Change history

Version	Valid and binding as of:	New minor version	Description, comments (by author)	Author's initials
2.0	**01.04.18**		**Content chapter 2 modified**	**dst**
1.0	**27.02.18**		**New QM ident: MU101_20_004e_MB** **Old QM ident: MU101_21_012e_MB**	**feh**
04	**29.09.14**		**Launch of ElViS**	**lc**

A short Guideline for Marketing Authorization Holders

The obligation to report Adverse Drug Reactions and all other safety issues is laid down in the Swiss Regulations HMG, VAM, and VKlin. It starts with the company's first application at Swissmedic to notify a clinical trial (or the application for a marketing authorization) and ends with the expiry date of the last distributed batch. However, relevant information obtained thereafter should also be reported. The reporting responsibilities for marketed products lie with the Marketing Authorization Holder (MAH), and the manufacturer. The reporting responsibilities in clinical trials lie with the sponsor.

1 Post marketing Reporting Duties – ADR(s)/Safety Issues originating outside Swissmedic Notified Clinical Trials

Every individual case safety report must be accompanied by the duly filled-in backing form (for reports transmitted by Swissmedic Pharmacovigilance Gateway, see below). The form can be downloaded from the website www.swissmedic.ch.

The form is available in German and English – please refer to:

German: MU101_21_012d_FO Begleitformular Spontanmeldungen von Firmen

English: MU101_21_012e_FO Backingform spontaneous ADR reports from MAH

(Home >Market surveillance>Human medicines> Pharmacovigilance>Forms)

For reports transmitted by the Swissmedic Pharmacovigilance Gateway or by the **E**lectronic **Vi**gilance **S**ystem (ElViS), the backing form is not needed. Instead, please provide the respective information either in "sender's comment" (preferably) of the report, or via e-mail.

1.1 ICSR

Please report all serious (expected or unexpected) and all non-serious + unexpected ADRs occurring in Switzerland. In addition, ADR(s) for which an unexpected increase in frequency is observed or clusters of expected and unexpected ADR(s) as well as unexpected rises of serious cases of misuse or abuse of a medicine should be reported.

Swissmedic operates an electronic gateway and in addition an electronic reporting platform called ElViS (**E**lectronic **Vi**gilance **S**ystem) to exchange ICSR in the ICH E2B format. Single case reporting via E2B is the technical method preferred by Swissmedic. The Swissmedic internet provides guidance on the prerequisites to establish gateway or ElViS connection between Swissmedic and MAH(s).

Timelines

- Immediately but no later than 15 days for fatal and/or life threatening ADR(s)
- 15 days for all other serious ADR(s)
- 60 days for non serious-unexpected ADR(s)

For cases not reported in the E2B format, preferably report in electronic format (CIOMS form as a PDF file allowing copying from the text). ICSR(s) are to be sent to vigilance@swissmedic.ch or to Swissmedic, **Division Safety of Medicines** (Abteilung Arzneimittelsicherheit).

Swissmedic • Hallerstrasse 7 • CH-3000 Berne 9 • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12

Please **do not**:

- Send other than domestic reports
- Send reports that do not fulfil all the above mentioned criteria

2 Safety Issues identified at National or International Level

Please refer to:
MU101_20_005d_MB Arzneimittelsignale (German version)
MU101_20_005f_MB_Signaux_relatifs_medicaments (French version)
MU101_20_005d_MB_Drug_Safty_Signals (English version)
(Home > Human medicines > Market surveillance >Pharmacovigilance > Instructions and information sheets)

3 Reporting Requirements in Swissmedic Notified Clinical Trials (CT)

Please refer to:
BW101_20_002e_MB_Safety_of_Medicines Safety relating to clinical trials - Compulsory notification
(Home > Human medicines > Clinical trials > Clinical trials on medicinal products > Safety measures in clinical trials)

4 Quality Defects

Quality defects occurring in Switzerland or concerning batches distributed in Switzerland must be reported to:
market.surveillance@swissmedic.ch or to Swissmedic, **Division Monitoring of Medicines** (Abteilung Marktkontrolle Arzneimittel).

Timelines
Class I defects: within 24 hours
Class II defects: within 3 days
Class III defects: within 15 days

For further information please refer to:

MU102_10_001e_mbnotificationofqualitydefects
(Home > Human medicines > Market surveillance > Quality defects and batch recalls > Reporting quality defects)

Swissmedic • Hallerstrasse 7 • CH-3000 Berne 9 • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12