Cabinet

Regulation No. 416

Adopted 26 June 2007

**Procedures Regarding the Distribution and Quality Control of Medicinal Products**

*Issued pursuant to*

*Section 5, Clauses 3 and 25 and Section 19 of the Pharmaceutical Law*

*[8 October 2013]*

**I. General Provisions**

1. This Regulation prescribes the procedures for the distribution and quality control of medicinal products (except veterinary medicinal products), including homeopathic medicinal products and herbal medicinal products, as well as the procedures for and amount of wholesale data necessary for analysis of availability of medicinal products.

*[8 October 2013]*

2. This Regulation shall apply to the medicinal products which:

2.1. have been manufactured industrially or prepared, using a method which includes an industrial process;

2.2. in accordance with a prescription *(formula magistralis)* have been prepared at a pharmacy for an individual patient;

2.3. have been prepared at a pharmacy according to pharmacopoeial monographs and which are intended to be supplied directly to the patients who are served by the relevant pharmacy *(formula officinalis)*;

2.4. a natural person imports, exports, sends by post or receives by post for personal use;

2.5. have been received or sent by postal consignments. It shall also apply to the states other than the European Union and European Economic Area states (hereinafter – the third countries);

2.6. have been given as a gift.

*[27 July 2010]*

3. In free ports and special economic zones, and places referred to in Section 9, Paragraph two of the Customs Law, the requirements for distribution and quality control of medicinal products, as well as the control and surveillance measures specified in this Regulation shall be applied.

*[27 July 2010]*

4. This Regulation shall not apply to the import of medicinal products across the customs border from the states other than the European Union and European Economic Area states and the export of medicinal products across the customs border to the third countries (except medicinal products which a natural person imports or receives by post for personal use).

5. For the purpose of this Regulation:

5.1. suspicion of a defect shall be raised, if such notification regarding medicinal products has been received in which it is indicated that they do not have the quality specified in the registration documentation of the medicinal products;

5.2. medicinal products have a quality defect, if the whole batch of medicinal products or a part thereof does not comply with the prescribed requirements and the medicinal products pose a danger to the user, also if it is related to the packaging of the product;

5.3. a registration owner is a person referred to in the laws and regulations regarding the procedures for registering medicinal products;

5.4. a recall of a batch are activities performed to withdraw a batch of medicinal products from the network of distribution and users;

5.5. a retail trade of medicinal products is the distribution of medicinal products to the public by a pharmacy;

5.6. the wholesale of medicinal products are all the activities which include the acquisition, storage, supply or export of medicinal products (bringing out of medicinal products from the customs territory of a European Economic Area state to the third countries), except the supply of medicinal products to the public;

5.7. [8 October 2013];

5.8. medicinal products given as a gift is distribution of medicinal products free of charge in compliance with the requirements specified in Paragraph 10 of this Regulation, regardless of which of the market participants is giving the medicinal products as a gift;

5.9. brokering of medicinal products are all activities in relation to the sale or acquisition of medicinal products (except the wholesale distribution of medicinal products) that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;

5.10. good distribution practice of medicinal products is a part of the quality assurance system which guarantees that the quality of medicinal products is conserved in all stages of the delivery chain from the manufacturing plant of medicinal products to a pharmacy or medical treatment institution, social care institution, practising veterinarians, practitioners, or institutions engaged in veterinary medical care;

5.11. repackaging is movement of primary packaging of medicinal products from one secondary packaging to another secondary packaging, placement of the package leaflet in the secondary packaging or attaching thereof to the packaging of medicinal products (also by using a sticker), as well as attaching of a sticker or new labelling on the packaging or covering of the text part of the labelling.

*[27 July 2010; 8 October 2013; 3 December 2013; 2 February 2016]*

6. The parallel import of medicinal products is the primary placement on the market of medicinal products, registered within a national registration procedure (also mutual recognition procedure and decentralised procedure) and delivered from a European Economic Area state, for distribution in Latvia to a pharmacy, medical treatment institution, social care institutions, practising veterinarians, practitioners, and an institution engaged in veterinary medical care, if they are placed on the market by such wholesaler of medicinal products which is not the manufacturer of such medicinal products, the registration owner or their authorised representative (hereinafter – the parallel importer).

*[2 February 2016]*

7. The parallel distribution of medicinal products is the placement on the market of medicinal products, registered within the centralised registration system and delivered from a European Economic Area state, in Latvia, if they are placed on the market by such wholesaler of medicinal products which is not the manufacturer of such medicinal products, the registration owner or their authorised representative (hereinafter – the parallel distributor).

*[2 February 2016]*

8. The centralised registration procedure is the registration of medicinal products pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (hereinafter – Regulation No 726/2004 of the European Parliament and of the Council).

9. Regarding the deliveries of narcotic and psychotropic medicinal products from a European Economic Area state and to a European Economic Area state in addition to the requirements laid down in this Regulation, the requirements which are specified in the Law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products shall be observed.

10. Medicinal products given as a gift shall comply with the following requirements:

10.1. medicinal products shall be given as a gift only to a medical treatment institution or a social care institution in accordance with the requirements of the laws and regulations regarding the procedures for the acquisition, storage, use and accounting of medicinal products in medical treatment institutions and social care institutions;

10.2. a written consent for receipt of particular medicinal products has been received from a medical treatment institution or a social care institution, specifying the name of medicinal products, strength or concentration, form, quantity in one packaging and the number of containers. If medicinal products are given as a gift to a medical treatment institution, the medicinal products to be given as a gift and the quantity thereof shall conform to the profile of activities and volume of work of the medical treatment institution, and shall be suitable for treatment of patients present at the medical treatment institution. If medicinal products are given as a gift to a social care institution, medicinal products to be given as a gift shall be suitable for treatment of patients present at the social care institution;

10.3. only registered non-prescription medicinal products shall be given as a gift to social care institutions;

10.4. a medical treatment institution is permitted to receive the following as a gift:

10.4.1. such registered medicinal products that are not included in the list of reimbursable medicinal products, which is referred to in the laws and regulations regarding the procedures for the reimbursement of expenses for the acquisition of medicinal products and medical devices intended for out-patient medical treatment (hereinafter – the list of reimbursable medicinal products) (shall not refer to the medicinal products from List C of the list of reimbursable medicinal products);

10.4.2. unregistered medicinal products available for compassionate use within the framework of the programme referred to in Sub-paragraph 94.3 3.3 of this Regulation, only to such a medical treatment institution which is indicated in the relevant authorisation for distribution of unregistered medicinal products for individually granted medicinal products. The donor of the medicinal products shall ensure that the conditions referred to in Article 83(8) of Regulation (EC) No 726/2004 of the European Parliament and of the Council are met;

10.5. the donor of medicinal products shall ensure that the patients who are treated with the given medicinal products are able to continue medical treatment with these medicinal products as long as it is necessary or until such period of time when such medicinal products are included in the list of reimbursable medicinal products and are available within the scope of the reimbursement system for the acquisition of medicinal products;

10.6. at the moment of receipt of medicinal products, not less than one year shall remain until the expiry date of the medicinal products, but if the total period for use of the medicinal products is less than one year, not less than a half of the total period for use of the medicinal products shall remain until the expiry date of the medicinal products;

10.7. a bill of lading shall be drawn up for the medicinal products given as gifts;

10.8. the donor of the medicinal products shall ensure the collection and disposal of the unused medicinal products that were given as a gift in accordance with the laws and regulations governing the circulation of hazardous waste.

*[27 July 2010]*

**II. Requirements for the Wholesale of Medicinal Products**

11. Such merchant or person registered with the State Revenue Service as a performer of economic activity (hereinafter – the performer of economic activity) is allowed to distribute medicinal products in wholesale to whom, in accordance with the laws and regulations regarding the procedures for the licensing of pharmaceutical activity, the State Agency of Medicines has issued:

11.1. a special authorisation (licence) for the opening (operation) of a medicinal product wholesaler;

11.2. a special authorisation (licence) for the manufacturing or import of medicinal products which grants a holder of the authorisation the right to wholesale distribution of the medicinal products manufactured by it which the State Agency of Medicines has, when issuing the abovementioned special authorisation (licence), included in the database in conformity with the laws and regulations regarding the procedures for the licensing of pharmaceutical activity;

11.3. [27 July 2010].

*[11 September 2012; 2 February 2016]*

11.1 [8 October 2013]

12. The person referred to in Paragraph 11 of this Regulation (hereinafter – the wholesaler of medicinal products) shall ensure the implementation of the following requirements when distributing medicinal products in wholesale:

12.1. ensure that the premises, equipment and installations are available to officials of the Health Inspectorate for control at any time;

12.2. acquire medicinal products (or receive them in a postal consignment) only from such persons which hold the special authorisation (licence) referred to in Sub-paragraph 11.1 or 11.2 or Paragraph 13 of this Regulation;

12.3. deliver medicinal products (or send them in a postal consignment) only to such persons which have the right to distribute medicinal products in wholesale trade or retail trade and to medical treatment institutions, social care institutions, practising veterinarians, institutions engaged in veterinary medical care which have the right to acquire the medicinal products in accordance with the laws and regulations regarding the procedures for the acquisition, storage, use, accounting and destruction of medicinal products in medical treatment institutions and social care institutions, the procedures by which a person engaged in veterinary medical practice shall perform activities with narcotic and psychotropic medicinal products, and the procedures by which a person engaged in veterinary medical practice shall acquire, store and use medicinal products. Medicinal products shall be delivered without dividing the secondary packaging, except in the case when they have been repackaged;

12.4. develop an emergency situation plan in co-operation with the relevant manufacturer of the medicinal products or the owner of the medicinal products, or according to the order of the Health Inspectorate in order to ensure an effective recall of the medicinal products from the market;

12.5. record each transaction involving medicinal products received and supplied, using the purchase and sale invoices, or electronically, using a computer, or in any other way. At least the following information shall be indicated regarding medicinal products, also medicinal products which are a subject-matter of brokering of medicinal products:

12.5.1. the date of the transaction;

12.5.2. the name of the medicinal product, the form and strength or concentration of the medicinal product. For medicinal products registered in Latvia and parallel imported medicinal products in addition the product number which is assigned by the State Agency of Medicines for each size of packaging of medicinal products and which is indicated in the Medicinal Product Register of Latvia shall be indicated. For medicinal products registered in centralised registration procedure and parallel distributed medicinal products the European Union number assigned by the European Medicines Agency to the size of the packaging of strength of each pharmaceutical form which is indicated as the “Product number” in the Medicinal Product Register of Latvia, shall be indicated. For unregistered medicinal products the identification number indicated in the authorisation referred to in Paragraphs 86 and 94 of this Regulation for distribution of unregistered medicinal products for individually granted medicinal products (hereinafter – the identification number of medicinal products) shall be indicated;

12.5.3. the quantity of the medicinal products which is received, supplied, or which are a subject-matter of brokering of medicinal products;

12.5.4. the name and address of the consignee and supplier, as well as data for the identification thereof (for example, number of the special authorisation (licence));

12.5.5. the number and term of validity of each manufacturing batch of medicinal products supplied;

12.5.6. the price at which the medicinal products have been sold to the consignee of the medicinal products;

12.6. ensure that the data referred to in Sub-paragraph 12.5 of this Regulation are retained and available to officials of the Health Inspectorate for at least five years, but in regard to narcotic and psychotropic medicinal products and substances – at least 10 years;

12.7. observe the good distribution practice of medicinal products according to the guidelines for good distribution practice of medicinal products published by the European Commission (available in the official language on the website of the State Agency of Medicines);

12.8. ensure proper and continuous delivery of medicinal products to pharmacies which have received a special authorisation (licence) for the opening (operation) of a pharmacy (hereinafter – the pharmacy) and to persons who are entitled to deliver medicinal products in order to ensure the needs of patients, as well as, by fulfilling obligations towards public service, to guarantee permanent access to a sufficient range of medicinal products and the delivery of any quantity of medicinal products ordered in conformity with the request in a short period of time, also in place of medicinal products which are withdrawn from the market, if the distribution of medicinal products has been suspended and the medicinal products are being withdrawn from the market in accordance with Sub-paragraph 115.1 of this Regulation. The wholesaler that specialises in sale and delivery of medicinal products of a particular manufacturer shall guarantee execution of the duties specified in this Sub-paragraph in respect of the medicinal products of this manufacturer;

12.9. the wholesaler of medicinal products shall deliver as soon as possible medicinal products requested to be delivered urgently and present in the medicinal product stock by taking into account the distance to the place of delivery. Medicinal products that are included in the list of reimbursable medicinal products in accordance with the laws and regulations regarding the procedures for reimbursing expenses for the acquisition of medicinal products intended for medical treatment shall be delivered to a pharmacy upon a request of the pharmacy within 24 hours;

12.10. distribute only such medicinal products regarding prices of which information has been provided in accordance with the laws and regulations regarding the principles for determination of the price of medicinal product. This requirement shall not be applicable to unregistered medicinal products;

12.11. inform the Health Inspectorate and, if necessary, the owner of the medicinal product registration certificate without delay, if the medicinal products received or supplied are counterfeit or there are grounds for suspecting that they might be counterfeit;

12.12. create and maintain a quality system in which the duties, processes, and risk management measures are specified in relation to the type and volume of activity;

12.13. for all supplies of medicinal products a document shall be enclosed where the following is indicated:

12.13.1. the date of supply;

12.13.2. the supplied quantity (for each medicinal product);

12.13.3. the information referred to in Sub-paragraphs 12.5.2, 12.5.4 and 12.5.6 of this Regulation;

12.14. approve the official responsible for conformity with good distribution practice who is a pharmacist or whose qualification and experience is similar to the qualification of the responsible official specified in the laws and regulations regarding manufacturing control of medicinal products;

12.15. indicate the information on the labelling and package leaflet for medicinal products which are distributed to a pharmacy, medical treatment institution, social care institutions, practising veterinarians, practitioners, and institutions engaged in veterinary medical care in the official language in accordance with the laws and regulations regarding the procedures for labelling medicinal products and the requirements to be brought forward for a package leaflet. For medicinal products which are distributed in wholesale trade in order to export them to a third country or to supply them to another European Economic Area state, it shall be clearly indicated in the accompanying document that “Medicinal products are intended for export to the third countries or for supply to another European Economic Area state”. For parallel imported medicinal products in addition “Parallel imported medicinal products” shall be indicated in the accompanying document.

