

**Information sheet**  
**eGov Services BNB Modul OCABR**

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## Terms

The following definitions apply:

OCABR	<p><i>Official Control Authority Batch Release.</i> Official batch release.</p> <p>Swiss legislation specifies that certain categories of medicinal products, such as blood products, immunological medicinal products, vaccines and animal sera, are subject to official batch inspections.</p> <p>Both human and veterinary medicinal products are affected.</p> <p>In the Swiss OMCL, the term "OCABR" is used superordinately for all activities of the official batch release</p>
OBPR	<p><i>Official Batch Protocol Review</i></p> <p>Official batch release based on the review of the Summary Protocol of the manufacturer without doing additional laboratory analysis. The term "OBPR" is in an international context only used for immunological veterinary medicinal products</p>
MIF	<p><i>Marketing Information Form.</i> Application form for notifications</p>
Electronic transactions	<p>legal</p> <p>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)</p>

## 1 Subject matter

These Special Terms of Use regulate only those aspects that are specific to the OCABR 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 an OCABR contract module for the OCABR eGov service.

## 3 Services and responsibility of Swissmedic

### 3.1 General

A description of the OCABR eGov service can be found in the information sheet "Swissmedic eGov Portal – OCABR 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 submission of applications for batch inspections, plasma pool testing or notification requires the currently valid application forms 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. In the case of authorisation, the authorisation holder bears full responsibility for the accuracy of the information submitted.

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

Incorrect applications must be corrected and resubmitted via the Portal – which may incur costs.

### 3.4 Decisions issued by Swissmedic

If the eGov party has declared its consent by checking the corresponding checkboxes in the contract, decisions

concerning applications submitted electronically will usually be opened electronically as part of the OCABR eGov service. In justified exceptions, Swissmedic may deviate from this arrangement and issue decisions by post.

Consent to accept electronic delivery can be withdrawn by sending written notification by post or via the eGov service.

Decisions are considered to have been legally delivered when they are opened within a period of 7 days after upload. The time of uploading that determines the 7-day time limit is communicated to the eGov party as an information component of the delivery receipt. If it is not opened within the 7-day time limit, the decision will be delivered by registered mail.

In the event of the repeated failure to acknowledge receipt of decisions on time, Swissmedic can revert from electronic opening to postal opening.

### 3.5 Dispatch by Swissmedic

Certificates, test reports and any other documents will be issued to the eGov party electronically via the OCABR eGov service – provided this is available under the service.

## 4 Obligations and responsibility of the eGov party

### 4.1 General

In this connection, see the "eGov Portal – OCABR 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. Swissmedic reserves the right to request the original information, data or documents, or paper copies, from the eGov party.

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.

#### a. Data submissions to Swissmedic

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 delivering or collecting data 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. However, for the purpose of observing time limits, business hours are considered to be 8.00 a.m. – 5.00 p.m. CET. The next working day is therefore regarded as the time limit for data submitted after these business hours.

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. 1 ECAPO. A recognised electronic signature in accordance with Art. 21a para. 2 APA is therefore not required.

The eGov party undertakes to preserve signed originals of submission documents that, according to federal law or international standards, have to be signed so that these can, if necessary, be presented or sent by post to Swissmedic (see Art. 4 para. 2 e ECAPO).

#### b. Decisions issued by Swissmedic

The eGov party undertakes to check the electronic mailbox associated with the party account at regular intervals, but at least once every 5 working day