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Conditions and procedure for the wholesale of medicinal products[1]

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20.05.2016	RT I, 25.05.2016, 4	28.05.2016

This regulation is enacted in accordance with section 26(9)(1) of the Medicinal Products Act of the Republic of Estonia.

§ 1. General provisions

(1) This regulation establishes requirements for the wholesale of medicinal products, including requirements for personnel, enclosed premises, furnishings, handling operations, documentation of activities related to handling operations, records and reports regarding medicinal products and for internal audit.

(2) The requirements established in this regulation are also to be applied to the wholesale of medicinal products by the holder of an activity licence for the manufacture of medicinal products. In that case, in this regulation, wholesaler means manufacturer.

§ 2. Requirements for storage rooms and furnishings

(1) The storage of medicinal products must be arranged in a separate room or separate rooms in which the conditions required for the storage of medicinal products must be ensured. The walls, floor and the ceiling of the storage room must be smooth, the surfaces suited to wet cleaning. The room must be well-ventilated, clean and free of pests. The room must have central heating or stationary electric heating.

(2) The storage room must contain the requisite number of shelves, cupboards or pallets for the storage of medicinal products. The furnishings must be made of materials that are easily cleanable.

(3) Dedicated locations must be established for the reception and dispensation of medicinal products.

(4) The location where medicinal products are received or dispensed must provide protection to the medicinal products from adverse weather conditions.

§ 3. Requirements for personnel

(1) The manager of a wholesaler must appoint, in writing, the persons to act as the substitute for the competent person.

(2) Every person employed by a wholesaler must have a job description.

(3) A job description is a written document by which the manager of the wholesaler or the employee appointed by the manager specifies an employee’s job duties and sphere of responsibility.

§ 4. Work procedure rules and persons responsible for activities related to handling of medicinal products

(1) Internal work procedure rules must be established with regard to activities that affect the quality of medicinal products and activities related to the handling of medicinal products.

(2) The rules must provide a detailed description of the following activities, their documentation and the preservation of the documents:
1) the ordering of medicinal products;
2) the applying for special authorisations and distribution permits, the notifying of imports and exports;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
3) the receipt of medicinal products;
4) the storage of medicinal products and verification of the storage conditions;
5) the restricting of access to medicinal products by unauthorised persons;
6) the handling of narcotic drugs and psychotropic substances;
7) the preparation and preservation of shipping documents;
8) the dispensation of medicinal products;
9) the shipping of medicinal products;
10) the arranging of re-labelling and of other contract work;
11) the withdrawal of medicinal products from market and their subsequent handling;
12) the removal from the saleable stock of medicinal products that have passed their shelf life;
13) the removal from the saleable stock of defective medicinal products;
14) the suspending of the dispensation of medicinal products, the terminating of the dispensation and the recalling of medicinal products;
15) the handling of returned medicinal products;
16) the keeping of records of medicinal products and the preparation of reports regarding medicinal products;
17) the cleaning and maintenance of the rooms of the wholesaler;
18) pest control on the enclosed premises of the wholesaler;
19) the conducting of internal audits.

(3) The work procedure rules may also specify other activities that involve the handling of medicinal products and that have not been listed in subsection 2 of this section.

(4) The work procedure rules must be up to date, signed and dated by the manager of the wholesaler or by an employee appointed by the manager. Previous versions of the work procedure rules must be preserved for a period of at least five years.

(5) The manager of the wholesaler must appoint, in writing, the employee in charge of each operation and a substitute employee.

(6) Employees must be familiar with the work procedure rules and legislation that their job duties are based on.

(7) Employees must certify that they have read the work procedure rules by stating the relevant date and affixing their signature.

§ 5. Documenting of activities related to handling of medicinal products

(1) The documentation required under legislation regulating medicinal products must be prepared during the execution or immediately after completion of the activity, unless otherwise specified in the relevant legislation.

