

Training Manual for MAH

EIViS (Electronic Vigilance System)



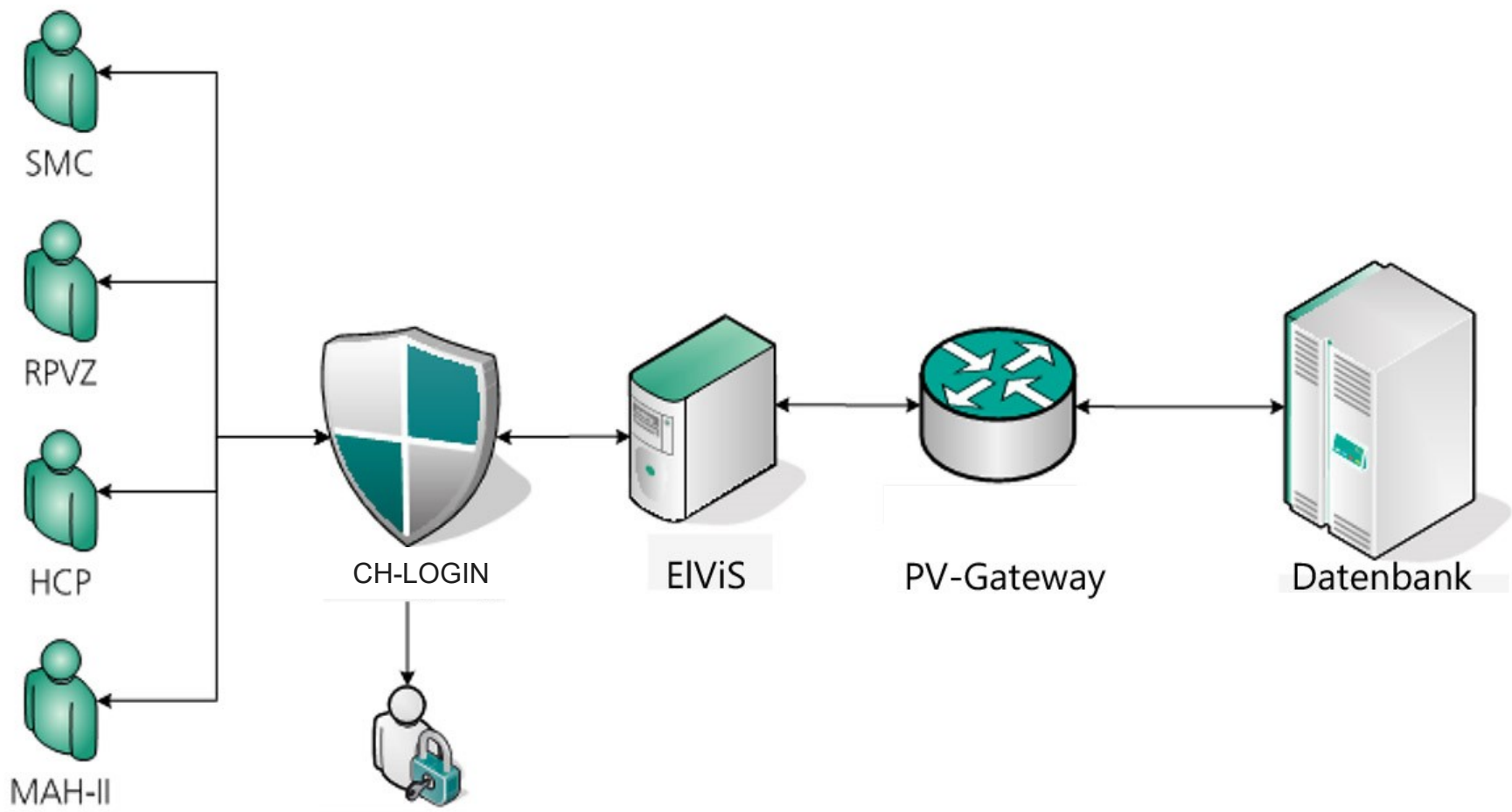


What is ELViS?

Development and implementation of an application for the **electronic exchange of ADR** incl. attachments between Healthcare Professionals (HCP) and Regional Pharmacovigilance Centres (RPVC) as well as between Swissmedic (SMC) and Marketing Authorization Holders (MAH) without PV-gateway in **Switzerland**.

The receipt of the Individual Case Safety Reports (ICSR) will be **acknowledged electronically**.

The project supports the **strategic objectives** of SMC and is an important part of the IT-roadmap concerning the electronic information exchange with stakeholders.