*[21 October 2008; 27 July 2010; 8 October 2013; 3 December 2013; 2 February 2016]*

12.1 A merchant or a performer of economic activity who has been issued a special authorisation (licence) for the opening (operation) of a pharmacy, shall distribute medicinal products to medical treatment institutions, social care institutions, practising veterinarians, and institutions engaged in veterinary medical care, ensuring the fulfilment of the requirements laid down in Sub-paragraphs 12.1, 12.2, 12.3, 12.4, 12.5, 12.6 and Chapter III of this Regulation.

*[27 July 2010; 11 September 2012; 8 October 2013; 3 December 2013]*

12.2 In order to implement the condition referred to in Sub-paragraph 12.2 of this Regulation, the wholesaler of medicinal products shall check, in cases if medicinal products have been obtained from another wholesaler of medicinal products, whether the supplier of medicinal products wholesaler complies with the good distribution practice specified in Sub-paragraph 12.7 of this Regulation and whether the supplier of medicinal products to a wholesaler of medicinal products has the licence referred to in Sub-paragraph 11.1 or Paragraph 13 of this Regulation. If medicinal products are obtained from the manufacturer of medicinal products, the wholesaler of medicinal products shall check whether the manufacturer has the licence referred to in Sub-paragraph 11.2 of this Regulation for manufacturing of medicinal products or the licence referred to in Paragraph 13 of this Regulation. If medicinal products are obtained from the importer of medicinal products, the wholesaler of medicinal products shall check whether the importer has the licence referred to in Sub-paragraph 11.2 of this Regulation for importing of medicinal products.

*[8 October 2013; 3 December 2013]*

12.3 [2 February 2016]

12.4 If the medicinal products are directly received from a third country and it is not intended to place them on the market in Latvia or another European Economic Area state, but the medicinal products are acquired in the third countries from persons who are entitled to supply medicinal products, the requirement referred to in Sub-paragraph 12.2 of this Regulation shall not be applied to the wholesaler of medicinal products.

*[8 October 2013; see Paragraph 171.6]*

13. The requirements laid down for the wholesaler of medicinal products in this Regulation shall apply to the wholesalers of medicinal products which distribute medicinal products in Latvia in accordance with the requirements of Section 25.1 of the Pharmaceutical Law (a special authorisation (licence) issued in another European Economic Area state for the wholesale trade of medicinal products or manufacturing/import of medicinal products).

14. An undertaking registered in the European Economic Area state to which a special authorisation (licence) for the wholesale trade of medicinal products or manufacturing/import of medicinal products has been issued in the home state, prior to the commencement of the medicinal product wholesale in the territory of the Republic of Latvia, shall provide the State Agency of Medicines with the following information:

14.1. the type, date of issue, number of the special authorisation (licence) granted in a European Economic Area state and the competent authority of the state which has granted the special authorisation (licence);

14.2. the firm name of the branch of a foreign merchant, the registration number within the Register of Enterprises, the legal address and the address of the place of operation, telephone and fax number, electronic mail address of the undertaking;

14.3. the given name, surname, actual address of the place of employment, telephone and fax number and other means of communication of the official who is responsible for a good distribution practice.

15. The Health Inspectorate in accordance with the conditions of Section 25.1 of the Pharmaceutical Law shall:

15.1. require information from the relevant foreign competent authority regarding the licence of the undertaking and according to the competence shall ensure the exchange of information with foreign states;

15.2. inform undertakings regarding the obligations towards public services.

*[21 October 2008]*

16. The wholesaler of medicinal products shall appoint an official who is responsible for the fulfilment of the obligations towards public service and shall ensure that the abovementioned official is available (by telephone or using other means of communication) at any time of day or night, also, if in the case of emergency (spread of pathogens, toxins, chemical substances or nuclear radiation, during catastrophes, nature disasters, epidemics including pandemics), pharmacies or medical treatment institutions request medicinal products as a matter of urgency.

17. The wholesaler of medicinal products shall:

17.1. ensure an easy public access to the information regarding the distributable medicinal products and the prices thereof on its website;

17.2. notify the State Agency of Medicines of and indicate the website address of the wholesaler of medicinal products, where information regarding medicinal products and prices thereof is available.

*[27 July 2010]*

18. The persons referred to in Sub-paragraphs 11.1 and 11.2 and Paragraphs 12.1 and 13 of this Regulation shall notify the State Agency of Medicines regarding the sales data of medicinal products (including regarding parallel imported and parallel distributed medicinal products) for each month by the 15th date of the next month or for another time period requested by the State Agency of Medicines. The following shall be indicated in the notification:

18.1. the name of the medicinal products, the form, strength or concentration of the medicinal products, the number in the packaging, the quantity of distributed packagings, and the sales price of the medicinal products;

18.2. for medicinal products registered in Latvia and parallel imported medicinal products – the product number in the Medicinal Product Register of Latvia. For medicinal products registered in centralised registration procedure and parallel distributed medicinal products – the European Union number assigned by the European Medicines Agency.

18.3. for unregistered medicinal products – the identification number indicated in the authorisation referred to in Paragraphs 86 and 94 of this Regulation for distribution of unregistered medicinal products for individually granted medicinal products;

18.4. the consignee of the medicinal products by including an indication “pharmacy”, “wholesaler of medicinal products”, “medical treatment institution”, “veterinary medical care institution”, “practising veterinarian”, “practitioner”, “exported”, “brought out to a European Economic Area state” and “another consignee” (specifying if any).

*[27 July 2010; 11 September 2012; 8 October 2013; 3 December 2013; 2 February 2016]*

19. Once every six months (by 31 July and by 31 January) the wholesaler of medicinal products shall notify the State Agency of Medicines regarding the data on the quantity of the imported and exported medicinal products (it also refers to the deliveries both from and to the European Economic Area states). Data on the total turnover (in euros) (including value added tax), the turnover of medicinal products sold in Latvia (in euros) (including value added tax), and volume of the medicinal products exported and supplied to a European Economic Area state (in euros) shall be indicated in the notification.

*[8 October 2013; 3 December 2013 / Amendments shall come into force on 1 January 2014. See Paragraph 2 of the amendments]*

19.1 If the merchant or performer of economic activity referred to in Paragraph 12.1 of this Regulation receives or delivers medicinal products to a European Economic Area state, he shall ensure compliance with the requirement referred to in Paragraph 19 of this Regulation.

*[27 July 2010; 11 September 2012; 8 October 2013]*

20. Upon a request of the State Agency of Medicines, especially in relation to the pharmacovigilance system, the registration owner shall submit to the State Agency of Medicines all data regarding the sales volume of the medicinal products and any other data owned (governed) thereby which apply to the quantity of the used medicinal products.

*[8 October 2013]*

**III. Requirements for Good Distribution Practice of Medicinal Products for General or Open Type Pharmacy which Distributes Medicinal Products to Medical Treatment Institutions, Social Care Institutions, Practising Veterinarians and Institutions Engaged in Veterinary Medical Care**

*[3 December 2013]*

21. The properties of medicinal products may not change during the distribution process of medicinal products.

22. A person to whom a special authorisation (licence) for the opening (operation) of a pharmacy has been issued shall establish a quality system in order to ensure that:

22.1. the medicinal products, which are distributed, are permitted in conformity with the legal acts of the European Community and the Republic of Latvia (those registered in the Medicinal Product Register of Latvia, registered within a centralised procedure or other European Economic Area State, as well as permitted unregistered medicinal products);

22.2. the storage conditions of medicinal products are being observed at all times (also during the transportation of medicinal products) and they comply with the requirements specified by the manufacturer;

22.3. the contamination of the medicinal products from the addition of or mixing with other products may not be possible;

22.4. the turnover of the stored medicinal products conforms to the requirements laid down in this Chapter;

22.5. the medicinal products are stored in safe and secure areas;

22.6. the ordered medicinal products are delivered to the addressee in accordance with Sub-paragraph 12.8 of this Regulation;

22.7. the procedures for determination of any quality defects of the medicinal products are specified, and there should be an effective recall procedure.

*[8 October 2013; 3 December 2013]*

23. [3 December 2013]

24. [3 December 2013]

25. Orders of medicinal products shall be addressed only to persons who hold the special authorisation (licence) referred to in Sub-paragraphs 11.1 and 11.2 of this Regulation or to the persons referred to in Paragraph 13 of this Regulation.

26. In addition to the conditions specified in the laws and regulations regarding operation of pharmacies, the manager of the pharmacy shall ensure the development of written procedures regarding removal of medicinal products from the stock of medicinal products to be sold, returning and recall of medicinal products in accordance with the conditions referred to in Paragraph 31 of this Regulation, including in case of falsifications.

*[3 December 2013]*

27. Descriptions of the procedures shall be approved by the manager of the pharmacy with a signature.

*[3 December 2013]*

28. The manager of the pharmacy shall ensure that each acquisition and sale operation of medicinal products is recorded in minutes (records are made). The records (minutes) shall contain data by which all significant activities or events are traceable. The records (minutes) shall be retained for five years, and they shall be readily available. The information referred to in Sub-paragraph 12.5 of this Regulation shall be specified in the records (minutes).

