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**Change history**

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# 1 Introduction

This guidance intends to assist all marketing authorization holders (MAHs) in preparing the electronic transmission of Individual Case Safety Reports (ICSRs) in pharmacovigilance. This document discusses general issues related to the electronic transmission of ICSRs, with the goal of achieving common standards, for a successful electronic exchange of ICSRs.

Swissmedic has adapted its pharmacovigilance systems and is able to support electronic transmission of ICSRs. In developing its electronic reporting systems Swissmedic has the ability to generate and receive electronic reports that comply with the ICH standards.

For the purposes of harmonizing the switch to electronic reporting, Marketing Authorization Holders (MAHs) are encouraged to be prepared for electronic reporting. The electronic reporting requirements apply to all MAHs which do have ICH-E2B compliant pharmacovigilance systems.
For companies which do not fulfil the conditions to introduce an electronic ADR reporting system, the current ADR reporting procedures will be kept on in the midterm, including the electronic reporting system named ElViS (Electronic Vigilance System) which is available since October 2014. You may find further details about ElViS on the Swissmedic website (www.swissmedic.ch)



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# 2 Goal

This guideline stipulates the requirements for MAHs to participate in E2B electronic exchange of ICSR between Swissmedic and MAHs (bidirectional) and provides guidance on the technical and procedural standards applied by Swissmedic.

# 3 Scope

MAHs are obliged by law to report certain ICSRs to Swissmedic and Swissmedic reports ICSRs received from sources other than concerned MAH to concerned MAH. The scope of this guideline covers Swissmedic and all MAH for products marketed in Switzerland.

# 4 General Principles / Information

## 4.1 Electronic exchange / reporting of ICSRs

Electronic transmission of ICSR is a two-way process. It is a change of the reporting mechanism only. The legal reporting requirement does not change (see TPA Art. 58, 59 and TPO Art. 61-66).

According to the legislation the MAHs are required to submit the following Individual Case Safety Reports (ICSRs) referred also as safety reports to Swissmedic:

- all spontaneous Swiss serious ICSRs
- all spontaneous Swiss non-serious unexpected ICSRs including ICSRs from observational / non-interventional Studies, PASS, registries, compassionate use etc.
- abuse
- medication errors and “near miss” on individual bases with focus on risk minimization possibility
- lack of effect according to the international standard (vaccines, contraceptives, biological etc.)



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This note for guidance does currently not address:

- SUSARs (suspected unexpected serious adverse reactions reports) from at Swissmedic notified Interventional Clinical Trials.

A valid ICSR for reporting to Swissmedic must fulfil the four minimum reporting criteria: an identifiable reporter, an identifiable patient, a reaction and a suspected medicinal product.

For anonymization of the case report the EMA rules should be applied (see chapter 10.2).

The complete information for an ICSR that is available to the sender should be reported in the structured fields and in the narrative. Any supporting information related to the case must be sufficiently described within the ICSR and should be listed in section A.1.8.2 (document list), A.2.2 (literature reference) or the narrative (B.5.1). See chapter 10.2.

For ICSR arising from literature, the adequate/correct reference must be placed in the section A.2.2 (literature reference). The article itself must be submitted by mail to vigilance@swissmedic.ch attached as a separate PDF document.
In addition, whenever more recent important information on an individual case is submitted, (e.g. follow-up information, ICSR highlighted for nullification) the complete (entire) information on the case has to be provided and not only partial information e.g. changes or updates.
For those ICSRs that are highlighted for nullification ('Report nullification', A.1.13, set to 'yes') also the reasons for nullification must be indicated, see chapter 10.2.

## 4.2 Important Notes

MAHs are advised to reduce the number of follow-ups to a minimum; only new and medical relevant information such as outcome, alternative medical conditions, other suspect drugs, results of performed investigations or any other data with impact on causality should initiate follow-up information. Ideally an initial case should be followed by one follow-up, at the time of case closed.

