessed (Art. 9a TPA). The temporary authorisation is contingent on the timely fulfilment of conditions. After they have been met, the temporary authorisation can be transformed into an ordinary authorisation.

If the veterinary medicinal product with temporary authorisation is brought onto the market with foreign packaging, this must display an additional label stating at least the following information: "Temporary authorisation", reference to the Swiss medicinal product information, authorisation number with pack code, licence symbol, authorisation holder. In certain situations the name of the medicinal product, the target animal species and the quantity of active substance must additionally be shown.

6.2.2 Review phase

The process of assessing an application for temporary authorisation is carried out as described in the [Annex 8.1](#). The time limits for processing an application for temporary authorisation are based on the guidance document *Time limits for authorisation applications H MV4*.

6.2.3 Time limits for assessment

The time limits are based on the guidance document *Time limits for authorisation applications HMV4*.

6.2.4 Granting of the temporary authorisation

- No document protection is granted when an application for temporary authorisation is approved.
- The following is stated on the authorisation certificate issued with the approval decision: “Temporary authorisation as per Art. 9a TPA”.

6.2.5 Post-authorisation phase

The phase after temporary authorisation has the following features.

6.2.5.1 Timetable and conditions

The authorisation is granted for a maximum of two years. It is contingent on the fulfilment of defined conditions at agreed time points. It is the clear expectation of Swissmedic that the marketing authorisation holder will fulfil their responsibility to submit all the agreed documentation that is essential in order to transform a temporary authorisation into an ordinary authorisation without delay and on time for assessment and approval. As a rule the veterinary medicinal product with temporary authorisation should be authorised by the ordinary procedure before the time limit expires. The process and the time limits for fulfilling the conditions are the same as for any other authorisation conditions.

6.2.5.2 Extension of the temporary authorisation

If the temporary authorisation cannot be transformed into an ordinary authorisation before it expires, it is possible in exceptional cases, i.e. in scientifically justified cases (Art. 21 para. 3 TPLO) to extend the temporary authorisation on application. The authorisation holder must submit an interim report on the status of and progress with meeting the determined conditions with the application for extension. As a rule the extension of the temporary authorisation may not exceed 1 year. Exceptions are possible in justified cases.

Sixty calendar days before expiry of the temporary authorisation, the authorisation holder must apply for transformation into an ordinary authorisation, extension of temporary authorisation or discontinuation of temporary authorisation.

6.2.6 Application for ordinary authorisation

If all the reports on the conditions attached to the temporary authorisation have been submitted and assessed, and if Swissmedic has decided that the conditions have been met, the authorisation holder can submit an application for transformation of the temporary authorisation into authorisation for five years. The application must be accompanied by a detailed tabular summary showing which individual conditions have been submitted at which points in time and with which application and have been deemed by Swissmedic to have been fulfilled. The application is then reviewed and, if approved, the temporary authorisation is transformed into authorisation for 5 years (ordinary authorisation).

The authorisation number and the pack codes of the medicinal product with temporary authorisation are retained when transformation into ordinary authorisation takes place.

6.2.7 Ex officio temporary authorisation

If an application for ordinary authorisation of a medicinal product is submitted to Swissmedic, and if Swissmedic finds during the assessment that the documentation is incomplete or inadequate to support the requested indication, Swissmedic can draw the applicant's attention to this situation at the end of assessment phase I when the LoQ is sent and/or issue a preliminary rejection notification at the end of assessment phase II and suggest temporary authorisation. The process is shown in [Annex 8.2](#).

