Use of eGov services
Special Terms of Use
GMP/GDP certificate module

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Terminology

The following definitions apply:

GDP	GDP Good Distribution Practice
GMP	GMP Good Manufacturing Practice
GMP/GDP certificates	Certificates which, on the basis of a valid establishment licence from Swissmedic, confirm that the listed activities are performed in conformity with the requirements of GMP or GDP at the stated site. They are site-specific and are written in English.
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 transmissions in connection with an administrative procedure (VeÜ-VwV, SR 172.021.2)

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1   Subject matter

These Special Terms of Use regulate only those aspects that are specific to the GMP/GDP certificate eGov service, 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 GMP/GDP certificate contract module for the GMP/GDP certificate eGov service.

3   Services and responsibility of Swissmedic

3.1   General

The GMP/GDP certificate eGov service is described in the "GMP/GDP certificate_eGov_service_Standard functions" information sheet.

3.2   Electronic legal transactions

Swissmedic provides internet-based eGov services for electronic legal transactions and 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 VeÜ-VwV, 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 VeÜ-VwV.

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

An order for a GMP/GDP certificate requires the currently valid order 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.

When ordering GMP/GDP certificates, the eGov party undertakes to provide no details other than those in the establishment licence validly approved by Swissmedic. The date stated as the date of the last inspection must be the date of the most recent *completed* basic inspection. In this context,

an inspection is considered to have been completed if the person(s) responsible for technical matters at the site concerned has/have received the respective completion letter from the competent inspection body.

Only eGov parties that are the holders of an establishment licence or companies authorised by the holder of the establishment licence to order GMP/GDP certificates are authorised to order GMP/GDP certificates. In the case of such authorisation, the holder of the establishment licence still bears full responsibility for the accuracy of the information submitted.

The eGov party cannot view GMP/GDP certificate orders other than those it has entered itself. There are no other authorisation levels. This also applies to external users authorised by the eGov party.

When orders have been submitted to Swissmedic, they can no longer be cancelled or changed. The GMP/GDP certificate is issued – as ordered – and charged for.

3.4   Dispatch by Swissmedic

The GMP/GDP certificates will be printed on deed paper, stamped, signed and sent to the company that has ordered them by post.

4   Obligations and responsibility of the eGov party

4.1   General

In this connection see, in particular, the "GMP/GDP certificates_eGOV_service_Standard functions" information sheet.

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 placing orders in good time such that any time limits can still be observed even in the event of any planned or unplanned system interruption.

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 VeÜ-VwV. A recognised electronic signature in accordance with Art. 21a para. 2 VwVG is therefore not required.