(2) Any corrections in the documentation must be dated and signed by the person who makes the correction, while retaining the original entry and stating the reason for the amendment where applicable.

(3) The requirements set out in subsections 1 and 2 must also be followed in electronic documentation.

(4) Where a wholesaler commissions the repackaging or relabelling of medicinal products from another company that holds an activity licence for the manufacture of medicinal products, the commissioning party and the contractor must conclude a detailed agreement specifying the contract work and the related liability.

(5) In the case described in subsection 4, the medicinal products must be delivered to the contractor and delivery of the labelled and packaged medicinal products must be taken in accordance with an instrument of delivery and receipt. The instrument of delivery and receipt must state the description of the medicinal products, their batch numbers and quantity, and include a reference to the agreement concluded with the contractor.

§ 6. Reception of medicinal products at a wholesaler

(1) The delivery to the wholesaler of each consignment of medicinal products must be documented and dated, and signed by the person who takes the delivery.

(2) After delivery of medicinal products is taken, a delivery inspection must be performed to ascertain the following:
1) the existence of the relevant special authorisation and the distribution permit where such are required under the Medicinal Products Act;

[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
2) the existence, form and correspondence to the batch of the quality verification documents (hereinafter, 'certificate of quality') and the shipment documents;
3) in the case of human vaccines and medicinal products derived from human blood, the Official Control Authority Batch Release (OCABR) certificate;
[RTL 2005, 105, 1604 – entry into force 21.10.2005]
31) in the case of veterinary vaccines, the Official Control Authority Batch Release (OCABR) certificate or the Official Batch Protocol Review (OBPR) certificate, if the State Agency of Medicines has established one of the aforementioned requirements in respect of the vaccine batch to be imported;
[RTL 2005, 105, 1604 – entry into force 21.10.2005]
4) the correspondence of the number of packages and their labelling with the shipment documents;
5) the shelf life expiration dates;
6) the storage conditions;
7) the existence of information in Estonian (outer package information in Estonian and information in Estonian on the package leaflet);
8) whether the package is in conformity with the marketing authorisation.

(3) Where there is doubt as to the quality of the medicinal product or where the required certificates are missing, dispensation of the medicinal product may be permitted after approval has been received from the State Agency of Medicines.

(4) Where the supplier of the medicinal products is another wholesaler, the latter must, at the request of the wholesaler receiving the medicinal products, present a copy of the distribution permit if one has been issued by the State Agency of Medicines.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(5) The person who carries out the delivery inspection of a consignment of medicinal products authenticates it by stating the date and affixing his or her signature.

(6) When marketing medicinal products with the same active substance and route of administration, the wholesaler, except for a wholesaler who only markets the medicinal products of a single marketing authorisation holder, gives priority to the procurement and availability of medicinal products with respect to which a price agreement has been entered into in accordance with section 45 of the Health Insurance Act.
[RT I, 26.07.2011, 8 – entry into force 29.07.2011]

§ 7. Storage of medicinal products at a wholesaler

(1) As of the moment of delivery of medicinal products to the wholesaler, the wholesaler is responsible for preserving the quality of the products.

(2) Medicinal products must be stored following the procedure established in accordance with section 34(5) of the Medicinal Products Act.

(3) The following medicinal products do not need to be physically separated in storage, but must bear relevant markings or be subject to other efficient measures ensuring their distinguishability:
1) medicinal products whose dispensation is suspended;
2) unauthorised medicinal products which have a distribution permit;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
3) unauthorised medicinal products which have no distribution permit.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

§ 8. Dispensing of medicinal products at a wholesaler

(1) When a sales offer of medicinal products is made to companies and institutions that are authorised to make wholesale purchases of medicinal products, the price list may not contain any medicinal products ordered in accordance with section 21(1) of the Medicinal Products Act.

(2) The medicinal products prepared for dispensing must be stored at the location where they are to be dispensed until their transportation to the client.

(3) The wholesaler must ensure that the correct medicinal product reaches the consignee in time and together with the requisite documents.

