H4 The Regulation of the Minister of Social Affairs No. 17 of April 29, 1996

Unofficial translation
MINISTRY OF SOCIAL AFFAIRS
REGULATION OF MINISTER No. 17 Tallinn, 29 April 1996

Approval of the Procedure for Wholesale Trade of Medicinal Products

On the basis of section 8 of the Medicinal Products Act (RT I 1996, 3, 1996),
I regulate that:
1. The attached Procedure for Wholesale Trade of Medicinal Products is approved.
2. Regulation No. 26 of 31 March 1994 of the Minister of Social Affairs Amendments to the rules concerning wholesale trade of medicinal products (RTL 1994, 19, 640) is repealed.
3. The committee of experts granting activity licences for the manufacture, wholesale and retail trade of medicinal products shall operate on the basis of this regulation.
4. Supervision over compliance with this Regulation is assigned to the State Agency of Medicines.

Toomas Vilosius
Minister

Jaan Rüütmann
Secretary General

Approved by Regulation No 17 of 29 April 1996 of the Minister of Social Affairs
PROCEDURE FOR WHOLESALE TRADE OF MEDICINAL PRODUCTS

1. MAIN REQUIREMENTS
1.1. Wholesale trade of medicinal products shall be subject to the conditions set out in the wholesaling licence and comply with the legislation relating to medicinal products.
1.2. An enterprise wholesaling medicinal products (hereinafter wholesaler) shall ensure the appropriate conditions of storage and transport of medicinal products and the timely supply to the consignee.
1.3. A wholesaler shall employ a person with a completed higher education in pharmacy or in other appropriate field, designated as responsible for the quality of medicinal products.
1.4. Internal procedures for the work operations which affect the quality of medicinal products and are connected with the movement of products (receipt, storage, maintenance of premises and equipment, vermin control, handling of products removed from sale or recalled) shall be approved and responsible persons designated. The procedures shall be approved by the head of the wholesaler or by the person who is responsible for the quality of medicinal products.

2. APPLICATION FOR IMPORT AND EXPORT CERTIFICATE
2.1. For import and export of medicinal products, a wholesaler shall apply to the State Agency of Medicines for a permit for each consignment, stating the importer, exporter, boarder crossing point and mode of transport. The permit is issued as an import or export certificate.
2.2. Upon application for an export certificate for narcotic or psychotropic substances, the wholesaler shall present, in addition to the application, the import licence for each consignment, issued by the state importing such medicinal products.
2.3. An application for an import or export certificate shall be submitted to the State Agency of Medicines at least five working days before the arrival of the consignment of medicinal products at the boarder crossing point.
2.4. Upon application for an import or export certificate of medicinal products, the following information concerning each product shall be submitted to the State Agency of Medicines:
- the trade name of the medicinal product;
- the pharmaceutical form;
- the active ingredient(s) and the content thereof;
- the content of a packaging;

- the manufacturer;
- the ATC code of the medicinal product;
- the total number of packagings.

Upon application for an import certificate for a medicinal product which is not registered in Estonia, the wholesaler shall, at the request of the State Agency of Medicines, submit information about the product concerning the manufacturing conditions and characteristics of use.

2.5. The State Agency of Medicines may refuse to grant an import or export certificate if:
- upon application for the certificate, insufficient or false information is submitted;
- the wholesaler does not comply with the legislation relating to medicinal products;
- the operations of the wholesaler do not ensure the quality or identification of the medicinal products marketed by it;
- the use of the medicinal product to be imported is prohibited in Estonia or the use of the medicinal product to be exported is prohibited in the importing state;
- there is reason to doubt in the quality of the product;
- the wholesaler does not comply with the procedure for the recording and reporting concerning medicinal products.

3. RECEIPT, STORAGE AND SALE OF MEDICINAL PRODUCTS

3.1. Conclusion of contracts for procurement of medicinal products, placing of orders and receipt of medicinal products shall be arranged by the head of a wholesaler or a person with an appropriate qualification designated by him or her.

3.2. Upon receipt of medicinal products, the acceptor shall check the packaging and labelling against the consignment notes, examine the expiry dates and the validity of execution of the consignment notes.

3.3. Upon procurement of medicinal products or raw materials a wholesaler shall require, from the manufacturer or other wholesaler, the presentation of documents which certify the quality of the batch (quality certificates). Upon the request of the purchaser of the medicinal product, the quality certificate shall be delivered to him or her.

3.4. A medicinal product shall be subject to physical separation from other medicinal products and keeping of separate records if:
- the quality of the medicinal product, on the basis of the consignment notes, is not guaranteed;
- the quality or identity of the medicinal product is suspicious for other reasons;
- the medicinal product was supplied as humanitarian aid;
- the expiry date of the medicinal product has passed;
- the medicinal product is in a defective packaging or clearly or probably contaminated.

3.5. Separate written records shall be kept concerning narcotic medicinal products and the medicinal products which are specified by the Minister of Social Affairs or the State Agency of Medicines as subject to special recording.

3.6. Upon arrival of a consignment of narcotic medicinal products, a wholesaler shall call in an inspector of the State Agency of Medicines who shall inspect the arrived medicinal products against the consignment notes.

3.7. A wholesaler shall be responsible for the quality of the medicinal products as of the moment of their acceptance.

3.8. Medicinal products shall be stored according to the conditions established by the manufacturer.

3.9. Upon marketing a medicinal product, a wholesaler shall issue a consignment note which will set out:
- the date of distribution of the medicinal product;
- the seller and the purchaser (consignee);
- the trade name of the medicinal product;
- the pharmaceutical form;
- the content of active ingredients;
- the content of the packaging;
- the total number of packagings;
- the batch number of the medicinal product;
- the manufacturer of the medicinal product and the home country of the manufacturer;
- the categorisation of the medicinal product as an over-the-counter or a prescription medicinal product;
- the sale price.

