swissmedic

# Guidance document

# Authorisation procedures for Covid-19medicinal products during a pandemic

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# 1 Terms, definitions, abbreviations

## 1.1 Definitions

**Pandemic**
A pandemic occurs when a specific infectious disease spreads across many countries or continents.

## 1.2 Abbreviations

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|---|---|
| Access Consortium | Australia-Canada-Singapore-Switzerland-United Kingdom Consortium |
| MPLO | Ordinance of 14 November 2018 on Licensing in the Medicinal Products Sector (SR 812.212.1) |
| TPLRO | Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22) |
| FOPH | Federal Office of Public Health |
| FONES | Federal Office for National Economic Supply |
| COVID-19 Ordinance 3 | Ordinance 3 of 19 June 2020 on Measures to Combat the Coronavirus (SR 818.101.24) |
| FeeO-Swissmedic | Ordinance of the Swiss Agency for Therapeutic Products of 14 September 2018 on Fees (SR 812.214.5) |
| TPA | Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21) |
| ICMRA | International Coalition of Medicines Regulatory Authorities |
| LoQ | List of Questions |
| SECO | State Secretariat for Economic Affairs |
| 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 (812.212.23) |
| TPO | Therapeutic Products Ordinance of 21 September 2018 (SR 812.212.21) |
| WL | Guidance document |

# 2 Introduction

In the exceptional situation of a pandemic, Swissmedic is offering applicants various options for the fastest possible processing of authorisation applications for medicinal products used to prevent and treat a pandemic disease. The measures are designed to ensure that patients can be supplied with these medicinal products as quickly as possible.

### 2.1 Legal framework

The procedures for authorising medicinal products in the event of a pandemic are based on the following legal provisions in particular:

**COVID-19 Ordinance 3**
- Art. 21 Exceptions to the requirement of authorisation for medicinal products
- Annex 4
- Annex 5

**TPA**
- Art. 9 Marketing authorisation
- Art. 9a Temporary authorisation
- Art. 9b para. 2 Temporary authorisation for use and limited placing on the market
- Art. 10 Conditions for granting a marketing authorisation
- Art. 11 Application for a marketing authorisation
- Art. 13 Medicinal products and procedures authorised in foreign countries
- Art. 16 Authorisation decision and period of the marketing authorisation
- Art. 17 Official batch release

**TPO**
- Art. 9 Marketing authorisation
- Art. 16 to Art. 20 Medicinal products and procedures authorised in foreign countries (Art. 13 TPA)
- Art. 21 to Art. 25 Variation of the authorisation

and the provisions of the relevant ordinances, particularly the Therapeutic Products Licensing Requirements Ordinance (TPLRO), Medicinal Products Licensing Ordinance (MPLO) and the Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (TPLO).

## 3 Objective

This guidance document (WL) is primarily intended for administrative bodies and does not directly specify the rights and obligations of private individuals. Swissmedic uses this WL mainly as a resource for deciding on possible authorisation procedures in the exceptional situation of a pandemic in a consistent and equitable manner. For applicants, its publication is intended to elucidate the specific preconditions and requirements that must be fulfilled so that procedures can be used and applications processed as quickly and efficiently as possible during a pandemic.

## 4 Scope

This WL applies to new authorisations and type II variations, i.e. additional indications used to prevent or treat COVID-19.

## 5 Description

### 5.1 COVID-19 Ordinance 3

Medicinal products that are manufactured with active substances under Annex 5 of the COVID-19 Ordinance 3 for the treatment of COVID-19 patients may, following the submission of an application for authorisation of a medicinal product containing one of these active substances, be placed on the market without authorisation pending Swissmedic's decision on authorisation (Art. 21 para. 1 COVID-

19 Ordinance 3). This measure is designed to ensure that those therapeutic options that are considered to be promising based on experience acquired in medical practice can be made available to patients as quickly as possible.