(4) It is prohibited, at the wholesaler's, to divide any package approved in the marketing authorisation.

(5) It is forbidden to dispense defective medicinal products and medicinal products whose shelf life is to end in less than two months. In the latter case, the medicinal product may be dispensed if the consignee is informed of the end of the shelf life and provides a written declaration of consent to receive the medicinal product.

(6) Before dispensing medicinal products, the wholesaler must make sure that the consignee has the right, under relevant legislation, to take delivery of the medicinal products. If necessary, the recipient's holding of an activity licence, the conditions of the licence and the validity of the licence must be checked.

(7) A shipping list must be drawn up with respect to each consignment of medicinal products, setting out the following:
1) the registration number of the shipping list;
2) the date of dispensation of the medicinal product;
3) the name and address of the dispenser and the consignee, and, in the case the medicinal products are dispensed to a veterinarian, the registration number of the activity licence of the veterinarian;
4) the package code;
[RT I, 25.05.2016, 4 – entry into force 28.05.2016]
5) the name of the proprietary medicinal product;
6) the pharmaceutical form;
7) the strength of the active substance(s);
8) the quantity in a package;
9) the number of packages;
10) batch number;
11) shelf life expiration date;
12) holder of the marketing authorisation or, in the absence of the latter, the manufacturer;
13) the classification of the medicinal product as one that is not subject to medical prescription, one that is subject to prescription or one that is subject to prescription and restricted use;
14) the price of the medicinal product at the time of dispensation.

(8) Any unauthorised medicinal products must be clearly identifiable as such in the shipping list.

(9) The shipping list is prepared at least in two copies, one of which is kept by the dispenser and one by the consignee. The shipping list must leave sufficient space for the recording of the retail price.

(10) The shipping list may be drawn up and transmitted solely in the electronic form provided it is electronically accessible and reproducible on the premises of the dispenser and of the recipient.

(11) The consignee certifies the receipt of the consignment by stating the relevant date and affixing its signature. Where the shipping list is transmitted in the electronic form, the consignee may also confirm receipt of the consignment on another document accompanying the consignment that does not need to include the entirety of the information listed in subsection 7 of this section, but must contain a reference to the shipping list.

(12) When a medicinal product is dispensed to a wholesaler or manufacturer of medicinal products, the consignee must be provided with a copy of the certificate of quality, except where the consignee declares that it already possesses the certificate of quality for the batch. In the case of other consignees of medicinal products, a copy of the quality certificate must be provided at the request of the consignee.

(13) When starting materials are dispensed, the consignee of the such materials must always be provided with a copy of the certificate of quality.

(14) When a medicinal product is dispensed to the holder of the marketing authorisation as a sample, the package must be marked with a clearly visible stamp that reads 'Mitte müügiks' [Not For Sale].

(15) A medicinal product for human use may be sold wholesale to veterinarians only if the veterinary medicinal product that contains the same active substance in the same strength and pharmaceutical form has no valid marketing authorisation in Estonia or if the said veterinary medicinal product is not available at the Estonian wholesalers. Where a medicinal product for human use is dispensed to a veterinarian, it must be marked with the special label 'Ainult veterinaarseks kasutamiseks' [Veterinary Use Only].

(16) Where the medicinal products ordered by a veterinarian are paid for by a farm, the veterinarian must send to the wholesaler the order form for the medicinal products.

(17) The order form referred to in subsection 16 must contain the following information:
1) the name of the veterinarian who ordered the medicinal products and the registration number of the activity licence of the veterinarian;
2) the name and address of the economic unit that pays for the medicinal products;
3) the name of the ordered medicinal products, their pharmaceutical form, the strength and quantity of the active substance in the package;
4) the number of the ordered packages;
5) the date on which the order was drawn up;
6) the signature and the personal seal of the veterinarian or, in the case of the electronic order form, the digital signature of the veterinarian.

