Contents

1 Objective

The notification requirement for suspected illegal trading in medicinal products has been regulated by the Therapeutic Products Act (TPA, SR 812.21) since 1 January 2019. It applies to both medicinal products and medical devices. This information sheet specifies the notification requirement solely for (ready-to-use and not ready-to-use) medicinal products.

2 Introduction / background

2.1 Medicrime Convention (SR 0.812.41)[1]

Falsified therapeutic products represent a major threat to public health. To date the risk of prosecution and sanctions remains low, while the potential profits are enormous. It is against this background that falsified therapeutic products are becoming more widespread globally. The threat is global as a result of online transactions. The Medicrime Convention seeks to control falsified therapeutic products and

[1] The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Convention; SR 0.812.41)

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similar crimes on an international level and, for this purpose, provides for repressive and preventive measures to be taken. Switzerland signed the Convention in Moscow on 28 October 2011.[2]

The revisions of the legislation governing therapeutic products in response to the implementation of the Medicrime Convention entered into force on 1 January 2019.
The Convention requires the contracting states to prosecute the manufacturing and supplying of, or the offering to supply, falsified medicinal products and medical devices.
Issues relating to patent protection and intellectual property are explicitly outside the scope of the Convention.

2.2 Requirement to report

Anyone who manufactures, distributes or dispenses medicinal products often becomes aware of violations of relevant regulations by third parties sooner than the authorities. A new paragraph 3bis was added to Article 59 TPA with a view to enabling effective prosecution and the implementation of Article 17 para. 2 of the Convention. The new paragraph states that these persons must report to Swissmedic any suspicion of trade in illegal therapeutic products by third parties that comes to their attention in connection with their activities, one of their products or the components of such a product. This paragraph is an addendum to the existing Article 59 para. 3 TPA, which states that persons employed in the health sector must report to Swissmedic any serious facts that they observe (including suspected falsification) and quality defects that are relevant for medicinal product safety.

It points out that companies and healthcare professionals are not required to act as investigators or to carry out investigations themselves. Neither does it imply any requirement to initiate criminal proceedings but merely an obligation to notify Swissmedic, as is the case for other types of information mentioned in Article 59 TPA.

Failure to notify may lead to administrative proceedings as described in Article 66 TPA and to prosecution (cf. Art. 87 para. 1 letter c TPA).

3 Legal basis

3.1 Art. 59 para. 3bis TPA: Notification requirement/Annex 4 of the MPLO

Supplementary to Art. 59 para. 3bis TPA, Annex 4 of the Ordinance on Licensing in the Medicinal Products Sector (MPLO, SR 812.212.1), and with it the international rules of Good Distribution Practice (GDP) as stated in the following Guidelines, applies:

- Guidelines of the European Commission of 5 November 2013 on Good Distribution Practice of medicinal products for human use
- Implementing Ordinance (EU) 2021/1248 of 29 July 2021 as regards measures on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
- Guidelines of the European Commission of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use
- Implementing Ordinance (EU) 2021/1280 of the Commission of 2 August 2021 as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products.

In order for falsified medicinal products to be combated effectively, all stakeholders in the supply chain must adopt a uniform approach. The Guidelines contain suitable tools designed to support all

[2] Wording based on the text of Dispatch Federal Gazette 2017 3135

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stakeholders in their activities and to prevent falsified medicinal products from entering the legal supply chain. Among other things, they contain provisions concerning

- the handling of medicinal products suspected of being falsified (e.g. informing the competent authority and the authorisation holder, separate storage, detailed investigation and documentation)
- training in aspects of product identification
- procedure for identifying medicinal products suspected of being falsified
- due-diligence review to evaluate suitability, competence and reliability (e.g. taking into account offers of medicinal products more likely to be falsified or at unusual prices).

