Common code of statutes concerning healthcare, medical care, social services, medicinal products, public health, etc.

ISSN xxx-xxxx, Article number xxxxxxxx
Published by: Head of Legal Department, Pär Ödman, National Board of Health and Welfare

The Swedish Medical Products Agency's regulations on trade in certain non-prescription medicinal products

HSLF-FS 2024:xx

Published on [date] [month] 2024

adopted on [date] [month] 2024.

The Swedish Medical Products Agency lays down[1] the following pursuant to Section 6, paragraphs 1 and 3, and Section 7 of the Ordinance (2009:929) on trade in certain non-prescription medicinal products and Chapter 9, Section 11 of the Medicinal Products Ordinance (2015:458).

Scope, definitions, etc.

Section 1 These regulations shall apply to the retail sale of medicinal products as regulated by the Act (2009:730) on trade in certain non-prescription medicinal products and the Ordinance (2009:929) on trade in certain non-prescription medicinal products.

Section 2 The terms and concepts used in the Act (2009:730) on trade in certain non-prescription medicines have the same meaning in these regulations. For the purposes of these regulations, the following definitions shall apply:

Distribution: any handling of consignments that takes place between the dispatch of the consignment from the operator's premises until it has been handed over to the recipient or the arrival of the consignment to the operator in the event of return.

Withdrawal: the recall of medicinal products from an operator.

Original packaging: the packaging of medicinal products packaged by the manufacturer/marketing authorisation holder.

Complaint: an accusation of suspected lack of quality or defect in medicinal products;

[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.

Operator: a retailer of certain non-prescription medicinal products.

Handover: when medicinal products are handed over to the recipient.

Section 3 Chapter 10, Section 1 of the Medicinal Products Act (2015:315) states that anyone who 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.

Section 2 of the Act (2009:730) on trade in certain non-prescription medicinal products states that the retail trade must be conducted 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 4 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 5 The Swedish Medical Products Agency's regulations (LVFS 2009:6) on the marketing of medicinal products for human use include, inter alia, rules on the marketing of medicinal products and samples of medicinal products.

Notification of trade

Section 6 A notification that a trader intends to trade in certain non-prescription medicinal products shall be made using a form made available on the Swedish Medical Products Agency's website; www.lakemedelsverket.se.

Section 7 A notification that a trader intends to trade in certain non-prescription medicinal products shall contain the following information.

1. The operator's name, postal address and email address or, if the operator is a legal person, the company name, postal address and email address;

2. Personal identification number or corporate identity number;

3. Name, address, telephone number and email address of the point of sale;

4. Main activity conducted at the point of sale;

5. Whether the operator intends to sell only medicinal products containing nicotine or other non-prescription medicinal products as well;

6. Contact person at the point of sale;

7. Billing address

Persons intending to trade in certain non-prescription medicinal products in accordance with the Act (2002:562) on electronic commerce and other information society services shall, in addition to the information referred to in the first paragraph, also provide the following information.

1. The date on which this trade commences.

2. The address ('Uniform Resource Locator (URL)') of the website used in this trade, and other relevant information if necessary to identify the website.

Notification of material changes

Section 8 The operator shall notify significant changes to the activity on a form provided on the Swedish Medical Products Agency's website. www.lakemedelsverket.se.

Purchase of medicinal products

Section 9 The operator shall ensure that medicinal products are purchased only from a trader authorised to engage in wholesale trade in the medicinal products in question.

Receipt of deliveries

Section 10 Upon receipt of deliveries, it shall be verified that the medicinal products delivered do not have visible defects or deficiencies and that the delivery conforms to the order made. Medicinal products requiring special storage conditions shall be dealt with directly upon receipt and stored accordingly.

Storage, exposure and supply

Section 11 Medicinal products shall be stored in good order, in an appropriate place and under conditions of storage authorised for the medicinal products.

Medicinal products which may not be placed on the market under Sections 15 or 23 shall be kept separate from other medicinal products.

Section 12 Medicinal products shall be displayed and stored in such a way as to make it clear that the products are medicinal products.