Objectives

- Improvement of **quality** of ICSR by structured and checked data recording (completeness, plausibility)
- Earlier and improved detection of **risk signals**
- **Enhanced PV**: proactive collecting of information
- **Safe** record and exchange of sensitive patient data incl. attachments (e.g. laboratory tests, hospital letters)
- **Assistance** by reduction of data recording, faster processing, reduction of paper burden and simplification of archiving



Characteristics

- **Explorer** (min. Version 9) or **Firefox** (min. Version 24)
- Registration of **2 administrators/MAH** (SMC Portal)
- **Direct data insert** or **upload** of E2B-files
- **Language:** English **Login:** mTAN required
- **MedDRA coding** required
- **Initial** and **FU-reports** incl. **attachments, queries** and **messages**
- No database, **local archiving** necessary (acknowledgment, ICSR as E2B-file and pdf)
- **Support:** Hotline Mo. - Fr. 7:30 – 17:30 h



MAH – Registration

1. Webform on <https://www.swissmedic.ch/swissmedic/de/home/services/egov-services/portal/egov-portal-registration.html>
2. ISCS (Informatik Service Center Swissmedic) creates contract for the Swissmedic-Portal
3. Company signs the contract and delegates a Partner-Administrator
4. ISCS creates the Partner-Administrator Account

Home > Services & lists > eGovernment Services > Swissmedic Portal > Registration Swissmedic Portal

Registration Swissmedic Portal

Registering the user administrator(s)

Each authorisation holder may designate at least one or maximum two user administrators, who are authorised by Swissmedic to communicate via the portal and to register, authorise and manage other persons in the company as users.

Only one application is needed per authorisation holder.

On reception of your application, we send a usage contract by post to the Responsible Person (RP) of your company.

As soon as we receive the signed contract, the authorisation holder – as a contractual partner – is authorised to use the Portal.

Your request New registration Extension Administrator Mutation

Product (eGov Service):

EIVS (Vigilance Reporting)

Please select...

eSubmissions platform (Swissmedic Portal)

Informatik
Service
Center
Swissmedic

SWISSmedic Anmeldeformular für einen Nutzungsvertrag Swissmedic eGov Portal
1000336

Der Anmelder Unternehmen Pharmaziegene-Zentrum Kantone/Defekte Andere

Name: Quadrat AG
 Betriebs-Ort: SOHN
 Adresse: Wäldlistrasse 10
 Adressort: MILDTEN
 PLZ/CH: 8001 Zürich

erklärt hiermit, das Swissmedic-Portal nutzen zu wollen und die folgenden:
 "Nutzungsbedingungen Swissmedic-Portal" Version 1.3 vom September 2010 zu akzeptieren.
 Der Anmelder (bzw. der Inhaber/Präsident) des Nutzer Administrator(s) genehmigt diesen
 Nutzungsbedingungen.

Nutzer Administrator 1
 Name: Frau
 Nachname: COUSASSET
 Vorname: CATHY
 Abteilung: REGISTRIERUNG / QUALITÄT
 E-mail: cothbert@quadrat.ch
 Handy-Nr. / Smartphone: 079 223 37 25 GSM FR CH

Nutzer Administrator 2
 Name: Dic
 Nachname: EDWILLICH
 Vorname: SCHAFNIGER
 Abteilung: MEDICAL QUALITÄT
 E-mail: edwillech@quadrat.ch
 Handy-Nr. / Smartphone: 079 223 37 25 GSM FR CH

SWISSmedic Anmeldeformular für einen Nutzungsvertrag Swissmedic eGov Portal

Korrespondenz-E-Mail-Adresse für automatische Benachrichtigungszustellungen:
 Tragen Sie in diesem Feld bitte eine E-Mail-Adresse für automatische Benachrichtigungszustellungen
 des eGov Portals ein. So wird zum Beispiel auf diese E-Mail-Adresse eine Mitteilung gesendet,
 nachdem ein Arzneimittel ein FFP-Dokument eingereicht wurde.

Korrespondenz-E-Mail: cothbert@quadrat.ch

Rechtserhebliche Unterschrift

Ort/Orten: Zürich, 16. Juni 2014

Name, Funktion: Amer, General Manager

Unterschrift(en): [Signature]

Eile zuschicken an:
 Swissmedic, 1025
 Hofackerstrasse 7
 3000 Bern D
 * Informations-Kosten



MAH – Registration

To use the ELVIS application, you will need

- A CH-LOGIN user account to verify your identity/authorisation
- You will receive an email with your onboarding code to associate your CH-LOGIN user account with the applications released in the eIAM portal (such as ELVIS)
- Short instruction for your registration and onboarding [here](#)
- Read [here](#) more about how an administrator can set up a new ELVIS user in eIAM Portal



Login in ELVIS

Login

User account e-mail address

Password

[Forgot password?](#)

Cancel

Continue

New registration

You do not have a user account of the Federal Administration yet? Then register an account here. This can be used to log in to a wide range of applications.

New registration



Overview

Welcome Thomas Schwartz

Create new report

Create new standard report

Create new parent/child report



Continue saved report

Continue locally saved report

Create follow-up report

Create follow-up report

Reports

The following Reports are new:

Report number	Report date	Valid until	Type	Sender	
SMCELVIS-2014-06-24-00534	24.06.2014	05.08.2014	Initial Report	Bi Swissmedic	No attachments available
SMCELVIS-2014-06-24-00554 <small>SGU_2014_06_24_002</small>	24.06.2014	05.08.2014	Initial Report	B Swissmedic	No attachments available
SMCELVIS-2014-06-25-00612	25.06.2014	06.08.2014	Initial Report	Bi Swissmedic	No attachments available
SMCELVIS-2014-06-25-00613	25.06.2014	06.08.2014	Initial Report	B Swissmedic	No attachments available

Sent reports

Report number	Report date	Valid until	Type	Status	
SMCELVIS-2014-06-24-00518 <small>JP-SIGMATAU-ST2014.0571</small>	24.06.2014	05.08.2014	Initial Report	acknowledged with errors	

EIViS Hotline

For any questions regarding EIViS, please contact our EIViS Hotline:

by E-Mail

it@swissmedic.ch

by phone

+41 58 462 06 00

Business hours

The EIViS Hotline is available Mon-Fri, 08:00 - 18:00 hours.



