

**Terms**

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**Terms**

The following definitions apply:

Licences – major changes	Contract module for the eGov service ‘Licences – major changes’ relating to the submission of major changes as defined in the Medicinal Products Licensing Ordinance (MPLO; SR 812.212.1)
Electronic legal transactions	Official communications by means of legally binding electronic messages, i.e. the electronic transmission of data submissions arising from the issuing of a decision by Swissmedic and decisions issued by Swissmedic as defined in the Ordinance of 18 June 2010 on Electronic Communication in Administrative Proceedings (ECAPO, SR 172.021.2)

## 1 Subject matter

These Special Terms of Use cover only those aspects that are specific to the eGov service 'Licences – major changes', otherwise the General Terms of Use shall apply.

## 2 Add-on contract module

The eGov party has concluded a basic eGov services contract with Swissmedic that is now being supplemented by a 'Licences – major changes' contract module for the eGov service 'Licences - major changes'.

## 3 Services and responsibility of Swissmedic

### 3.1 General

The description of the eGov licences – major changes can be found in the information sheet 'eGOV\_Service\_Licences - major changes-standard-functions'.

### 3.2 Electronic legal transactions

Swissmedic provides internet-based eGov services for electronic legal transactions and for information and data sharing. These services extend and supplement the communication channels for individual business transactions. Electronic legal transactions with Swissmedic are authorised exclusively for new administrative procedures after the contract has been concluded and the terms of use accepted.

Legally binding data submissions to Swissmedic and decisions issued by Swissmedic are not usually transmitted via an acknowledged delivery platform as defined in Art. 2 ECAPO, but via the Swissmedic eGov services. In the context of electronic legal transactions, these services constitute a 'different transmission method' as defined by Art. 9 para. 2 ECAPO.

Swissmedic attaches a digital signature to e-mails sent in connection with electronic data submissions or decisions.

The following arrangements apply in particular.

### 3.3 Electronic data submissions to Swissmedic

The reporting of major changes in the eGov service 'Licences – major changes' requires the currently valid report form available on the Swissmedic website to be filled in and submitted online.

Data submitted electronically will be rejected in the following cases:

The e-mail or documents contained in the e-mail

- are not machine readable or processable or
- contain harmful software (viruses, malware, etc.)

In such cases, the eGov party will receive an error message.

Major changes may be submitted via the eGov service 'Licences – major changes' only by eGov parties that

- are establishment licence holders or companies that have been authorised by the establishment licence holder to submit major changes via the eGov service 'Licences – major changes'. In the case of such authorisation, the establishment licence holder still bears full responsibility for the accuracy of the information submitted.
- possess a valid establishment licence according to the new legislation, i.e. after the entry into force of the new Therapeutic Products Act (TPA, SR 812.21) and the Medicinal Products Licensing Ordinance (MPLO, 812.212.1 of 1 January 2019); otherwise a corresponding application for the renewal of the licence should be submitted.

The eGov party can only view those 'Licences – major changes' that it has entered itself. There are no other authorisation levels.

When 'Licences – major changes' have been submitted to Swissmedic, they can no longer be cancelled or changed.

### 3.4 Dispatch by Swissmedic

The official decision is sent to the licence holder by post.

## 4 Obligations and responsibility of the eGov party

### 4.1 General

In this connection, please see, in particular, the information sheet 'eGOV\_Service\_Licences - major changes-standard-functions'.

### 4.2 Electronic legal transactions

The eGov party is responsible for storing messages and receipts on its system for evidential purposes in such a way that their content and the exchange of messages that took place can, if necessary, be accurately reconstructed.

It is the responsibility of the eGov party to ensure that it has a functioning internet connection with sufficient bandwidth to open messages and receipts.

The eGov party uses Swissmedic eGov services entirely at its own risk, particularly for the purpose of observing time limits. Accordingly, the eGov party is solely responsible for submitting reports of 'Licences – major changes' in good time such that any time limits can still be observed even if a planned or unplanned system interruption occurs.

Data can be submitted electronically at any time. Electronic data submissions to Swissmedic do not require an electronic signature. The basic contract on the use of Swissmedic eGov services permits sender identification and transmission integrity by an alternative suitable method in accordance with Art. 6 para. 2 ECAPO. A recognised electronic signature in accordance with Art. 21a para. 2 APA is therefore not required.