

## Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
3.0	01.09.2019	Actualisation of references in chapter 2	dst
<b>2.0</b>	<b>01.04.2018</b>	<b>Content chapter 2 modified</b>	<b>dst</b>
1.0	27.02.2018	<b>New QM ident: MU101_20_004e_MB</b> <b>Old QM ident: MU101_21_012e_MB</b>	feh
04	29.09.2014	Launch of EIViS	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](http://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 **Electronic Vigilance System (EIViS)**, 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 EIViS (**E**lectronic **V**igilance **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 EIViS 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](mailto:vigilance@swissmedic.ch) or to Swissmedic, **Division Safety of Medicines** (Abteilung Arzneimittelsicherheit).

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\_001d\_WL Wegleitung Arzneimittelsignale H MV4 (german version)

MU101\_20\_001f\_WL Guide complémentaire Signaux relatifs à des médicaments H MV4 (french version)

MU101\_20\_001i\_WL Guida Segnalazioni relative a medicinali H MV4 (italian version)

MU101\_20\_001e\_WL Guidance document Drug Safety Signals H MV4 (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\\_relativ\\_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](mailto: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\\_mnotificationofqualitydefects](#)

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