

## Conditions and Procedure for Wholesale Distribution of Medicinal Products<sup>1</sup>

Approved by Regulation No. 27 of the Minister of Social Affairs of 17 February 2005 (RTL<sup>2</sup> 2005, 22, 308), entered into force 01.03.2005

Amended by the following Regulations: 07.10.2005 No 103 entered into force 21.10.2005 - RTL 2005, 105, 1604

This Regulation is established on the basis of clause 26 (9) 1) of the Medicinal Products Act (RT<sup>3</sup> I 2005, 2, 4).

### § 1. General Provisions

(1) This Regulation establishes the requirements to the wholesale distribution of medicinal products, including the requirements for the staff, premises and installations, handling of medicinal products, documentation of handling operations, maintaining records of medicinal products, reporting and internal audit.

(2) The requirements of this Regulation apply also to wholesale distribution of medicinal products by holders of an activity licence for manufacture of medicinal products. In such case a wholesaler means a manufacturing enterprise in this Regulation.

### § 2. Requirements for premises and installations

(1) Separate premises shall be provided for the storage of medicinal products where conditions for proper storage of medicinal products shall be ensured. The walls, floor and ceiling of storage premises shall be smooth; the interior finish shall enable moist cleaning. The premises shall be well ventilated, clean and pest-free. The premises shall be supplied with central heating or stationary electrical heating.

(2) The required amount of shelves, cupboards or pallets shall be provided in the storage premises for the storage of medicinal products. The furnishings shall be made of material which can be cleaned easily.

(3) Separate facilities shall be provided for the receipt and for the dispensing of medicinal products intended for such purpose.

(4) The facilities for the receipt and for the dispensing of medicinal products shall protect the medicinal products against weather effects.

### § 3. Requirements for staff

(1) The head of a wholesaler shall appoint the substitute(s) for the competent person in writing.

- (2) Each person employed with a wholesaler shall have a job description.
- (3) A job description is a written document in which the head of a wholesaler or a person appointed thereby shall establish the duties and sphere of responsibility of an employee.

§ 4. Operational rules and persons responsible for handling operations of medicinal products

(1) There shall be internal written operational rules concerning the operations which affect the quality of medicinal products and are related to the handling of medicinal products.

(2) The operational rules shall set out a detailed description of the following operations, documentation of operations and preservation of documentation:

- 1) ordering of medicinal products;
- 2) application for special authorisations and authorisations for use, notification of import and export;
- 3) receipt of medicinal products;
- 4) storage of medicinal products and inspection of storage conditions;
- 5) protection of medicinal products from access by unauthorised persons;
- 6) handling of narcotic and psychotropic substances;
- 7) preparation and preservation of accompanying documents;
- 8) dispensing of medicinal products;
- 9) transportation of medicinal products;
- 10) organisation of re-labelling and other works under jobbing contracts;
- 11) withdrawal of medicinal products from the market and further handling thereof;
- 12) removal of expired medicinal products from dispensation storage;
- 13) removal of defective medicinal products from the dispensation storage;
- 14) suspension of dispensation, termination of dispensation and recall of medicinal products;
- 15) handling of returned medicinal products;
- 16) maintaining records of and reporting on medicinal products;
- 17) cleaning and maintenance of the premises and equipment of wholesalers;
- 18) pest control in wholesalers' premises;
- 19) internal audit.

(3) Operational rules may include also the description of other handling operations of medicinal products not specified in subsection (2) of this section.

- (4) Operational rules shall be up-to-date and confirmed by a date and the signature of the head of the enterprise or a person appointed thereby. The previous versions of operational rules shall be preserved for at least five years.
- (5) The head of a wholesaler shall appoint in writing a person responsible for each operation and a person substituting for the person responsible.
- (6) Each employee shall be familiar with the operational rules and legislation on which his or her duties are based upon.
- (7) An employee shall certify the examination of operational rules by entering the date and his or signature.

#### § 5. Documentation of handling operations of medicinal products

- (1) Documentation prescribed in legislation concerning medicinal products shall be carried out during the performance of an operation or immediately after completion of an operation unless otherwise determined in the abovementioned legislation.
- (2) The person who makes corrections in documentation shall confirm the corrections by entering the date and signing it and by leaving the first entry visible, and where applicable, indicate the reasons for making the corrections.
- (3) The requirements of subsections (1) and (2) shall be adhered to also upon documentation by electronic means.
- (4) If a wholesaler orders the repackaging or re-labelling service from another enterprise who holds an activity licence for manufacture of medicinal products, a detailed contract concerning the work ordered and the responsibility shall be entered into between the ordering party and the person executing the order.
- (5) In the case specified in subsection (4), delivery of medicinal products for execution of an offer and receipt of packaged or labelled medicinal products shall be carried out on the basis of an instrument of delivery and receipt. The instrument shall set out the names, batch number and quantity of the medicinal products delivered and received and reference to the jobbing contract.