(18) The order forms referred to in subsection 16 must be preserved at the place of wholesale business for the duration of one year since the dispensation of the medicinal products.

(19) A certificate confirming the veterinarian's employment with the agricultural business referred to in section 27(2)(1) of the Medicinal Products Act, signed by the manager of the company and by the veterinarian, must be available at the place of wholesale business.

(20) When marketing medicinal products with the same active substance and route of administration, the wholesaler, except for a wholesaler who only markets the medicinal products of a single marketing authorisation holder, gives priority to the offering of medicinal products with respect to which a price agreement has been entered into in accordance with section 45 of the Health Insurance Act.
[RT I, 26.07.2011, 8 – entry into force 29.07.2011]

§ 9. Shipping of medicinal products

(1) Medicinal products may be dispensed only to the person named on the shipping list. Medicinal products may not be delivered to, or left in the possession of, a third party.

(2) If a wholesaler purchases shipping services from another company, the wholesaler must enter into an agreement with that company, establishing the obligations of the parties to ensure the preservation of the quality of medicinal products and their delivery to the right recipient. The wholesaler must regularly check the arrangements and conditions of the shipping service.

(3) Delivery of medicinal products from the wholesaler to the consignee by post is not permitted. Courier delivery of medicinal products, except for narcotic medicinal products, is permitted on the condition that the medicinal products are delivered directly to the consignee and that delivery is made on the same day.

§ 10. Handling of returned usable medicinal products

(1) The wholesaler may receive the medicinal products returned by the clients for the purpose of re-dispensing them only if it is convinced that:
1) the appearance of the medicinal product and the packaging leaves no doubt as to the quality of the medicinal product;
2) the medicinal products have been stored and handled as required;
3) the medicinal products have a reasonable period of shelf life left;
4) the wholesaler has in its possession the certificate of quality for the batch of medicinal products.

(2) The employee who is responsible for handling returned medicinal products at the wholesaler must assess the returned medicinal product and issue a signed and dated permit allowing the medicinal product to be returned to the saleable stock. Until the permit is issued, the returned medicinal products must be marked accordingly and stored separately from other medicinal products.

(3) The return, assessing and further handling of medicinal products must be documented.

§ 11. Handling of defective medicinal products

(1) The defects must be documented by stating the information concerning the medicinal product, the holder of the marketing authorisation, intermediator, the nature of the defect, the circumstances related to the defect or the arising of the defect and concerning further handling (storage, destruction, return to the supplier, etc.) of the defective medicinal product.

(2) The competent person must receive information concerning each defective medicinal product discovered by the wholesaler in the course of handling medicinal products.

(3) The State Agency of Medicines must be immediately notified of any defective or presumably defective medicinal products. No notice is required if it is evident that the defect was caused by incorrect handling by the wholesaler itself or during shipping.

(4) A medicinal product is not regarded as defective for lacking information in Estonian if it is dispensed to another wholesaler and if that information is added in the course of subsequent handling.

(5) The State Agency of Medicines and the holder of the marketing authorisation must be notified without delay of any counterfeit or presumably counterfeit medicinal products.

§ 12. Suspension or termination of dispensation of medicinal products and recalling of medicinal products

(1) A wholesaler must establish a system for the suspension or termination of the dispensation of medicinal products or for the recalling of dispensed medicinal products (hereinafter, 'restriction on dispensing') in cases where:
1) the medicinal product is defective or is presumed to be defective;
2) it turns out that an expired medicinal product has been dispensed;

3) the corresponding order is given by the State Agency of Medicines, the manufacturer of the medicinal product, wholesaler or marketing authorisation holder.

(2) The wholesaler must have an appointed contact person who can be contacted by telephone in relation to a restriction on dispensation, including outside the working hours in the case of a dangerous defect. The contact person must have immediate access to the information concerning dispensations.

(3) If the contact person is changed, the State Agency of Medicines must be immediately notified in writing of the name of the new contact person and of the title of his or her position. If the contact person's telephone number changes, the State Agency of Medicines must be immediately notified in writing of the new telephone number.

