Notification of Quality Defects of Medicinal Products and active product ingredient (API)

Due to the adaptation of procedures within Swissmedic and recurring questions, Swissmedic has decided to summarise the most important points relating to the mandatory notification of quality defects of medicinal products.

1 What is meant by quality defect?

The quality of a ready-to-use medicinal product is deemed inadequate if its specifications authorized by Swissmedic are not fulfilled, in case of deviations from the Good Manufacturing Practices (GMP) during its manufacture or in case of awareness of formerly unknown quality issues which could endanger the health of humans or animals.

Quality defects of medicinal products can be discovered in the following situations (among others):

- during their application by the patient or doctor;
- in the pharmacy;
- in distribution channels;
- in quality or stability analyses by the marketing authorisation holder;
- in Swissmedic's ongoing market surveillance;
- as a result of pharmacovigilance reports[1].

Notes:

Currently, counterfeit medicinal products give cause for increasing concern. During the evaluation of a quality defect, this should be taken into consideration.

If a quality defect is suspected to be the cause of adverse effects and incidents, this suspected defect has to be reported as well.

2 Why do quality defects have to be notified?

It is only allowed to place high quality, safe and effective medicinal products on the market (Art. 1 of the Law on Therapeutic Products LTP; SR 812.21). Therefore all quality defects that affect the established use, efficacy or safety of the medicine have to be reported to Swissmedic (Art. 59, paragraphs 2 and 3 of the LTP).

3 Which quality defects have to be reported to Swissmedic?

All quality defects of batches of medicinal products that are marketed in Switzerland and / or in the Principality of Liechtenstein (Article 59, paragraphs 2 and 3 of the LTP).

Quality defects of batches of medicinal products that are manufactured in Switzerland or in the Principality of Liechtenstein, even if the said products are not distributed in these countries, i.e. manufactured for export only.

All quality defects of batches of medicinal products authorised in Switzerland that are only marketed abroad, and that concern the general basis for assessing the product (such as its pharmaceutical properties, its safety or its effectiveness). All class I and II quality defects have to be reported.

All quality defects of active ingredients used in medicinal products manufactured or authorised in Switzerland and/or in the Principality of Lichtenstein (e.g.: GMP issues, CEP withdrawal etc.)

All quality defects of active ingredients manufactured in Switzerland.

[1] Suspected undesirable side-effects of medicinal products for human or animal use, serious occurrences with medical devices and haemovigilance are not covered by the definition of quality defects, even though they may be caused by quality defects. However, they have to be notified to Swissmedic, too, using the respective forms (see www.swissmedic.ch or www.vpt.uzh.ch)

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Quality defects which do not necessarily have to be notified to Swissmedic are isolated, minor defects (e.g. a few slightly damaged secondary packages) that obviously do not affect the specified use, the safety or the efficacy of the medicinal product. Such defects only need to be reported to the marketing authorisation holder. In case of doubt, the Swissmedic Division Market Monitoring of Medicines should be contacted.

4 Who has to report defects?

Basically, anyone may notify a quality defect relating to a medicinal product to Swissmedic (Art. 59 LTP). However, it is mandatory for the following groups to submit a report:

- Companies manufacturing or distributing medicinal products in Switzerland, i.e. marketing authorisation holders, manufacturers and wholesalers (Art. 59 paragraph 2 LPT, Art. 61 paragraph 6 Arzneimittelverordnung VAM; SR 812.212.21 / Medicinal Product Ordinance)
- Any person professionally administering or supplying medicinal products, such as doctors, pharmacists and chemists (Art. 59 paragraph 3 LTP, Art. 63 paragraph 1 VAM).

In companies with operating licences issued by Swissmedic, the Qualified Person is responsible for the quality of the medicinal product manufactured or distributed, and therefore for submitting notifications of quality defects and for taking the necessary measures (including emergency measures) (Art. 5 Arzneimittelzulassungsverordnung AMBV; SR 812.212.1 / Medicinal Product Authorisation Ordinance).

