Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
4.0	01.07.2021	Electronic reporting of ICSR for MAH mandatory.	ts
3.0	01.09.2019	Actualisation of references in chapter 2	dst
2.0	01.04.2018	Content chapter 2 modified	dst
1.0	27.02.2018	New QM ident: MU101_20_004e_MB Old QM ident: MU101_21_012e_MB	feh
04	29.09.2014	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 Reporting Duties for individual case safety reports (ICSR) originating outside Swissmedic Notified Clinical Trials

Please report all serious (expected or unexpected) and all non-serious + unexpected adverse drug reactions (ADRs) occurring in Switzerland. In addition, ADR(s) for which an unexpected increase in frequency is observed or clusters of expected or 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 required by Swissmedic. The Swissmedic internet provides guidance on the prerequisites to establish gateway or ElViS connection between Swissmedic and MAH(s).

Timelines

- 15 days for all serious ADR(s)
- 15 days for clusters of expected or unexpected ADR(s)
- 60 days for non-serious unexpected ADR(s)

Swissmedic expects all ICSR submitted by pharmaceutical companies to include a medical assessment. For all submitted ICSR at least two requests for follow-up information should be made at an interval of not more than four weeks if relevant information for assessing the case is missing. For further information please refer to: FAQs: General Pharmacovigilance (swissmedic.ch)

Please **do not**:

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

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2 Safety Issues identified at National or International Level

Please refer to:
MU101_20_001d_WL Wegleitung Arzneimittelsignale HMV4 (german version)
MU101_20_001f_WL Guide complémentaire Signaux relatifs à des médicaments HMV4 (french version)
MU101_20_001i_WL Guida Segnalazioni relative a medicamenti HMV4 (italian version)
MU101_20_001e_WL Guidance document Drug Safety Signals HMV4 (english version)
(Home > Human medicines > Market surveillance >Pharmacovigilance > Instructions and information sheets)

3 Reporting Requirements in Swissmedic Notified Clinical Trials (CT)

Please refer to:
https://www.swissmedic.ch/dam/swissmedic/en/dokumente/bewilligungen/klv/bw101_20_002d_mbmeldepflichtzurarzneimittelsicherheitbeiklinisch.pdf.download.pdf/BW101_20_002e_MB_Safety_of_Medicines.pdf
(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)

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