Create new report

Enter report data

Check report

Send report

Report information

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Type of report ? *

Spontaneous

Country of occurrence ? *

Switzerland

Country of primary source ? *

Switzerland

Serious ? *

Yes No

Reason for seriousness ? *

Death

Hospitalization/prolonged

Congenital-anomaly

Life-threatening

Disabling

Other medically important condition

Sender Information

Type of sender

Pharmaceutical Company

Organization
Bergwacht DE

Contact person
Thomas Schwartz

Phone number

Date first received at sender ? *

15.06.2014

Address
Bernstrasse 91
Flachdorf

E-mail
pvgateway@swissmedic.ch

Worldwide unique number

Authority report number ? *

Company report number *

TS-2014-06-100

Information on primary source

Reporter qualification ? *

Physician

Literature reference (2,000 Characters left)



Red star: mandatory field

Grey star: one of the fields is mandatory

Continue >



Create new report

Enter report data

Check report

Send report

Report information

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Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Patient characteristics

Patient initials ? *

e.g. JM for John Miller

Sex ? *

Male Female [Clear](#)

Date of birth ? *

DD.MM.YYYY

Age at time of onset ? *

Age group ? *

Body weight (in kg)

e.g. 78

Body height (in cm)

e.g. 178

Death related information

Death date

DD.MM.YYYY

Death cause ?

e.g. Cardiac failure

Autopsy performed

Yes No Unknown [Clear](#)

Continue >

Age at onset, age group: will automatically be calculated from 'onset date of reaction' and 'date of birth' if both those dates are completely entered; may be entered also.

Death cause: MedDRA terminology



Create new report

Enter report data

Check report

Send report

Report information

Patient

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Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Patient characteristics

Patient initials ? *

JM

Sex ? *

Male Female [Clear](#)

Date of birth ? *

15.02.1925

Age at time of onset ? *

89

Year

Age group ? *

Elderly (> 69 years)

Body weight (in kg)

75

Body height (in cm)

171

Death related information

Death date

DD.MM.YYYY

Death cause ?

e.g. Cardiac failure

Autopsy performed

Yes No Unknown [Clear](#)

Continue >



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reaction(s)

Assessment

Add attachments

Results of tests and procedures

Results of tests and procedures (free text) ? (1.923 Characters left)

Blood pressure: 85/70 mmHg (01.06.2014)
Heart rate: 42 beats/min (01.06.2014)

Test

+ Add new test

Continue >



Add test ✕

Test type ? *
Blood pressure

Low range ? High range ? Test unit

Date Results ? *

+ Add new result

Cancel Add



Test type: MedDRA terminology



Create new report

Enter report data

Check report

Send report

Report information

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Tests & Procedures

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Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Results of tests and procedures

Results of tests and procedures (free text) ? (1,923 Characters left)

Blood pressure: 85/70 mmHg (01.06.2014)
Heart rate: 42 beats/min (01.06.2014)

Test

Heart rate



Blood pressure



+ Add new test

Continue >





Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Relevant medical history

Relevant medical history (free text) ? (9.963 Characters left)

Atrial fibrillation diagnosed in 2013

Diagnosis

+ Add relevant medical history

Continue >



Add relevant medical history ✕

Diagnosis ? *

Atrial fibrillation

Continuing

Yes
 No
 Unknown

Start date

2013

Cancel **Add**



Diagnosis: MedDRA terminology



Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Relevant medical history

Relevant medical history (free text) ? (9,963 Characters left)

Atrial fibrillation diagnosed in 2013

Diagnosis

Atrial fibrillation



+ Add relevant medical history

Continue >





Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

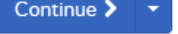
Add attachments

Relevant past drug therapy

Drug Name

+ Add past drug therapy

Continue >





Add past drug therapy ✕

Drug name ? *
Metoprolol

Start date
07.2013

End date
10.2013

Indication ? (231 Characters left)
Atrial fibrillation

Reaction ? (239 Characters left)
Bradycardia

Cancel Add



Drug name: brand (preferred) or active substance
Indication, Reaction: MedDRA terminology



Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

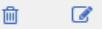
Assessment

Add attachments

Relevant past drug therapy

Drug Name

Metoprolol



+ Add past drug therapy

Continue >





Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Reactions

List of reactions *

Please enter at least one reaction. To do so, click on "Add new reaction".



+ Add new reaction

Continue >



Add new reaction ✕

Reaction term ? *

Reaction as reported by primary source ? (179 Characters left)

Onset date

End date

Duration ?

Outcome of reaction ? *

Time interval between suspect drug administration and reaction onset

First dose ?