Medicinal products that are manufactured with active substances under Annex 5a of COVID-19 Ordinance 3 for the prevention of a COVID-19 infection in immunosuppressed patients in whom sufficient immunity could not be established despite immunisation or who cannot be vaccinated may, following the submission of an application for authorisation of a medicinal product containing one of these active substances, be placed on the market without authorisation pending Swissmedic's decision on authorisation (Art. 21 para. 1$^{bis}$ COVID-19 Ordinance 3).
Moreover, variations to the authorisation for a medicinal product authorised in Switzerland containing an active substance under Annex 4 number 1 of the COVID-19 Ordinance 3 that is used to treat COVID-19 patients in Switzerland may be implemented immediately after the submission of a corresponding variation application to Swissmedic (Art. 21 para. 2 COVID-19 Ordinance 3). This provision applies to authorisation extensions, type II variations, indication extensions and new dosage recommendations.
Swissmedic will confirm submission of an authorisation application involving an active substance under Annex 5 or an application for a variation under Annex 4 of COVID-19 Ordinance 3, provided the following documents have been submitted as a minimum:

- Cover letter
- Form *New authorisation of human medicinal products HMV4 or*
  Form *Variations and authorisation extensions HMV4*
- Information for healthcare professionals or comparable information material for professionals (English versions will be accepted)
- Patient information, if available, in two official languages in accordance with Art. 26 para. 2 TPO
- Mock-up packaging (if applicable – English versions will be accepted)
- Timetable for submitting the scientific modules

To ensure efficient application submission and document review, a presubmission meeting must also be held prior to submission.

## 5.2 National and international collaboration in a pandemic

The Federal Office of Public Health (FOPH) is primarily responsible for assessing the current status of a pandemic and arranging corresponding measures. If a pandemic arises, close links are maintained between the national and international authorities and with expert groups. At national level, close collaboration exists with the FOPH, which ensures collaboration with other stakeholders (e.g. FONES, Armed Forces Pharmacy, SECO). At international level, there are bilateral (e.g. with the EMA or FDA) and multilateral (e.g. in connection with the ICMRA or Access Consortium) links. Further details on national and international collaboration are published on the Swissmedic website.

## 5.3 Advice and authorisation procedures in the event of a pandemic

Swissmedic will give priority to authorisation applications for medicinal products used to prevent and treat a pandemic disease (e.g. COVID-19) and fast-track these according to the pandemic situation so that effective and safe medicines can be made available to patients as quickly as possible.

### 5.3.1 Scientific Advice

Applicants are advised to request a preliminary discussion of the available data material and development programme in the form of a Scientific Advice Meeting. The documents to be submitted are based on the provisions of the WL *Meetings for applicants held with the Authorisation sector HMV4.*
Within the scope of this WL, Swissmedic can waive the fee for the Scientific Advice (Art. 12 FeeO-Swissmedic).

### 5.3.2 Presubmission meeting

The possible procedures for authorising a medicinal product during a pandemic described below and the submission modalities should be clarified in good time during a presubmission meeting to be held with Swissmedic (see *WL Meetings for applicants held with the Authorisation sector HMV4*). Provided the planned authorisation procedure is being conducted in parallel with a foreign authority, the applicant will be asked during the presubmission meeting to let Swissmedic know whether it will provide Swissmedic with the review results (e.g. correspondence, LoQ) of the foreign partner authority, or whether it will allow Swissmedic to share information about the ongoing application with the foreign authority.
Within the scope of this WL, Swissmedic can waive the fee for the presubmission meeting (Art. 12 FeeO-Swissmedic).

### 5.3.3 "Rolling submission"

For the exceptional case of a pandemic, and at the request of the applicant during a presubmission meeting, an authorisation application may be submitted as a "rolling submission". The rolling submission procedure represents a special form of a first authorisation procedure or a variation procedure. In contrast with a regular application for authorisation under Art. 11 TPA, the applicant does not need to provide Swissmedic, as early as the initial submission of the authorisation application, with a complete dossier or complete documentation on the proposed medicinal product or on the variation application for the medicinal product. The data required for the authorisation of the medicinal product will be collected and compiled continually by the applicant and made available to Swissmedic as soon as possible.
During the presubmission meeting, the applicant will provide Swissmedic with a plan showing the dates on which it expects to be able to submit the individual data packages. The applicant is required to inform Swissmedic in advance of the submission date for each individual data package so that it can plan the staff resources required to review the data material.
The review will then be started as soon as Swissmedic has received a documentation package. On completion of the partial review, the applicant will immediately be sent a List of Questions (LoQ) to clarify any issues. The applicant will be granted a reasonable period of time in which to answer the questions. Each data package should be submitted to Swissmedic as a separate eCTD sequence. This review cycle will be used for each individually submitted documentation package.
As soon as Swissmedic is in possession of the documentation required for reviewing the authorisation application, and all the questions asked by Swissmedic have been fully answered, Swissmedic will inform the applicant of the scheduled decision as a preliminary decision.