The ICSR accompanying Reporting Form (CIOMS-I Form) must not be submitted to Swissmedic if the comment to the labelling in the Product Information (PI) is placed in an E2B free text field such as sender comment (B.5.4) or the case narrative (B.5.1), see chapter 10.2.

If the ADR is not adequately / literally indicated in PI a short extract of the concerned Organ Class from Product Information should be placed in the above proposed free text fields.

## 4.3 The Swissmedic PV System and ICH Guidelines

Vigilance One Ultimate, the Swissmedic Pharmacovigilance System, is designed on top of the E2B format with the aim of being E2BR3 compatible. Therefore no major difficulties regarding E2B interpretation are expected.
Safety and acknowledgement messages have to follow the content and format of the respective ICH guidelines:

- Data Elements for the Electronic Transmission of Individual Case Safety Reports' version 4.4.1 dated 5 February 2001, see chapter 10.2
- Electronic Transmission of Individual Case Safety Report Message Specification version 2.3 (ICH ICSR DTD Version 2.1). Document Revision February 2001



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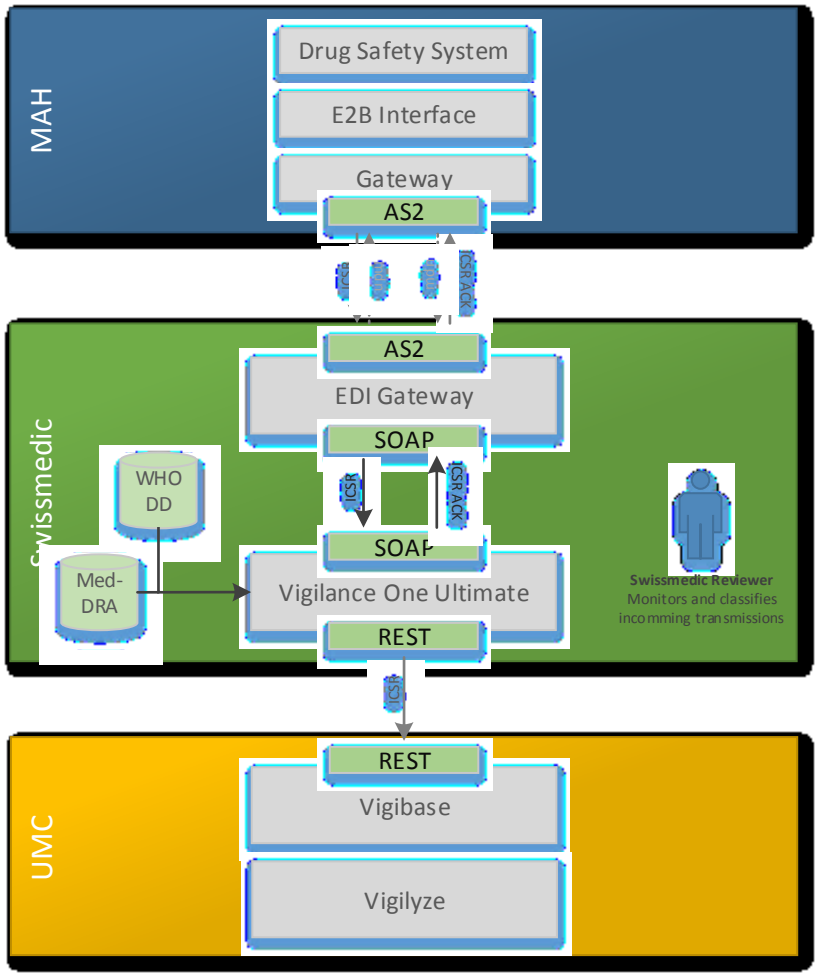
# 5 Processing of safety reports (ICSRs)

Vigilance One Ultimate, the Swissmedic PV system has the ability to generate and receive electronic reports that comply with the ICH standards as detailed in E2B (M). The following chapter describes the processing and management of safety reports and some important standard procedures.