Last dose ?

Reaction term: MedDRA terminology

Duration: calculated automatically if onset date and end date are different and completely entered; may also be entered.





Add new reaction ✕

Reaction term ? *

Syncope

Reaction as reported by primary source ? (200 Characters left)

Onset date

01.06.2014

End date

01.06.2014

Duration ?

5

Minute(s)

Outcome of reaction ? *

Recovered

Time interval between suspect drug administration and reaction onset

First dose ?

7

Day(s)

Last dose ?

Cancel

Add





Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Reactions

List of reactions *

Hypotension		
Bradycardia		
Syncope		

+ Add new reaction

Continue >





Create new report

Enter report data

Check report

Send report

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Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Drugs

Suspected drugs *

Concomitant drugs

Drug name

Drug name

Please enter at least one suspected drug.

+ Add new drug

+ Add new drug



Suspected drugs: Please assess labelledness in sender comments.

Continue >



Add suspected drug ✕

Drug name ? *
Isoptin 80 mg

Characterization ? *
 Suspect Interacting [Change to concomitant](#)

Batch number
Unknown

Route of administration
oral

Pharmaceutical form
coated tablet

Action taken
Drug withdrawn

Did the reaction recur after rechallenge? ?
 Yes No Unknown [Clear](#)

Start of administration
26.05.2014

End of administration
01.06.2014

Dose information

Dosage regimen ?
 Structured Free text

Dose
80 mg

Doses in interval
3

Definition of interval
1 Day(s)

Cumulative dose to first reaction ?
1680 mg

Active substance ? *
Verapamil

Indication (231 Characters left)
Atrial fibrillation

Additional information (100 Characters left)

Duration ?
7 Day(s)

Time interval between administration and reaction onset

First dose ?
7 Day(s)

Last dose ?

Cancel Add

Indication: MedDRA terminology

Duration: calculated automatically if start date and end date are completely entered; may also be entered.





Add concomitant drug

Drug name ? *
Marcoumar

Characterization
[Change to suspected](#)

Batch number

Route of administration
oral

Action taken
Dose unchanged

Pharmaceutical form
tablet

Start of administration
01.08.2013

End of administration
DD.MM.YYYY

Active substance ? *
Phenprocoumon

Indication (228 Characters left)
Thrombosis prophylaxis

Additional information (100 Characters left)

Duration ?
Time interval between administration and reaction onset
First dose ?
Last dose ?

Dose information

Dosage regimen ? Structured Free text
(84 Characters left)
1 Tablet per day

Cumulative dose to first reaction ?

Cancel Add



Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Drugs

Suspected drugs *

Drug name

Isoptin 80 mg



+ Add new drug

Concomitant drugs

Drug name

Marcoumar



+ Add new drug

Suspected drugs: Please assess labelledness in sender comments.

Continue >





Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Relatedness of drug(s) to reaction(s)

Isoptin 80 mg

Hypotension

Possible

Bradycardia

Possible

Syncope

Possible

Continue >



Causality assessment by MAH is expected. Further details of the medical assessment should be given in sender comments.



Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Assessment

Case narrative ? (19.825 Characters left)

This initial spontaneous report was received from a physician on 15 June 2014. This report refers to a 89-year-old male patient who was hospitalised on 1 June 2014 due to.....

Reporters comments ? (381 Characters left)

The reporter assessed the causality between the administration of Isoptin 80 mg and the reported reactions as probable.



Senders comments ? (1.731 Characters left)

The reported reactions hypotension, bradycardia and syncope occurred in temporal relationship with the administration of Isoptin 80 mg and are labelled in the Suisse SmPC of Isoptin 80 mg. The MAH assesses the causality as possible. Follow-up information was requested.
Risk minimizing measures are not required.

Continue >





Create new report



- Report information
- Patient
- Tests & Procedures
- Relevant medical history
- Relevant past drug therapy
- Reactions
- Drugs
- Relatedness of drug(s) to reaction(s)
- Assessment
- Add attachments

Add attachments

+ Add file



✓ Check report



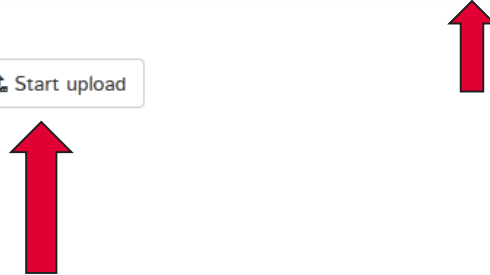
Create new report



- Report information
 - Patient
 - Tests & Procedures
 - Relevant medical history
 - Relevant past drug therapy
 - Reactions
 - Drugs
 - Relatedness of drug(s) to reaction(s)
 - Assessment
- Add attachments**

Add attachments

ECG.docx





Create new report

Enter report data

Check report

Send report

Report information

Patient

ECG.docx

Uploaded.



Tests & Procedures

Relevant medical history

+ Add file

Start upload

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

✓ Check report





Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug therapy

Reactions

Drugs

Relatedness of drug(s) to reaction(s)

Assessment

Add attachments

Add attachments

ECG.docx

Uploaded.