Furthermore, medicinal products must be stored separately from non-medicinal products.

Section 13 At the point of sale, the medicinal products shall be kept in locked cabinets or under the direct supervision of staff. Direct supervision means that a member of the staff continuously monitors the medicinal products and is able to prevent undue access to the medicinal products or tampering with the medicinal products.

Section 14 A medicinal product may only be supplied in its original packaging.

Section 15 The packaging of a medicinal product which has been opened, has visible defects or deficiencies or an excessively short shelf life may not be sold. Excessively short shelf life means that the shelf life ends during the expected period of use.

A medicinal product referred to in the first paragraph shall be dealt with in an appropriate manner.

Section 16 The text of the EU logo referred to in Section 16a, paragraph 2 of the Act (2009:730) on trade in certain non-prescription medicinal products shall be in the Swedish language.

Distribution

Section 17 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.

Section 18 Medicinal products shall be distributed under storage conditions which are authorised for the medicinal products. The medicinal products shall not be exposed to conditions which may adversely affect quality, damage the packaging or contaminate the medicinal products.

Section 19 During distribution, medicinal products shall be protected from theft and illegal activity.

Section 20 A consignment containing medicinal products 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.

Complaints, withdrawals, other returns or consignment returns of medicinal products

Section 21 In the case of complaints concerning medicinal products, the operator shall receive and handle the information as well as the medicinal products and their packaging provided to the operator by the consumer. This applies to medicinal products which the operator has in their sales range, irrespective of whether the medicinal product has been dispensed by the operator or by others.

In the event of a complaint, the operator shall promptly inform the holder of the marketing authorisation for the medicinal product or their representative of the complaint received. However, this does not apply if the complaint relates exclusively to the operator's own handling of the medicinal product.

The Consumer Sales Act (2022:260) contains provisions on sales law which set out traders' obligations when consumers make a complaint about goods because of defects in the goods.

Section 22 The operator is required to take the necessary measures in the event of withdrawal of medicinal products.

Where a withdrawal concerns medicinal products which have already been supplied to a consumer, the operator shall accept returned medicinal products which it has in its sales range. This applies even if the medicinal product has not been sold by the operator.

Section 23 Medicinal products returned to the operator as a result of complaints, withdrawals or any other reason may not be resold. Such medicinal products shall be dealt with appropriately. Medicinal products subject to a withdrawal shall be dealt with in the manner specified for each withdrawal.

Section 24 A consignment containing a medicinal product which has been sold and sent to a recipient but could not be handed over to the recipient shall be returned to the point of sale as soon as possible.

In the case of return under the first paragraph, the requirement in Section 18 concerning distribution under storage conditions approved for the medicinal product shall not apply.

Section 25 Consignments containing medicinal products and which could not be handed over to the recipient and have been returned to the point of sale in accordance with Section 24 shall be kept separate from medicinal products which have not been sold and consignments which have not been dispatched.

On arrival at the point of sale, it shall be ensured that the contents of the returned consignment corresponds to the one that was sent.

Medicinal products which have been returned to the point of sale shall not be resold or re-sent to the recipient and shall be handled in an appropriate manner.

Documentation

Section 26 In order to ensure traceability, the operator shall keep records of all purchases of medicinal products. The documentation shall include the date of arrival, the number of packages, the size of the package and the name, pharmaceutical form and strength of the medicinal product. The name and address of the person selling the medicinal product to the operator shall be provided.

All handling and all measures taken in relation to complaints and withdrawals shall be documented. Documentation shall also be drawn up of medicinal products that are discarded, destroyed or returned for other reasons.

Section 27 In order to allow traceability, the distribution of medicinal products sold shall be documented. The documentation shall include the following information for each consignment sent by the operator:

1. The date of dispatch of the consignment.
2. The name, pharmaceutical form and strength, package size and number of packages of the respective medicinal product;
3. The name and address of the recipient;
4. The means of distribution and, where appropriate, subcontractor;
5. The handover date.