6.2.8 Temporary authorisation in accordance with Art. 13 TPA

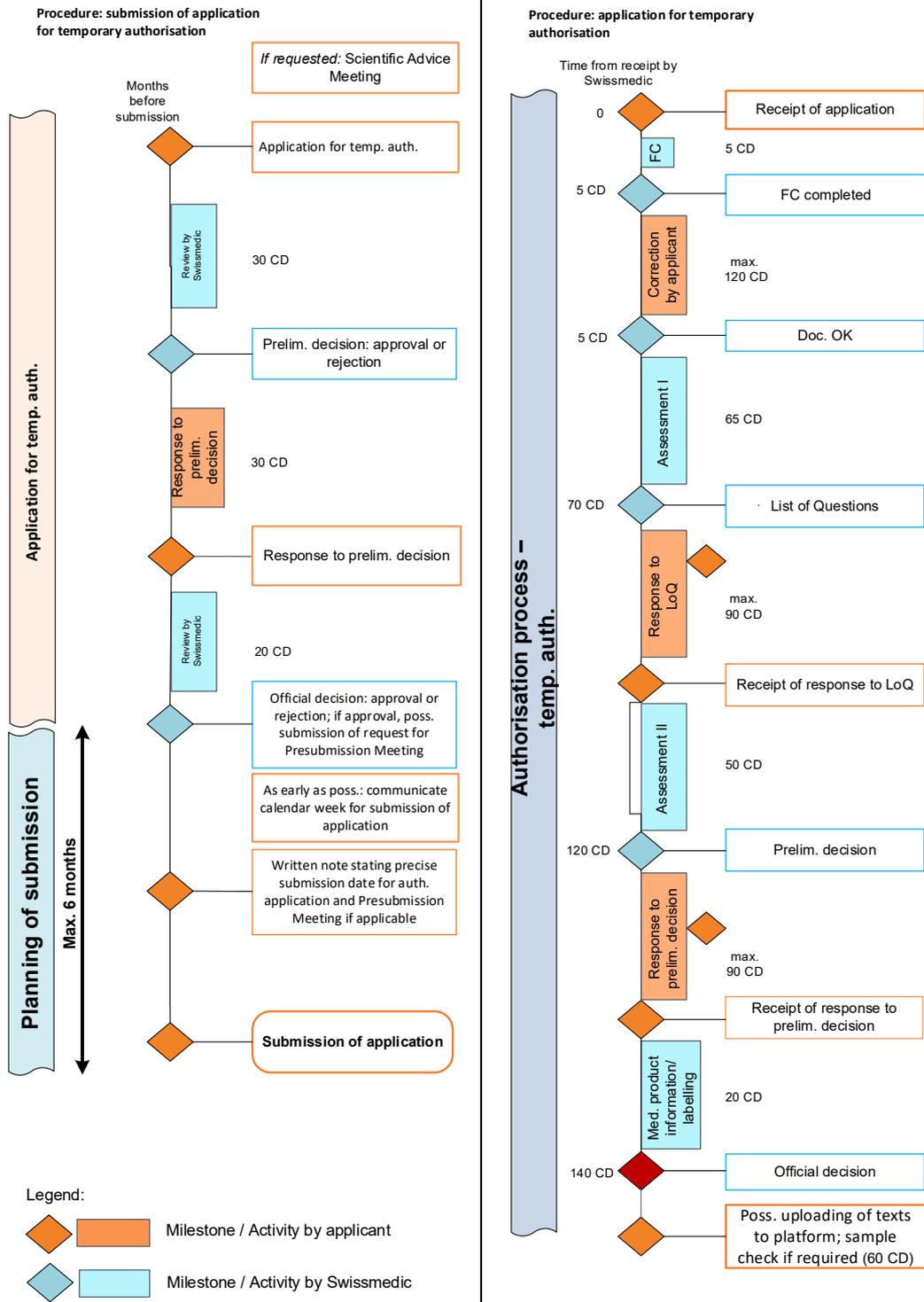
A reduced assessment in accordance with Art. 13 TPA for an application for temporary authorisation is possible if Swissmedic has approved the preceding application for a procedure for temporary authorisation. The application for temporary authorisation should be submitted taking account of the requirements stated in the guidance document *Authorisation veterinary medicinal product under Art. 13 TPA H MV4*.