+ Add file

Start upload

Send report







Create new report



If you want to check your data before sending, please click on “Create PDF of report” and you will receive an overall view (in a new browser-window).

 Create PDF of report 

Report data

Patient initials	Sex	Date of birth	Age
JM	Male	15.02.1925	89
Receiver			
Swissmedic			

Attachments

#	Filename	
1	ECG.docx	

[← Back](#) [✖ Cancel](#) [Send report >](#)



Report information					
<i>Type of report</i>	<i>Date first received at sender</i>	<i>Date receipt most recent info</i>	<i>Version</i>		
Spontaneous	15.06.2014		1		
<i>Literature reference</i>					
<i>Reporter qualification</i>		<i>Country of occurrence</i>	<i>Country of primary source</i>		
Physician		Switzerland	Switzerland		
<i>Serious case?</i>		Yes			
<i>Death</i>	No	<i>Life-threatening</i>	No	<i>Hospitalization / prolonged</i>	Yes
<i>Disabling</i>	No	<i>Congenital anomaly</i>	No	<i>Other medical important condition</i>	No
Sender information					
<i>Type of sender</i>	<i>Organization</i>	<i>Authority report number</i>	<i>Company report number</i>		
Pharmaceutical Company	Bergwacht DE		TS-2014-06-100		
<i>Contact person</i>		<i>Phone number</i>	<i>E-mail</i>		
Schwartz			pvgateway@swissmedic.ch		
<i>Sender Address</i>	Pharmaceutical Company Flachdorf				

Patient characteristics							
<i>Initials</i>	<i>Sex</i>	<i>Date of birth</i>	<i>Age at onset</i>	<i>Age group</i>	<i>Weight (kg)</i>	<i>Height (cm)</i>	<i>Death date</i>
JM	Male	15.02.1925	89	Elderly (> 69 years)	75	171	

<i>Death cause</i>	<i>Death date</i>
<i>Autopsy performed</i>	<i>Death cause after autopsy</i>

Relevant medical history			
<i>Diagnosis</i>	<i>Start date</i>	<i>End date</i>	<i>Continuing</i>
Atrial fibrillation	2013		Yes
<i>Relevant medical history - free text</i>			
Atrial fibrillation diagnosed in 2013			

Relevant past drug therapy				
<i>Drug name</i>	<i>Start date</i>	<i>End date</i>	<i>Indication</i>	<i>Reaction</i>
Metoprolol	07.2013	10.2013	Atrial fibrillation	Bradycardia

Reaction(s)/Event(s) (MedDRA)

<i>Reaction term</i>	<i>Onset date</i>	<i>End date</i>	<i>Duration</i>	<i>Outcome</i>
Hypotension	01.06.2014			Not recovered
Bradycardia	01.06.2014			Not recovered
Syncope	01.06.2014	01.06.2014	1 Day(s)	Recovered

Causality of Drug to Reaction (CIOMS V)
<i>Isoptin 80 mg</i>
Hypotension - Possible; Bradycardia - Possible; Syncope - Possible

Suspected drugs	
<i>Isoptin 80 mg</i>	Verapamil

<i>Characterization</i>	<i>GF Batchno</i>	<i>Indication</i>	<i>Route</i>	<i>Additional information</i>	<i>Pharmaceutical form</i>	<i>Action taken</i>
Suspected	Unknown	Atrial fibrillation	oral		coated tablet	Drug withdrawn

<i>Start of administration</i>	<i>End of administration</i>	<i>Duration</i>	<i>First dose</i>	<i>Last dose</i>	<i>Recur after rechallenge</i>
26.05.2014	01.06.2014	7 Day(s)	7 Day(s)		

<i>Dose</i>	<i>Doses in interval</i>	<i>Definition of interval</i>
80 mg	3	1 Day(s)

<i>Cumulative dose to first reaction</i>	1680 mg
--	---------

Concomitant drugs						
<i>Marcoumar</i>		Phenprocoumon				
<i>Characterization</i>	<i>GF Batchno</i>	<i>Indication</i>	<i>Route</i>	<i>Additional information</i>	<i>Pharmaceutical form</i>	<i>Action taken</i>
Concomitant		Thrombosis prophylaxis	oral		tablet	Dose unchanged

<i>Start of administration</i>	<i>End of administration</i>	<i>Duration</i>	<i>First dose</i>	<i>Last dose</i>	<i>Recur after rechallenge</i>
01.08.2013					

<i>Dose free text</i>	1 Tablet per day
-----------------------	------------------

<i>Cumulative dose to first reaction</i>	
--	--

Tests and procedures	
<i>Results of tests and procedures</i>	Blood pressure: 85/70 mmHg (01.06.2014) Heart rate: 42 beats/min (01.06.2014)

<i>Test type</i>	<i>Low range</i>	<i>High range</i>	<i>Test unit</i>	<i>Date</i>	<i>Result</i>
Blood pressure			mmHg	01.06.2014	85/70



Print date: 27.06.2014

External printout - page 3 of 3

Heart rate	60	100	beats/min	01.06.2014	42
------------	----	-----	-----------	------------	----

Description and Assessment

Reporters comment:

The reporter assessed the causality between the administration of Isoptin 80 mg and the reported reactions as probable.

