Legal requirements and mandatory due diligence by Swiss firms wishing to engage in foreign trade with medicinal products or ATMPs from Switzerland, and on supply chain traceability if products are imported for re-export

Document valid from:	**09.12.2025**	
Document number:	**I-SMI.TI.18e**	**Version 4.0**
Classification:	**Public**	
Replaced document:	**I-SMI.TI.18_03**	dated: 04.01.2022
Root SMI documents:	**--**	
Referenced QMI documents:	**I-SMI.RL.02**	

Approval	Date:	Signature:
Author:	14.10.2025	Christian Schärer
Technical verification:	25.11.2025	Federico Cimini
Formal verification: (Release VS-QMI):	09.12.2025	Michelle Scheidegger

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1. Purpose and scope

Within the framework of the international trade in medicinal products, a key role is played by firms trading abroad globally with medicinal products, i.e. without the goods entering the territory of the country in which the firm concerned has its registered offices. To minimize the risk of trading with falsified medicines and to guarantee the safe supply of medicinal products to patients, it is essential for such a business model to consistently ensure and be able to prove at all times that the quality of the medicines being traded is guaranteed throughout the entire distribution chain.
Switzerland is one of the few countries where this type of business activity requires a licence. Firms that trade out of Switzerland with medicinal products and without these products ever entering Switzerland therefore require an establishment licence granted by Swissmedic, in accordance with Swiss legislation on therapeutic products (Therapeutic Products Act, TPA, art. 18, para. 1, let. c). These firms are regularly inspected.

This technical interpretation outlines in more details the legal requirements and due diligence for holder of an establishment licence for foreign trade with medicinal products, which include active substances, intermediates, drug products and TpP/GT/GVO products (ATMP).

As defined by TPA, art. 18, para. 1, let. c, in case of foreign trade activities, the products are not entering Swiss territory. There are, however, some companies that have a similar business model, with the difference that they import the product to Switzerland, with the only purpose of re-exporting them directly. Such import and export activities require a corresponding authorisation for import and export, and compliance with international GDP standards (EU-GDP for Europe and Switzerland) is mandatory for import and export activities. GDP requires a robust qualification of suppliers and customers, and this document clarifies that the requirements regarding supply chain traceability are equivalent for companies trading abroad and those importing for re-export.

2. Basics

- Therapeutic Products Act (TPA; SR 812.21), art. 18 para. 1 let. a and c, art. 18 para. 4, art. 21, art. 28
- Medicinal Products Licensing Ordinance (MPLO; SR 812.212.1), art. 21 – 23
- Transplantation Act (SR 810.21)
- I-SMI.RL.02 Description, harmonisation and steering of the Swiss GMP/GDP inspection system for medicinal products, ch. 5.5

3. Interpretation

3.1 Legal framework conditions in Switzerland

3.1.1 Therapeutic Products Act

Like all activities in connection with medicinal products that require licences, the conditions and valid due diligence requirements within the framework of obtaining an establishment licence for trading abroad are based on the provisions of the therapeutic products act. In addition to general due diligence, the licence holder must in general do everything that is required in accordance with the current state of science and technology to avoid endangering the health of humans and animals (art. 3 TPA). This applies not only to the manufacturing and distribution of ready-to-use medicinal products, but also to the manufacturing of active pharmaceutical ingredients and semi-finished medicinal products and ATMPs).

Since manufacturers of medicinal products must comply with the recognised rules for good manufacturing practice (GMP) (art. 7 para. 1 TPA) and guarantee the quality of active substances and medicinal products purchased throughout the entire supply chain, this requires firms that only distribute or trade active pharmaceutical ingredients or semi-finished medicinal products to guarantee the compliance and quality of the goods they acquire and deliver (e.g. GMP-compliant manufacturing in the case of active pharmaceutical ingredients) and to document this for the manufacturers. For certain medicinal products, trade abroad is moreover prohibited (art. 21 TPA).

3.1.2 Medicinal Products Licensing Ordinance

The Medicinal Products Licensing Ordinance (MPLO) sets out the legal requirements and prerequisites regarding due diligence and states that the holders of licences for trading abroad must operate an effective quality system to guarantee the pharmaceutical quality of medicinal products (art. 21, para. 1, letter a), clearly document the relevant processes (art. 21 para. 1 let. d MPLO) and to ensure the safe trading with medicinal products and the traceability of the purchasing and sales of medicinal products (art. 22 para. 1 MPLO). It is important to note that the licence for trade abroad does not entitle the holder to issue manufacturing orders (art. 21 para. 3 MPLO).