## 5.1 PV System Overview




## 5.2 Import

It is important that MAHs comply with the below listed checks when submitting electronic ICSRs to ensure that reports are not automatically rejected (negative ACK-Log) by the system.

1. In a first step the drug safety system checks each incoming file if:

- the incoming file is a valid xml file (as defined by W3C)
- the safety message is in accordance with the ICH ICSR Document Type Definition (DTD), see chapter 10.2.
- the sender information is complete (the fields “sender information”, “sender organization” and “sender identifier”).

2. In a second step the drug safety system checks each safety report for:

- field lengths
- lexicon / dictionary values



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- a missing safety report id
- the worldwide unique number (rejects initial if it is missing or if both authoritynumb and company numb are filled in)
- a missing report type

The Swissmedic PV System accepts MedDRA terminology and other (not WHO) Drug Dictionaries.

### 5.3 Export

The Swissmedic PV system uses the WHO Drug Dictionary for coding drugs and active substances.

In order to be able to comply with the revised EMA business rules in preparing and processing ICSRs, a validation tool based on the EMA business rules is implemented in Vigilance One Ultimate (see chapter 10.2).
The exported files are checked against the EMA business rules (see chapter 10.2). Some fields however cannot be validated or are not of relevance.

The table below outlines these exceptions:

| E2B (R2) - field | name | comments |
|---|---|---|
| N/A | 'EudraVigilance Gateway date' | Not relevant |
| M.1.5<br>M.1.6<br>A.3.1.2<br>A.3.2.2a | messagereceiveridentifier<br>messagesenderidentifier<br>senderorganization<br>receiverorganization | The SM identifier may not correspond to the EMA identifier list. |
| A.1. | reporttype | Not relevant |
| A.2.1.2e<br>A.2.1.2 | reporterstate<br>reporterpostcode | Not relevant |
| A.2.3.1<br>A.2.3.2 | studyname<br>sponsorstudynumb | Not relevant |
| A.3.2. | receivertype | Not relevant |
| B.1.7.1a.1<br>B.1.8f.1<br>B.1.8g.1<br>B.1.9.2a<br>B.1.9.4a<br>B.1.10.7.1a.1<br>B.1.10.8f.1<br>B.1.10.8g.1<br>B.2.i.1.a<br>B.2.i.2.a<br>B.4.k.11a<br>B.4.k.17.2a<br>B.5.3a | patientepisodenamemeddraversion<br>patientindicationmeddraversion<br>patientdrgreactionmeddraversion<br>patientdeathreportmeddraversion<br>patientdetermautopsmeddraversion<br>parentmdepisodemeddraversion<br>parentdrgindicationmeddraversion<br>parentdrgreactionmeddraversion<br>reactionmeddraversionllt<br>reactionmeddraversionpt<br>drugindicationmeddraversion<br>drugrecuractionmeddraversion<br>senderdiagnosismeddraversion | |



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| E2B (R2) - field | name | comments |
|---|---|---|
| B.4.k.18.1a | drugreactionassesmeddraversion | |
| B.1.7.1a.2<br>B.1.8f.2<br>B.1.8g.2<br>B.1.9.2.b<br>B.1.9.4b<br>B.1.10.7.1a.2<br>B.1.10.8f.2<br>B.1.10.8g.2<br>B.2.i.1.b<br>B.2.i.2.b<br>B.3.1c<br>B.4.k.11b<br>B.4.k.17.2b<br>B.5.3b<br>B.4.k.18.1b | patientepisodename<br>patientdrugindication<br>patientdrugreaction<br>patientdeathreport<br>patientdetermineautopsy<br>parentmedicalepisodename<br>parentdrugindication<br>parentdrugreaction<br>reactionmeddrallt<br>reactionmeddrapt<br>testname<br>drugindication<br>drugrecuraction<br>senderdiagnosis<br>drugreactionasse | |
| B.1.8a<br>B.1.10.8 | patientdrugname<br>parentdrugname | The SM safety system uses the WHO drug dictionary which does not correspond to the EMA medicinal products list. Furthermore free text is allowed. |
| B.4.k.2.1 | medicinalproduct | The SM safety system uses the WHO drug dictionary which does not correspond to the EMA medicinal products list. Furthermore free text is allowed and this field is not mandatory (as well as B.4.k.2.2) in the SM safety system. |
| B.4.k.2.2 | activesubstancename | The SM uses the WHO drug dictionary which does not correspond to the EMA medicinal products list. Furthermore free text is allowed and this field is not mandatory (as well as B.4.k.2.1) in the SM safety system which will most likely not affect the companies since Swissmedic will check that field. |
| B.4.k.7 | drugdosageform | Not relevant |
| B.4.k.18.2 | drugassessmentsource | Not relevant |
| B.4.k.18.3 | drugassessmentmethod | The SM safety system places “WHO causality” into these fields (provided as free text). |