Case narrative:

Case number is an initial spontaneous report received from physician on 15 Jun 2014. This report refers to a 89 year old male patient who was hospitalised on 1 Jun 2014 due to....

Senders comment:

The reported reactions hypotension, bradycardia and syncope occurred in temporal relationship with the administration of Isoptin 80 mg and are labelled in the Suisse SmPC of Isoptin 80 mg. The MAH assesses the causality as possible. Follow-up information was requested.

Attachments

<i>Name</i>	ECG.docx
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Overview


Welcome Thomas Schwartz

Report sent

The report was sent successfully.
Once the report has been processed by the system, you will receive a confirmation.

Create new report

 Create new standard report

 Create new parent/child report

Continue saved report

 Continue locally saved report

Create follow-up report

 Create follow-up report

EIViS Hotline

For any questions regarding EIViS, please contact our EIViS Hotline:

by E-Mail

it@swissmedic.ch














by phone

+41 58 462 06 00

Business hours

The EIViS Hotline is available Mon-Fri, 08:00 - 18:00 hours.



 Antworten	 Allen antworten	 Weiterleiten	 Löschen	 In Ordner verschieben	 Regel erstellen	 Andere Aktionen	 Absender sperrern	 Keine Junk-E-Mail	 Kategorisieren	 Nachverfolgung	 Als ungelesen markieren	 Suchen	
Antworten			Aktionen				Junk-E-Mail		Optionen			Suchen	

Von: Swissmedic {No-reply} [noreply-ref@swissmedic.ch]
An: Schwartz Thomas Swissmedic
Cc:
Betreff: ELVIS: ICSR Acknowledgment Message N° SMCELVIS-2014-06-26-00698

Dear Sir or Madam

This e-Mail confirms, that your report SMCELVIS-2014-06-26-00698 has been successfully imported by Swissmedic.

Swissmedic will now work on your report.

Please download the complete report including all necessary documents for archiving reasons.

Link: https://www.gate-r.swissmedic.ch/elvis/secure/details.xhtml?safetyreportid=IPFTG3ryED4OhZISO-Zg6OCck_vm2nUGIevb1RkAG3w&version=zWyBTIL5OsLdmUUSa1DkXg

Warning: The documents are only available until the date of expiration: 08.08.2014. After this date the files will be automatically deleted from the system.

Best regards,
Your Swissmedic Team



Overview

Welcome Thomas Schwartz

Create new report

Create new standard report

Create new parent/child report

Continue saved report

Continue locally saved report

Create follow-up report

Create follow-up report

Sent reports

Report number	Report date	Valid until	Type	Status	
SMCELVIS-2014-06-26-00698 <i>TS-2014-06-100</i>	27.06.2014	08.08.2014	Initial Report	acknowledged	



EIViS Hotline

For any questions regarding EIViS, please contact our EIViS Hotline:

by E-Mail

it@swissmedic.ch

by phone

+41 58 462 06 00

Business hours

The EIViS Hotline is available Mon-Fri, 08:00 - 18:00 hours.



Report data

Report number

SMCELVIS-2014-06-26-00698

Report date

27.06.2014

Receiver

Swissmedic

Status

acknowledged

Company report number

TS-2014-06-100

Sender

Bergwacht DE

Actions

→ Create follow-up report



Creation of follow up reports, when initial reports are still sores in ELVIS

Documents

#	Name	Available until	
1	Report as E2B XML file	08.08.2014	
2	Report as PDF file	08.08.2014	
3	Confirmation XML	08.08.2014	
4	Confirmation PDF	08.08.2014	

Do not forget!



Download all documents as ZIP

Attachments

#	Name	Available until	
1	ECG.docx	08.08.2014	

← Back

Download all attachments as ZIP



Create new report

Enter report data

Check report

Send report

Report information

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Add attachments

Type of report ? *

Spontaneous

Country of occurrence ? *

CH - Switzerland

Country of primary source ? *

CH - Switzerland

Serious ? *

Yes No

Reason for seriousness ? *

Death

Hospitalization/prolonged

Congenital-anomaly

Life-threatening

Disabling

Other medically important condition

Sender Information

Type of sender

Pharmaceutical Company

Organization
Bergwacht DE

Contact person
Thomas Schwartz

Phone number

Date first received at sender ? *

15.06.2014

Address
Bernstrasse 91
Flachdorf

E-mail
pvgateway@swissmedic.ch

Worldwide unique number

Authority report number ? *

Company report number *

TS-2014-06-100

Information on primary source

Reporter qualification ? *

Physician

Literature reference (2,000 Characters left)

Continue >





Overview

Welcome Thomas Schwartz

Create new report

Create new standard report

Create new parent/child report

Continue saved report

Continue locally saved report

Continue a report saved in EIViS

Report number	Saved on	Available until	Type	
SMCELVIS-2014-06-26-00698 <i>TS-2014-06-100</i>	27.06.2014	08.08.2014	Follow-up Report	



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by phone

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Create new report

Enter report data

Check report

Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug
therapy

Reactions

Drugs

Relatedness of drug(s) to
reaction(s)

Assessment

Assessment

Case narrative ? (19.714 Characters left)

Case number is an initial spontaneous report received from physician on 15 Jun 2014. This report refers to a 89 year old male patient who was hospitalised on 1 Jun 2014 due to...