Section 28 In the case of consignments which have been returned in accordance with Section 24, documentation to enable traceability must be kept which shall contain the following information:

1. The date of arrival of the consignment to the operator;
2. The name, pharmaceutical form and strength of the returned medicinal product, number of returned packages and package size of the respective medicinal products;
3. The means of distribution and, where appropriate, the subcontractor for the return;
4. Implementation and handling in accordance with Section 25.

The documentation referred to in the first paragraph shall be traceable in relation to the documentation referred to in Section 27 for the same consignment.

Section 29 The following documentation for self-monitoring shall be drawn up:

1. Mapping in accordance with Section 30.
2. Description and results of risk assessments to be carried out in accordance with Section 31, first paragraph.
3. Description and results of the systematic monitoring and evaluation to be carried out in accordance with Section 31, third paragraph.
4. Description and results of checks to be carried out in accordance with Section 32.

Self-monitoring

Distribution

Section 30 Before an operator offers distribution of medicinal products sold, mapping of the planned activity shall be carried out. The mapping shall include all stages and factors in the distribution of medicinal products.

Section 31 A risk assessment shall be carried out on the basis of the mapping in accordance with Section 30 in order to identify and assess the risks that may arise during distribution.

In order to ensure safe distribution while maintaining the quality of medicinal products, the mapping and risk assessment shall be used as a basis for choosing the means of distribution, the type of packaging material and the means of handover.

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

Section 32 In order to ensure that distribution will be carried out in accordance with these regulations, checks of 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 is in accordance with the regulatory requirements. The frequency and extent of checks shall be proportionate to the results of the checks carried out and the risks and deviations identified.

Section 33 Deviations and deficiencies in the handling of medicinal products during distribution shall be dealt with and investigated as a matter of urgency. Corrective and preventive action shall be taken as soon as possible. The deviations and deficiencies, as well as the investigations and measures taken in response thereto, shall be continuously documented, compiled and evaluated. Summaries and evaluations shall also be documented. The staff concerned shall be informed of any deviations and the measures taken.

Self-monitoring programme

Section 34 Section 16, paragraph 1 of the Act (2009:730) on trade in certain non-prescription medicinal products states, among other things, that retailers must ensure that there is a self-monitoring programme appropriate to the activity. The self-monitoring programme shall be appropriate for the individual activity and shall be established at the start of the activity. The self-monitoring programme shall be in writing and kept up to date and revised in accordance with an established instruction. The self-monitoring programme shall be made available for inspection and control purposes.

The operator is responsible for ensuring that staff involved in the retail trade are familiar with the content of the self-monitoring programme established and with the relevant provisions in force.

Section 35 The self-monitoring programme shall include:

(1) instructions on how to submit notifications of significant changes in accordance with Section 8;

(2) instructions on how to ensure that medicinal products are purchased in accordance with Section 9;

(3) instructions for the receipt and control of deliveries in accordance with Section 10;

(4) instructions on how medicinal products are to be stored, displayed and supplied in accordance with Sections 11–15;

(5) instructions on how medicinal products which may not be placed on the market pursuant to Section 15 shall be handled in an appropriate manner;

(6) where applicable, instructions on how to comply with the requirements of Section 17;

(7) where applicable, instructions describing how the distribution is to take place in such a way that the requirements of Sections 18 and 19 are met;

(8) where applicable, instructions on how to comply with the handover requirements laid down in Section 20;

(9) instructions on how complaints and withdrawals of medicinal products are to be handled in accordance with Sections 21 and 22;

(10) instructions on how medicinal products which may not be resold under Section 23 shall be handled in an appropriate manner;

(11) where appropriate, instructions on how to comply with the requirements of Sections 24 and 25 in respect of medicinal products which have not been handed over;

(12) instructions on how to comply with the documentation requirements in Sections 26–29 and 40;

(13) where appropriate, instructions describing how the mapping, risk assessment, systematic follow-up and evaluation of the distribution pursuant to Sections 30 and 31 are to be carried out;