(4) The competent person must receive information on each operation related to restrictions on dispensation. The employee responsible for the suspension or termination of the dispensation of medicinal products or for the recalling of dispensed medicinal products must have easy access to the information concerning dispensations.

(5) The operations concerning restrictions on dispensation must allow for commencement without delay. Depending on the defect, the consignees must be informed of the restriction on dispensation of the medicinal product within a reasonable time period or within the time period determined by the State Agency of Medicines, and the recall of the medicinal product from the consignees must be arranged up to the specified level of consignment.

(6) Where the order to restrict dispensing is not issued by the State Agency of Medicines and the reason behind the restriction was a defective or a presumably defective medicinal product, the State Agency of Medicines must be immediately notified of the restriction and the related circumstances.

(7) Recalled medicinal products and medicinal products whose dispensation has been terminated must be identified and stored separately to prevent their inclusion among saleable stock until further notice regarding their handling.

(8) The restriction on dispensing must be documented, including a description of the reasons for the restriction on dispensing and of further action, and a list of persons who were notified of the restriction must be prepared. The inventory quantity of the medicinal product must be recorded as of the moment of the establishment of the restriction on dispensing. The data contained in the documentation must make it possible to identify the medicinal product.

(9) Where a medicinal product is recalled, the relevant report must be drawn up, indicating the amounts of the medicinal product received, dispensed and recalled and the manner of further handling of the medicinal product.

(10) The documentation relating to the restriction on dispensing and the recall report must be submitted at the request of the State Agency of Medicines.

§ 13. Records

(1) The receipt, pricing and dispensation of each medicinal product must be reflected in the records which are kept in relation to medicinal products.

(2) The wholesaler's records in relation to medicinal products must be such as to allow the identification of the supplier and consignee of each medicinal product.

(3) The records must contain the following information in relation to each batch of medicinal products:
1) the name of the proprietary medicinal product;
2) the pharmaceutical form;
3) the active substance(s) and its (their) strength;
4) the quantity in a package;
5) the ATC code;
6) the package code;
[RT I, 25.05.2016, 4 – entry into force 28.05.2016]
7) the batch number;
8) the holder of the marketing authorisation and the manufacturer;
9) the name and address of the supplier;
10) the date of receipt;
11) the total number of received packages;
12) the purchase price and selling price of the medicinal product;
13) the registration number of the special authorisation and the distribution permit issued by the State Agency of Medicines where these documents exist;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
14) the registration number of the shipping list;
15) the date of dispensation of the medicinal product, the quantity dispensed;
16) the name and address of the consignee of the medicinal product.

(4) The information relating to each batch of medicinal products as specified in subsection 3, as well as related special authorisations, distribution permits, certificates of quality and shipping lists must be preserved at the place of wholesale business for the duration of one year since the dispensation of the batch of medicinal products.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(5) The wholesaler must preserve the information and documents listed in subsections 3 and 4 for at least for five years, in relation to narcotic medicinal products, for at least ten years.

§ 14. Internal Audit

(1) At least once a year, the wholesaler must conduct an internal audit to monitor implementation of and compliance with the requirements established in legislation and adherence to work procedure rules and job descriptions, and to make proposals concerning measures to be taken.

(2) The results of the internal audit must be drawn up as a report. The report must specify the audit findings and the proposals concerning measures to be taken. The auditors must date and sign the report.

§ 15. Reporting

(1) The holder of the activity licence for wholesale distribution must submit to the State Agency of Medicines a consolidated report that covers all its wholesale operations and sets out information concerning the procurement and dispensation of medicinal products during the preceding reporting period, and the amount of medicinal products in stock. If, during the reporting period, no medicinal products have been procured or dispensed, this must be notified to the State Agency of Medicines by the date set out in subsection 2 of this section.

