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The Swedish Medicinal Products Agency's regulations on distance sales in outpatient pharmacies

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By virtue of Sections 14(3), 10, 14 and 15 and Section 15 of Ordinance (2009:659) on Trading in Medicinal Products, Chapter 9, Sections 2, 9(1) and (2), 11 and 12 of the Medicinal Products Ordinance (2015:458) and Section 11 of the Ordinance (1992:1554) on the Control of Drugs, the Swedish Medicinal Products Agency hereby lays down[1] the following.

Scope, definitions, etc.

Section 1 These regulations contain provisions that apply to persons holding a licence in accordance with Chapter 2, Section 1 of the Act (2009:366) on Trading in Medicinal Products to conduct retail sales of medicinal products to consumers and which supplement the Swedish Medicinal Products Agency's Regulations (LVFS 2009:9) on retail sales in outpatient pharmacies and the Swedish Medicinal Products Agency's regulations (HSLF-FS 2021:75) on prescribing and dispensing medicinal products and industrial alcohol.

Section 2 These Regulations shall apply to distance trading of medicinal products and industrial alcohol at outpatient pharmacies to:

1. a consumer or their courier, including where another outpatient pharmacy is used as a collection point;
2. those authorised to order medicinal products;
3. public health authority;
4. hospital and other healthcare institution; or
5. veterinary practice.

[1] See Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

These rules apply to the supply of medicinal products and industrial alcohol in the context of distance trade to public health authorities and hospitals as referred to in the first paragraph. For the distribution to or within hospitals through hospital pharmacies, which have been commissioned by a healthcare provider to an outpatient pharmacy, the Swedish Medicinal Products Agency Regulations (LVFS 2012:8) on the supply of medicinal products to hospitals shall apply instead.

Section 3 The provisions on medicinal products in these regulations shall also apply to goods and groups of products referred to in Chapter 18, Section 2 of the Medicinal Products Act (2015:315).

Section 4 The terms and concepts used in European Parliament and Council Regulation (EU) 2019/6 of 11 December 2018 on Veterinary Medicinal Products and repealing Directive 2001/82/EC, the Medicinal Products Act (2015:315) and the Act (2009:366) on Trading in Medicinal Products have the same meaning in these regulations.

For the purposes of these regulations:

Distance trade: The retail sale by an outpatient pharmacy of medicinal products or industrial alcohol involving distribution from the outpatient pharmacy to the recipient, when the recipient does not have access to the goods at the premises of the outpatient pharmacy;

Distribution: Any handling of medicinal products or industrial alcohol that takes place from the moment the product is dispensed until it is handed over to the recipient or until it arrives at the outpatient pharmacy in the event of return.

Recipient: The consumer or their courier, the person authorised to order medicinal products or the person authorised to receive medicinal products or industrial alcohol from the public health authority, hospital and other medicinal establishment or veterinary practice;

Special medicinal products: Medicinal products as referred to in Appendix 11 to the Swedish Medicinal Products Agency's regulations (HSLF-FS 2021:75) on prescribing and dispensing medicinal products and industrial alcohol.

Industrial alcohol: The product referred to in Chapter 1, Section 4 of the Alcohol Act (2010:1622).

Dispensing: When a medicinal product or industrial alcohol is dispensed from the premises of the outpatient pharmacy for distribution to a recipient.

Handover: When a medicinal product or industrial alcohol is handed over to the recipient.

Section 5 Chapter 10, Section 1 of the Medicinal Products Act (2015:315) states that anyone who professionally manufactures, imports, sells, transports, stores or otherwise professionally handles medicinal products must take the necessary measures and other precautions to prevent medicinal products from harming people, property or the environment and to ensure that the quality of medicinal products is not impaired.

Chapter 1, Section 2 of the Act (2009:366) on Trading in Medicinal Products states that medicinal products must be traded in such a way that the medicinal products do not harm people, property or the environment and that the quality of medicinal products is not impaired.

Section 6 The Act (2005:59) on Distance Contracts and Off-Premises Contracts regulates, inter alia, the information that a trader must provide to a consumer before a contract is concluded and when a distance contract has been concluded.

Section 7 Sections 31–34 of the Swedish Medicinal Products Agency's regulations (LVFS 2009:9) on retail sales in outpatient pharmacies lay down requirements for the licence holder when using subcontractors.

Information and advice

Section 8 Personalised information and advice in accordance with Chapter 2, Section 6(11) and Section 9a of the Act (2009:366) on Trading in Medicinal Products shall be provided at the latest when the medicinal product is handed over and in such a way that the consumer or their courier can consult it.

Where the information and advice is essential to eliminate the risk of harm to patients, the supply of the medicinal product shall not take place until information and advice has been provided.