The result of these legal obligations on the part of the licence holders is that they among others:

a. Ensure access to and retention of records appropriate to demonstrate the pharmaceutical quality of the medicinal products procured.
b. Ensure access to and retention of complete transactional records, including at least the transaction dates, quantity, batch number, expiry date, precise description of the medicinal product as well as the name and address of the supplier and customer.
c. Maintain a robust procedure and documented evidence, to regularly qualify suppliers and customers.
d. Ensure and provide documented evidence that suppliers and customers are authorised to carry out the respective relevant activities and comply with the relevant standards of Good Manufacturing and/or Distribution Practice (EU/PIC/S-GMP and EU-GDP).
e. Ensure and provide documented evidence that the necessary storage and transport conditions remain within the limits determined by the manufacturer or stated on the packaging.
f. Provide customers for each delivery with details of the original manufacturer and the original batch number of the goods delivered and ensure for each transaction that the information on the packaging has been verified and is correct.
g. Verify the supply chain of finished products back to the original marketing authorisation holder/manufacturer and make sure that all companies involved in the supply chain worked in compliance with the relevant standards of Good Manufacturing and/or Distribution Practice (EU/PIC/S-GMP and EU-GDP).
h. If there are any doubts regarding the quality of a certain medicinal product, request information (e.g. verification of batch number) directly from the competent marketing authorisation holder or manufacturer.
i. Forward all information relevant to quality and safety of the products, or relevant for the authorities, to the customer and/or the supplier.
j. Immediately inform the competent authority and the MAH (for authorized products) of any medicinal products they identify as falsified or suspect to be falsified. This applies not only to products they purchase, but also to products they are offering and which they suspect to be falsified.
k. Have in place an effective procedure for any recalls of medicinal products needed.

It is the duty of the responsible person to ensure that there is close, expert supervision within the firm and that safety and product integrity is ensured and maintained at any time.

Based on article 21 paragraph 2 MPLO, Swissmedic may specify further technical requirements and details. Events in recent years have prompted Swissmedic in May 2021 to demand that licence holders check suppliers more rigorously when trading in finished medicinal products sourced from third parties. This applies to all products traded but especially to products from countries outside the EU that do not have equivalent GDP requirements and to products sourced via wholesalers in such countries (see also 3.4).

3.2 Falsified medicinal products

Falsified medicinal products constitute a particular threat to the health of consumers and are considered a scourge by the international community. Not only is their trading prohibited, of course, but licence holders have the particular duty to identify falsified medicines and to avoid – or, using the appropriate measures, to prevent – them from entering any legal supply channels.

Basically, all types of medicinal products can be falsified. From experience, however, the following categories are particularly liable to be falsified:

- Expensive medicinal products such as oncological medicines and those against the HI virus (AIDS).
- Medicinal products that are also used as “lifestyle drugs” and have a wide user base: for example erectile stimulants, slimming products, anabolic steroids.
- Medicinal products that have already appeared in the form of falsified products in other European countries.
- Life-saving products such as antibiotics or commonly used medicines that are experiencing regional or global shortages.

If such medicinal products are offered on the market at particularly low prices or if their origin is unclear, particular care is necessary. This also applies with regard to products offered from countries or regions with less stringent official controls and thus known to lead to a greater risk of falsified medicinal products in circulation. This should also be taken into account by licence holders when selecting and examining sources of supply.

3.3 Control of specific weaknesses in international trade

The vulnerability of international trade in medicinal products with regard to falsification is well known. Swissmedic therefore considers it to be essential for firms located in Switzerland and trading abroad with medicinal products to strictly comply with the legal requirements, to carry out their due diligence and to take the necessary measures to minimise the risks inherent to trading in medicinal products. Below, specific measures that can be taken by Swiss firms trading abroad, to minimise the risk of falsified medicines, as well as issues that are particularly worthy of note, are indicated. These aspects are also examined within the framework of official inspections in accordance with article 19 TPA. The companies should be in a position to show relevant records at any time to Swissmedic or to the inspectors.