3.2 Art. 69 para. 4 TPA: Swissmedic is the national contact point

According to Art. 69 para. 4 TPA, Swissmedic is the national contact point as per Article 17 para. 3 and Article 22 para. 2 of the Medicrime Convention (cf. Section 2.1) that liaises with the designated contact points in other countries.

4 Illegal trade

The Act states that any suspicion of illegal trade in medicinal products must be reported to Swissmedic, i.e. in the following cases:

4.1 Falsifications

Art. 4 letter j of the Medicrime Convention states that the term “falsification” shall mean a false representation as regards identity and/or source.

This definition does not, however, apply to unintentional quality defects or violations of intellectual property rights.

A falsified medicinal product is thus any ready-to-use or not ready-to-use medicinal product for which the following features in particular have been falsified:

- Identity:
  This applies not only to its composition (active substances and excipients) but also to the packaging (including seals), labelling, the name, product information leaflets, etc.
- Origin in terms of its source:
  Manufacturer, country of manufacture, country of origin, marketing authorisation holder, etc.
- Origin in terms of its history:
  This applies to records and documents relating to the distribution channels and manufacturing steps used, e.g.:
  - falsified delivery documentation, invoices or other documents related to origin, certificates;
  - use of active substance or excipient batches that do not conform to the original product, or falsified records, documents, certificates of analysis that are obtained, for example, through an intermediary, and the origin of which can therefore not be documented.

4.2 Other illegal trade in medicinal products

Trading in medicinal products is also illegal if, for example:

- Medicinal products that require authorisation are placed on the market without authorisation,
- Medicinal products are suspected of having been obtained by theft,
- Medicinal products that, for example, were donated for humanitarian purposes in a specific country or region or supplied at heavily reduced prices are subsequently transferred back (diverted) to the “unrestricted” wholesale trade contrary to their intended purpose, or

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- Goods are obtained through a channel not intended to be part of a legal distribution chain (e.g. goods from suppliers without the necessary licence),
- Goods that were already at the point of dispensing are subsequently passed back into the distribution chain.
  - With respect to the specific case of goods returned from a pharmacy, attention is drawn to Section 6.3 of the Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01) which refers in detail to returned goods.

Basically any type of medicinal product can be falsified or traded illegally. However, Swissmedic's experience to date shows that the following medicinal products or offers require particular caution:

- Expensive medicinal products, e.g. oncology drugs, monoclonal antibodies or medicinal products to treat HIV etc.;
- Medicinal products that are also used as "lifestyle drugs", e.g. erectile stimulants, slimming products, anabolic steroids;
- Medicinal products, falsified versions of which have already been found in other (European) countries;
- Products offered on the market at unusually low prices or whose origin is not clear;
- Products originating from countries in which checks performed by the authorities are usually less strict, e.g. countries in Africa or Western Asia/the Middle East.

In such cases suppliers must be checked more thoroughly to prevent poor-quality or falsified goods or goods that have already been offered for retail sale in the past from being made available.

Falsified products turn up repeatedly in international trade in medicinal products in particular. Swissmedic has issued Technical interpretation I-SMI.TI.18[3] concerning "Legal requirements and mandatory due diligence by Swiss firms wishing to engage in foreign trade with medicinal products from Switzerland", which deals specifically with the area of falsified medicinal products, to provide guidance when inspecting companies with a licence to engage in foreign trade.
This document also points out the need for licence holders to perform more stringent checks when engaging in international trade with wholesalers outside the EU.

5 Reporting

The form "Report regarding suspected illegal trading in medicinal products", which is available online, can be used to report both suspected or confirmed illegal trade in medicinal products and suspicious offers of medicinal products or thefts.
If new knowledge comes to light about a case that has already been reported, the reporter must submit an update and mark it as such.
After the report has been submitted, an automated mail is sent to confirm receipt of the report by Swissmedic. Swissmedic only contacts reporting persons if this is necessary to check the report.