Based on the discussion with the applicant during the presubmission meeting, the submitted clinical data material and the results of the evaluation, Swissmedic decides whether the medicinal product can be authorised in the regular procedure, or whether temporary authorisation can be granted on the basis of Art. 9a TPA (see "Application of Article 9a TPA").

### 5.3.4 Rolling questions

Like the rolling submissions procedure, "rolling questions" represents a special form of a new authorisation or variation procedure. At the request of the applicant during a presubmission meeting, Swissmedic decides whether this procedure is possible. In the "Rolling Questions" procedure, the applicant possesses complete documentation. The authorisation application must include the information and documents listed in Article 11 TPA in conjunction with Articles 2 to 5 TPLRO. The review is started as soon as the formal check has been concluded with a positive result. In contrast with the standard procedure, Swissmedic will ask its questions that must be answered by the applicant within the specified time limit on an ongoing basis. The classical LoQ milestone of the standard procedure does not apply. As with the "Rolling Submission" procedure, based on the discussion with the applicant during the presubmission meeting, the submitted data and the result of the evaluation, Swissmedic decides whether the medicinal product can be authorised in the regular procedure, or whether temporary authorisation can be granted on the basis of Art. 9a TPA (see "Application of Article 9a TPA").

### 5.3.5 Review of the authorisation application within the framework of the Access pilot project

The Access work-sharing initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines Health Regulatory Agency, MHRA) and Swissmedic and the pharmaceutical industry. Even during a pandemic, it is possible to ask for an authorisation application to be reviewed within the framework of the work-sharing initiative of the Access Consortium. The participating authorities coordinate the review of the corresponding applications, which must be submitted in at least two of the five possible countries. For the review of an application within the framework of the Access work-sharing initiative, all the authorisation documents and complete documentation needs to be submitted to Swissmedic. Further details on this collaboration are published on the Swissmedic website.

### 5.3.6 Fast-track authorisation procedure

Swissmedic will give priority to authorisation applications for medicinal products used to prevent and treat a pandemic disease (e.g. COVID-19) and fast-track these according to the pandemic situation. If, however, an application should be assessed in a fast-track authorisation procedure (FTP) according to Art. 7 TPO, a corresponding request must be made to Swissmedic before the application is submitted. The FTP process is described in more detail in the guidance document *Fast-track authorisation procedure HMV4*. The request procedure can be shortened according to the pandemic situation.

### 5.3.7 Authorisation under Art. 13 TPA

For applications according to Art. 13 TPA, the requirements of WL *Authorisation human medicinal product under Art. 13 TPA HMV4* apply.
Swissmedic will also give priority to authorisation applications under Art. 13 TPA for medicinal products used to prevent and treat a pandemic disease (e.g. COVID-19) and fast-track these according to the pandemic situation

### 5.3.8 Temporary authorisation on request (Art. 9a TPA)

Even during a pandemic, great importance is attached to the submission of the necessary clinical data, particularly on the safety and efficacy.
The temporary authorisation of medicinal products for life-threatening diseases is possible, provided their use is expected to have a major therapeutic benefit and is compatible with the protection of health, no equivalent medicinal product is authorised or no comparable medicinal product is available in Switzerland, or the collection of all the required data and the processing and evaluation of the data would take so long that irreversible harm might occur or be aggravated (see WL *Temporary authorisation of human medicinal products HMV4*).
If a medicinal product should be authorised temporarily, a corresponding request must be sent to Swissmedic before the application is submitted. The request procedure is described in more detail in WL *Temporary authorisation of human medicinal products HMV4*.
The request procedure can be shortened according to the pandemic situation. Swissmedic may, at any time during its review of a medicinal product for which an application for ordinary authorisation has been submitted, make use of the option to issue a temporary authorisation ex officio.

## 5.4 Efficacy of medicinal products against new SARS-CoV-2 variants

### 5.4.1 Background

The marketing authorisation holder must continuously monitor the efficacy of medicinal products used to prevent and/or treat COVID-19 against current SARS-CoV-2 variants according to the conditions imposed.

