Terminology

The following definitions apply:

ElViS	Electronic Vigilance System; eGov service for reporting adverse drug reactions.
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/.
ADR	Adverse Drug Reactions
ICSR	Individual Case Safety Report
Direct insert	Manual entry of an ADR in an entry mask
File upload	Submission of an ADR by uploading an E2B-compatible file (XML format)
E2B	Electronic transmission to Business
PV Gateway (E2B)	Pharmacovigilance E2B Gateway
HCP	Health Care Professional
RPVC	Regional Pharmacovigilance Centre
MAH	Marketing Authorisation Holder

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1 Subject matter

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

The ElViS contract module should be signed by the eGov party's Responsible Person for Pharmacovigilance. If the latter is not authorised to sign, the signature of an authorised signatory is also required.

3 Services and responsibility of Swissmedic

3.1 General

The non-conclusive service description for the ElViS eGov service can be found on the Swissmedic website at :

- MU101_21_003e_MB Guidance for Industry Electronic exchange of ICSRs through ElViS
- MU101_21_012e_MB_Drug Safety Reporting Duties in Switzerland

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.

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 VeÜ-VwV).

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.

3.3 Notification e-mail

Notification e-mails sent by the ElViS eGov service always contain the subject line: "ElViS".

4 Obligations and responsibility of the eGov party

eGov parties that select the Direct insert option must have attended the corresponding Swissmedic training beforehand. Training is recommended for eGov parties that select the File upload option.

Once their ADR report has been successfully sent, eGov parties should save the report and acknowledgement of receipt on their local storage drive for their own records.

5 Data protection

ADR reports can contain particularly sensitive personal data. The confidentiality, integrity and availability of such data must be guaranteed (Art. 7 FADP, Art. 8 ff. DPO), and the data must be stored in accordance with the legal requirements applicable to particularly sensitive personal data (data protection and security) and in a manner that guarantees their confidentiality, integrity and availability (Art. 7 FADP, Art. 8 ff. DPO).
For reasons of data protection, the data in ADR reports should always be entered in been anonymised form. However, eGov parties should always verify anonymisation – particularly in respect of annexes, for example – separately.

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