(14) where applicable, instructions describing how initial and regular checks of distribution pursuant to Section 32 are to be planned and carried out;

(15) where appropriate, instructions on how to ensure the handling of deviations and deficiencies in accordance with Section 33;

(16) instructions for keeping staff continuously familiar with the content of the self-monitoring programme and the relevant provisions in force in accordance with Section 34;

(17) where appropriate, instructions on how to comply with Sections 37–39;

(18) instructions on how to comply with the provisions on the age limit for the purchase of medicinal products in Sections 12 and 13 of the Act (2009:730) on trade in certain non-prescription medicinal products;

(19) instructions on how to comply with the information requirement in Section 15 of the Act (2009:730) on trade in certain non-prescription medicinal products; and

(20) instructions on how information is to be provided to the Swedish eHealth Agency in accordance with Section 16, paragraph 4 of the Act (2009:730) on trade in certain non-prescription medicinal products.

Subcontracting

Section 36 Operators hiring subcontractors shall be responsible for ensuring that such subcontractors carry out their tasks in line with the applicable regulations in this area.

Section 37 Before engaging a subcontractor, the operator shall assess whether the subcontractor is in a position to carry out the envisaged tasks. The assessment shall be documented.

Section 38 The operator shall ensure that the tasks performed by a subcontractor comply with the applicable requirements by:

(1) entering into a written contract with the subcontractor which regulates the assignment; and

(2) providing the subcontractor with necessary information and instructions.

Section 39 In addition to the provisions laid down in Section 38, the operator shall ensure that tasks performed by a subcontractor in relation to the distribution of medicinal products comply with the applicable requirements by:

(1) ensuring that deviations occurring at a subcontractor that relate to the operator's activities are reported to the operator and that the deviations are dealt with in accordance with Section 33, and

(2) carrying out an audit at least once a year of the part of the activities carried out by the subcontractor. Records of audits carried out and records of the corrections and preventive measures taken as a result of the audits shall be drawn up.

Miscellaneous provisions

Section 40 The following records shall be stored in such a way that they are not at risk of being lost or destroyed:

1. Documentation of traceability in accordance with Sections 26–28.

2. Documentation of self-monitoring in accordance with Section 29.

3. Documentation of deviation management in accordance with Section 33.

4. Documentation of the assessment in accordance with Section 37.

5. Contracts, information and instructions in accordance with Section 38.

6. Records of audits carried out and documentation of corrections and preventive measures taken as a result of the audits in accordance with Section 39, paragraph 2.

The documentation referred to in the first paragraph shall be kept available for inspection and control for a period of three years.

Section 41 If there are special reasons, the Swedish Medical Products Agency may, in individual cases, grant exemptions from the provisions of these regulations.

Exemption may not, however, be granted if it entails failure to comply with Sweden's obligations under EU law.

———

1. These regulations will enter into force on 1 September 2025.
2. The regulations repeal the Swedish Medical Products Agency's Regulations (LVFS 2009:20) on the retail sale of certain non-prescription medicinal products.
3. An operator who, on the entry into force of these regulations, offers distribution of medicinal products sold shall carry out mapping, risk assessment and checks of the ongoing activity in accordance with Section 30, the first and second paragraphs of Section 31 and the first paragraph of Section 32 by 1 September 2025 at the latest.
4. An operator who, at the time of entry into force of these regulations, has already engaged the services of a subcontractor, shall com-

ply with the requirements of Sections 37 and 38 by 1 September 2025 at the latest.

Swedish Medical Products Agency

NILS GUNNAR BILLINGER

Joakim Brandberg

HSLF-FS can be downloaded or ordered at
Online: www.xxxxxxxxxxxxx.xx
E-mail: xxxxxxxx@xxxxxxx.xx

Contact
Xxxxxxxxxxx
Address
Telephone: xx xxxxxxxxx Fax: xx xxxxxxxxx
E-mail: xxxxxxxx@xxxxxxx.xx
Online: www.xxxxxxxxxxxxx.xx

Imprint: Printing house and year of publication