*[3 December 2013]*

29. The manager of the pharmacy shall ensure conformity with the following requirements:

29.1. premises, equipment and installations ensure proper conservation and distribution of medicinal products. Monitoring devices are calibrated and verified;

29.2. implementation of the following requirements is ensured in the receipt of medicinal products:

29.2.1. the receiving bay is arranged so that medicinal products are protected from weather influences during unloading. The reception area is separated from the storage area. It is checked whether the ordered medicinal products have been received and if the packaging of medicinal products is not damaged;

29.2.2. medicinal products subject to specific storage measures (for example, narcotic medicinal products, medicinal products requiring a specific storage temperature – immunological products) are immediately identified and stored in accordance with the description of procedures and requirements referred to in Sub-paragraph 29.3 of this Regulation;

29.3. implementation of the following requirements is ensured in storage of medicinal products:

29.3.1. medicinal products are stored in accordance with the temperature regime specified on the labelling and package leaflet of the medicinal products, taking into account that:

29.3.1.1. room temperature is from +15 ° to +25 ° Celsius;

29.3.1.2. a cool place is from +8 ° to +15 ° Celsius;

29.3.1.3. a cold place is from +2 ° to +8 ° Celsius;

29.3.2. thermolabile medicinal products (medicinal products which are sensitive to higher or lower temperatures) are stored in a cold room or a refrigerator, ensuring the appropriate temperature regime and its recording;

29.3.3. medicinal products that are sensitive to light are stored in places impervious to light (for example, tightly sealed containers, special packaging). If the medicinal products do not have special packaging impervious to light, they are stored in a dark place;

29.3.4. volatile substances and substances sensitive to moisture are stored in a cool place tightly sealed. Hygroscopic substances are stored in a dry room in hermetically sealed containers or plastic packaging, the container is sealed and paraffined, if necessary;

29.3.5. colourants and flavouring substances are stored apart from other medicinal products and substances (for example, within separate cupboards in tightly sealed packaging);

29.3.6. medicinal plants and herbs thereof are stored in a dry, well-ventilated room. Glass, paper or plastic packaging is used for the storage of medicinal plants and herbs thereof. Plants containing essential oils are stored in tightly sealed packaging;

29.3.7. the temperature regime in the medicinal products storage room is monitored and recorded periodically;

29.3.8. if medicinal products require a specific storage temperature (for example, immunological preparations), the storage area is equipped with temperature recorders or other devices that will indicate the time periods when the specific temperature range has not been maintained. The control is adequate to maintain all parts of the storage area within such temperature range;

29.3.9. it is ensured that storage facilities are clean and free from litter, dust and pest, and relevant precautions are taken against spillage or packaging damage, micro-biological attack and cross contamination or mixing of medicinal products;

29.3.10. it is ensured that a system of stock rotation functions according to the principle that the product for which the term of validity expires first is distributed first (FEFO principle), as well as regular, periodic checks of system operation are carried out. Products beyond their expiry date or shelf life are stored apart from the usable stock, it is prohibited to either deliver or sell them;

29.3.11. if possible contamination is suspected, as well as medicinal products with a damaged seal or damaged packaging are withdrawn from the stock to be sold, and if not immediately destroyed, they are kept in a separated area so that they cannot be accidentally mixed in with other goods or sold in error. If necessary, such medicinal products are destroyed in accordance with the laws and regulations regarding hazardous waste disposal.

*[3 December 2013]*

30. The manager of the pharmacy shall ensure that deliveries of medicinal products conform to the following requirements:

30.1. [3 December 2013];

30.2. [3 December 2013];

30.3. [3 December 2013];

30.4. the medicinal products are transported in such a way that:

30.4.1. the identification thereof is not lost;

30.4.2. they do not contaminate or are not mixed together with other products or materials;

30.4.3. precautions are taken against their spillage, packaging damage or theft;

30.4.4. they are in a safe place (secure) and not subject to unacceptable temperature, light, moisture and other adverse influence, nor to microbiological attack and pests;

30.5. the medicinal products requiring controlled temperature storage are transported in accordance with the requirements laid down in Sub-paragraph 29.3.8 of this Regulation;

30.6. a person transporting medicinal products (a commercial carrier) takes the necessary precautionary measures to ensure that the vehicle is not used for illegal transport of medicinal products and informs the law enforcement authorities, if there is cause for suspicion that a vehicle is used illegally.

*[3 December 2013]*

31. The manager of the pharmacy shall ensure conformity with the following requirements:

31.1. in case of returning medicinal products, if medicinal products do not have quality defects, they are stored in such a manner as to prevent re-distribution of such medicinal products until a decision has been reached on their use;

31.2. in order to recall medicinal products, the following activities are performed:

31.2.1. an emergency plan for the urgent recall of medicinal products and procedures for the recall of medicinal products is developed in writing, if the emergency recall is not urgent, as well as a person responsible for the execution and co-ordination of recalls is appointed;

31.2.2. any recall operations are recorded at the time they are carried out. The minutes are accessible to officials of the Health Inspectorate in the pharmacy;

31.2.3. the system of recording of deliveries is developed to enable all consignees of medicinal products to be immediately identified and contacted;

31.2.4. if medicinal products are recalled, the persons to whom they have been supplied are notified regarding recall of medicinal products;

31.2.5. if medicinal products or a specific batch of medicinal products is recalled, according to the relevant class of quality faults the persons to whom they have been supplied are informed;

31.2.6. the medicinal products are recalled according to the notification approved by the registration owner, the manufacturer of medicinal products or the Health Inspectorate;

31.2.7. the recalled medicinal products are removed immediately from the stock of medicinal products to be sold and are stored in a secure area, labelled with a notification “nav paredzēts pārdošanai” [“not for sale”];

31.3. counterfeit medicinal products found in the distribution network are kept apart from other medicinal products to avoid any possibility of confusion. They are clearly labelled with a specific notification “nav paredzētas pārdošanai” [“not for sale”] and the registration owner and the Health Inspectorate are informed regarding them immediately, on the day of establishing the fact;

31.4. the return, rejection or recall of such medicinal products which are marked with a notification “nav paredzētas pārdošanai” [“not for sale”] as well as receipt of counterfeit medicinal products, is recorded at the time when the relevant operation is carried out. In each case a decision on the disposal of these products shall be taken, and it shall be documented and recorded.

*[3 December 2013; 2 February 2016]*

32. In order to monitor the implementation of and compliance with the good distribution principle, the manager of the pharmacy shall conduct self-control and shall record measures of the self-control.

*[3 December 2013]*

33. [3 December 2013]

**IV. Requirements for the Parallel Import of Medicinal Products**

34. The parallel import of medicinal products is allowed only in cases when the parallel importer has obtained an authorisation for distribution of parallel imported medicinal products within the Republic of Latvia in accordance with the requirements laid down in this Chapter and the abovementioned authorisation is valid.

34.1 A parallel importer shall request the information referred to in Parts II and II A of Annex 1 to this Regulation regarding parallel imported medicinal products from persons from whom medicinal products are acquired in another European Economic Area state. The parallel importer which supplies the parallel imported medicinal products to another wholesaler of medicinal products, shall provide the information referred to in Parts II and II A of Annex 1 to this Regulation to such wholesaler of medicinal products.

*[2 February 2016]*

35. A parallel importer shall notify, in accordance with Paragraph 39 of this Regulation, of its intention to distribute parallel imported medicinal products in Latvia to:

35.1. the registration owner (marketing authorisation owner);

35.2. the State Agency of Medicines;

35.3. the owner of the trademark of the medicinal products.

*[27 July 2010]*

36. If the parallel imported medicinal products are being re-packaged, a parallel importer shall, upon a request of the owner of the trademark of the medicinal products, deliver to him or her a sample of the re-packaged product.

37. The owner of a medicinal product trademark may not use the right to medicinal product trademark to prohibit re-packaging if:

37.1. the rights of the trademark used by the owner of the trademark in relation to the trading system developed by him or her promote artificial sharing of the market between the European Union Member States;

37.2. the re-packaging does not negatively affect the original condition of the product;

37.3. the re-packager and manufacturer of the product are indicated on the new packaging;

37.4. the packaging intended for the distribution of the re-packaged product does not cause detriment to the trademark and does not harm the reputation of the owner thereof;

37.5. the owner of the trademark receives advance notice prior to placing the product on the market.

38. Parallel imported medicinal products shall be registered (released for free circulation) in a European Economic Area state. Parallel import of medicinal products is allowed also, if a registration owner recalls registration of the medicinal product registered in Latvia due to economic reasons which are not related to the safety, efficiency and quality of the medicinal products, if the authorisation referred to in Paragraph 34 of this Regulation for distribution of parallel imported medicinal products in Latvia has been issued to the parallel importer and such authorisation is valid.

*[2 February 2016]*

39. In order to obtain the authorisation referred to in Paragraph 34 of this Regulation, a parallel importer shall submit to the State Agency of Medicines a request submission for an authorisation for distribution of parallel imported medicinal products (hereinafter – the submission) in accordance with Annex 1 to this Regulation, containing a certification that the parallel importer has notified the relevant medicinal product registration owner (marketing authorisation owner) and the owner of the trademark (brand) of the medicinal products regarding the intention to commence the distribution of the parallel imported medicinal products. Information regarding different types and sizes of packaging of parallel imported medicinal products (with the same pharmaceutical form and the same strength of medicinal products), as well as different countries from which the parallel imported medicinal products are supplied, may be indicated in one submission.

*[2 February 2016]*

40. The State Agency of Medicines shall, as soon as possible but not later than within five working days from the day of receipt of the submission at the State Agency of Medicines, perform primary expert-examination of the submitted information referred to in Paragraph 39 of this Regulation. It shall be checked in the primary expert-examination whether the submission has been drawn up in accordance with this Regulation and whether all documents have been submitted. The submitter of the submission shall be informed, without delay in electronic form, regarding the incomplete, incorrect information or information to be submitted in addition, as well as request for the competent authority of the state of origin of parallel imported medicinal products indicated in Annex 1 to this Regulation to submit the following information:

40.1. whether the particular medicinal product is registered (released for free circulation) in the state which is indicated in the request submission for an authorisation for distribution of parallel imported medicinal products (Annex 1), and whether the registration of the medicinal product (marketing authorisation) is valid, as well as the (registration) number and date of issue of the abovementioned authorisation;

40.2. the name, legal address and address of the place of operation of the medicinal product registration owner;

40.3. the firm name, legal address and address of the place of operation of the medicinal product manufacturer, as well as information regarding the fact whether the licence of the manufacturer is valid;

40.4. the qualitative and quantitative composition of a medicinal product;

40.5. the shelf life of the medicinal product and the recommended storage conditions;

40.6. [2 February 2016].

*[2 February 2016]*

41. The State Agency of Medicines shall check the submitted data and documents, taking into account the information received from another European Economic Area state, shall compare them to the relevant data of medicinal products registered in Latvia, and shall assess. Parallel imported medicinal products shall meet the following requirements:

41.1. the parallel imported medicinal products are registered (a marketing authorisation is issued) in the European Economic Area state which is indicated in the request submission for an authorisation for distribution of parallel imported medicinal products (Annex 1) as the state of origin;

41.2. the manufacturer of the parallel imported medicinal products (re-packager) has a special authorisation (licence) for manufacturing of the medicinal products, and the manufacturing conforms to the requirements of good manufacturing practice;

41.3. the package leaflet and labelling (in the official language) for parallel imported medicinal products conforms to the regulations regarding procedures for labelling medicinal products and the requirements to be brought forward for package leaflets of medicinal products, and the leaflet is not misleading and provides accurate and complete information regarding the nature, composition, therapeutic effect, use and storage of the product;

41.4. the parallel imported medicinal products are identical to the medicinal products registered in Latvia or they possess only such permissible differences which are indicated in the laws and regulations regarding the procedures for labelling medicinal products and the requirements to be brought forward for package leaflets of medicinal products. The differences may not influence the therapeutic effect of a parallel imported medicinal product, pose a threat to public health or mislead patients:

41.4.1. the parallel imported medicinal products and the medicinal products registered in Latvia are manufactured using the same manufacturing methods, they have the same active substances and therapeutic effect. The manufacturer of parallel imported medicinal products and the manufacturer of medicinal products registered in Latvia, indicated in the submission referred to in Paragraph 39 of this Regulation, may be the same undertaking or undertakings within the scope of the same group of undertakings, or in case if they are independent undertakings, the manufacturer of parallel imported medicinal products and the manufacturer of medicinal products registered in Latvia have a contract with the same registration owner of medicinal products;

41.4.2. the method of application introduced by the manufacturer of the medicinal products and the dose conform to the information regarding use and dose within the registration documentation of medicinal products registered in Latvia;

41.4.3. the difference (if such exists) in the colouring agent (other colour code) is small;

41.4.4. the difference (-s), if any, is(are) clearly indicated in the labelling;

41.5. [2 February 2016];

41.6. [2 February 2016];

41.7. a parallel imported medicinal product is re-packaged in accordance with the laws and regulations regarding manufacturing of medicinal products, and the labelling thereof is drawn up in conformity with the laws and regulations regarding the procedures for labelling medicinal products and the requirements to be brought forward for package leaflets of medicinal products.

*[2 February 2016]*

42. The State Agency of Medicines shall evaluate the compliance of parallel imported medicinal products with the requirements laid down in this Chapter and shall prepare an assessment report as soon as possible, as well as after assessment of parallel imported medicinal products shall take a decision to issue an authorisation for distribution of parallel imported medicinal products (Annex 2) or to refuse to issue an authorisation. An assessment report shall be prepared and a decision to issue an authorisation for distribution of parallel imported medicinal products or to refuse to issue an authorisation shall be taken in accordance with the procedures laid down in the Administrative Procedure Law within the following periods of time:

42.1. within one month from the day of receipt of the submission referred to in Paragraph 39 of this Regulation at the State Agency of Medicines;

42.2. within 15 days from receipt of the submission referred to in Paragraph 39 of this Regulation at the State Agency of Medicines, if the parallel imported medicinal products are identical to medicinal products registered in Latvia (only difference in the size of the packaging of medicinal products is admissible) – they have the same name and strength, as well as the registration owner of medicinal products and the manufacturer of medicinal products comply with Sub-paragraph 41.4.1 of this Regulation – or if the information on the packaging and the package leaflet is in the official language;

42.3. within five working days from receipt of the submission referred to in Paragraph 39 of this Regulation at the State Agency of Medicines, if the relevant medicinal products registered in Latvia are not available on the market and if, in case of not receiving the medicinal products in due time, the life of a patient is endangered or significant harm to the health of the patient is caused.