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| E2B (R2) - field | name | comments |
|---|---|---|
| B.4.k.18.4 | drugresult | The WHO causality is provided as free text. |

# 6 Starting electronic submission

Before the electronic transmission of ICSRs can be initiated, the MAHs should follow the steps as indicated below.

## 6.1 Send letter of intent

A Letter of Intent for the Electronic Transmission of ICSRs must be sent to the PV Specialist (Process Specialist) at Swissmedic (see conditions on www.swissmedic.ch ).

The Process Specialist will then contact the MAH to plan a time period for a Gateway setup.

## 6.2 Test Phase

During the test phase the currently established regulatory reporting mechanism remain unaffected.

It is recommended that the MAH keeps a copy of configuration settings including certificates (public key) used during the test phase to enable the MAH to reconstruct the identical test environment for subsequent testing at a later stage.

### 6.2.1 PV system compatibility test

For the tests the MAH and Swissmedic need to exchange and load the following XML test files into the drug safety system to check whether the E2B structure and the validation rules will work (exchanged by email as no gateway connection is established at that stage):

- an initial report (including medical and drug history)
- a follow-up report
- a parent child report
- a non-interventional (observational) study report
- a case reported in the literature
- a nullified / duplicate report (A.1.11; A.1.13) completed, see chapter 10.2

### 6.2.2 PV Gateway connection process

After configuration of the Gateways (Swissmedic and MAH), it is necessary to test whether the Gateways can communicate (technical layer AS2). It is tested if the party's Gateway is interoperable with the Swissmedic Gateway. Senders may have to adopt hardware, software and data communication configurations to meet the recommended communication standards.

The first of three steps to connect to the PV Gateway is the (1) system integration and test (test environment), (2) is the system configuration and end to end test between the drug safety systems (test environment) and finally (3) the system configuration and pilot (productive environment).

### 6.2.3 Exchange certificates

Swissmedic is not mandating any particular software for the electronic communication of ICSRs. If party's software is fully interoperable with the Swissmedic Gateway, then the sender will receive certification from Swissmedic to use it. Swissmedic also needs the public certificate of each participating MAH.

## 6.3 Operational phase

Following successful completion of the operational test phase, the operational phase is initiated when electronic transmission of ICSRs replaces the currently established regulatory transmission between the parties.



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## 6.4 Contingency plan

### 6.4.1 Malfunction Electronic Pharmacovigilance System Swissmedic

When Swissmedic detects malfunction of the electronic Pharmacovigilance System (database and/or gateway), Swissmedic investigates the root cause for system failure and carries out a preliminary estimation of expected system downtime within a maximum of 24 hours after detection of system malfunction. Two scenarios are used:

Scenario B

If system downtime is estimated to be equal to or less than 5 calendar days, the Swissmedic informs concerned MAH by e-mail that the electronic Pharmacovigilance System is expected to be out of service for a maximum of 5 calendar days and that electronic case submission is delayed. Concerned MAH will be informed by a separate e-mail to the same e-mail once the system is up and running again. The situation is continuously monitored and if after 4 business days it is deemed unlikely, that the system is up and running again after 5 days the failure is changed to scenario A. Swissmedic uses medical judgement to identify cases deemed critically important for processing under scenario A.