### 5.4.2 Regulatory requirements

The marketing authorisation holder must submit a Submission Plan on meeting the conditions via the Swissmedic Portal by the time WHO defines a SARS-Cov-2 variant as a variant of interest, variant of concern or lineage under monitoring (see WHO: Tracking SARS-CoV-2 variants) at the latest. The Submission Plan should include a schedule showing when the results of the tests to determine activity against certain variants will be submitted.
An evaluation of the study findings and their impact on the benefit-risk profile should be submitted in Module 2. The marketing authorisation holder is obligated to submit the required documentation together with updated medicinal product information as soon as relevant data on new SARS-CoV-2 variants are available.

### 5.4.3 Review process

The marketing authorisation holder informs Swissmedic in advance of the exact submission date so that the formal check by Swissmedic can be carried out promptly. Depending on the classification of the safety relevance, the deadlines may be shortened appropriately to ensure rapid inclusion in the medicinal product information.

## 5.5 Authorisation of new COVID-19 vaccines and adaptation of authorised vaccines to new SARS-CoV-2 variants

Together with the partner authorities of the Access Consortium, Swissmedic has established a position on the regulatory and scientific requirements for the development of new COVID-19 vaccines to accommodate the changing conditions with regard to performing clinical efficacy studies.
To ensure that COVID-19 vaccines that have already been authorised are safe and effective in the long term, it may be necessary to modify their composition to provide protection against strains of new or multiple variants in the pandemic context.
As regards scientific documentation requirements, Swissmedic is guided by the latest position papers of the Access Consortium, which are also published on the Swissmedic website.

## 5.6 Requirements applicable to product information texts and packaging

Swissmedic can approve deviations from the relevant provisions of therapeutic products legislation on the basis of a benefit/risk analysis for medicines used to prevent and combat COVID-19. Selected questions and answers concerning the requirements for product information texts and packaging can be found in the document *Requirements applicable to the packaging and labelling of medicinal products used to prevent and combat COVID-19*. Swissmedic will update this document at regular intervals. Link

## 5.7 Time limits

The procedures described under "Advice and authorisation procedures in the event of a pandemic" will not be processed according to the time limit schedule described in the WL *Time limits for authorisation applications HMV4*. Swissmedic will prioritise and fast-track the review given the exceptional situation and taking account of the available staff resources. The applicant can help expedite the authorisation procedure by replying promptly to the questions posed by Swissmedic and by delivering the documents required for processing an application as quickly as possible.

## 5.8 Fees

The fees are based on the FeeO-Swissmedic.

## Change history

| Version | Change | sig |
|---|---|---|
| 7.1 | New layout, no content adjustments to the previous version. | dei |
| 7.0 | New section 6.4: Activity of active ingredients against new SARS-CoV-2 variants<br>Section 6.5: Linguistic editing<br>Annex 1 and 2 to the previous Access position papers deleted | nma, blk, gec, pet |
| 6.0 | Chapter 6.1:<br>- New reference to Art. 12 para. 1bis of COVID-19 Ordinance 3<br>The patient information must be submitted in the official Swiss languages according to Art. 26 para 2 TPO.<br>- Clarifications on procedure for applications according to Art. 21 para. 1-2 COVID-19 Ordinance 3<br>Chapters 6.3 and 6.4: For applications in fast-track or temporary authorisation procedures, requests must be made for pandemic medicinal products.<br>Editorial clarifications | zsa, dts |
| 5.0 | New chapter 6.3.6 and new Annex 2: Immunobridging for the authorisation of COVID-19 vaccines | fg |
| 4.0 | Chapter 4: Scope simplified<br>Chapter 6.1: Minimum requirements for submitting applications involving active substances under Annexes 4 and 5 of Covid-19 Ordinance 3 specified in greater detail.<br>New chapter 6.4: Adaptation of vaccines to new SARS-CoV-2 variants<br>New Annex 1 Points to consider for strain changes in authorised COVID-19 vaccines in the ongoing SARS-CoV2 pandemic<br>Editorial clarifications | stb, mag, dts |
| 3.2 | Formal changes to header and footer<br>No content changes from the previous version. | dei |
| 3.1 | Chapter 6.3.8: Linguistic clarification | dts |
| 3.0 | Focus on the COVID-19 pandemic | vy, fg, dts |
| 2.1 | Formal adaptations to HMV4 | cis |
| 2.0 | Adaptations to the VIP project (supplying vaccines in a pandemic) | hbj |
| 1.0 | First version | vy |