swissmedic

Information sheet

Reporting quality defects in labile blood products

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1 Definitions and abbreviations

1.1 Abbreviations

para.	paragraph	GPG	Good Practice Guidelines
MPLO	Medicinal Products Licensing Ordinance (SR 812.212.1)	TPA	Therapeutic Products Act (SR 812.21)
Art.	Article	IBCT	incorrect blood component transfused
ST-SRC	Swiss Transfusion SRC	PDI	Post-donation information
CMV	cytomegalus virus	TPO	Therapeutic Products Ordinance (SR 812.212.21)
FSCA	Field Safety Corrective Action	e.g.	for example
GMP	Good Manufacturing Practice		

2 Introduction and objective

This information sheet summarises the key facts relating to mandatory reporting of manufacturing and quality defects in labile blood products.

3 Legal basis and scope

Only high-quality, safe and effective therapeutic products may be placed on the market (Art. 1 Therapeutic Products Act, TPA). Blood and labile blood products are therapeutic products and, according to Art. 4 para. 1 let. a TPA, are classified as medicinal products. Anyone manufacturing, distributing, dispensing or using therapeutic products must notify Swissmedic of any quality defects which cast doubt on the established use, efficacy or safety of the medicinal product (see Art. 59 para. 2 and 3 TPA). In this context and with respect to labile blood products, “serious defects in relation to the GMP rules

which have occurred during the blood collection process or the manufacturing of labile blood products" and the corresponding (protective) measures which have been taken – among other things – are subject to mandatory reporting (Art. 61 para. 7 TPO and Art. 37 para. 1 let. e and para. 2 MPLO).

4 Other valid documents

Document ID
I-310.AA.01-A09 Form HV Reporting quality defects in labile blood products
I-310.AA.01-A08 Form HV Reporting protective measures
I-310.AA.01-A06 Form HV Reporting serious incidents and facts

5 Description

5.1 Serious quality defects and serious defects during manufacture

The quality of a medicinal product is deficient if it displays characteristics which do not correspond to the specifications authorised by Swissmedic, if manufacture was not compliant with the rules of Good Manufacturing Practice (GMP/GMG), or if new findings concerning the quality of the medicinal product emerge which could endanger the health of humans or animals. In this document, the term "**quality defect**" is used to refer to defects affecting labile blood products which have been released for the market. The term "**defect during manufacture**" of labile blood products is used to refer to a deviation during manufacture which was identified before the products were released for the market.
Only blood products of flawless quality may be released for the market.

Quality defects should in particular be considered **serious** if a patient may be endangered. This is the case for labile blood products, for example, if the products are capable of transmitting an infection or are associated with an elevated rate of side effects, or if their efficacy may be impaired.

Serious defects during manufacture are deviations which are classified as particularly critical in terms of the risk posed to patients and infringement of requirements specific to blood products (e.g. traceability).

5.2 Examples of events subject to mandatory reporting

5.2.1 Serious quality defects (subject to mandatory reporting)

Deviations concerning blood products released for the market are quality defects that must be reported. The time at which they are discovered (e.g. still in the manufacturer's storage facility, in the presence of the user, already transfused) is not relevant for mandatory reporting.

- Error in the labelled blood group (any part of the labelled blood group)
- Mismatch during the manufacturing process (donor/sample/labelling mismatches)
- Incorrect information about product specification (e.g. product irradiated, product washed, IgA-deficient plasma, CMV antibody negative)
- Serious manufacturing defect (e.g. use of incorrect, defective, expired, uncertified materials, impurities)

- Serious infringements of donor suitability (e.g. content-relevant mistakes in the questionnaire; errors in the process of evaluating donor suitability)
- Serious deviations of product specifications (specification outside the established tolerance limits (see B-CH regulations: Quality controls), observation period: one year (*example: an event concerning the test parameter "platelet count" must be reported if the acceptance criterion (≥ 2.4x10e11/unit) is fulfilled in fewer than 90% of the controls performed in a year*)
- Product issued despite serious storage errors

5.2.2 Serious defects during manufacture (subject to mandatory reporting)

These deviations are subject to mandatory reporting if they occur during the manufacturing process – even if the products are not released for the market.

- Relevant infringements of traceability:
  - Mix-ups
    - Donor/donation mix-ups
    - Product mix-ups at another stage of manufacture
- Incorrect labelling (ABO RhD)

5.2.3 Special situations

Post-donation information / Reporting form for protective measures

According to Art. 37 para. 1 let. b, c and para. 2 MPLO, Swissmedic must be notified of the protective measures taken if tests for communicable diseases were not performed correctly or if the donor has undergone seroconversion or has contracted a blood-borne infection – details from « post-donation information» (PDI) may also fall into this category. In such cases the measures taken must be notified to Swissmedic using the form «HV Reporting protective measures» (I-310.AA.01-A08) (Forms / Classification (swissmedic.ch).

Materiovigilance

Serious events concerning medical devices are subject to mandatory reporting within the framework of **materiovigilance** (further information can be found on the Swissmedic website: Medical devices: Reporting incidents & FSCAs (vigilance) Users; *link:* Users (swissmedic.ch). An event only needs to be reported as a quality defect if a product with a serious quality defect was subsequently released (*examples: if a material defect resulted in a contaminated blood product; if a defect in an in vitro diagnostic medical device resulted in a blood group being labelled incorrectly*).

5.3 Mandatory reporting for activities involving patient samples

If the manufacturer acts as an immunohaematology laboratory for patient-related orders, they must comply with the mandatory reporting requirements for near misses and IBCT (transfusion errors). A more detailed explanation of this topic is available on the Swissmedic Haemovigilance website (What to report? (swissmedic.ch), reporting form «HV Reporting serious incidents and facts»). It is always the person discovering an event who is required to notify it; the fulfilment of this requirement may be managed in agreement with the client.

5.4 Reporting form, reporting pathways, reporting timelines

The report must be submitted to section Inspection Management and Blood Surveillance at Swissmedic. Please use form «HV Reporting quality defects in labile blood products» (I-310.AA.01-A09) (www.swissmedic.ch / Human medicines / Market surveillance / Haemovigilance / Forms / Classification; *link:* Forms / Classification (swissmedic.ch).

The form can be sent either by e-mail or by post (see contact information). The *web transfer service of the Federal Administration* is available to send large documents/attachments – please contact us directly if you would like to use it.

In accordance with Art. 62 para. 3 TPO, quality defects must be notified to Swissmedic without delay and no later than 15 days after their discovery. The associated protective measures (this affects licence holders, see Art. 61 para. 7 TPO and Art. 37 MPLO) may be notified at the same time or within a suitable timeline; notification of protective measures is usually expected within 60 days of a quality defect coming to light. Requests for further information can usually be expected from Swissmedic within 30 days of the notification being received.

5.5 Contact information

Swissmedic, Swiss Agency for Therapeutic Products
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Section Inspection Management and Blood Surveillance
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The e-mail address @hin.ch is part of the network operated by the provider "HIN" Health Info Net AG. HIN users can send e-mails to this address using the data encryption offered by HIN ("HIN-secured"). Please contact us directly if you have any questions relating to the security of data transmissions.

6 Changes to the previous version

- Transfer from MU to QMI with minor adjustments to the new organizational designations