Scenario A

If system downtime is estimated to be more than 5 days, cases fulfilling the Swissmedic criteria for expedited reporting are sent by e-mail with the data attached as a CIOMS I form as PDF from the database or in another suitable format if the database is down too. Swissmedic will assign a provisional case ID and will keep track of this number and will provide the database generated Swissmedic case identifier once the primary Pharmacovigilance System is up and running again.

Swissmedic will not manually enter cases received by e-mail under scenario A in the Swissmedic database system, but will review the cases to identify signals of critical importance irrespective of electronic pharmacovigilance System availability. Once the system is up and running again it is the responsibility of the MAH to transmit all cases fulfilling reporting criteria by electronic E2B transfer regardless of previous transmission by e-mail.

### 6.4.2 Malfunction Electronic Pharmacovigilance System MAH

When a MAH detects malfunction of the electronic Pharmacovigilance System (database and/or gateway), the MAH investigates the root cause for system failure and carries out a preliminary estimation of expected system downtime within a maximum of 24 hours after detection of system malfunction. Two scenarios are used:

Scenario B

If system downtime is estimated to be equal to or less than 5 calendar days, the MAH informs Swissmedic by e-mail to pvgateway@swissmedic.ch that the electronic Pharmacovigilance System is expected to be out of service for a maximum of 5 calendar days and that electronic case submission will include all cases not successfully sent before (ack-log received from Swissmedic). Swissmedic will be informed by a separate e-mail to the same e-mail once the system is up and running again. The situation is continuously monitored and if after 4 business days it is deemed unlikely, that the system is up and running again after 5 days the failure is upgraded to scenario A. The MAH uses medical judgement to identify cases deemed critically important for processing under scenario A.

Scenario A

If system downtime is estimated to be more than 5 days, cases fulfilling the Swissmedic criteria for expedited reporting are sent by e-mail to pvgateway@swissmedic.ch with the data attached as a CIOMS I form as PDF from the database or in another suitable format if the database is down too. The MAH will assign a provisional case ID and will keep track of this number and will provide the worldwide unique case identifier once the primary pharmacovigilance system is up and running again.



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Swissmedic will not manually enter cases received by e-mail under scenario A in the Swissmedic database system, but will review the cases to identify signals of critical importance irrespective of electronic pharmacovigilance System availability. Once the system is up and running again it is the responsibility of the MAH to transmit all cases fulfilling reporting criteria by electronic E2B transfer regardless of previous transmission by e-mail.