*[2 February 2016]*

43. If parallel imported medicinal products are different from medicinal products registered in Latvia with excipients, the State Agency of Medicines, if necessary, may perform a solubility test thereof and request a description of the manufacturing method from the competent authority of the relevant European Economic Area state, informing the submitter of the relevant submission thereof in writing. The samples for testing shall be submitted, upon request of the State Agency of Medicines, by the recipient of the authorisation for distribution parallel imported medicinal products. The expenses related to the sample testing of the medicinal product shall be covered by the parallel importer according to the price list of paid services of the State Agency of Medicines.

*[2 February 2016]*

44. The decision to issue an authorisation or to refuse to issue an authorisation shall be notified to the submitter in accordance with the procedures laid down in the Law On Notification.

*[2 February 2016]*

45. The State Agency of Medicines shall take a decision to refuse to issue an authorisation for distribution of parallel imported medicinal products if:

45.1. the submitted information does not comply with the requirements laid down in this Chapter;

45.2. due to safety, efficacy and quality of the medicinal products the distribution of the medicinal products registered in Latvia is prohibited or distribution has been suspended, or the medicinal product has been removed from the market in Latvia or another European Economic Area state;

45.3. registration of medicinal products registered in Latvia has been cancelled or suspended in accordance with the Pharmaceutical Law and the laws and regulations regarding the procedures for registering medicinal products. The abovementioned norm shall not apply to the case when the requester of registration has submitted a submission to suspend registration of medicinal products and the reason is not related to risks to the health of inhabitants;

45.4. the registration owner has revoked registration of medicinal products registered in Latvia and the reason for revocation is related to risks to the health of inhabitants (safety, quality and efficacy of medicinal products);

45.5. the medicinal products have not been re-registered;

45.6. re-registration of medicinal products has been refused.

*[11 September 2012]*

46. If variations to the registration documentation for medicinal products registered in Latvia have been approved in accordance with the laws and regulations regarding the procedures for registering medicinal products in respect of which an authorisation for distribution of parallel imported medicinal products has been issued or a submission for the receipt of an authorisation has been submitted, the State Agency of Medicines shall inform the parallel importer and the submitter in writing:

46.1. regarding approval of the variations and distribution of the remaining stock of medicinal products in accordance with Paragraph 78 or 79 of this Regulation;

46.2. how the variations affect the dispensation of medicinal products (variation of classification), whether variations concern significant parts of the registration documentation of medicinal products which conform to I B or II type variations in the registration documentation or which are related to expanding registration in accordance with Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (hereinafter – Regulation No 1234/2008 of the European Commission), and issue the approved package leaflet of medicinal products to the parallel importer for the registered medicinal products.

*[2 February 2016]*

47. [11 September 2012]

48. The parallel importer shall:

48.1. after receipt of the information referred to in Paragraph 46 of this Regulation from the State Agency of Medicines, if variations in the package leaflet and labelling of medicinal products must be made, submit a submission (Annex 1) to the State Agency of Medicines, notifying regarding introduction of variations to the package leaflet and labelling of the parallel imported medicinal products;

48.2. act according to the information provided by the State Agency of Medicines regarding conditions for distribution of the remaining stock of medicinal products;

48.3. suspend the distribution of medicinal products, if variations concern significant parts of the registration documentation of medicinal products which conform to I B or II type variations in the registration documentation or which are related to expanding registration in accordance with Regulation No 1234/2008 of the European Commission, and if registration of medicinal products has been suspended or cancelled, as well as supply of the medicinal products is prohibited and the medicinal products are withdrawn from the market;

48.4. submit a submission to the State Agency of Medicines, notifying regarding variations to the administrative data, contact information or size of the packaging of the medicinal products to be distributed;

48.5. follow the variations which are related to the medicinal products registered in the state which is indicated in the request submission for an authorisation for distribution of parallel imported medicinal products (Annex 1) as the state of origin, and inform the State Agency of Medicines regarding variations which concern the medicinal products and the conditions for distribution of the remaining stock of medicinal products.

*[2 February 2016]*

49. If the legal requisites of the owner of the authorisation for distribution of parallel imported medicinal products change, he or she shall notify the State Agency of Medicines thereof in writing. The State Agency of Medicines shall decide on issuing of a new authorisation in accordance with the procedures laid down in the Administrative Procedure Law.

50. The State Agency of Medicines shall determine a specific classification group to which the parallel imported medicinal products, conforming to the medicinal products registered in Latvia, shall belong in accordance with the laws and regulations regarding the procedures for classification of medicinal products.

51. If belonging of the medicinal products registered in Latvia to the classification group referred to in Paragraph 50 of this Regulation is changed, the parallel imported medicinal products shall be distributed in conformity to the new medicinal product classification group specified for the medicinal products registered in Latvia.

52. The parallel importer shall:

52.1. after any operation related to medicinal product delivery from another European Economic Area state, make an accurate entry in a registration journal or another document intended for that purpose which confirms the origin of the parallel imported medicinal products, the medicinal product batch numbers and quantity;

52.2. provide information to the Health Inspectorate and the State Agency of Medicines regarding parallel imported medicinal products upon request of such authorities;

52.3. keep the medicinal product packaging material, if the packaging has not been opened when re-packaging (re-labelling) the medicinal product;

52.4. keep one sample of each re-packaging operation product (a medicinal product, packaging material, package leaflet), if the packaging has been opened (for example, to change the outer packaging or package leaflet) when re-packaging (re-labelling) the medicinal product.

*[21 October 2008]*

53. The submitter of a submission shall cover the expenses for receipt of the authorisation for distribution of parallel imported medicinal products according to the price list of paid services of the State Agency of Medicines. The authorisation shall be issued in the form of an electronic document by sending it to the electronic mail address of the submitter of the submission within three working days after the relevant parallel importer has paid the specified charge for assessment of the documents according to the price list of paid services of the State Agency of Medicines. The authorisation in the form of a printed document shall be issued within three working days after receipt of a request for an additional charge according to the price list of paid services of the State Agency of Medicines.

*[3 December 2013; 2 February 2016]*

54. If the authorisation for distribution of parallel imported medicinal products is refused or cancelled, the charge referred to in Paragraph 53 of this Regulation shall not be refunded.

55. The State Agency of Medicines shall take a decision to cancel the authorisation for distribution of parallel imported medicinal products if:

55.1. the State Agency of Medicines cancels the relevant registration of the medicinal products registered in Latvia or the competent authority cancels the registration (marketing authorisation) in the state which is indicated as the state of origin in the request submission for authorisation for distribution of parallel imported medicinal products (Annex 1), for the parallel imported medicinal products due to such reasons as are associated with a threat to public health (safety, quality and efficacy of medicinal products) or prohibits supply of medicinal products and withdraws medicinal products from the market;

55.2. the State Agency of Medicines does not approve the variations of the parallel imported medicinal products;

55.3. manufacture of the parallel imported medicinal products does not conform to the requirements of the good manufacturing practice specified in the laws and regulations regarding the manufacture and control of medicinal products;

55.4. the owner of the authorisation has provided false information regarding the parallel imported medicinal products.

*[2 February 2016]*

56. The State Agency of Medicines shall take a decision to suspend the authorisation for distribution of parallel imported medicinal products if:

56.1. the State Agency of Medicines suspends the relevant registration of the medicinal products registered in Latvia or the competent authority suspends the registration (marketing authorisation) in the state which is indicated as the state of origin in the request submission for authorisation for distribution of parallel imported medicinal products (Annex 1), for the parallel imported medicinal products due to such reasons as are associated with a threat to public health (safety, quality and efficacy of medicinal products);

56.2. the owner of the authorisation has not submitted to the State Agency of Medicines data and documents regarding the variations or has not implemented the variations in accordance with the procedures laid down in this Regulation;

56.3. manufacture of the parallel imported medicinal products does not conform to the requirements of the good manufacturing practice specified in the laws and regulations regarding the manufacture and control of medicinal products.

*[2 February 2016]*

57. The State Agency of Medicines shall take a decision to cancel the suspension of the authorisation for distribution of parallel imported medicinal products on the basis of a submission of the authorisation owner, if the reasons for suspending the operation of the authorisation have been eliminated.

58. The Health Inspectorate shall monitor and control the distribution of parallel imported medicinal products.

*[21 October 2008]*

59. The State Agency of Medicines shall ensure that the competent authorities of the European Economic Area states upon request receive information regarding the parallel imported medicinal products.

**V. Requirements for Parallel Distribution of Medicinal Products**

60. The parallel distributor shall, in accordance with Paragraph 60.1 of this Regulation, declare the intention to distribute medicinal products registered in a centralised manner to:

60.1. the registration owner (marketing authorisation owner) and to the State Agency of Medicines, but if supplies are delivered to another Member State – to the competent authority of the relevant state;

60.2. the owner of the medicinal product trademark. Prior to putting the re-packaged product on sale, as well as upon request of the owner of the medicinal product trademark, he or she shall be supplied with a sample of the re-packaged product;

60.3. the European Medicines Agency in accordance with Paragraphs 63 and 64 of this Regulation.

*[27 July 2010; 8 October 2013]*

60.1 The parallel distributor shall submit to the State Agency of Medicines a certification that:

60.1 1. it has notified the relevant medicinal product registration owner (marketing authorisation owner) and the owner of the trademark of the medicinal products regarding the intention to commence the distribution of the specific parallel distributed medicinal products in Latvia, by indicating the particular addressee who has been notified and the date of providing the notification;

60.1 2. it has submitted to the European Medicines Agency the notification referred to in Paragraphs 63 and 64 of this Regulation regarding specific parallel distributed medicinal products, and it shall indicate the date of submission thereof.

*[27 July 2010]*

60.2 The parallel distributor shall submit to the State Agency of Medicines a notification regarding the actual date of commencing distribution (sale) of medicinal products, indicating the identification number of the product referred to in Sub-paragraph 18.2 of this Regulation for each size of the packaging of registered pharmaceutical form, and shall, without delay, inform regarding the medicinal products which are permanently or temporarily not placed on the market of Latvia.

*[2 February 2016]*

61. The owner of a medicinal product trademark shall not use trademark rights to prohibit re-packaging in the cases referred to in Paragraph 37 of this Regulation.

62. The distribution of parallel imported medicinal products is allowed, also if the registration owner of medicinal products registered in a centralised manner does not commence the distribution of such medicinal products in Latvia.

63. The parallel distributor shall submit a notification to the European Medicines Agency regarding the parallel distribution of centrally registered medicinal products (hereinafter – the notification) in conformity with the application form specified by the European Medicines Agency (published on the European Medicines Agency website) so that the European Medicines Agency may fulfil the requirements of Article 57(1)(o) of Regulation No 726/2004 of the European Parliament and of the Council.

*[27 July 2010; 8 October 2013]*

63.1 The parallel distributor shall pay a fee to the European Medicines Agency for medicinal products which have been registered in accordance with Regulation No 726/2004 of the European Parliament and of the Council in order for the European Medicines Agency to check whether the conditions provided for in the marketing authorisation are conformed to.

*[8 October 2013]*

64. If the annexes to the European Community marketing authorisation of medicinal products are amended or data in the information provided by the parallel distributor in the notification changes (for example, information regarding the re-packer or parallel distributor changes), the parallel distributor shall submit a notification regarding variations in the distribution of centrally registered parallel medicinal products in conformity with the application form specified by the European Medicines Agency (published on the European Medicines Agency website). This notification shall be submitted also in the case, if the state in which it is intended to distribute the medicinal products is changed.

*[27 July 2010; 8 October 2013]*

65. If a parallel distributor implements variations to the packaging of medicinal products registered in a centralised manner, the variations shall be justified by the necessity of distributing the medicinal products. It is permitted to implement the following variations:

65.1. the information in the labelling and package leaflet is in the language of such state in which the medicinal products are offered for sale, and the abovementioned information is identical in all the languages used in the labelling and package leaflet;

65.2. the variations in the size of the packaging ensure that the offered packaging is included in the medicinal product marketing authorisation for the relevant medicinal products registered in the centralised registration procedure, issued by the European Community.

