Requirements for the return of medicinal products

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1 Purpose and scope

Swiss pharmaceutical wholesalers are required to follow the rules of Good Distribution Practice, meaning they must comply with the rules of Good Distribution Practice defined in the Medicinal Products Licensing Ordinance (MPLO), Art. 15, No. 2.

This technical interpretation outlines the minimal expectations of the Swiss inspectorates regarding the handling by wholesalers of returned medicinal product from retailers, including the deadlines that must be respected between the delivery of the medical product and its return.

This document applies to the Swiss inspectorates, which conduct inspections under the jurisdiction of Swissmedic (i.e., the Swissmedic Inspectorate and the cantonal inspectorates within the relevant scope according to Art. 60 of the Therapeutic Products Act (TPA; SR 812.21)), hereinafter referred to as inspectorates, with the aim of ensuring consistent inspection practices.

2 Basics

- Therapeutic Products Act (TPA; SR 812.21)
- Medicinal Products Licensing Ordinance (MPLO; SR 812.212.1)
- European Commission: Principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use (EudraLex, Volume 4)
- EU Guidelines on Good Distribution Practice of medicinal products for human use (2013/C 343/01)
- EU Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)
- EU Regulation on measures for Good Distribution Practice for veterinary medicinal products (2021/1248)
- EU Regulation on measures for Good Distribution Practice for active substances used as starting materials for veterinary medicinal products (2021/1280)

3 Definitions and abbreviations

GDP	Good Distribution Practice according to annex 4 MPLO
Return/returned medicinal products	Medicinal products returned by the retailer (pharmacy, authorized healthcare professionals) to the wholesaler who supplied them, but not due to insufficient quality

4 Interpretation

4.1 Decision

The responsibilities of the qualified person include, among other things, the decision regarding the final disposition of returned medicinal products and the approval of any re-entry into the saleable stock. In doing so, the qualified person must adhere to the rules of Good Distribution Practice. For human medicinal products, the requirements of Chapter 6 of the GDP Guidelines 2013/C 343/01 are particularly applicable.

For the decision of a wholesaler regarding the re-entry of returned medicinal products from retail into saleable stock, the following points must be considered:

- Medicinal products returned by the wholesaler's customer within 10 days can be accepted through a routine procedure.
- Medicinal products returned after 10 but within 30 days must be proven to be returns in the sense of legitimate returns and not a resale by the retailer to the wholesaler (e.g., due to stock clearance). Returns of sold goods for stock clearance reasons are not permitted.
- Medicinal products returned after 30 days do not meet the conditions in Article 6.3 (ii) of the GDP Guidelines 2013/C 343/01.
- If more than 30 days have passed between delivery and return of a medicinal product, this must correctly be considered as a sale from the retailer to the wholesaler, which is generally not permitted (see Article 5.2 of the GDP Guidelines 2013/C 343/01, which states that the wholesaler can only purchase medicinal products from persons who are themselves in possession of a wholesale distribution authorisation, or who are in possession of a manufacturing authorisation manufacturer of the purchased product).After 30 days, the goods can be therefore returned to the sales stock only in exceptional cases and only if based on the results of a thorough investigation of the situation within the deviation management framework.

The Good Distribution Practice (GDP) rules set out further requirements for the returning goods to saleable stock, which must also be adhered to, but which are not addressed in this technical interpretation.

With regard to the legal provisions on the return of actives substances, veterinary medicinal products, and active substances of veterinary medicinal products, the guidelines (2015/C 95/01) and the implementing regulations (2021/1248 and 2021/1280) establish analogous criteria, meaning the points listed above also apply accordingly to these returns.

A procedure in which a wholesaler routinely accepts the return of medicinal products sold to retailers for resale after months or years violates the rules of Good Distribution Practice and the legal regulations in the TPA and the MPLO.

4.2 Swissmedic Journal

In the past, Swissmedic has addressed the handling of returns in relation with the licensing requirement in the Swissmedic Journal 05/2010. Since the enactment of the GDP Guidelines (2013/C 343/01) and the comprehensive revision of the MPLO in 2019, the contents of this Swissmedic Journal publication (05/2010) are therefore no longer valid.

5 Changes to the previous version

- None

6 Annexes

- None