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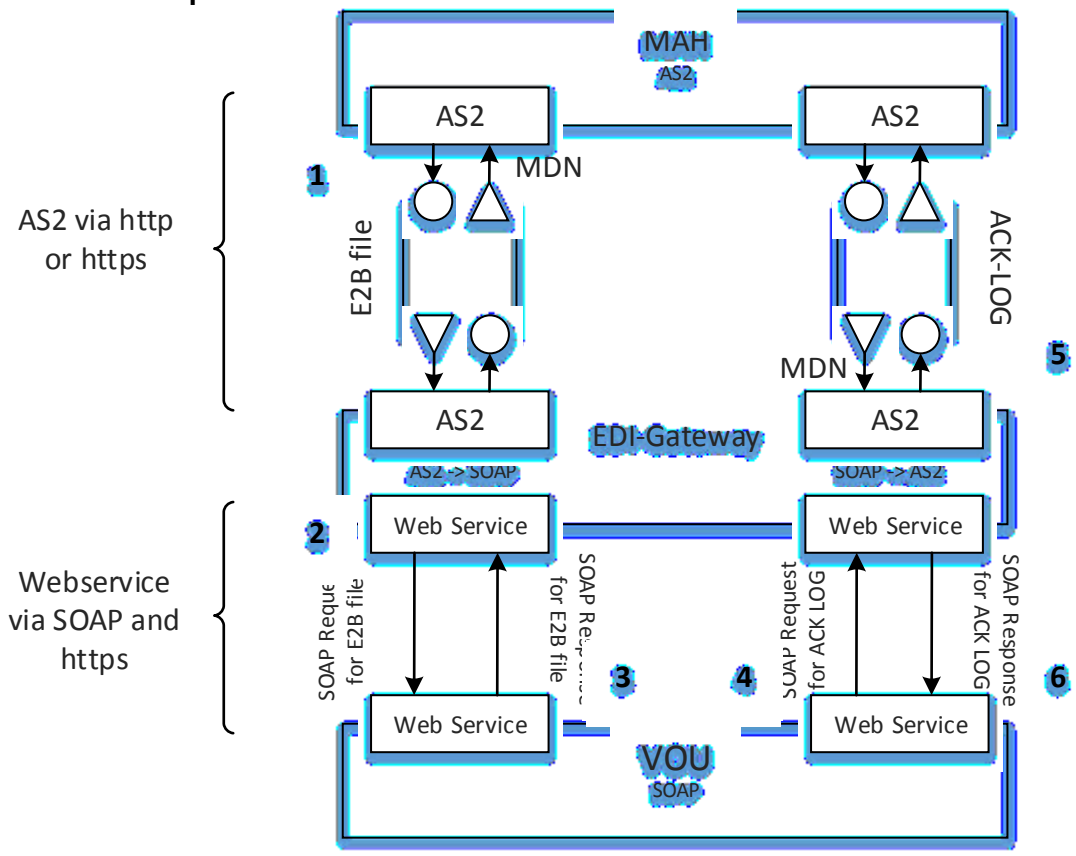
# 7 Description of the Swissmedic Gateway

The Swissmedic Gateway follows the ICH M2 Gateway Recommendation for the Electronic Transfer of Regulatory Information (see chapter 10.2).

## 7.1 Communication Overview and process

### 7.1.1 Mock-up MAH transmits E2B to Swissmedic




### 7.1.2 Process MAH transmits E2B to Swissmedic

**1:** MAH transmits an E2B-file to the EDI-Gateway via HTTP/S per AS2 HTTP interface (AS2 quits with MDN)

**2:** The EDI-Gateway forwards the E2B-file to VOU via WEB-service (SOAP request)

**3:** VOU answers via SOAP response to the EDI-Gateway.

**4:** VOU transmits an ACK-LOG to the EDI-Gateway via WEB-service (SOAP Request).

**5:** The EDI-Gateway forwards the ACK-LOG to the accordant MAH. Whether via HTTP/S per AS2 HTTP interface (AS2 quits with MDN)

**6:** The EDI-Gateway answers via SOAP response to VOU.

The EDI-Gateway stores the MDN temporarily on the file-system (90 days). After 90 days the MDN's will be stored for 10 years on a storage system.