3.3.1 Risk management process

Companies must remain diligent regarding their supply chains and should establish a risk management process to protect their business from fraudulent approaches. They should never rely solely on information provided by the supplier or customer but should establish mechanisms to use independent information when verifying their business partners, and to regularly validate available information (including information such as e.g. contact details, calling numbers, bank details, online presence) in line with the expectations from experience. It may be necessary to

ensure that other departments (e.g. finance) also report changes to supplier and customer details to the responsible person to ensure that potential signals are identified, detected and properly assessed in a timely manner.

Additional measures should be considered as part of the due diligence of business partners in order to protect the own business against false impersonation, phishing, etc. Companies should be mindful when publishing establishment licenses or certificates issued by regulatory agencies on their own websites because this increases the risk of misuse and is therefore strongly discouraged.

Implementation of robust procedures for establishing the authority and legitimacy of customers and suppliers as part of an effective quality management is required. Swiss licence holders who are suspected of trading with falsified products will be officially investigated and may be faced with a batch recall involving publication or even with revocation of their establishment licence as part of administrative proceedings. Depending on the matter in question, administrative penal proceedings may also be initiated. Checking more rigorously on suppliers from countries with no equivalent GDP requirements thus not only benefits patient safety but is in licence holders' interests, too.

3.3.2 Trading partners

The entitlement for trading partners (suppliers and customers) to handle medicinal products must be proven and regularly checked. The procurement and transmission of medicinal products must be designed in such a way that the products are protected against manipulation by unauthorised third parties and that falsified medicines are prevented from entering the legal distribution chain. Checking trading partners is particularly important if the goods are not obtained from the original manufacturers or from their official trading partners but from another trader of medicinal products. The establishment licence holder must be able to prove the status of the suppliers as officially approved wholesaler or manufacturer of medicinal products at any time.

The authenticity of wholesale or manufacturing licences of suppliers and customers can be checked in EudraGMDP database and other public lists of competent authorities. Furthermore, online information provides an opportunity for independent checks of licence details. However, due diligence of business partners should not be limited to such information. Swissmedic and other competent authorities have observed trends that falsified medicinal products have been sold into the legitimate supply chain, although copies of valid licences were presented by the suppliers or customers. Examples of stolen identities of legitimate companies are known, a situation that would not be detected by checks in EudraGMDP or any other public list of competent authorities. Regular requalification should assess if there have been significant changes in directorship or ownership.

Robust procedures for establishing the authority and legitimacy should therefore include diligent assessment of independent information and also careful checks for signals of stolen identification. It has been observed that fake websites were used that had been created in order to mimic legitimate companies. Small spelling mistakes, websites or mail addresses using slightly changing domain names or indications that websites were registered only recently, could be signals that have to be carefully assessed.

A trend had been observed of an increase in reported cases with involvement of Swiss companies distributing foreign presentations of medicinal products procured from non-EU wholesalers that later turned out to be falsifications. The products in question were targeted for sale abroad. Swiss licence holders must ensure that suppliers are fully qualified as already described. If the suppliers with wholesale licences from countries that do not apply the same GDP rules as Swit-

zerland and the EU In particular, they must verify that suppliers fully comply with all EU GDP requirements and that the supply chain traceability can be entirely demonstrated. A system to qualify suppliers should be in place, which also includes the performance of on-site audits. The decision not to conduct an on-site audit should be thoroughly justified based on the results of a well-founded risk assessment, and accompanied by the evaluation and, where necessary, the implementation of possible alternative measures. If issues arise or the traceability of the supply chain is not guaranteed, the need of a timely on-site audit as well to terminate the business relationship with the respective partner company must be assessed. Qualification also demands detailed knowledge of the legal situation, including the general legal and constitutional environment at the supplier's and customer's location. In connection with this, licence holders are expected to be able to reconstruct the entire supply chain for a finished medicinal product as far as to the manufacturer or the authorisation holder and to verify the legality of the supply chain at each of its steps. If there are any doubts, or if anything is unclear, it is essential to request information directly from the manufacturer or authorisation holder in question and to check independent information.

Documentation and proof of a proper qualification of suppliers and customers as well as documentation covering the entire supply chain (starting with the respective product authorisation holder) should be available on site for each transaction. Depending on the language, consideration should be given to gather authenticated translations of the documents.

Particular precautionary measures are also necessary to ensure that in principle, it can be excluded that ready-to-use medicines are brought back from retail trade into international trade. This option should only be considered in very exceptional cases and for which full evidence can be provided, in accordance with international standards, that the goods were appropriately handled at all times and the risk for falsified medicines can be fully excluded. It is required that the supplier and the customer address this topic in the quality agreement and define the responsibilities.