#### § 6. Receipt of medicinal products at wholesaler

- (1) The arrival of each consignment of medicinal products at a wholesaler shall be documented and certified by entering the date and the signature of the person who receives the consignment.

(2) A check on the reception of medicinal products shall be performed immediately on the arrival in the course of which the following shall be ascertained:

1) the existence of special authorisation and authorisation for use, if such authorisation is required on the basis of the Medicinal Products Act;

2) the existence and format of the documents certifying quality (hereinafter certificate of quality) and accompanying documents and the correspondence of the documents to the batch of medicinal products;

3) in the case of vaccines for human use and medicinal products derived from human blood, the Official Control Authority Batch Release (OCABR) certificate;

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3)<sup>1</sup> in the case of vaccines used in veterinary medicine, the Official Control Authority Batch Release (OCABR) certificate or the Official Batch Protocol Review (OBPR) certificate where the State Agency of Medicines has established one of the abovementioned requirements for an imported batch of vaccines;

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4) the correspondence of the number of packages and labelling to the accompanying documents;

5) dates of expiry;

6) storage conditions;

7) the existence of information in Estonian (packaging and package leaflet in Estonian);

8) the compliance of the packaging with the marketing authorisation.

(3) If there is doubt concerning the quality of a medicinal product or the required certificates are missing, the medicinal product may be released after obtaining a decision on approval from the State Agency of Medicines.

(4) If medicinal products are supplied by another wholesaler, the latter shall submit a copy of the authorisation for use at the request of the receiving wholesaler if it has been issued by the State Agency of Medicines.

(5) The person who performs a check on the reception of medicinal products shall certify it by entering the date and his or her signature.

## § 7. Storage of medicinal products at wholesaler

(1) A wholesaler shall be responsible for the preservation of the quality of medicinal products from the moment of arrival of the medicinal products at the wholesaler.

(2) Medicinal products shall be stored pursuant to the procedure established on the basis of subsection 34 (5) of the Medicinal Products Act.

(3) The following medicinal products need not be physically separated, but they shall be labelled appropriately or other effective measures which ensure distinguishing shall be applied:

- 1) medicinal products the dispensation of which is suspended;
- 2) medicinal products without marketing authorisation which have authorisation for use;
- 3) medicinal products without marketing authorisation which do not have authorisation for use.

#### § 8. Dispensing of medicinal products from wholesaler

(1) The medicinal products ordered on the basis of subsection 21 (1) of the Medicinal Products Act shall not be published in the price list upon making a sales offer to enterprises and agencies which have the right to make wholesale purchases of medicinal products.

(2) The medicinal products compiled for dispensing shall be stored in the facilities for dispensing until the medicinal products are transported to the customer.

(3) A wholesaler shall ensure that medicinal products reach the recipient in time and together with the required documents.

(4) It is prohibited to divide a packaging certified by a marketing authorisation at a wholesaler.

(5) Defective medicinal products and medicinal products the date of expiry of which is in less than two months shall not be dispensed. In the latter case, a medicinal product may be dispensed if the recipient is notified of the date of expiry and the recipient grants written consent to receive the medicinal product.

(6) Before dispensing a medicinal product, a wholesaler shall be convinced that the recipient has the right to receive the medicinal product pursuant to legislation. If necessary, the existence of the activity licence of the recipient of the medicinal product, the conditions and validity thereof shall be verified.

(7) A separate delivery note shall be prepared with respect to each consignment of medicinal products which shall set out:

- 1) the number of the delivery note;
- 2) the date of dispensing the medicinal product;
- 3) the name and address of the deliverer and the recipient, in the case of dispensing to a veterinarian also the number of the activity licence of the veterinarian;

- 4) the code of the Coding Center;
- 5) the name of the proprietary medicinal product;
- 6) the pharmaceutical form;
- 7) the content of active substance(s);
- 8) the quantity in a packaging;
- 9) the number of packagings;
- 10) the batch number of the medicinal products;
- 11) the date of expiry;
- 12) the market authorisation holder or, in the absence thereof, the manufacturer;
- 13) whether the medicinal product belongs to medicinal products not subject to prescription, prescription medicinal products or medicinal products subject to restricted use;
- 14) the selling price.