5.1 Who submits the reports?

Under the terms of Art. 59 para. 3bis TPA, the following persons are required to submit reports:

- Holders of a Swissmedic licence to
  - manufacture medicinal products
  - engage in wholesale trading in medicinal products
  - engage in import, export and transit trade in medicinal products
  - trade in medicinal products in foreign countries from Switzerland

[3] https://www.swissmedic.ch/dam/swissmedic/de/dokumente/bewilligungen/inspektorat/i-smi_ti_18e_legalrequirementsandmandatoryduediligencebyswissfir.pdf.download.pdf/i-smi_ti_18e_legalrequirementsandmandatoryduediligencebyswissfir.pdf

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- engage in brokerage or agency activities in connection with medicinal products

- Holders of a cantonal retail trading licence to dispense medicinal products in
  - pharmacies
  - drugstores and
  - other retail trading businesses and
  - other healthcare professionals licensed to dispense medicinal products
- Other persons who are authorised to dispense medicinal products under the terms of Art. 24 and 25 TPA.

5.2 What is reported?

Suspected (by establishments/persons required to submit reports) falsified products or illegal trade (as described in Section 4) involving Switzerland, in particular:

5.2.1 Medicinal products manufactured for the Swiss market

- Any suspicion of falsification of or illegal trade in medicinal products, either in Switzerland or abroad.

5.2.2 Medicinal products manufactured for foreign markets

- Falsified or illegally traded medicinal products discovered or suspected in Switzerland.
- Falsified or illegally traded medicinal products, the original versions of which are manufactured in Switzerland, which are discovered or suspected in another country must **only** be reported **if one of the following criteria is fulfilled**:
  - The medicinal product was manufactured for a country with medicinal product controls comparable to those in Switzerland[4,5] **or**
  - The medicinal product was discovered in a country with medicinal product controls comparable to those in Switzerland.

    Cases which are nonetheless relevant for the Swiss market (e.g. a connection to a batch number distributed in Switzerland), on the other hand, must be reported under all circumstances.

5.2.3 Offers

- Suspicious offers to Swiss licence holders or points of dispensing, even if no purchase has occurred (possible falsified medicinal products or diversions).

5.2.4 Theft

- Theft of medicinal products in Switzerland or of medicinal products manufactured for the Swiss market abroad. This includes losses in which there is a justified suspicion of theft.
- A theft or loss should only be reported if it involves large quantities (not individual packs) or if illegal trading is suspected.

5.2.5 Trade

- Trading by third parties in Switzerland of medicinal products that require authorisation but have not been authorised, if this is discovered in the course of the reporter's own business activities.

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[4] https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl_hmv_iv/zl000_00_011d_vzlisteallerlaendermitvergleichbarerhumanarzneimittelkontrolle.pdf.download.pdf/ZL000_00_011d_VZ%20Verzeichnis%20Liste%20aller%20L%C3%A4nder%20mit%20vergleichbarer%20Humanarzneimittelkontrolle%20HMV4.pdf

[5] https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl_hmv_iv/zl000_00_012d_vz.pdf.download.pdf/ZL000_00_012d%20VZ%20Liste%20L%C3%A4nder%20mit%20vergleichbarer%20Tierarzneimittelkontrolle.pdf

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5.3 When is a report submitted?

In accordance with Article 62a of the Therapeutic Products Ordinance (TPO, SR 812.212.21) Swissmedic must be informed immediately (within 5 days at the latest) using the form which is available online.

5.4 The following must also be observed

Depending on the circumstances, it should be noted that recalls must be prepared and arranged in consultation with the competent authority and/or other competent authorities must be informed of the illegal trade.

Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
2.0	01.09.2022	Modification / clarification of the criteria for reportable cases in the context of the mandatory notification of illegal trading in medicinal products	mc
1.2	01.01.2022	The form for submitting a report, which was formerly accessible via a link, is now only available online	mc
1.1	25.01.2021	Revised 2021. No changes.	mc
1.0	01.01.2019	First version	mc

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