



Engaging in Foreign Trade by a Swiss-Based Entity? Be Sure the Required Swiss Establishment License for Foreign Trade Is in Place

[Eva von Mühlennen](#) and [Andreas Balsiger Betts](#)

To our knowledge, Switzerland is the only country worldwide that makes it mandatory for Swiss-based companies trading with medicinal products outside of Switzerland, that is, without these products' ever entering Swiss territory, to obtain an establishment license for trading abroad (so-called Licence for Foreign Trade; see [Art. 18 \(1\) lit. c Swiss Federal Act on Medicinal Products and Medical Devices, Therapeutic Products Act](#)).

Foreign trade is a wholesale activity abroad, that is, without the goods' entering the territory of the country in which the entity concerned has its registered offices. It can be conducted within a foreign state or between two different foreign states. In this context, wholesale trade as defined by Swiss law means all activities abroad on behalf of a Swiss-based entity relating to the paid or unpaid transferring or provision of medicinal products — from acquisition, stockage, storage, offering, and advertising to the supply of medicinal products — to persons authorized to trade in them, process them, dispense them, or use them in a professional capacity.

Furthermore, the license requirement applies not only to ready-to-use medicinal products/ finished pharmaceutical products (FPP) but also to semifinished medicinal products and active pharmaceutical ingredients (API). Ready-to-use medicinal product/FPP means a medicinal product that has been released technically on the basis of the entire manufacturing process and is available in a form and presentation enabling it to be used as intended. API means substances or mixtures to which the effect of a ready-to-use medicinal product is attributed and which are used in ready-to-use medicinal products. The trade in excipients, however, is not subject to the license requirement discussed here because they have no direct pharmacological effect.

Failure to comply with the license requirements may quickly result in a threat to the supply chain structure. If Swissmedic becomes aware of such noncompliant activities, it will immediately open administrative proceedings to suspend the relevant trading activities. Furthermore, trading abroad without the required license is classified as a crime if done commercially, with correspondingly possible prison sentences for persons responsible and high penalties for the concerned company. It is therefore essential for enterprises located in Switzerland and trading abroad in medicinal products to strictly comply with the legal

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requirements, to carry out their due diligence, and to take the necessary measures to minimize the risks inherent to trading in medicinal products.

To remain diligent regarding their supply chains, Swiss-based companies and global corporations with Swiss-based subsidiaries engaging in trading activities abroad are well advised to ensure that all required Swiss establishment licenses are in place — so that all bittersweet experiences are reserved for those with Swiss chocolate.

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