(2) The quarterly report on medicinal products must be submitted:
1) by 15 April, reflecting the situation as of 31 March;
2) by 15 July, reflecting the situation as of 30 June;
3) by 15 October, reflecting the situation as of 30 September;
4) by 15 January, reflecting the situation as of 31 December;
[RT I, 26.07.2011, 8 – entry into force 29.07.2011]

(3) The report must contain the following information in relation to each medicinal product:
1) the name of the proprietary medicinal product;
2) the pharmaceutical form;
3) the ATC code;
4) the active substance(s) and its (their) strength;
5) the quantity in a package;
6) the holder of the marketing authorisation or, in the absence of the latter, the manufacturer;
7) the package code;
[RT I, 25.05.2016, 4 – entry into force 28.05.2016]
8) the number of packages of medicinal products in stock at the beginning of the reporting period;
9) the quantities received, distinguishing the quantities of imported medicinal products and medicinal products purchased from Estonian handlers of medicinal products;
10) the quantities dispensed, distinguishing the following categories: the quantities exported, the quantities dispensed to Estonian general pharmacies, hospital pharmacies, veterinary pharmacies, wholesalers of medicinal products, wholesalers of veterinary medicinal products, veterinarians and other institutions;
11) the quantities removed from the market or quantities otherwise written off;
12) the quantities returned to the supplier or manufacturer;
13) the quantities sent for verification analysis;
14) the quantities distributed as free samples for promotional purposes;
15) the number of packages of medicinal products in stock at the end of the reporting period;

(4) The total wholesale price must be provided with regard to the quantities dispensed in each category referred to under point 10 of subsection 3,

(5) The State Agency of Medicines publishes guidelines for drawing up the reports on its webpage.

(6) At least once a year, the wholesaler must check its inventory. Any discrepancies must be documented and communicated to the State Agency of Medicines in the report that follows the check.

§ 16. Termination of wholesale-related activities

(1) When the holder of the activity licence is wound up or when the operations referred to in the activity licence are terminated, the medicinal products stored at the wholesaler must be transferred to the holder of an activity licence for the handling of medicinal products or to an institution entitled to make wholesale purchases of medicinal products, or be removed from the market within two months after the winding up date, unless

the State Agency of Medicines has decided otherwise. Information regarding the transfer or removal of the medicinal products must be submitted to the State Agency of Medicines at the request of the Agency.

(2) When transferring medicinal products, the requirements established in section 8 must be observed.

(3) When the wholesale operation is terminated, a report must be submitted to the State Agency of Medicines with the following information:
1) the name of the proprietary medicinal product;
2) the batch number;
2) the pharmaceutical form;
4) the strength of the active substance(s);
5) the quantity in a package;
6) the holder of the marketing authorisation or, in the absence of the latter, the manufacturer;
7) the quantity held in stock.

(4) When the transfer of medicinal products has been completed, a report concerning the period that followed the last quarterly report must be submitted to the State Agency of Medicines following the procedure established in section 15.

(5) After the winding up of the wholesale operations, and until completion of the transfer of the medicinal products, including transfer for the purpose of destruction and including on-site destruction, or return of, the products, responsibility for maintaining the quality of medicinal products and for preserving the relevant cover documents lies with the competent person or the manager of the company.

§ 17. Implementing provisions

(1) Within one month as of the date on which this regulation enters into force, the wholesaler must communicate in writing to the State Agency of Medicines the name of the contact person referred to in section 12(2), the title of his or her position and his or her telephone number(s).

(2) This regulation enters into force on 1 March 2005.

(3) Sections 8(7)(4), 13(3)(6) and 15(3)(7) enter into force on 1 October 2005.

[1]Directive 2001/82/EC of the European Parliament and Council on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, pp. 1–66); Directive 2001/83/EC of the European Parliament and Council on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, pp. 67–128); Directive 2004/27/EC of the European Parliament and Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.04.2004, pp. 34–57); Directive 2004/28/EC of the European Parliament and Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.04.2004, pp. 58–84);