(8) Unauthorised medicinal products shall be marked in the delivery note accordingly in a clearly understandable manner.

(9) A delivery note shall be prepared in at least two original copies, one of which shall remain with the deliverer and the other with the recipient. Space shall be left in the delivery note for indicating the retail price.

(10) A delivery note may be prepared and submitted by electronic means if it can be accessed and reproduced at the deliverer and the recipient of the medicinal product.

(11) The consignee shall confirm the receipt of a consignment of medicinal products by the date and his or her signature. If a delivery note is submitted by electronic means, the consignee may confirm the receipt of the consignment also in another document accompanying the consignment of goods which need not contain all the information specified in subsection (7) of this section but shall include a reference to the delivery note.

(12) Upon dispensing medicinal products to a wholesaler or manufacturing enterprise, a copy of the certificate of quality shall be submitted to the recipient unless the recipient confirms the existence of the certificate of quality of the batch. Other recipients of medicinal products shall receive a copy of a certificate of quality upon the request thereof.

(13) Upon dispensing of raw materials, the recipient of the raw materials shall always receive a copy of a certificate of quality.

(14) If a medicinal product is dispensed to a marketing authorisation holder as a sample, the packaging shall be marked with a clearly visible seal "*Mitte müügiks*" [Not for sale].

(15) Medicinal products for human use may be sold wholesale to a veterinarian only if a veterinary medicinal product with the corresponding active substance, content of active

substance and pharmaceutical form does not have a valid marketing authorisation in Estonia or the abovementioned veterinary medicinal product is not for sale at Estonian wholesalers. A special labelling bearing the words "Ainult veterinaarseks kasutamiseks" [for veterinary use only] shall be attached to medicinal products for human use which are dispensed to veterinarians.

(16) If medicinal products ordered by a veterinarian are paid for by an agricultural enterprise, a veterinarian shall send an order form of medicinal products to the wholesaler.

(17) An order form specified in subsection (16) shall contain the following information:

- 1) the name and the number of the activity licence of the veterinarian who ordered the medicinal products;
- 2) the name and address of the enterprise who pays for the medicinal products;
- 3) the name, the pharmaceutical form, the content of the active substance and the quantity in the packaging of the ordered medicinal products;
- 4) the number of ordered packagings;
- 5) the date of preparation of the order;
- 6) the signature and personal seal of the veterinarian, digital signature in the case of sending an order form by electronic means.

(18) The order forms specified in subsection (16) shall be preserved at the place of business of the wholesaler for one year as of dispensing the medicinal product.

(19) A confirmation signed by the head of an agricultural enterprise and a veterinarian concerning the employment of the veterinarian in this agricultural enterprise specified in clause 27 (2) 1) of the Medicinal Products Act shall be available at the place of business of the wholesaler.

#### § 9. Transportation of medicinal products

(1) Medicinal products may be dispensed only to the person indicated in the delivery note. Delivery of medicinal products to or leaving the medicinal products into the possession of third persons is not permitted.

(2) If a wholesaler purchases transportation service from another enterprise, a contract shall be entered into with the latter which shall establish the obligations of the parties in order to ensure the preservation of the quality of the medicinal products and the receipt of the medicinal products by the correct recipient. A wholesaler shall inspect regularly the organisation and conditions of transportation.

(3) It is not permitted to send medicinal products from a wholesaler to the recipient of the medicinal products by post. Courier service may be used upon the delivery of medicinal products, except of narcotic drugs, on condition that the medicinal products are delivered directly to the recipient of the medicinal products on the same day.

#### § 10. Handling of returned usable medicinal products

(1) A wholesaler may accept medicinal products returned by the customers for further dispensing thereof only if the wholesaler is convinced that:

- 1) the appearance of the medicinal product and of the packaging do not cast doubt on the quality of the medicinal product;
- 2) the medicinal products have been stored and handled under conforming conditions;
- 3) there is sufficient time until the date of expiry;
- 4) the wholesaler has the certificate of quality of the batch of medicinal products.

(2) An employee engaged in the handling of returned medicinal products at a wholesaler shall give his or her opinion on the medicinal product and permission to return it to the dispensation storage and confirm it by the date and his or her signature. Until permission is granted the returned medicinal products shall be marked correspondingly and stored separately from other medicinal products.

(3) Returning, provision of an opinion and further handling shall be documented.

#### § 11. Handling of defective medicinal products

(1) Defects shall be documented by setting out information concerning to the medicinal product, manufacturer, retailer, the nature of the defect, the circumstances related to the defect or cause of the defect and further handling of the defective medicinal product (preservation, destruction, returning to the supplier, etc.).