Section 9 Consignments of medicinal products shall contain clear information that the medicinal product shall not be used if the medicinal product or its packaging has visible defects or deficiencies.

The first paragraph shall not apply to consignments of medicinal products that have been requested by someone who is authorised to order medicinal products in accordance with Chapter 2 of the Swedish Medicinal Products Agency's regulations (HSLF-FS 2021:75) on prescribing and dispensing medicinal products and industrial alcohol.

Distribution

Quality and safety

Section 10 Medicinal products shall be distributed under storage conditions that are authorised for the medicinal products. The medicinal products shall not be exposed to conditions that may adversely affect quality, damage the packaging or contaminate the medicinal products.

Section 11 During distribution, medicinal products and industrial alcohol shall be protected from theft and illegal activities.

Dispensing and handover

Section 12 In the event of delay or non-delivery of a prescribed medicinal product or industrial alcohol, the necessary measures shall be taken in accordance with the needs of the person to whom the prescription relates. The same shall apply if the conditions for delivery change in some other way after the order.

Section 13 Prior to the dispensing, it shall be ensured that the handover can take place in accordance with Sections 14 and 15.

Section 14 A consignment containing medicinal products or industrial alcohol shall be handed over to the correct recipient. The handover shall be carried out in such a way that the consignment is not left readily accessible to unauthorised persons.

Section 15 In the case of a handover of a consignment containing special medicinal products on prescription, the identity of the recipient shall be verified. If such an identity check cannot be carried out, the consignment shall not be handed over. In addition, if the consignment is to be delivered to a courier, the courier's authorisation to receive the consignment must also be proven.

Medicinal products and industrial alcohol that could not be handed over

Section 16 A consignment containing a medicinal product or industrial alcohol that has been dispensed but could not be handed over to the recipient shall be returned to the outpatient pharmacy as soon as possible.

In the case of returns under the first paragraph, the requirement in Section 10 concerning distribution under storage conditions approved for the medicinal product shall not apply.

Section 17 Consignments that could not be delivered to the recipient, which contained medicinal products or industrial alcohol which have been returned to the outpatient pharmacy, shall be kept separate from items and goods that have not been dispensed.

On arrival at the outpatient pharmacy, it shall be ensured that the contents of the returned consignment correspond to the one that was dispensed.

Medicinal products and industrial alcohol that have been returned to the outpatient pharmacy shall not be re-dispensed and shall be disposed of in an appropriate manner.

Section 18 If another outpatient pharmacy has been used as a collection point for a consignment and it has not been possible to hand it over to the recipient, the outpatient pharmacy may also be used to destroy the medicinal products and the industrial alcohol contained in the consignment instead of being returned in accordance with Section 16.

Distance trade in case of urgent need

Section 19 If an individual consumer has an urgent need for a prescribed medicinal product, and an outpatient pharmacy is unable to supply the medicinal product immediately, the outpatient pharmacy may be used as a collection point by another outpatient pharmacy, which, in exceptional cases of urgent need, dispatches and distributes the medicinal product. A requirement for this procedure is that the need for medicinal products cannot be met by applying normal ordering procedures.

Dispatch and distribution referred to in the first paragraph shall not be subject to the following provisions:

1. the requirement for documentation in accordance with Section 22;

2. the requirements for mapping, risk assessment and control in accordance with Sections 25–27, and

3. the requirement for instructions in the self-monitoring programme in accordance with Section 28.

Documentation

Section 20 In order to allow traceability of the distribution of medicinal products and industrial alcohol, each consignment dispensed from the outpatient pharmacy shall have documentation containing the following information:

1. The date of dispensing;

2. The name, pharmaceutical form and strength, package size and number of packages of the respective medicinal product or industrial alcohol covered by the consignment;

3. The name and address of the recipient;

4. Means of distribution and, where appropriate, subcontractor;

5. The handover date.

6. How the requirements of Section 15 have been complied with for consignments covered by those requirements.

The documentation referred to in the first paragraph shall be traceable in relation to the verification drawn up in accordance with Chapter 8, Sections 42 or 43 of the Swedish Medicinal Products Agency's regulations (HSLF-FS 2021:75) on prescribing and dispensing medicinal products and industrial alcohol for medicinal products and industrial alcohol dispensed on prescription or requisition.

Section 21 In order to allow traceability of the distribution of medicinal products and industrial alcohol, every consignment which has been returned in accordance with Section 16, first paragraph, must be accompanied by documentation containing the following information:

1. Date of arrival of the consignment at the outpatient pharmacy.

2. The name, pharmaceutical form and strength of the returned medicinal product or industrial alcohol, the number of returned packages and the pack size of the respective medicinal product or industrial alcohol;

3. The means of distribution and, where appropriate, the subcontractor contracted for the purpose of return;

4. Security and handling in accordance with Section 17.

The documentation referred to in the first paragraph shall be traceable in relation to the documentation referred to in Section 20 for the same consignment.