Follow-up Information received on 26 Jun 2014:
The patient has recovered from hypotension and bradycardia.














Senders comments ? (1.641 Characters left)

The reported reactions hypotension, bradycardia and syncope occurred in temporal relationship with the administration of Isoptin 80 mg and are labelled in the Suisse SmPC of Isoptin 80 mg. The MAH assesses the causality as possible. Follow-up information was requested.

Follow-up information received on 26 Jun 2014:
The medical assessment remains unchanged.

Continue >



 Antworten	 Allen antworten	 Weiterleiten	 Löschen	 In Ordner verschieben	 Regel erstellen	 Andere Aktionen	 Absender sperren	 Keine Junk-E-Mail	 Kategorisieren	 Nachverfolgung	 Als ungelesen markieren	 Suchen
Antworten			Aktionen				Junk-E-Mail		Optionen			Suchen

Von: Swissmedic {No-reply} [noreply-ref@swissmedic.ch]
An: Schwartz Thomas Swissmedic
Cc:
Betreff: ELVIS: ICSR Acknowledgment Message N° SMCELVIS-2014-06-26-00698

Dear Sir or Madam

This e-Mail confirms, that your report SMCELVIS-2014-06-26-00698 has been successfully imported by Swissmedic.

Swissmedic will now work on your report.

Please download the complete report including all necessary documents for archiving reasons.

Link: https://www.gate-r.swissmedic.ch/elvis/secure/details.xhtml?safetyreportid=IPFTG3ryED4OhZISO-Zg6OCck_vm2nUGIevb1RkAG3w&version=-8lgHqkpEDcMqsGPp2orww

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Best regards,
Your Swissmedic Team



Overview

Welcome Thomas Schwartz

Create new report

Create new standard report

Create new parent/child report

Continue saved report

Continue locally saved report

Create follow-up report

Create follow-up report

← Creation of follow up reports, when initial reports are no longer sores in ELVIS

Sent reports

Report number	Report date	Valid until	Type	Status	
Q SMCELVIS-2014-06-26-00698 <i>TS-2014-06-100</i>	27.06.2014	08.08.2014	Initial Report	acknowledged	
Q SMCELVIS-2014-06-26-00698 <i>TS-2014-06-100</i>	27.06.2014	08.08.2014	Follow-up Report	acknowledged	

EIViS Hotline

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by E-Mail

it@swissmedic.ch

by phone

+41 58 462 06 00

Business hours

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Create follow-up report

Upload report file

Modify Follow-up

Check Follow-up

Send Follow-up

E2B File

Durchsuchen...

Keine Datei ausgewählt.

✕ Cancel


Modify Follow-up >



Overview

Welcome Thomas Schwartz

Create new report


 Create new standard report

 Create new parent/child report

Continue saved report

 Continue locally saved report





Continue a report saved in EIViS

Report number	Saved on	Available until	Type
Q SMCELVIS-2014-07-03-00180	03.07.2014	04.07.2014	Initial Report   

Create follow-up report

 Create follow-up report

Incoming reports and queries

Report number	Report date	Available until
Q SMCELVIS-2014-07-02-00167 <i>US-UCBSA-021769</i>	03.07.2014	04.07.2014 
Q SMCELVIS-2014-07-01-00153 <i>SGU 2014 07 03 003</i>	03.07.2014	04.07.2014 
Q SMCELVIS-2014-06-30-00007  <i>SGU 2014 30 06 001</i>	03.07.2014	04.07.2014 

EIViS Hotline

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by E-Mail

it@swissmedic.ch

by phone

+41 58 462 06 00

Business hours

The EIViS Hotline is available Mon-Fri, 08:00 - 18:00 hours.

You will be notified by e-mail about new reports, queries and messages!



Report data

The asked query refers to following report:

Report number

SMCELVIS-2014-06-30-00007

Report date

03.07.2014

Sender

Swissmedic

Available until

04.07.2014

Patient

-

Age

34

Drug

Tavegil

Reaction


Vomiting blood

Actions

[→ Edit](#) 

Attachments

#	Filename	Available until	
1	Query.docx	04.07.2014	

 Download all attachments as ZIP



Report data

The asked query refers to following report:

Report number

SMCELVIS-2014-06-30-00007

Report date

03.07.2014

Sender

Swissmedic

Available until

04.07.2014

Patient

-

Age

34


Drug

Tavegil

Reaction

Vomiting blood

Attachments

#	Filename	Available until	
1	Query.docx	04.07.2014	



 Download all attachments as ZIP

Respond to query

 Add Attachment

 Cancel 



Report-ID: ¶
SMCELVIS-2014-06-30-00007 ¶

¶

¶

<u>Questions</u> ¶	<u>Answers</u> ¶
Do you know the sex of the patient? ¶	¶
What is the outcome of the reaction vomiting blood? ¶	¶