5 When and how quickly do defects have to be reported?

In general, all quality defects have to be reported to Swissmedic, if the medicinal product concerned has been released for distribution.

The time frame for notifying a quality defect after identification is maximum 15 days (Art. 63 Abs. 3 VAM) and is inferred from the defect classification (risk category). It is binding for the persons listed in paragraph 4 above.

The classification of the defects into classes I, II and III is based on Standard Operating Procedure PI 010 “Procedure for handling rapid alerts and recalls arising from quality defects” published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S):

Classification of Defect	Definition	Time limit for notification
Class I	Potentially life threatening or could cause serious risk to health	24 hours
Class II	Could cause illness or incorrect treatment but is not Class I	3 calendar days
Class III	No significant hazard to health is expected	15 calendar days

For all quality defects for which the marketing authorisation holder intends to initiate a batch recall, Swissmedic has to be informed in advance (document PE 009 “Guide to good manufacturing practice for medicinal products – Part I” published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S), chapter 8.26).

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6 How should defects be reported and to whom?

Defects have to be notified to the Swissmedic Division Market Monitoring of Medicines. (www.swissmedic.ch / Human medicines / Market surveillance – Quality defects and batch recalls / Reporting quality defects) by using:

- form MU102_10_001e_FO_Defective Product Report
  or
- the on-line form

as well as the form in word format are available for the notification.

For Class I defects, the Swissmedic contact point should first be contacted by telephone, to ensure that the notification can be handled within the short time limit imposed for such serious quality defects.

7 Contact details

Swissmedic, Swiss Agency for Therapeutic Products
Market Monitoring of Medicines Division
Quality defects / Batch recalls
Hallerstrasse 7
3012 Bern, Switzerland

Market Monitoring of Medicines Division:	+41 (0)58 462 05 80
Outside office hours:	+41 (0)58 462 05 55
e-mail:	market.surveillance@swissmedic.ch
Fax:	+41 (0)58 462 07 22

E-mail and fax-machine are only checked for incoming reports during office hours.

8 What measures are taken when a defect is reported?

The Swissmedic Division Market Monitoring of Medicines contacts the Qualified Person of the marketing authorisation holder as rapidly as possible and specifies the next steps to be taken. Quality defects may lead to batch recalls or to the distribution of communication letters. If appropriate, the international therapeutic products authorities will be informed by means of the EMA Rapid Alert System for the competent Authorities of the European Economic Area (EEA), the PIC/S member states, partner authorities and international organisations (WHO, European Commission).

Defects which are due to violations of the Good Manufacturing Practice (GMP) or Good Distribution Practice (GDP) will be brought to the attention of the Swissmedic Inspectorates and Licences division, and may lead to for cause inspections. If necessary, Swissmedic may also take other measures in accordance with the Law on Therapeutic Products and its implementation ordinances.

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Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
2.1	25.05.2022	Chapter 8, corrigendum Name of Inspectorates and Licences Division	prf
2.0	01.04.2022	Chapter 6, implementation on-line notification form. Deletion of PIC/S Guideline versions. Change of phone number.	prf
1.3	22.08.2019	Corrected error on page 2, number 4 (replace Art. 59 paragraph 3bis LPT in Art. 59 paragraph 2 LPT)	prf
1.2	06.03.2018	Updating of cross-references to LTP, VAM. AMBV, PIC/S. Correction of error in Section 6 (wrong Document Code: MU102_00_104e instead of MU102_10_001e) Update of postal code within the document and in the footer.	prf
1.1	16.01.2018	Corrected error on page 3, number 8 (replace EMEA with EMA)	pej
01	08.05.2017	Old QM ident: MU102_00_001, New QM ident: MU102_10_001 The remaining content of the document was not reviewed and stays unchanged.	dms
05	29.09.2014	Telephone and fax numbers within the document updated, telephone and fax number in the footer updated, new change history inserted in the document, document name modified in the header	sel

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