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Terminology

The following definitions apply:

CPP	A Certificate of a Pharmaceutical Product, or product certificate, is a certificate for the attention of foreign licensing authorities which describes in a structured format the status of the companies concerned and of the licensed pharmaceutical product; CPP eGov service for ordering product certificates
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)

1 Subject matter

These Special Terms Of Use regulate only those aspects that are specific to the CPP 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 CPP contract module for the CPP eGov service.

3 Services and responsibility of Swissmedic

3.1 General

A description of the CPP eGov service can be found in the information sheet "CPP_eGOV_service_Standard functions".

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 CPP 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 CPPs, the eGov party undertakes to provide no details other than those officially approved by Swissmedic. If different details are required, the authorisation must first be modified using the relevant application procedure. This applies, for example, to details of the manufacturer, composition of the medicinal product, shelf-life, dispensing category, etc.

CPPs can be ordered only for products authorised in Switzerland, for which the eGov party is the registered authorisation holder or in respect of which the eGov party has been accredited by the authorisation holder to order the CPPs. In the case of such accreditation, the authorisation holder still bears full responsibility for the accuracy of the information submitted.

The eGov party cannot view CPP orders other than those it has entered itself. There are no other authorisation levels. This also applies to external users accredited by the eGov party.

When orders have been submitted to Swissmedic, they can no longer be cancelled or changed. The CPP is issued – as ordered – and charged for. CPPs with different content may be obtained only by submitting a new order using a corrected order form.

3.4 Dispatch by Swissmedic

The CPPs are printed on security paper, stamped and signed, and sent to the stated address in Switzerland by post.

In the event of a direct delivery to a third party (e.g. Federal Chancellery or consular service), Swissmedic is unable to provide any support; this means that enquiries regarding the whereabouts of the CPP will not necessarily be answered.

4 Obligations and responsibility of the eGov party

4.1 General

In this connection see, in particular, the "CPP_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.