3.3.3 Proof of the quality of the goods traded

The licence holder must carry out appropriate checks on the quality of the goods traded and be able to provide proof thereof for each batch in a suitable form. Such proof may among other things, be based on certificates from the original manufacturer containing details of the quality of the goods and confirming compliance with internationally recognised GMP requirements during manufacturing. These controls of the quality aspects of the active pharmaceutical ingredient or the formulated medicinal product should however also take into consideration the correctness of the primary container, its labelling, the packaging, the shelf life or the secondary packaging. Section 17.20 of the EU GMP Guide Part II, for example, states that traders must maintain complete traceability and retain documents relating to the identity of the goods and of the original manufacturer, purchase orders, bills of lading, receipt documents, transportation (including temporary storage) and distribution records, plus authentic analysis certificates, manufacturer's batch number and information regarding retest and expiry dates. The controls should be documented and the documents should be available on site for each transaction.

3.3.4 Storage

Storage premises of the goods traded must be suitable and qualified for storing medicinal products. Written proof thereof must be provided on request (e.g. qualification of warehouse and service providers).

3.3.5 Transport

The transport conditions for each incoming and outgoing delivery of medicinal products must be appropriate throughout the entire transport chain and the relevant proof must be available.

This includes the following measures:

a. Agreements must be concluded with the suppliers, recipients and service providers, specifying that the conditions must be respected and be fully documented during transport and during any intermediate storage. Assignment of responsibility for transport should be clearly specified in the agreement.
b. For products subject to mandatory cold chain conditions, it must be possible to prove that the cold chain remains unbroken. It must be possible to provide the corresponding protocols for incoming and, if applicable, outgoing deliveries.
c. The means of transport must be qualified and the transport processes verified. The storage conditions during the transport must be defined in full and documented.
d. The transport chain must be protected from risks of falsification.
e. The transport companies used must be assessed by the company ordering the transport regarding their suitability for guaranteeing the transport conditions required. The specific conditions and measures to guarantee safe transport must be laid down in the agreements.

3.3.6 Recall

The rapid recall of goods delivered must be possible at all times. This can be carried out on the initiative of the supplier or the MAH; otherwise, it is the duty of the licence holder to carry out a recall in the case of doubts regarding the quality, safety or efficacy of the goods traded. This also applies in the case of suspected falsified goods. The licence holder's procedures must be specified in detail in a standard operating procedure, and must include that information has to be provided to the competent medicinal product control authority rapidly. The licence holder is responsible for checking possible recalls of medicinal products by the competent authorities.

3.4 Supply chain traceability if products are imported for re-export

The import followed by the unchanged re-export of medicinal products is a slightly different business model. In that case, it should be noted that having medicinal products or ATMP stored in customs or bonded storage is already considered to be importing (art. 18 para. 4 TPA) and thus requires an import licence from Swissmedic plus more extended due diligence (art. 18 para. 1, let. a and art. 28 TPA). For holders of import-export licenses GDP according to Annex 4 MPLO apply.

While this Technical Interpretation mainly focuses on holders of foreign trade licenses, it is highlighted here that companies holding a license for import and export need to comply with the relevant GDP requirements, and must also verify the entitlement for their trading partners similarly to the requirements in 3.3.2, and be able to reconstruct the entire supply chain for a finished medicinal product as far as back to the marketing authorisation holder and to verify the legality of the supply chain at each of its steps.

3.5 Mandatory notification regarding suspected illegal trading in medicinal products

Anyone who manufactures, distributes or dispenses medicinal products often becomes aware of violations of relevant regulations by third parties sooner than the authorities. Article 59 paragraph 3bis TPA states that any person must report to Swissmedic any suspicion of illegal trading in medicinal products by third parties that come to its attention in connection with its activities, its products or their components. Any suspicion of fraudulent activity or attempts to impersonate

a licence holder should be reported to Swissmedic. Failure to notify may lead to administrative proceedings as described in article 66 TPA and to prosecution (cf. art. 87 para. 1 let. c TPA).

4. Changes to the previous version

- General: Improvement of language
- General: Change of title to include supply chain traceability requirements under GDP for import for export
- Chapter 3.4: New chapter on supply chain traceability requirements if products are imported for re-export

5. Annexes

- None