Falsified medicinal products entering the supply chain

Swissmedic intensifies controls on international trade with suppliers from non-EU countries

Increased vigilance in international trading in medicinal products – Swissmedic responds to cases of falsified products with stricter controls. A targeted campaign uncovers shortcomings.

Imagine that you are a South American patient with a specific form of leukaemia, pinning all your hopes on a new drug that is not authorised in your country. Your doctor arranges for the drug to be procured from a recognised Swiss trading company. After your doctor has treated you, it is discovered in Europe that falsified versions of this medicine are in circulation. Rather than the life-saving active substance, the tablets that you had taken merely contain a tiny amount of paracetamol that would not even be able to cure a headache. Such cases of falsified medicinal products occur from time to time, and clearly highlight both the internationally networked supply chain and the importance of safety measures in the fight against falsified products.

In recent years, a number of incidents have emerged in which Swiss trading companies were involved in distribution chains with medicinal products from third-party suppliers (particularly from Turkey) that subsequently proved to be falsifications. Swissmedic's investigations revealed considerable shortcomings in the qualification of suppliers outside the EU and the tracking of the supply chain. Consequently, on 4 May 2021 Swissmedic published the requirement for authorisation holders to tighten their controls when engaging in international trade in foreign medicinal products via non-EU countries (International trade with wholesalers outside the EU). To date, the Swiss market has not been directly affected by falsified medicinal products, since the products in question were destined for sale abroad. However, the EU discovered that falsified medicinal products had made their way into distribution channels within the European Union via parallel imports delivered by such suppliers.

Despite the publication, Swissmedic subsequently received a report of a falsified cancer drug originating from Turkey. Swissmedic therefore launched a campaign to inspect Swiss companies specialising in the international trade in finished medicinal products via non-EU countries.

To this end, Swissmedic identified 73 Swiss companies using the Swissmedic „Import for export" licence module. Such companies are allowed to import medicinal products from other countries only if they are then destined directly for export. Placing these imported medicinal products on the market in Switzerland is not permitted. Based on the import data from the Federal Office for Customs and Border Security, 16 companies were selected for closer scrutiny.

These companies had to submit detailed documentation to prove the origin of medicinal products imported from non-EU countries. Most of these imports originated from Turkey, China and India. The results of the Swissmedic inspection were startling:

- Nine administrative proceedings revealed deficiencies, including significant shortcomings by five companies in the documentation of the supply chain. Swissmedic objected to the fact that the companies were unable to provide the required evidence confirming the exact origin of the purchased medicinal products and their supply chain back to the authorisation holder. They have therefore been asked to improve the controls and their documentation. Two of these five companies also operate as community pharmacies in parallel, and Swissmedic objected to the mixing of their activities as a pharmacy and as a company with a wholesale trading licence.
- Seven administrative proceedings were concluded without objection and therefore without incurring any costs. However, it emerged that two companies had imported non-compliant finished medicinal products from non-EU countries for dispensing to Swiss patients by medical professionals. Swissmedic informed the competent cantonal authorities about these violations.

Overall, it became clear that there was often a lack of awareness of the legal requirements and obligations regarding supply chain traceability.

Swissmedic examined 16 companies with the "Import for export" licence module – a summary of the key details

5 companies submitted insufficient documentation.

Minor deficiencies were identified at **4 companies**.

No deficiencies were identified at **7 companies**.

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Key findings and consequences

According to Art. 15 para. 2 of the Ordinance on Licensing in the Medicinal Products Sector (MPLO; SR 812.212.1), companies that import medicinal products for the sole purpose of re-exporting them must comply with the guidelines of Good Distribution Practice as stated in Annex 4 of the MPLO (European Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use). In its publication of May 2021, Swissmedic had specified that companies must be able to verify the supply chains back to the authorisation holder for medicinal products procured abroad in order to minimise the risk of trading in falsified products. Many companies were unaware of these stricter requirements for supply chain traceability back to the marketing authorisation holder. Swissmedic will therefore intensify its checks on compliance with these due diligence obligations. The identification of inadequate implementation of the publication, including the applicable EU Guidelines on Good Distribution Practice, may result in the opening of criminal proceedings.

The checks and improvements to processes are designed to minimise the risk of patients being exposed to falsified medicinal products. Swissmedic is thereby underpinning its legally defined basic mission under the Therapeutic Products Act, which stipulates the need for human and animal health to be protected.

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