6.3 Fees

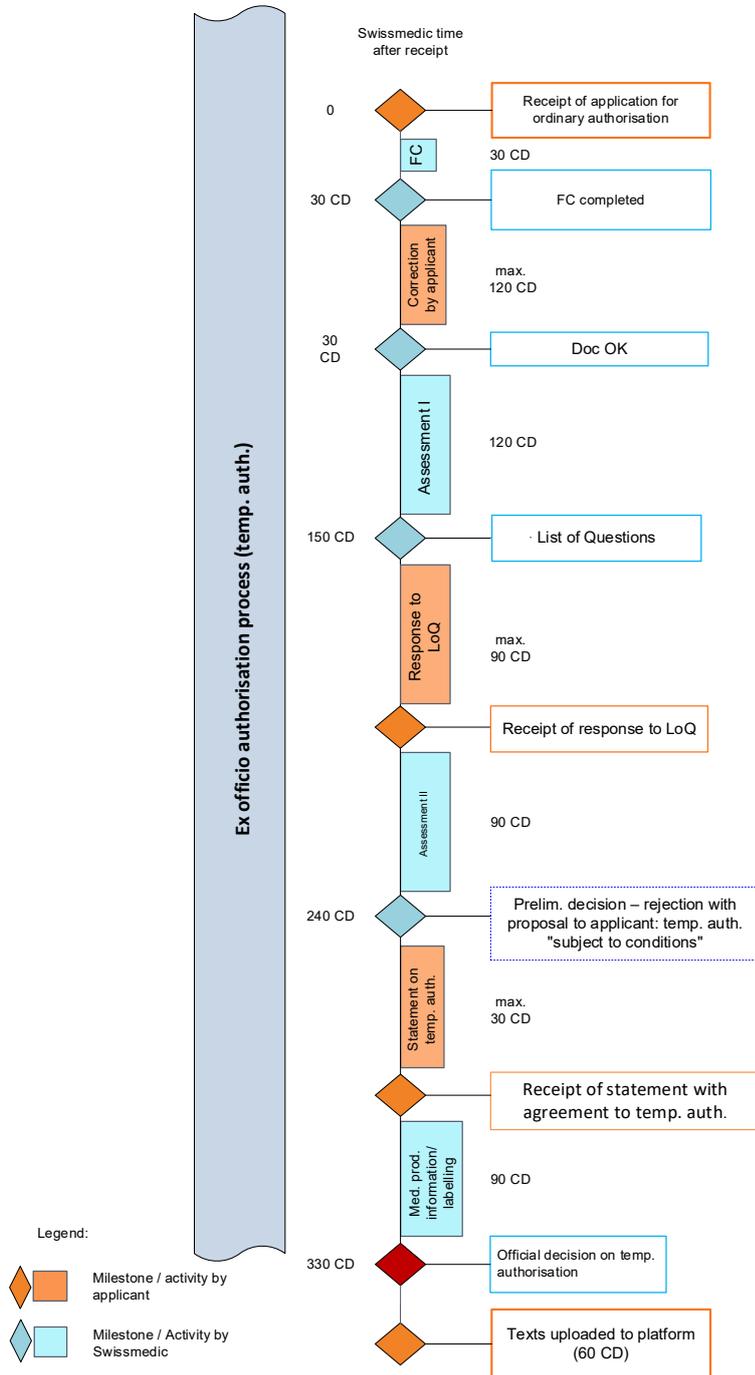
The fees specified in the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products apply. The fees for assessment of documentation for the removal of conditions attached to the temporary authorisation will be calculated according to the work involved.

7 Annex

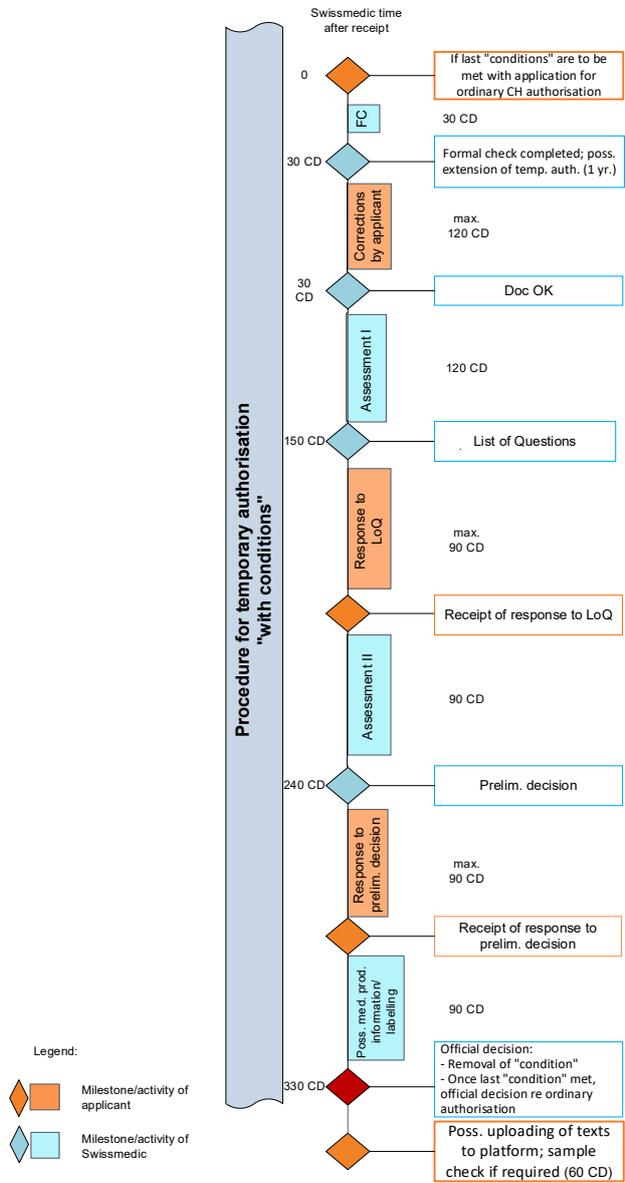
7.1 Procedure / application for temporary authorisation



7.2 Ex officio temporary authorisation



7.3 Application for removal of a condition attached to a temporary authorisation



Change history

Version	Change	sig
1.2	New layout, no content adjustments to the previous version.	dei
1.1	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
1.0	Implementation of TPO4	ps