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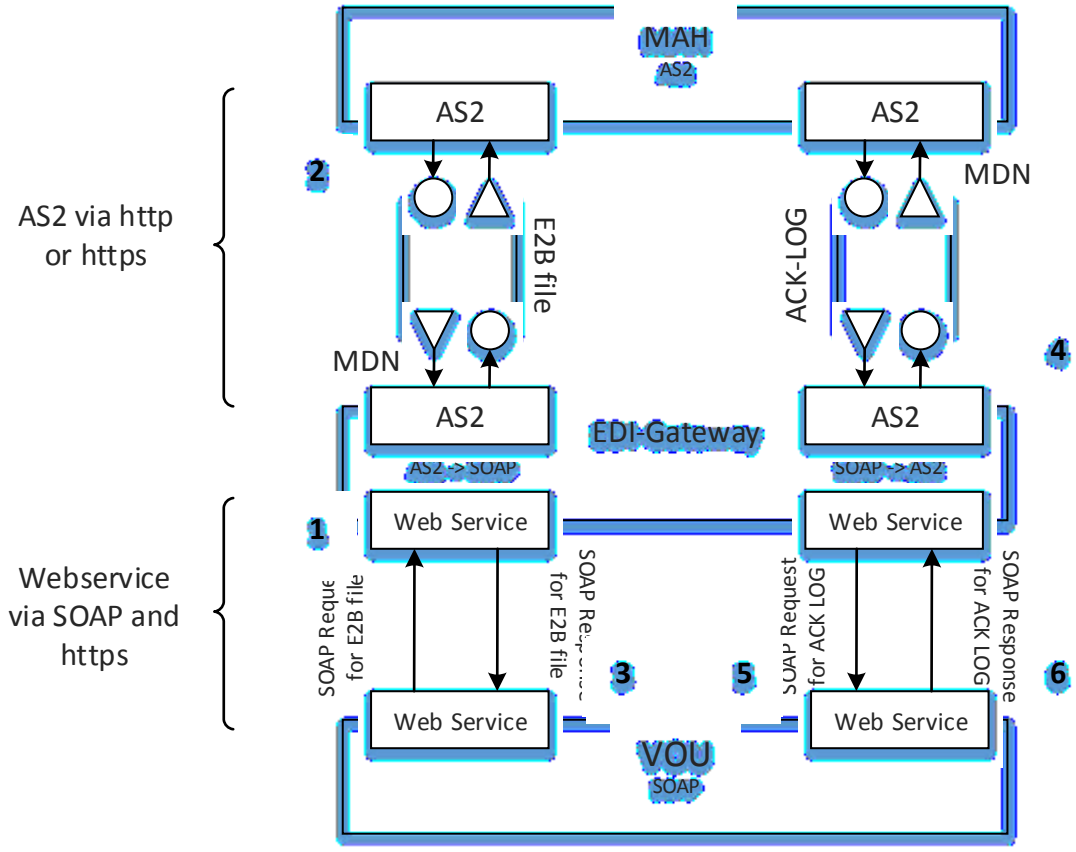
### 7.1.3 Mock-up Swissmedic transmits E2B to MAH




### 7.1.4 Process Swissmedic transmits E2B to MAH

1. VOU transmits an E2B-file to a MAH via WEB-Service (SOAP Request) to the EDI-Gateway.
2. The EDI-Gateway forwards the E2B-file to the accordant MAH via HTTP/S per AS2 HTTP interface (AS2 quits with MDN)
3. The EDI-Gateway answers via SOAP response to VOU.
4. The MAH, who received the E2B-file, transmits an ACK-LOG to the EDI-Gateway via HTTP/S per AS2 HTTP interface (AS2 quits with MDN)
5. The EDI-Gateway forwards the ACK-LOG via WEB-service (SOAP request) to VOU.
6. VOU answers via SOAP response to the EDI-Gateway.

The EDI-Gateway stores the MDN temporarily on the auf file-system. The MDN will be deleted within 90 days. After 90 days the MDN's will be stored for 10 years on a storage system.

## 7.2 Additional Information

### 7.2.1 Operational requirements to communicate with the Swissmedic Gateway

Each party must provide, all the equipment, software and services necessary to create, transmit, receive, translate, record and store safety, acknowledgement and MDN messages in compliance with the respective ICH standards and the requirements as defined in this Guidance.

### 7.2.2 Security Aspects

To facilitate the secure transmission of safety and acknowledgement messages over the Internet, each party has to purchase, install and operate applications that allow for the successful transmission and receipt of encrypted and digitally signed safety and acknowledgement messages via the Swissmedic Gateway.



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The applications chosen by each party must provide the essential functionality and interoperability as outlined in chapter 6.
Encrypting and digitally signing safety and acknowledgement messages by using certificates provides the parties assurance about each transaction.

### 7.2.3 Acknowledgments and error codes

The codes of the negative ACK-LOGs are not yet determined. Most of them will contain a free text field with a description of the problem.



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# 8 Information to connect the Swissmedic PV Gateway

## 8.1 General Information

The following section provides information on the organizational and technical framework of Swissmedic and lists the information MAHs must provide to Swissmedic in order to set up a Gateway connection between MAHs and Swissmedic. It also lists the contact persons at Swissmedic.

