

Use of eGov services

Special Terms of Use MESA

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Terminology

The following definitions apply:

MESA	National trade register for controlled substances, eGov service for reporting deliveries of controlled substances – either as constituents of medicinal products or as substances – from one company or organisation in Switzerland to another.
(for controlled substances) Responsible Person RP	The Responsible Person (RP) for controlled substances within a company or organisation is specifically named in the narcotics establishment licence issued by Swissmedic. This person is responsible with regard to Swissmedic for all issues relating to narcotics and/or controlled substances. This also includes the legal obligation to report domestic deliveries of medicinal products and/or active substances.
Controlled substances	Narcotics, psychotropic substances, precursors and auxiliary chemicals as well as raw materials and products suspected of having effects similar to narcotics in accordance with the Swiss Narcotics Act.
eGov Portal	Internet-based system offering various eGov services for the electronic exchange of information and data with eGov parties that can be accessed at https://www.portal.swissmedic.ch/ .

Subject matter

These Special Terms of Use govern only those aspects that are specific to the MESA eGov service. Otherwise, the General Terms of Use shall apply.

Add-on contract module

The eGov party has concluded a basic eGov services contract with Swissmedic that is now being supplemented by a MESA contract module for the MESA eGov service.

The MESA contract module should be signed by the eGov party's Responsible Person for controlled substances.

Services and responsibilities

a. General

The non-conclusive user handbook for the MESA eGov service can be found on the Swissmedic website at:

b. 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 of the Ordinance on Electronic Communication in Administrative Proceedings (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.

The following rules apply in particular.

a. Data submissions to Swissmedic

The list published on the internet by the Federal Chancellery (www.bk.admin.ch) provides information about the specific communication channels and data formats that are approved for electronic submissions to Swissmedic (see Art. 4 ECAPO).

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.

Calculation of Swissmedic's time limit then begins on the next working day.

c. Notification e-mail

Notification e-mails sent by the MESA eGov service always contain the subject line: "MESA".
Authorised administrators can modify the e-mail address directly in the application.