66. The Health Inspectorate shall monitor and control that the parallel distribution of medicinal products conforms to the requirements (labelling, package leaflet and batch identification) specified in the Annexes to the marketing authorisation of medicinal products from the European Community and that the notification provided by the European Medicines Agency in which the completion of notification examination is indicated, is applied.

*[21 October 2008]*

**V.1 Brokering of Medicinal Products**

*[8 October 2013]*

66.1 If medicinal products have been obtained via brokering, the wholesaler of medicinal products shall check whether the broker involved has complied with the requirements laid down in this Chapter.

66.2 Brokering of medicinal products may be carried out only by a person registered with the State Agency of Medicines. In order to register with the State Agency of Medicines, a person shall submit a submission to the State Agency of Medicines for registering a person who carries out transactions involving medicinal products (hereinafter – the registration submission) (Annex 2.1). At least the following information shall be indicated in the registration submission:

66.2 1. the given name and surname (performers of economic activity) or the firm name, legal address;

66.2 2. the address of the place of operation in Latvia;

66.2 3. the contact information in Latvia.

66.3 The person who carries out brokering of medicinal products shall notify the State Agency of Medicines regarding any variations in the data referred to in Paragraph 66.2 of this Regulation without delay, submitting the registration submission with the indicated variations (Annex 2.1).

66.4 The State Agency of Medicines shall register the person who carries out brokering of medicinal products, taking a decision to include it in the register which is publicly accessible on the website of the State Agency of Medicines. The State Agency of Medicines shall indicate the data referred to in Sub-paragraphs 66.2 1 and 66.2 2 of this Regulation regarding the person who carries out brokering of medicinal products in the abovementioned register.

66.5 A registration certificate (Annex 2.2) issued by the State Agency of Medicines shall certify the fact of registration. The State Agency of Medicines shall send the registration certificate in the form of an electronic document to the registered person to the electronic mail address indicated in the submission within three working days after payment for the expert-examination of the documentation submitted for the issuance of a registration certificate and for the performance of a check has been made. The registration certificate in the form of a printed document shall be issued within three working days after receipt of a request and for an additional charge for such service according to the price list of paid services of the State Agency of Medicines.

*[2 February 2016]*

66.6 The persons carrying out brokering of medicinal products shall:

66.6 1. ensure that the medicinal products which are the subject-matter of brokering, are registered in Latvia or in the centralised registration procedure referred to in Paragraph 8 of this Regulation;

66.6 2. create and maintain a quality system in which the duties, processes, and risk management measures are specified in relation to the type and volume of their activity.

66.7 The requirements laid down in Sub-paragraphs 12.4, 12.5, 12.6, 12.7 and 12.11 of this Regulation shall also be applied to brokering of medicinal products.

66.8 If the person carrying out brokering of medicinal products does not comply with the requirements referred to in Paragraphs 66.3, 66.6 and 66.7 of this Regulation, the State Agency of Medicines is entitled to take a decision to exclude the relevant person from the register referred to in Paragraph 66.4 of this Regulation. The State Agency of Medicines shall notify the decision to exclude from the register to the abovementioned person in accordance with the procedures laid down in the Law On Notification.

**VI. Special Requirements for Distribution of Medicinal Products in Pharmacies**

67. A pharmacy (a retailer of medicinal products) shall, within distribution of medicinal products, ensure implementation of the requirements referred to in Sub-paragraphs 12.1, 12.2, 12.4, 12.5, 12.6, 22.1, 22.2, 22.3, 22.5, 22.6, 22.7, 29.1, 29.2, 29.3, 31.3 and 31.4 of this Regulation.

*[27 July 2010]*

67.1 Medicinal products shall not be placed in the part of the customer servicing area in which customers are present.

*[4 August 2009 / Paragraph shall come into force on 1 September 2009. See Paragraph 171.1]*

68. A pharmacy is allowed to acquire medicinal plants (herbs) from the public and to distribute them to the public, if the head of the pharmacy has examined the medicinal plants (herbs) that have been acquired and has determined the conformity thereof to the description of the permitted pharmacopoeia monograph, as well as, if the place of medicinal plant harvesting and conditions of herb preparation are known to the head of the pharmacy.

69. Unregistered medicinal products may be dispensed in a pharmacy to inhabitants:

69.1. on the basis of a prescription completed in accordance with the laws and regulations regarding the writing out of prescriptions;

69.2. without a prescription, if the medicinal products are included in the authorisation for distribution referred to in Paragraph 86 of this Regulation and the State Agency of Medicines has determined inclusion of the particular medicinal products in the category of medicinal products not subject to medical prescription in accordance with the laws and regulations regarding the procedures for the classification of medicinal products.

*[27 July 2010]*

70. Medicinal products shall be dispensed in conformity with the quantity indicated in the prescription. If parallel imported medicinal products are different from the medicinal products registered in Latvia, when dispensing the abovementioned medicinal products in a pharmacy, the patient and doctor (by telephone) shall be informed regarding the difference between the parallel imported medicinal products and the medicinal products registered in Latvia.

70.1 Upon dispensing medicinal products for a prescription written out by a doctor, the pharmacists shall ascertain that the patient will be able to use the medicinal products dispensed, using them according to the dosage and frequency of use indicated by the physician, before expiry of their term of validity. Upon dispensing non-prescription medicinal products, the pharmacist shall inform the patient regarding the term of validity of medicinal products, if less than two months have left until expiry of the term of validity.

*[2 February 2016]*

71. If the medicinal products are not in the stocks of a pharmacy, the pharmacy, upon request of a patient, medical treatment institution, social care institution, practising veterinarian or institution engaged in veterinary medical care (hereinafter – the request of an institution and practising veterinarian) shall order the necessary medicinal products from the person referred to in Sub-paragraphs 11.1 and 11.2 and Paragraph 13 of this Regulation on the same day after receipt of the request. In respect of unregistered medicinal products the pharmacy shall ensure conformity with the requirements laid down in Paragraph 72 of this Regulation. After receipt of the medicinal products, the pharmacy shall:

71.1. immediately deliver the medicinal products or inform regarding receipt of the medicinal products the medical treatment institution, social care institution, practising veterinarian or institution engaged in veterinary medical care which has requested the medicinal products;

71.2. notify the patient who has ordered the medicinal products regarding receipt thereof.

*[27 July 2010; 8 October 2013]*

72. The pharmacy shall comply with the following requirements in distribution of medicinal products:

72.1. the pharmacy shall accept and register the prescription or the request of an institution and practising veterinarian referred to in Paragraph 71 of this Regulation, if unregistered medicinal products are not present in the stocks of the pharmacy;

72.2. contact the person referred to in Paragraph 11 or 13 of this Regulation on the matter of delivery of the unregistered medicinal products and submit to the abovementioned person a written request of the pharmacy for the delivery of the medicinal products. The prescription referred to in Sub-paragraph 72.1 of this Regulation and the request of an institution and practising veterinarian need not be appended to the request of the pharmacy. The pharmacy shall indicate the following in the request:

72.2.1. the name of the unregistered medicinal products to be delivered, the form, strength or concentration of the medicinal products, the quantity in the packaging unit, the quantity of the packaging units, the time period in which the medicinal products must be delivered, the name, licence number, contact information of the pharmacy, and the request number of the pharmacy;

72.2.2. the person who has written out the prescription, and the medical treatment institution, social care institution, institution engaged in veterinary medical care and practising veterinarian who requests the medicinal products;

72.2.3. the manufacturer of the medicinal products, if necessary;

72.3. is permitted not to provide a written request to the wholesaler of medicinal products regarding medicinal products which:

72.3.1. comply with the list of medicinal products specified by the National Health Service in accordance with the laws and regulations regarding the procedures for the acquisition, storage, use, accounting and destruction of medicinal products in medical treatment institutions and social care institutions, and which are required for provision of inpatient health care services paid from the State budget (hereinafter – the list of usable medicinal products) (shall apply to the request of an institution and practising veterinarian);

72.3.2. are distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment in accordance with the laws and regulations regarding the procedures for reimbursement of expenses for the acquisition of medicinal products and medical devices intended for out-patient medical treatment (hereinafter – the medicinal products which are distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment) (shall apply to the request of the pharmacy);

72.4. store the prescription, as well as the request of the institution and practising veterinarian, at the pharmacy.

*[27 July 2010; 11 September 2012; 2 February 2016]*

72.1 A pharmacy, upon receipt of prescriptions written out in the European Union, European Economic Area states and the Swiss Confederation, shall conform to the following requirements:

72.1 1. ascertain whether the prescription form contains at least the following specified elements:

72.1 1.1. information regarding the patient – the given name, surname (written in full names, without using initials), the date of birth and the address;

72.1 1.2. information regarding the prescriber of the medicinal products – the given name, surname (written in full names, without using initials), address, telephone, fax, e-mail, speciality, identification number and signature of the physician who wrote out the prescription;

72.1 1.3. the date of writing out the prescription;

72.1 1.4. indicated international nonproprietary name of the medicinal products or, if none, the generally accepted name of the medicinal products, or if the doctor has indicated the reasons for prohibition substitution or has prescribed medicinal products of biological origin – the name assigned by the manufacturer of medicinal products;

72.1 1.5. information regarding the pharmaceutical form (pills, liquid, ointment, etc., quantity, strength, and dosage;

72.1 2. upon dispensing medicinal products for a prescription written out in the European Union, European Economic Area states and the Swiss Confederation, the pharmacist shall issue accurate information (a cashier's cheque or a receipt) in which the name, strength, quantity, price of the issued medicinal products and the date of issuance is indicated;

72.1 3. it is possible not to recognise a prescription written out in the European Union, European Economic Area states and the Swiss Confederation in a pharmacy:

72.1 3.1. if there are justified suspicions regarding its authenticity;

72.1 3.2. if the content of the prescription is incomprehensible, including it is not possible to identify the medicinal products prescribed or the instructions for the use of medicinal products;

72.1 3.3. if there are other ethical reasons which preclude from dispensing the medicinal products to the patient and conform to the activities which are necessary and commensurate with human health protection, and are not discriminating;

72.1 4. recognition of a prescription written out in the European Union, European Economic Area states and the Swiss Confederation prescribing narcotic or psychotropic medicinal products, as well as narcotic analgesics;

72.1 5. after dispensing of medicinal products the prescription remains in the pharmacy. If the patient requests, the pharmacy shall issue a copy of the prescription.

*[3 December 2013]*

73. When medicinal products have been dispensed (except an ordinary prescription on which the prescribed medicinal products may be dispensed repeatedly), as well as the requests of the institution and practising veterinarian shall remain at the pharmacy.

*[27 July 2010]*

74. A pharmacy shall, in accordance with the laws and regulations regarding the distribution of narcotic and psychotropic medicinal products, register in the strict account register for narcotic and equivalent thereto psychotropic medicinal products such medicinal products and substances for medicinal products to be manufactured, which contain the following substances:

74.1. atropine sulphate;

74.2. silver nitrate;

74.3. arsenous acid anhydride;

74.4. crystalline sodium arsenate;

74.5. tetracaine hydrochloride (dicaine);

74.6. narcotic analgesics which have been recognised as such by the State Agency of Medicines.

*[27 July 2010]*

75. The request of an institution and practising veterinarian for the dispensing of medicinal products shall be stored at a pharmacy for three years. Bills of lading regarding the circulation of the substances and medicinal products referred to in Paragraph 74 of this Regulation, shall be kept and reports shall be provided thereof in accordance with the laws and regulations regarding the circulation of narcotic and psychotropic medicinal products.

*[27 July 2010]*

76. The holder of a special authorisation (licence) for the opening (operation) of a pharmacy shall submit a report on the wholesale data of medicinal products four times a year – by 20 April, 20 July, 20 October and 20 January – to the State Agency of Medicines in the form of an electronic document. The product number (for unregistered medicinal products the identification number indicated in the authorisations referred to in Paragraph 94 of this Regulation shall be indicated instead of the product number), anatomically-therapeutic chemical classification number (ATC code) of the medicinal product, the name of the medicinal product – international nonproprietary name (INN) (if any) after which the strength or concentration and pharmaceutical form of the medicinal product are indicated, the quantity of distributed medicinal products – the number in the packaging and the number of distributed packagings, as well as the consumer group – recipients of medicinal products:.“inhabitants”, “pharmacy”, “medical treatment institution”, “institution engaged in veterinary medical care”, “practising veterinarian”, “practitioner”, and “other” (specifying if any), shall be indicated in the report.