If the consignment has not been returned, but has been handled in accordance with Section 18, the documentation does not need to include the information in points 1 and 3 of the first paragraph.

Section 22 The following documentation for self-checks shall be drawn up:

1. Mapping in accordance with Section 25.

2. Description and results of risk assessments that shall be carried out in accordance with Section 26, first paragraph.

3. Description and results of the systematic monitoring and evaluation to be carried out in accordance with Section 26, third paragraph.

4. Description and results of checks to be carried out in accordance with Section 27.

Section 23 The documents referred to in Sections 20–22 shall be stored and kept available for inspection for five years.

For consignments containing only non-prescription medicinal products that have not been ordered, it is sufficient that the documentation referred to in Sections 20 and 21 is stored and kept available for inspection for three years.

Self-monitoring

Section 24 Sections 21–23 of the Swedish Medicinal Products Agency's regulations (LVFS 2009:9) on retail sales in outpatient pharmacies lay down requirements for self-monitoring. Section 23 of LVFS 2009:9 states that if distance trade is carried out, it must also be covered by self-monitoring.

Mapping, risk assessment and control

Section 25 Before a licence holder commences distance trade in an outpatient pharmacy, a mapping of the planned activity shall be carried out. The mapping shall include all stages and factors in the distribution of the medicinal products and industrial alcohol that may be traded at distance.

Section 26 A risk assessment shall be carried out based on the mapping in accordance with Section 25 in order to identify and assess the risks that may arise during distribution.

To achieve secure distribution while maintaining the quality of medicinal products, the mapping and risk assessment serve as a basis for the choice of the means of distribution, the type of packaging and the means of handover.

Distribution shall be systematically monitored and evaluated. In the case of changes, identified anomalies or new factors affecting distribution, a new risk assessment as referred to in the first paragraph shall be carried out.

Section 27 In order to ensure that distribution will be carried out in accordance with these regulations, checks on the planned distribution shall be carried out prior to the commencement of the activity.

Regular checks shall then be carried out to verify that distribution takes place in accordance with the regulatory requirements. The frequency and extent of the checks shall be proportionate to the results of the checks carried out and the risks and deviations identified.

Self-monitoring programme

Section 28 The Swedish Medicinal Products Agency's regulations (LVFS 2009:9) on retail sales at outpatient pharmacies regulate what is to be included in the outpatient pharmacy's self-monitoring programme. In addition to what is stated in LVFS 2009:9, the following instructions shall be included in the self-monitoring programme for outpatient pharmacies engaged in distance selling:

1. Instructions on how the requirements concerning information and advice under Chapter 2, Section 6(11) and Section 9a of the Act (2009:366) on Trading in Medicinal Products and the specific requirements in Sections 8 and 9 of these Regulations shall be met.

2. Instructions describing how the distribution and other handling of medicinal products shall take place in such a way that the requirements of Chapter 10, Section 1 of the Medicinal Products Act (2015:315), Chapter 1, Section 2 of the Act (2009:366) on Trading in Medicinal Products and the requirements of Sections 10 and 11 of these regulations shall be met.

3. Instructions describing how the requirements of Section 12 concerning the necessary measures shall be met.

4. Instructions on how the requirements for dispensing and handover in Sections 13–15 shall be met.

5. Instructions on how the requirements in Sections 16–18 concerning medicinal products and industrial alcohol that have not been handed over shall be met.

6. Instructions on how the requirements for documentation in Sections 20–23 shall be met.

7. Instructions describing how the mapping, risk assessment, systematic follow-up and evaluation of the distribution pursuant to Sections 25 and 26 shall be carried out.

8. Instructions describing how initial and regular checks of distribution under Section 27 shall be planned and carried out.

In addition, the self-monitoring programme shall contain such additional instructions as may be necessary to ensure compliance with the rules on distance trading.

Exemption

Section 29 The Swedish Medicinal Products Agency may, if there are special reasons, issue an exemption from the provisions of these regulations. Exemption may not, however, be granted if it entails a disregard of Sweden’s obligations under EU law.

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1. These regulations enter into force on 1 September 2025.

2. The regulations repeal the Swedish Medicinal Products Agency's Regulations (LVFS 2009:10) on distance sales in outpatient pharmacies.
3. The licence holder who, on the entry into force of these regulations, engages in distance trade in an outpatient pharmacy shall carry out a mapping study, risk assessment and checks of the ongoing activities in accordance with Section 25, the first and second paragraphs of Section 26 and the first paragraph of Section 27 by 1 September 2025 at the latest.

Swedish Medicinal Products Agency

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