## 8.2 Swissmedic

| | |
|---|---|
| National Competent Authority address | Swissmedic<br>Hallerstrasse 7<br>CH-3012 Bern |
| PV-GW Specialist (Process Specialist) contact | Swissmedic<br>Name: Christine Lucas<br>Phone: +41 58 462 04 22<br>e-Mail: pvgateway@swissmedic.ch<br>Address: see above |
| Technical contact | Swissmedic<br>Name: Manuel Künzi<br>Phone: +41 58 464 57 94<br>e-Mail: WSG@bit.admin.ch |

### 8.2.1 MAH Certificate test and production

Please send us your certificate to the following e-Mail address: pvgateway@swissmedic.ch

**Attention: It is not allowed to provide self-signed certificates!**

Note: The provided Data will be used to setup a partner configuration on the PV Gateway, e.g. “Require Signature = Yes” means that the PV Gateway will sign the messages to MAH.
Time to Acknowledge: The time that the MAH has to acknowledge the reception of a message via a MDN.
After the „Time to Acknowledge“ passed, the message will be resent as often as needed, the delay corresponds to the „Time to Acknowledge".



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# 9 Basic conditions

## 9.1 Timeframes

The time conditions are acting in accordance to the used standards within Switzerland (CET).

## 9.2 Location

The services will be adduced within the premises of the accordant participant.

- PharmApp Solutions GmbH, Erkrath, Germany
- FOITT, Bern, Switzerland
- Swissmedic, Bern, Switzerland
- MAH, MAH city, MAH country

# 10 Utilities & Equipment

## 10.1 Equipment

- Phone
- Functional Mail account PV Gateway Swissmedic pvgateway@swissmedic.ch
- e-Mail-Client
- HP ALM 12.0 (for testing and requirement-specification)
- Internet portal and actual information. The URL will be communicated to all parties during MAH-coordination meeting (Hint: personal access need to be granted by Swissmedic)

## 10.2 Relevant documents

- Electronic Transmission of Individual Case Safety Reports Message Specification, http://estri.ich.org/icsr/ICH_ICSR_Specification_V2-3.pdf, (accessed 03.05.2012)
- DTD 2.1; http://estri.ich.org/icsr/ich-icsr-v2_1_dtd.zip
- Note for guidance – EudraVigilance Human – Processing of safety messages and individual case safety reports (ICSRs), containing the EMA business rules:
  (accessed 17.04.2013)



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# 11 Glossary

| | |
|---|---|
| ACK-Log | Acknowledgment Log. Automatically by receiver generated receipt in after uploading an E2B into the Drug Safety System or Vigilance One Ultimate |
| ADR | Adverse Drug Reaction |
| AS2 | Applicability Statement 2 (AS2) |
| E2B | Electronic to Business - ICH Standard for electronic transmission of adverse drug reactions in XML format |
| EMA | European Medicines Agency |
| FOITT | Federal Office of Information Technology, Systems and Telecommunication |
| HP QC | Hewlett Packard Quality Centre |
| ICH | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) |
| ICSR | Individual Case Safety Report |
| Local Company Number | Internal case number MAH |
| MAH | Marketing Authorization Holder |
| MDN | Message Disposition Notification. Standard receipt AS2 communication |
| NCA | National Competent Authority |
| PASS | Post Authorization Safety Study |
| PI | Product Information |
| RPVZ | Regional Pharmacovigilance Centre |
| SM | Swissmedic |
| TPA | Therapeutic Product Act |
| TPO | Therapeutic Product Ordinance |
| UMC | Uppsala Monitoring Centre |
| Vigilance One Ultimate (VOU) | By Swissmedic used Drug Safety System |
| WHO | World Health Organisation |
| WHO-Art | WHO Adverse Reaction Terminology |
| WHO-Drug | WHO-Drug Dictionary |
| XML | Extended mark-up language |



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