*[2 February 2016 / New wording of the Clause shall come into force on 1 July  2017. See Paragraph 3 of amendments]*

77. The distribution of medicinal products in vending (sales) machines is prohibited.

**VII. Conditions for the Distribution of the Remaining Stock of Medicinal Products after Confirmation of Variations to Registration Documentation**

78. After the variations to registration documentation have been approved in accordance with the laws and regulations regarding the procedures for registering medicinal products, the registration owner is entitled to place on the market medicinal products and the manufacturer of medicinal products or wholesaler of medicinal products (including parallel importer) and pharmacies are entitled to distribute, and medical treatment institutions and social care institutions, institutions engaged in veterinary medical care or practising veterinarians are entitled to use such medicinal products until expiry of their term of validity, except the case if the State Agency of Medicines:

78.1. has stipulated a time period for distribution of the remaining stock of medicinal products;

78.2. does not permit the sale of the remaining stock of medicinal products and the distribution of medicinal products, if the variations to registration documentation are not approved and if their implementation is related to urgent security restrictions or to protection of the public health and safe use of medicinal products (for example, changes in therapeutic indications, doses, contra-indications, warnings, new information regarding the safe use of medicinal products has been obtained).

*[2 February 2016]*

79. The State Agency of Medicines shall, without delay, notify the decision referred to in Sub-paragraphs 78.1 and 78.2 of this Regulation to the registration owner, parallel importer and the Health Inspectorate, as well as publish it on its website.

*[2 February 2016]*

80. After the decision to approve variations to the registration documentation has been taken, the registration owner shall ensure the implementation of changes in the labelling and package leaflet observing the regulations and deadline specified by the State Agency of Medicines.

81. If the registration owner does not re-register the medicinal products, the remaining stock of medicinal products may be distributed for six months, if the manufacturer of medicinal products has not recalled the medicinal product. If re-registration of medicinal products is refused or registration of medicinal products is cancelled or suspended, the State Agency of Medicines shall indicate the time period for the sale of the remaining stock of medicinal products in accordance with the laws and regulations regarding the procedures for registering medicinal products, assessing the information provided by the registration owner of medicinal products regarding the remaining stock of medicinal products and the public health risks. The State Agency of Medicines shall also inform the parallel importer regarding the decision taken.

*[2 February 2016]*

82. Upon request of the State Agency of Medicines registration owners, manufacturers of medicinal products, medicinal product wholesalers, pharmacies, medical treatment institutions, practising veterinarians, institutions engaged in veterinary medical care and social care institutions shall provide the State Agency of Medicines and the Health Inspectorate with a notification regarding the remaining stock of medicinal products in which the approved variations to registration documentation are not implemented (that shall also apply to the distribution of medicinal products for parallel import and parallel distribution). The following shall be indicated in the notification:

82.1. the name, strength and form of the medicinal product;

82.2. the batch number and quantity.

*[21 October 2008; 27 July 2010; 8 October 2013]*

**VIII. Requirements for Distribution of Unregistered Medicinal Products**

83. The Health Inspectorate, but in respect of medicinal products for human use which are intended to be used by animals – the Food and Veterinary Service, is entitled to verify the justification for the writing of prescription for unregistered medicinal products.

*[21 October 2008; 27 July 2010]*

84. If doubts or suspicion arise regarding the distribution of unregistered medicinal products, the State Agency of Medicines is entitled to request the Health Inspectorate to verify the justification for the writing of prescriptions for unregistered medicinal products, but in respect of medicinal products which are intended to be used by animals – the Food and Veterinary Service.

*[21 October 2008; 27 July 2010]*

85. A doctor, medical treatment institution, as well as a practising veterinarian and an institution engaged in veterinary medical care, before prescribing and assigning unregistered medicinal products to a patient (shall not apply to medicinal products concerning which an authorisation referred to in Paragraph 86 of this Regulation for distribution of medicinal products registered in a European Economic Area state, but not registered in the Republic of Latvia, has been issued) shall obtain information regarding the properties of such medicinal products in order to evaluate the therapeutic efficacy and safety thereof for a patient and to ensure monitoring of their use, as well as shall be responsible for prescribing or assigning such medicinal products.

*[27 July 2010; 8 October 2013]*

86. In order to receive an authorisation for distribution of medicinal products registered in a European Economic Area state, but not registered in the Republic of Latvia (Annex 4), a holder of a marketing authorisation issued in a European Economic Area State (a registration owner) or a submitter of the registration submission (if the medicinal products are in the process of registration) shall submit a submission (Annex 5) to the State Agency of Medicines.

*[27 July 2010; 11 September 2012]*

86.1 The State Agency of Medicines is entitled to take a decision to issue the authorisation referred to in Paragraph 86 of this Regulation, also upon proposal of the National Health Centre or a medical treatment institution, as well as to put forward a proposal itself to issue the authorisation on the basis of the public health consideration, if the submission referred to in Paragraph 86 of this Regulation has not been submitted to the State Agency of Medicines.

*[27 July 2010; 11 September 2012]*

86.2 The State Agency of Medicines shall issue the authorisation referred to in Paragraph 86 of this Regulation in the name of the holder of the marketing authorisation issued in a European Economic Area State (the registration owner) or, if medicinal products are in the process of registration in a European Economic Area State, the relevant marketing authorisation requester.

*[27 July 2010]*

86.3 The State Agency of Medicines shall take a decision to issue the authorisation referred to in Paragraph 86 of this Regulation for the definite time period – five years. The abovementioned decision shall become invalid, if the medicinal products referred to in Paragraph 86 of this Regulation are being registered in Latvia and included in the Medicinal Product Register of Latvia.

*[27 July 2010; 2 February 2016]*

86.4 After five years following taking of the decision referred to in Paragraph 86.3 of this Regulation, the State Agency of Medicines is entitled to take a decision to issue the authorisation referred to in Paragraph 86 of this Regulation for an unlimited time period, except the case if, on the basis of evidence acquired in pharmacovigilance, the State Agency of Medicines has taken a decision to issue the relevant authorisation for the definite time period – five years. The abovementioned decision shall become invalid, if the medicinal products specified in the authorisation are being registered in Latvia and included in the Medicinal Product Register of Latvia.

*[27 July 2010; 8 October 2013; 2 February 2016]*

87. Prior to the issuance of the authorisation for distribution of unregistered medicinal product referred to in Paragraph 86 of this Regulation, taking into account public health reasons, the State Agency of Medicines shall:

87.1. notify the registration owner in the European Economic Area state regarding the proposal to grant an authorisation for distribution of the relevant medicinal product in the Republic of Latvia;

87.2. request the competent authority of the relevant European Economic Area state to submit a copy of the medicinal product assessment report and a valid relevant marketing authorisation of the medicinal product;

87.3. inform the authorisation holder regarding the requirements for the advertising, labelling and package leaflet of the medicinal product;

87.4. inform the authorisation holder regarding the requirements in monitoring of adverse effects caused by the medicinal product use.

*[27 July 2010]*

87.1 The State Agency of Medicines shall take a decision to grant the authorisation after receipt of the medicinal product assessment report provided by the competent authority of the relevant European Economic Area state and the medicinal product marketing authorisation. If the competent authority of the European Economic Area state has not approved the medicinal product assessment report, the State Agency of Medicines shall request the relevant competent authority of the European Economic Area state to submit the package leaflet of the relevant registered medicinal products and a description of the medicinal products in the original language or in English, if the package leaflet and description of the medicinal products have been approved in English. In such case the State Agency of Medicines shall take a decision to grant an authorisation after receipt of the marketing authorisation of the medicinal products, the package leaflet of the medicinal products, and the description of the medicinal products. If the authorisation referred to in Paragraph 86 of this Regulation is requested by the holder of registration of medicinal products or the submitter of a registration submission (if the medicinal products are within the process of registration), the State Agency of Medicines shall request to submit a certified translation of the package leaflet of the medicinal products and of the description of the medicinal products in accordance with the laws and regulations regarding the procedures for certifying translations of documents in the official language.

*[11 September 2012]*

87.2 If a request of the competent authority of another European Economic Area state has been received at the State Agency of Medicines for submission of a copy of the medicinal product assessment report on medicinal products registered in Latvia and a valid registration certificate of the relevant medicinal products, the State Agency of Medicines shall submit the copy of the assessment report and the marketing authorisation of the relevant medicinal products within 30 days after receipt of the request.

*[8 October 2013]*

88. A holder of the authorisation (a registration owner) referred to in Paragraph 86 of this Regulation or a submitter of a registration submission (if the medicinal products are within the process of registration) shall, in accordance with the laws and regulations regarding procedures for labelling medicinal products, submit a labelled packaging and a package leaflet in the official language to the State Agency of Medicines.

*[11 September 2012]*

89. When issuing the authorisation referred to in Paragraph 86 of this Regulation, the State Agency of Medicines shall determine a classification group to which the medicinal products shall belong in accordance with the laws and regulations regarding the procedures for the classification of medicinal products.

*[11 September 2012]*

89.1 When issuing the authorisation referred to in Paragraph 86 of this Regulation for distribution of unregistered medicinal products, the State Agency of Medicines shall approve the labelling and package leaflet of the medicinal products in the official language by consulting, if necessary, with the registration owner, manufacturer and other competent authorities.

*[27 July 2010]*

89.2 The wholesaler of medicinal products which delivers the medicinal products, shall ensure that the distributable medicinal products have labelling and package leaflet in the official language in accordance with the laws and regulations regarding the procedures for labelling medicinal products stipulating the requirements for medicinal products and the package leaflet.

*[27 July 2010]*

90. The holder (owner) of the authorisation referred to in Paragraph 86 of this Regulation shall ensure:

90.1. the supervision of side effects which are caused by the use of the medicinal products, in accordance with the laws and regulations regarding the procedures for pharmacovigilance, analogous to that specified for registered medicinal products;

90.2. the compliance with the requirements specified in the laws and regulations regarding the advertising of medicinal products.

*[27 July 2010; 11 September 2012; 8 October 2013]*

91. The State Agency of Medicines shall ensure at the website address of the State Agency of Medicines publicly available information regarding unregistered medicinal products to which, in accordance with Paragraph 86 of this Regulation, an authorisation for distribution of unregistered medicinal products has been issued in accordance with Sub-paragraph 149.7 of this Regulation.

*[27 July 2010; 8 October 2013]*

92. The State Agency of Medicines shall notify the European Commission regarding medicinal products not registered in Latvia for which, in accordance with Paragraph 86 of this Regulation, an authorisation for distribution of unregistered medicinal products has been issued and medicinal products for which the authorisation for distribution of unregistered medicinal products is cancelled, and shall indicate the given name, surname or firm name and address of the authorisation holder.

93. The authorisation referred to in Paragraph 86 of this Regulation gives the wholesaler of medicinal products referred to in Paragraphs 11 and 13 of this Regulation the right to distribute the medicinal products in wholesale trade, while the merchant or performer of economic activity who has been issued a special authorisation (permit) for opening (operation) of a pharmacy – to distribute the medicinal products in accordance with Paragraph 12.1 of this Regulation.

*[11 September 2012; 8 October 2013]*

94. The wholesale distribution of medicinal products not registered in Latvia for which the authorisation referred to in Paragraph 86 of this Regulation has not been issued, if the following has been received:

94.1. the authorisation for distribution of unregistered medicinal products for individually granted medicinal products (applies to medicinal products registered and used in other countries):

94.1.1. to a clearly known patient or individual patients (Annex 6), by carrying out the *bona fide* request, and to the person who has prescribed or assigned the medicinal products, taking responsibility for prescribing or assigning the medicinal products;

94.1.2. on the basis of the decision of the Minister for Health referred to in Section 10, Clause 7, Sub-clause “c” of the Pharmaceutical Law, if the medicinal products are required for provision of medical assistance in case of an emergency, natural disaster or epidemics, as well as for eliminating possible or already detected diffusion of pathogenic, toxic, chemical substances or radiation which could cause harm;

94.2. the authorisation for distribution of unregistered medicinal products for individually granted medicinal products (Annex 6) available for compassionate use pursuant to Article 83(2) of Regulation (EC) No 726/2004 of the European Parliament and of the Council (hereinafter – medicinal products for compassionate use). If the therapeutic indication of an unregistered medicinal product differs from that specified in the description of the medicinal product, it shall not be considered to be a medicinal product for compassionate use (the use of such medicinal product shall be considered to be “use without regard to the labelling”).