(2) The competent person shall be informed of each defective medicinal product discovered upon handling of medicinal products at a wholesaler.

(3) The State Agency of Medicines shall be immediately notified of each defective or presumably defective medicinal product. Notice need not be given if it is clear that the defect was caused by incorrect handling at the wholesaler or during transportation.

(4) Medicinal products which do not have information in Estonian and which are dispensed to other wholesalers and to which information is attached upon further handling are not deemed to be defective medicinal products.

(5) The State Agency of Medicines and the market authorisation holder shall be immediately notified of counterfeit or presumably counterfeit medicinal products.

§ 12. Suspension of dispensation, termination of dispensation and recall of medicinal products

(1) A wholesaler shall have a functioning system for suspension of dispensation, termination of dispensation of medicinal products or recall of dispensed medicinal products (hereinafter restriction on dispensing) for the cases where:

- 1) a medicinal product turns out to be defective or presumably defective;
- 2) it becomes evident that an expired medicinal product was dispensed;
- 3) the State Agency of Medicines, the manufacturer, wholesaler or holder of the marketing authorisation of a medicinal product makes the corresponding order;

(2) A wholesaler shall appoint a contact person who can be contacted at all times by telephone in connection with restriction on dispensing, in the case of a hazardous defect also outside working hours. The contact person shall have immediate access to the information concerning dispensing.

(3) Upon change of a contact person, the State Agency of Medicines shall be immediately notified of the name and title of office of the new person in writing. Upon change of the telephone number of a contact person, the State Agency of Medicines shall be immediately notified of the new number in writing.

(4) A competent person shall be informed of each act related to restriction on dispensing. Information concerning dispensing shall be easily accessible by the employee responsible for suspension of dispensation, termination of dispensation of medicinal products or recall of dispensed medicinal products.

(5) It shall be possible to initiate the acts concerning restriction on dispensing immediately. Depending on the defect, the recipients of the medicinal product shall be notified within the period of time prescribed by the State Agency of Medicines or within a reasonable period of time and recall of the medicinal product from the recipients shall be organised up to the prescribed level.

(6) If the order concerning restriction on dispensing was not issued by the State Agency of Medicines and the reason for applying the restriction is a defective or presumably defective medicinal product, the State Agency of Medicines shall be immediately notified of the restriction on dispensing and the circumstances relating thereto.

- (7) Recalled medicinal products and medicinal products the dispensation of which is terminated shall be identified and stored separately in order to preclude their accidental occurrence in the dispensation storage until a decision is adopted concerning further handling.
- (8) A restriction on dispensing shall be documented and a description concerning the reason for the restriction on dispensing and further handling shall be provided and a list of the persons who were notified of the restriction shall be compiled. The inventory of the medicinal product shall be registered at the time of establishment of a restriction on dispensing. The information included in the documentation shall enable identification of the medicinal product.
- (9) A report shall be prepared concerning a recall which shall set out the quantity of the received, dispensed and recalled medicinal products and the way of further handling of the medicinal products.
- (10) The documentation concerning a restriction on dispensing and the report concerning a recall shall be submitted at the request of the State Agency of Medicines.

### § 13. Maintaining records

- (1) The arrival, price formation and dispensing of each medicinal product shall be registered in the records of medicinal products.
- (2) The records of medicinal products maintained at a wholesaler shall ensure identification of the supplier and recipient of each medicinal product.
- (3) The records shall include the following information with regard to each batch of medicinal products:
  - 1) name of the proprietary medicinal product;
  - 2) pharmaceutical form;
  - 3) active substance(s) and the content thereof;
  - 4) quantity in the packaging;
  - 5) ATC-code;
  - 6) code of the Coding Centre;
  - 7) number of the batch of medicinal products;
  - 8) market authorisation holder and manufacturer;
  - 9) the name and address of the supplier;
  - 10) date of arrival;
  - 11) total number of the arrived packages;
  - 12) purchase and selling price of the medicinal product;

13) number of the special authorisation and authorisation for use granted by the State Agency of Medicines, if such documents exist;

14) number of the delivery note;

15) date of dispensing and quantity of the medicinal product;

16) name and address of the recipient of the medicinal product.

(4) The information concerning a batch of medicinal products specified in subsection (3), special authorisations, authorisations for use, certificates of quality and delivery notes shall be preserved at the place of business of the wholesaler for one year as of the sale of the batch of medicinal products.

(5) A wholesaler shall preserve the information specified in subsections (3) and (4) for at least five years, the information concerning narcotic drugs for at least ten years.