3.10. The consignment note shall be made in two copies, one of which shall be kept by the seller and the other by the purchaser (consignee) of the medicinal product. The consignment note shall have space for the calculation of the retail price.
3.11. If, on the basis of consignment documents, the quality of a medicinal product is not guaranteed as required (e.g. the quality certificate is missing) or if the quality of the medicinal product is suspicious for other reasons, the medicinal product may be marketed only after a corresponding permit is obtained from the State Agency of Medicines.
3.13. A wholesaler is prohibited to market sub-standard medicinal products and medicinal products with expiry dates in less than two months' time.
3.14. A wholesaler may market medicinal products only in the original packaging of the manufacturer.
3.15. Raw materials which are used in the manufacture of medicinal products may be re-packaged by the wholesaler only under the conditions and pursuant to the procedure established by the State Agency of Medicines. Re-packaging shall mean all the operations in the course of which the original packaging marketed by the manufacturer is changed.
3.16. Transport of medicinal products shall be arranged in a manner which avoids contamination of and by other products; breaking of packaging, thefts and such conditions of temperature, humidity, light, etc. which are inappropriate for medicinal products.
3.17. A wholesaler is required to inform the purchaser immediately about the source of procurement and price formation concerning the purchased medicinal product.
3.18. If a medicinal product is sub-standard or its date of expiry has passed, the medicinal product shall be rendered harmless or returned pursuant to procedure established by the Minister of Social Affairs.

4. RECORDING CONCERNING MEDICINAL PRODUCTS
4.1. A wholesaler shall keep records concerning medicinal products which permit the identification of the source of procurement and the consignee(s) of each medicinal product.
4.2. The book keeping of a wholesaler shall record the receipt, price formation and sale of each medicinal product.
4.3. A wholesaler shall keep records which include the following information concerning each medicinal product:
- the trade name of the medicinal product;
- the pharmaceutical form;
- the active ingredient(s) and the contents thereof;
- the content of the packaging;
- the ATC code;
- the batch number of the medicinal product;
- the manufacturer of the medicinal product and the home country of the manufacturer;
- the date of receipt of the medicinal product;
- the total number of packagings received;
- the customs declaration number of the consignment;
- the import price of the medicinal product;
- the numbers of the certificate and the marketing permission issued by the State Agency of Medicines;
- the date of sale and the price of the medicinal product;
- the purchaser (consignee) of the medicinal product.
4.4. The information specified in point 4.3. concerning each batch of medicinal products, import and export certificates, quality certificates and consignment notes shall be retained by a wholesaler for five years; in the case of narcotic and psychotropic medicinal products for ten years.
4.5. A wholesaler shall have an effective system for suspension of distribution and for recall of a distributed medicinal products if the product has been proven sub-standard or if an order to this effect is given by the State Agency of Medicines. A wholesaler shall have written procedures and a person designated as responsible for suspension of distribution and recall. The recorded data shall ensure the identification of the medicinal product, state the reason for the recall and the decision concerning the measures to be taken. The manufacturer shall inform the State Agency of Medicines of each recall.

5. REPORTING CONCERNING MEDICINAL PRODUCTS

5.1. All wholesalers shall present a semi-annual report to the State Agency of Medicines by 15 July (as at 30 June) and an annual report by 1 February (as at 31 December) concerning the medicinal products purchased, sold and kept in stock by them.
5.2. A report presented to the State Agency of Medicines shall include the following information concerning each medicinal product:
- the trade name of the medicinal product;
- the pharmaceutical form;
- the active ingredient(s) and the contents thereof;
- the content of the packaging;
- the ATC code;
- the manufacturer of the medicinal product and the home country of the manufacturer;
- the total number of packagings.
5.3. A report shall show the sources of procurement (imported, purchased from a wholesaler in Estonia, procured from other sources) separately, stating the names of the enterprises,
5.4. Concerning the marketing of medicinal products, a report shall distinguish between the medicinal products exported, sold to pharmacies in Estonia, sold to wholesalers in Estonia, sold to health care institutions in Estonia, and sold to other institutions in Estonia, stating the names of the consignees. The medicinal products removed from sale and those sent for analysis shall be shown separately.
5.5. A report shall be presented in accordance with the ATC classification pursuant to the procedure established by the State Agency of Medicines.
5.6. A wholesaler shall take stock at least once a year; the differences must be documented and shown in the annual report to the State Agency of Medicines.

6.CONTROL
6.1. The State Agency of Medicines shall, at least once in two years, inspect all the wholesalers and examine the compliance of the storage and record keeping concerning medicinal products with the established requirements and the conditions specified upon the granting of the wholesaling licence.
6.2. In the course of an inspection, the State Agency of Medicines may take samples for control analysis if necessary. If the quality of a medicinal product does not meet the requirements, the costs of the analysis shall be borne by the manufacturer of the medicinal product. The analysis costs must not be added to the import price in the cost-plus pricing of the medicinal product.
6.3. The course and results of an inspection by the State Agency of Medicines shall be documented. After the end of the inspection, the wholesaler shall be informed of the results and, if necessary, precepts are made in two copies which shall be signed by the inspector and the representative of the inspected wholesaler. A complete report of the inspection shall be written within two weeks and, at the request of the wholesaler, a copy of the report will be sent to it. All reports shall be retained at the State Agency of Medicines for ten years after the date of the inspection.