*[27 July 2010]*

94.1The condition referred to in Sub-paragraph 94.2 of this Regulation shall not be applicable to the medicinal products:

94.1 1. not subject to the centralised registration procedure pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council;

94.1 2. for the distribution of which the authorisation referred to in Sub-paragraph 94.1 of this Regulation has been issued;

94.1 3. registered in the centralised registration procedure pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, but the conditions for use of such medicinal products and the target group differ from the information specified in the registration documentation of the registered medicinal products.

*[27 July 2010]*

94.2The authorisation referred to in Sub-paragraph 94.1 of this Regulation for distribution of unregistered medicinal products for individually granted medicinal products to a clearly known patient or individual patients (Annex 6), by carrying out the *bona fide* request, shall not be necessary to the merchant and performer of economic activity referred to in Paragraph 12.1 of this Regulation which has received the unregistered medicinal products from the wholesaler of medicinal products to which the authorisation referred to in Paragraph 94 of this Regulation has been issued.

*[27 July 2010; 11 September 2012; 8 October 2013]*

94.3 In order to receive the authorisation referred to in Paragraph 94 of this Regulation, the person referred to in Paragraphs 94.4 and 94.5 of this Regulation shall submit a submission (Annex 7) to the State Agency of Medicines to which the following shall be appended:

94.3 1. the request of the pharmacy referred to in Sub-paragraph 72.2 of this Regulation for the acquisition of the medicinal products, if the medicinal products are ordered by a pharmacy, and the request of the institution or practising veterinarian for the acquisition of the medicinal products, if the medicinal products are ordered by an institution or practising veterinarian. The abovementioned request for the acquisition of medicinal products may be omitted, if the medicinal products comply with the list of usable medicinal products or are distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment. The requirement shall not apply to the authorisation referred to in Sub-paragraph 94.2 of this Regulation;

94.3 2. the labelling of the medicinal product, package leaflet and translation thereof in the official language, if the medicinal products are intended to be delivered to a medical treatment institution, social care institution, practising veterinarian and institutions engaged in veterinary medical care. The requirement shall not apply, if the medicinal products are intended to a clearly known patient, and shall not apply to the authorisation referred to in Sub-paragraph 94.2 of this Regulation;

94.3 3. in regard to medicinal products for compassionate use:

94.3 3.1. a certification of the authorisation requester regarding the compliance with the requirement stipulated in Article 83(2) of Regulation (EC) No 726/2004 of the European Parliament and of the Council that the submission for registration of the particular medicinal products has been submitted to the European Medicines Agency or that the medicinal products are undergoing clinical trials;

94.3 3.2. a reasoned substantiation of the medical treatment institution for the use of the medicinal products – medical or epidemiological data regarding the compliance of the patients and the group of patients (special medical treatment programme) with Article 83(2) of Regulation (EC) No 726/2004 of the European Parliament and of the Council:

94.3 3.2.1. a chronic or seriously debilitating disease or a disease which is considered to be life-threatening;

94.3 3.2.2. by treating patients with the medicinal products registered in Latvia in the national registration procedure, mutual recognition registration procedure and decentralised registration procedure, or with the medicinal products registered in the European Union in the centralised registration procedure, a satisfactory medical treatment result cannot be achieved;

94.3 3.3. the programme for the use of the medicinal products drawn up by the authorisation requester. The description of the abovementioned programme shall contain information regarding the relevant medicinal products and the use thereof:

94.3 3.3.1. a draft of the medicinal product description, medicinal product labelling and package leaflet in the official language;

94.3 3.3.2. information meant for a patient, including a sample form regarding the informed consent in accordance with the Law On the Rights of Patients;

94.3 3.3.3. description of the group of patients, including the foreseeable number of patients in Latvia, information concerning whether the relevant medicinal products are used in other countries, the expected duration of use and the quantity of the packaging units;

94.3 3.3.4. the duties of the medical practitioner and recipient of the authorisation, including supervision of the patient, data accumulation, pharmacovigilance, the procedures by which a medical practitioner shall notify regarding the adverse effects of the medicinal products, the current and planned clinical trials (also the sponsor, site of the clinical trials in Latvia and abroad shall be indicated);

94.3 3.4. if necessary, a copy of the registration submission and the data and documents appended thereto submitted to the European Medicines Agency;

94.3 3.5. an opinion of the Committee for Medicinal Products of the European Medicines Agency (if any) and an opinion of the competent authority of another European Community Member State regarding the relevant medicinal products.

*[27 July 2010; 8 October 2013]*

94.4 The wholesaler of medicinal products referred to in Paragraphs 11 and 13 of this Regulation is entitled to submit a submission for receipt of the authorisation referred to in Sub-paragraph 94.1 of this Regulation.

*[27 July 2010; 11 September 2012; 2 February 2016]*

94.5 The person in whose name it is anticipated to register medicinal products in the centralised registration procedure pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council and who has submitted the submission for the registration of the medicinal products to the European Medicines Agency or in whose name the authorisation for the commencement of clinical trials has been issued is entitled to submit the submission for receipt of the authorisation referred to in Sub-paragraph 94.2 of this Regulation.

*[27 July 2010]*

94.6 Prior to granting the authorisation referred to in Sub-paragraph 94.2 of this Regulation to medicinal products for compassionate use:

94.6 1. the State Agency of Medicines shall notify the European Medicines Agency regarding the possibility of using the relevant medicinal products and may request an opinion regarding the abovementioned medicinal products from the Committee for Medicinal Products of the European Medicines Agency:

94.6 1.1. patients of the target group – a restricted group of inhabitants, including age groups which gain benefit during the medical treatment (in respect of the therapeutic indication provided) and which are identified by the Committee for Medicinal Products of the European Medicines Agency;

94.6 1.2. conditions for the use of the medicinal products – recommendations for health care professionals regarding safe and effective assigning and use of the medicinal products, comprising the relevant information regarding the clinical, pharmacological and pharmaceutical properties of the medicinal products and the conditions for supervision of the patients;

94.6 1.3. conditions for the distribution of the medicinal products – restrictions on or circumstances for the delivery and use of the medicinal products pursuant to Article 9(4)(b) of Regulation (EC) No 726/2004 of the European Parliament and of the Council (shall not apply to the delivery strategy in Member States, for example, quantity of the product, choice of the Member State);

94.6 2. the relevant manufacturer of the medicinal products (if the submission for registration has not been submitted to the European Medicines Agency) or the authorisation requester (the submission for registration has been submitted to the European Medicines Agency):

94.6 2.1. is entitled to inform the European Medicines Agency, upon its own initiative, regarding the request for the authorisation submitted to the State Agency of Medicines which is referred to in Sub-paragraph 94.2 of this Regulation;

94.6 2.2. shall inform the State Agency of Medicines regarding the result of consultations with the European Medicines Agency.

*[27 July 2010]*

94.7 The authorisation referred to in:

94.7 1. Sub-paragraph 94.1.1 of this Regulation shall be issued in the name of the authorisation requester;

94.7 2. Sub-paragraph 94.2 of this Regulation shall be issued in the name of such medical treatment institution which provides the substantiation for the use of medicinal products referred to in Sub-paragraph 94.3 3.2 of this Regulation.

*[27 July 2010]*

94.8In the authorisation referred to in Paragraph 94 of this Regulation:

94.8 1. for medicinal products which are not on the list of usable medicinal products or which are not distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment, the quantity of packaging units shall be indicated after distribution of which it is necessary to receive a new authorisation for repeated distribution of the medicinal products (for importing from third countries). This condition shall apply to the authorisation referred to in Sub-paragraph 94.1.1 of this Regulation;

94.8 2. for medicinal products which conform to the list of usable medicinal products or which are distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment, the quantity of packaging units shall not be indicated and the authorisation shall be granted for one year. This condition shall apply to the authorisation referred to in Sub-paragraph 94.1.1 of this Regulation;

94.8 3. for medicinal products for compassionate use the term of validity and the quantity of the packaging units need not be indicated, taking into account the information regarding the anticipated number of patients, duration of use of the medicinal products and quantity of the packaging units specified in the description of the programme referred to in Sub-paragraph 94.3 3.3 of this Regulation. This condition shall apply to the authorisation referred to in Sub-paragraph 94.2 of this Regulation.

*[27 July 2010; 2 February 2016]*

94.9 Prior to assigning the medicinal products referred to in Sub-paragraph 94.2 of this Regulation to a patient, there shall always be a possibility for considering involving in a clinical trial. A medical practitioner who initiates medical treatment with particular medicinal products shall:

94.9 1. inform the particular patient or another person having the right to agree to the treatment of the patient in accordance with the Law On the Rights of Patients (hereinafter – informed person) regarding:

94.9 1.1. the circumstances leading to assigning the particular medicinal products;

94.9 1.2. the medicinal products assigned, and shall provide the characteristics thereof (for example, the anticipated benefit, possible risk);

94.9 1.3. supervision of the patient;

94.9 2. receive a written consent of the patient or informed person regarding the use of the particular medicinal products in accordance with the sample referred to in Sub-paragraph 94.3 3.3.2 of this Regulation.

*[27 July 2010]*

94.10A medical practitioner or a medical treatment institution shall prepare the substantiation for the use of medicinal products referred to in Sub-paragraph 94.3 3.2 of this Regulation after having acquainted themselves with the programme for the use of medicinal products referred to in Sub-paragraph 94.3 3.3 of this Regulation which has been drawn up by the authorisation requester and which the medical practitioner or the medical treatment institution shall receive from the person referred to in Paragraph 94.5 of this Regulation.

*[27 July 2010]*

94.11 If medicinal products have been granted the authorisation referred to in Sub-paragraph 94.2 of this Regulation which certifies the drawing up of the programme for the use of the medicinal products referred to in Sub-paragraph 94.3 3.3 of this Regulation, the person referred to in Paragraphs 94.4 and 94.5 of this Regulation shall ensure the following:

94.11 1. compliance with the conditions stipulated in Articles 24(1) and 83(8) of Regulation (EC) No 726/2004 of the European Parliament and of the Council;

94.11 2. compliance with the conditions referred to in Paragraph 94.12 of this Regulation.

*[27 July 2010]*

94.12 Medicinal products for compassionate use shall be distributed free of charge.

*[27 July 2010]*

94.13The authorisation referred to in Sub-paragraph 94.1 of this Regulation for distribution of unregistered medicinal products for individually granted medicinal products to a clearly known patient or individual patients (Annex 6), by carrying out the *bona fide* request, shall not be necessary to the merchant or performer of economic activity referred to in Sub-paragraph 11.1 of this Regulation which has received the unregistered medicinal products from the wholesaler of medicinal products to which the authorisation referred to in Paragraph 94 of this Regulation has been issued. In such case the norm referred to in Sub-paragraphs 95.2.1 and 95.2.2 of this Regulation is not applied.

*[8 October 2013; 2 February 2016]*

95. The person who has been issued the authorisation referred to in Paragraph 94 of this Regulation for distribution of unregistered medicinal products shall:

95.1. prior to commencing the distribution of the medicinal products notify the State Agency of Medicines regarding the batch numbers of the medicinal products to be distributed;

95.2. is entitled to distribute the unregistered medicinal products indicated in the authorisation only to the pharmacies, medical treatment institutions, social care institutions, practising veterinarians and institutions engaged in veterinary medical care according to the information indicated in the authorisation (Annex 6). If the authorisation has been granted to unregistered medicinal products which:

95.2.1. conform to the list of usable medicinal products, the medicinal products indicated in the authorisation shall be distributed only to hospitals and to pharmacies of closed type or of medical treatment institutions and of general or open type;

95.2.2. are distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment, the medicinal products indicated in the authorisation shall be distributed to pharmacies only;

95.2.3. are meant for compassionate use, the medicinal products indicated in the authorisation shall be distributed only to the patients or the group of patients specified in the authorisation;

95.3. prior to commencing the distribution of the medicinal products notify the State Agency of Medicines regarding the quantities of medicinal products imported and to be distributed;

95.4. notify without delay regarding all variations made in the data and documents submitted for the receipt of the authorisation;

95.5. issue medicinal products for compassionate use to a patient free of charge;

95.6. ensure, in respect of the medicinal products for compassionate use, execution of the duties of the medical practitioner or authorisation recipient specified in the programme for the use of the medicinal products referred to in Sub-paragraph 94.3 3.3 of this Regulation.

*[27 July 2010; 2 February 2016]*

95.1 The wholesaler of medicinal products referred to in Paragraphs 11 and 13 of this Regulation which brings in unregistered medicinal products for which the authorisation referred to in Paragraph 86 of this Regulation has been issued, prior to commencing the distribution of medicinal products, shall notify the State Agency of Medicines regarding the medicinal products to be distributed (name, strength or concentration, form, quantity in one packaging and number of packagings) and the batch numbers of the medicinal products.