#### § 14. Internal audit

(1) Internal audit shall be carried out at a wholesaler at least once a year in order to monitor implementation of and adherence to the requirements of legislation, adherence to the operational rules and job descriptions and make proposals for taking measures.

(2) Internal audits shall be formalised as reports. A report shall include the results of the audit, proposals for taking measures. An auditor shall confirm the report by the date and his or her signature.

#### § 15. Reporting

(1) A holder of an activity licence for wholesale distribution shall submit a consolidated report of all its wholesalers concerning the medicinal products procured, dispensed and stored during the previous accounting period. If medicinal products are not procured or dispensed during an accounting period, the State Agency of Medicines shall be notified thereof during the term established in subsection (2) of this section.

(2) Quarterly reports of medicinal products shall be submitted:

1) by 15 April as at 31 March;

2) by 15 July as at 30 June;

3) by 15 October as at 30 September;

4) by 1 February as at 31 December.

(3) A report shall contain the following information with respect to each medicinal product:

1) name of the proprietary medicinal product;

- 2) pharmaceutical form;
- 3) ATC code;
- 4) active substance(s) and the content thereof;
- 5) quantity in a packaging;
- 6) market authorisation holder or, in the absence thereof, manufacturer of the medicinal product;
- 7) code of the Coding Centre;
- 8) number of packagings of medicinal products in stock at the beginning of the accounting period;
- 9) the quantities arrived by differentiating the quantity of imported medicinal products and the quantity of the medicinal products purchased from the Estonian handlers of medicinal products;
- 10) the quantities dispensed by differentiating the following groups: the quantity exported, the quantity dispensed to Estonian general pharmacies, hospital pharmacies, veterinary pharmacies, wholesalers of medicinal products, wholesalers of veterinary medicinal products, veterinarians and other agencies;
- 11) the quantity withdrawn from the market or written off for any other reason;
- 12) the quantity returned to the supplier or manufacturer;
- 13) the quantity sent for control analysis;
- 14) the quantity delivered as advertising samples;
- 15) the number of packagings of medicinal products in stock at the end of the accounting period.

(4) In clause (3) 10) the total wholesale price of the dispensed quantity shall be indicated with regard to each differentiated group.

(5) The State Agency of Medicines shall publish instructions for the preparation of a report on its web site.

(6) Wholesalers shall check the stocks at least once a year. Discrepancies shall be documented and submitted to the State Agency of Medicines in the report following the abovementioned check.

## § 16. Termination of wholesale activities

(1) Upon dissolution of the holder of an activity licence or termination of the activity entered in an activity licence, the medicinal products at the wholesaler shall be transferred to the holder of an activity licence for handling of medicinal products or a person who has the

right to make wholesale purchases of medicinal products, or the medicinal products shall be withdrawn from the market within two months as of the date of termination unless otherwise specified by the State Agency of Medicines. Information concerning transfer or withdrawal shall be submitted to the State Agency of Medicines at the request thereof.

(2) The requirements established in § 8 shall be adhered to upon the transfer of medicinal products.

(3) Upon termination of wholesale activities, a report shall be submitted to the State Agency of Medicines containing the following information:

- 1) name of the proprietary medicinal product;
- 2) number of batch.
- 3) pharmaceutical form;
- 4) content of active substance(s);
- 5) quantity in a packaging;
- 6) market authorisation holder or, in the absence thereof, manufacturer of the medicinal product;
- 7) the quantity in stock.

(4) Upon termination of the transfer of medicinal products a report concerning the period following the last quarterly report shall be submitted to the State Agency of Medicines pursuant to the procedure established in § 15.

(5) After termination of the activities of a wholesaler, the competent person or the head of the enterprise shall be responsible for the transfer of medicinal products, including for the transfer of medicinal products for destruction, for the quality of medicinal products and preservation of the relevant accompanying documents until destroying them on site or until they are returned.

#### § 17. Implementing provisions

(1) Wholesalers shall, within one month as of entry into force of this Regulation, notify the State Agency of Medicines in writing of the name, title of office and telephone number(s) of the contact person specified in subsection 12 (2).

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

(3) Clauses 8 (7) 4), 13 (3) 6) and 15 (3) 7) of this Regulation enter into force on 1 October 2005.

<sup>1</sup> Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, pp. 1–6); Directive 2001/83/EC of the European Parliament and of the 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 of the 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 of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.04.2004, pp. 58–84).

<sup>2</sup> RTL = *Riigi Teataja Lisa* = *Appendix to the State Gazette*

<sup>3</sup> RT = *Riigi Teataja* = *State Gazette*