¶



Report ID ¶
SMCELVIS-2014-06-30-00007 ¶

¶

¶

<u>Questions</u> ¶	<u>Answers</u> ¶
Do you know the sex of the patient? ¶	The patient is a female. ¶
What is the outcome of the reaction vomiting blood? ¶	Outcome is recovered. ¶

¶



Report data

The asked query refers to following report:

Report number

SMCELVIS-2014-06-30-00007

Report date

03.07.2014

Sender

Swissmedic

Available until

04.07.2014

Patient

-

Age

34

Drug

Tavegil

Reaction

Vomiting blood

Attachments

#	Filename	Available until	
1	Query.docx	04.07.2014	

Download all attachments as ZIP

Respond to query

Add Attachment



Cancel

Send answer



Report data

The asked query refers to following report:

Report number

SMCELVIS-2014-06-30-00007

Report date

03.07.2014

Sender

Swissmedic

Available until

04.07.2014

Patient

-

Age

34

Drug

Tavegil

Reaction

Vomiting blood

Attachments

#	Filename	Available until	
1	Query.docx	04.07.2014	

Download all attachments as ZIP

Respond to query

Query_answered.docx

Uploaded.



+ Add Attachment

Upload selected files



Cancel

Send answer >




Overview

Welcome Thomas Schwartz

Consultation answer sent


Your answer to the query has been sent.

Create new report

 Create new standard report

 Create new parent/child report

Continue saved report

 Continue locally saved report

Create follow-up report

 Create follow-up report

EIViS Hotline

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by E-Mail

it@swissmedic.ch

by phone

+41 58 462 06 00

Business hours

The EIViS Hotline is available Mon-Fri, 08:00 - 18:00 hours.



Overview

Welcome Thomas Schwartz

Create new report

Upload new report



Please contact the EIViS Hotline if you would like to upload E2B-files because tests are required before!

Create follow-up report

Upload follow-up report

Sent reports

Report number	Report date	Valid until	Type	Status	
SMCELVIS-2014-07-10-00090 <i>TS-xyz</i>	11.07.2014	12.07.2014	Initial Report	submitting	

EIViS Hotline

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by E-Mail

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by phone

+41 58 462 06 00

Business hours

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Upload new report

Upload report file

Add attachments

Send report

E2B File

Durchsuchen...

Keine Datei ausgewählt.



× Cancel


Enter report data >



Overview

Welcome Thomas Schwartz

Create new report


 Upload new report

Create follow-up report

 Upload follow-up report



Sent reports

Report number	Report date	Valid until	Type	Status	
SMCELVIS-2014-07-10-00090 <i>TS-xyz</i>	11.07.2014	12.07.2014	Initial Report	submitting	

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Upload follow-up report

Upload report file

Add attachments

Send report

E2B File

Durchsuchen...

Keine Datei ausgewählt.



✕ Cancel

Enter report data >



Von: Swissmedic {No-reply} [noreply-ref@swissmedic.ch]
An: _SMC-PV Gateway
Cc:
Betreff: ELVIS: New Message to ICSR Message N° SMCELVIS-2014-11-17-00501

Dear Sir or Madam



This e-Mail is notifying you, that you have received a new Message to the ICSR report SMCELVIS-2014-11-17-00501.

Please visit the following link to see available report details.

Link: <https://www.gate-r.swissmedic.ch/elvis/secure/details.xhtml?messageid=rlcCi7CbTERhb40IFaXroDPFBk3qv5rrHNejKVXPE08>

Best regards,
Your Swissmedic Team



Reports SMC-Portal  

Overview

Welcome Thomas Schwartz

Create new report

[Create new standard report](#) [Create new parent/child report](#)

Continue saved report

[Continue locally saved report](#)

Create follow-up report

[Create follow-up report](#)

Received messages

Report number	Report date	Valid until	Sender		
SMCELVIS-2014-11-17-00501	17.11.2014	29.12.2014	Swissmedic		

Sent reports

Report number	Report date	Valid until	Type	Status				
SMCELVIS-2014-11-17-00501 <i>TS_1234</i>	17.11.2014	29.12.2014	Initial Report	acknowledged				

EIViS Hotline

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E-mail
it@swissmedic.ch

by phone
+41 58 462 06 00

Business hours
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Swissmedic · Swiss Agency for Therapeutic Products · Hallerstrasse 7 · Post box office · CH-3000 Bern 9 · Phone. +41 58 462 02 11 · Fax. +41 58 462 02 12 · EIViS V1.1.3



Reports

SMC-Portal



The message refers to the following report

Report data

Report number

SMCELVIS-2014-11-17-00501

Report date

17.11.2014

Receiver

Bergwacht DE

Sender

Swissmedic

Available until

29.12.2014

Patient

♂

Age

-

Drug

Sortis


Reaction

rash


Procedure

Please download the message and note that it should not be answered.

Attachments

#	Filename	
1	Sample Pharma.docx	



 Download all attachments as ZIP



URL Productive Environment

MAH Registration:

<https://www.swissmedic.ch/swissmedic/de/home/services/egov-services/portal/egov-portal-registration.html>

MAH Login:

<https://www.gate.swissmedic.ch/elvis>

MAH Login Swissmedic Portal (User creation):

<https://www.portal.eiam.admin.ch>