*[3 December 2013; 2 February 2016]*

96. The recipient of the authorisation referred to in Paragraphs 86 and 94 of this Regulation shall cover expenses for receipt of the authorisation according to the price list of paid services of the State Agency of Medicines.

*[2 February 2016]*

97. The State Agency of Medicines shall decide regarding the issuing of a new authorisation for distribution of unregistered medicinal products in accordance with the procedures laid down in the Administrative Procedure Law. The abovementioned authorisation shall be issued in the form of an electronic document, sending it to the electronic mail address of the submitter of the submission immediately after taking of the decision. Authorisations in the form of a printed document shall be issued within three working days after receipt of a request for an additional charge according to the price list of paid services of the State Agency of Medicines.

*[3 December 2013; 2 February 2016]*

98. The State Agency of Medicines shall take a decision to cancel the authorisation for distribution of unregistered medicinal products, if:

98.1. the medicinal products indicated in the authorisation are registered;

98.2. the State Agency of Medicines has information related to the safety, quality and efficacy of the medicinal product;

98.3. false information has been provided regarding the unregistered medicinal products.

*[27 July 2010; 2 February 2016]*

**IX. Distribution of Medicinal Products by Means of the Web, Postal Consignments and Medicinal Products for Personal Use**

*[27 July 2010]*

99. Only medicinal products not subject to medical prescription may be distributed to the public (in the territory of the Republic of Latvia) by means of the web.

*[27 July 2010]*

100. The retail trade distribution of medicinal products by means of the web is allowed only to a general or open type pharmacy which has:

100.1. provided the public with a possibility to reach the pharmacy by means of the web twenty-four hours a day and to receive free of charge information and consultations therefrom regarding the abovementioned medicinal products for provision of pharmaceutical care, in accordance with the laws and regulations regarding the requirements for the opening and operation of pharmacies;

100.2. in conformity with Paragraph 103 of this Regulation developed the website which is available to the public continuously at any time of day or night, and the information inserted therein conforms to the laws and regulations regarding the advertising of medicinal products;

100.3. received a special authorisation (licence) for opening of a general or open type pharmacy in annex to which the permitted condition of special activity “distribution of non-prescription medicinal products by means of the web” is indicated;

100.4. notified the Health Inspectorate regarding the date from which it offers distribution of non-prescription medicinal products to inhabitants by means of the web, as well as regarding discontinuation and renewal of the relevant activity.

*[27 July 2010; 8 October 2013]*

101. If a pharmacy distributes medicinal products in retail by means of the web, the owner of the special authorisation for opening (operation) of a pharmacy shall ensure the necessary power of the server and the capacity of the communication channel connection of the server.

*[27 July 2010]*

102. A pharmacy which distributes medicinal products in retail by means of the web shall, without delay, ensure updating of the information provided on the website and shall inform the State Agency of Medicines and the Health Inspectorate regarding the domain name, electronic mail address, website address, as well as regarding amendments thereto.

*[21 October 2008; 27 July 2010; 8 October 2013]*

103. The website referred to in Sub-paragraph 100.2 of this Regulation shall have the following structure and content:

103.1. the provision of the functions of the pharmacy and electronic communication possibilities:

103.1.1. the report of services provided by the pharmacy with explanatory particulars regarding the possibility of receipt of the services;

103.1.2. if a submission on a specific printed form is necessary for receipt of a service, the availability of the printed forms shall be ensured, and the option to print them from the website (in PDF or other universal formats) or to fill them in directly on the website shall be ensured, as well as explanations regarding the correct filling in of the forms. If forms are being filled in several languages, explanations shall be provided also in the relevant languages;

103.1.3. availability of interactive elements (for example, “Your Question”, “Answer of Pharmacy”, “Submissions, Complaints”, “Answers to Submissions, Complaints”);

103.1.4. a possibility to send a letter (a submission) to the pharmacy by electronic means (for example, using XML); and

103.1.5. the electronic mail address shall be indicated and a possibility to send suggestions regarding the website;

103.2. information regarding the pharmacy:

103.2.1. the name of the pharmacy, address, working hours, telephone and fax number, the number of the special authorisation (licence), the holder firm name of the special authorisation (licence), address, registration and bank details;

103.2.2. the given name, surname and registration number within the Latvian Pharmacist Society of such pharmacist who provides consultations regarding medicinal products; and

103.2.3. additional graphic elements – a map of the location of the pharmacy with a reference to the closest public transport and a graphic image of the special authorisation (licence) issued to the pharmacy for opening (operation) of the pharmacy;

103.3. the date of the last update of the information placed on the website;

103.4. a link to the opening page, as well as links to pages of a higher level, if the server of the website has a structure of several levels;

103.5. the contact information regarding the State Agency of Medicines and the link to the website of the State Agency of Medicines;

103.6. a logo conforming to the requirements of Article 1 of Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity (hereinafter – Implementation Regulation No 699/2014) (hereinafter – the common logo) with the following elements: pictogram, in a white rectangle in the middle (left side) of the logo – a picture of the flag of the Republic of Latvia, and a text;

103.7. a link to the website of the State Agency of Medicines in which the list of the licensed pharmacies referred to in Sub-paragraph 103.1 2 of this Regulation is located, has been appended to the common logo in accordance with the requirements laid down in Articles 3 and 4 of Implementation Regulation No 699/2014;

103.8. it is not permitted to add any text, symbol, logo or other element to the field of the common logo, as well as it is not permitted to colour the logo in colours which are not specified in Annex to Implementation Regulation No 699/2014. The logo may not be deformed or its form and visual elements may not be otherwise changed, it may not be disfigured, rotated, multiplied, a symbol and text may not be added. Another logo, symbol or text may not be added at the zone of logo elements.

*[27 July 2010; 8 October 2013; 2 February 2016]*

103.1 The State Agency of Medicines shall publish at least the following information on its website:

103.1 1. information regarding the laws and regulations which are applied to distribution of medicinal products in retail by means of the web, including information that specific medicinal products may have different classification in different Member States;

103.1 2. a list of the licensed pharmacies which are permitted to distribute medicinal products in retail by means of the web, indicating the website addresses of such persons;

103.1 3. additional information regarding the risk of use of such medicinal products which are supplied to inhabitants illegally by means of the web;

103.1 4. a link to the website of the European Medicines Agency in which the information referred to in Sub-paragraph 103.1 1 of this Regulation is provided regarding legal acts of the European Union which are applied to counterfeit medicinal products, as well as links to websites of the European Union Member States;

103.1 5. information regarding the purpose of use of the common logo.

*[8 October 2013; 2 February 2016]*

104. The sender of a postal parcel shall be clearly identifiable. Legal persons which receive or send medicinal products in postal consignments shall have at the disposal thereof:

104.1. the special authorisation (licence) referred to in Paragraph 11 or 13 of this Regulation. If medicinal products are received by a medical treatment institution, a statement regarding registration with the Register of Medical Treatment Institutions which has been issued by the Health Inspectorate;

104.2. an authorisation issued for each case by the State Agency of Medicines in accordance with the Law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, if the substances and medicinal products included in Registers II and III are transmitted or received.

*[27 July 2010; 2 February 2016]*

105. The person who sends medicinal products shall submit to the provider of postal services an instruction regarding the conditions for dispatch of the medicinal products (for example, ensuring a specific temperature regime) and conclude an agreement with the provider of postal services to ensure the implementation of the instruction.

106. A natural person has the right to (does not apply to narcotic and psychotropic medicinal products):

106.1. bring in from foreign states (for example, in a traveller's baggage) or receive by post medicinal products for personal use in accordance with Paragraphs 106.1, 106.2 and 106.3 of this Regulation, if they are in the original packaging in a particular pharmaceutical form, their manufacturer and state of manufacture are identifiable on the packaging and they have a purchase cheque or an equivalent document;

106.2. export medicinal products for personal use or send medicinal products by post to another state, if it is permitted by the national law of the state to which medicinal products are delivered.

*[27 July 2010; 2 February 2016]*

106.1 A natural person shall not be permitted:

106.1 1. to bring in narcotic analgesics, new psychoactive substances and active substances from foreign states for personal use;

106.1 2. to receive in a postal consignment:

106.1 2.1. narcotic analgesics, new psychoactive substances and active substances;

106.1 2.2. anabolic steroids, testosterones, growth hormones or their analogues;

106.1 2.3. [5 July 2016].

*[2 February 2016; 5 July 2016]*

106.2 In the case referred to in Sub-paragraph 106.1 of this Regulation the quantity of medicinal products provided for personal use is equivalent:

106.2 1. to 12-month use, if the medicinal products are brought in or receiving in a postal consignment from a European Economic Area state;

106.2 2. to 14-day use, if anabolic steroid, testosterone, growth hormone or their analogue is brought in from a European Economic Area state;

106.2 3. to six-month use, if the medicinal products are brought in from a third country.

*[2 February 2016]*

106.3 If in the case referred to in Sub-paragraph 106.1 of this Regulation:

106.3 1. the quantity of medicinal products exceeds three units of the packaging of the medicinal product (primary, secondary) for each medicinal product, the use of the medicinal product shall be justified by a written confirmation of the person containing an indication regarding the use of the medicinal product for personal needs and a confirmation that the medicinal products are not narcotic analgesics, new psychoactive substances and active substances, as well as anabolic steroids, testosterones, growth hormones or their analogues (if the medicinal products are received by post) and that the person takes responsibility for the use of the such medicinal products. Bringing in of anabolic steroids, testosterones, growth hormones or their analogues shall be justified by a prescription or a document issued by the medical treatment institution;

106.3 2. the medicinal products have been acquired in sale at a distance, the address and licence number of the pharmacy, the website address of the pharmacy, the licence issuing institution and address of the pharmacy shall be indicated on the packaging of the postal consignment;

106.3 3. the medicinal products received by post from the third countries shall be issued for a prescription or a document issued by the medical treatment institution. A certified translation in accordance with the laws and regulations regarding the certification of translations into the official language shall be attached to the documents in a foreign language.

*[2 February 2016; 5 July 2016]*

**X. Quality Control of Medicinal Products**

107. Prior to commencing the distribution of medicinal products, the medicinal products included in Sub-paragraphs 1.3 and 2.2, Paragraphs 3, 4 and 5, and Sub-paragraph 6.2 of Annex 8 to this Regulation shall be subject to quality control.

*[11 September 2012; 2 February 2016]*

108. If necessary, the State Agency of Medicines shall organise examination of samples and is entitled to recognise the test results of an official medicinal product control laboratory of another European Economic Area state or, if the medicinal products have been manufactured in Latvia, shall declare it to be in conformity with the approved specifications on the basis of the batch manufacturing protocol and the test results. The examination shall be carried out in accordance with the procedures laid down in the Administrative Procedure Law, but not later than within 60 days after receipt of the samples and documentation.

109. The Health Inspectorate is entitled to withdraw samples of medicinal products for examination, except the cases referred to in Paragraphs 4 and 5 of Annex 8 to this Regulation when the samples for examination are submitted by the registration owner. The registration owner is entitled not to submit the samples referred to in Paragraphs 4 and 5 of Annex 8 to this Regulation for testing, if:

109.1. an Official Control Authority Batch Release (OCABR) of a European Economic Area state for the medicinal products has been issued, certifying the conformity of the product with the specifications of the European Pharmacopoeia Monograph for the relevant product and its registration certificate. The registration owner of the medicinal products shall submit a copy of the abovementioned certificate together with information regarding distribution of medicinal products to the State Agency of Medicines. If a justified request to submit samples for testing has not been received from the State Agency of Medicines within seven working days, distribution of the medicinal products may be commenced;

109.2. it has been permitted by the State Agency of Medicines on the basis of public health considerations, if the medicinal products are not available on the market and there is an immediate risk in relation to the spread of virus-caused illnesses or risk to human health or life.

*[2 February 2016]*

110. A natural person is entitled to submit medicinal products to the State Agency of Medicines for the performance of quality control.

111. Expenses related to the medicinal product sample testing shall be covered by the person from which the samples have been withdrawn, or, in the case referred to in Paragraph 110 of this Regulation – by a natural person in accordance with the price list of paid services of the State Agency of Medicines.

*[2 February 2016]*

111.1 The expenses for testing referred to in Paragraph 111 of this Regulation shall be covered by the State Agency of Medicines for medicinal products which have been registered:

111.1 1. in a mutual recognition procedure and decentralised procedure, if samples for testing are taken or sent within the scope of market surveillance which is co-ordinated by the European Directorate for the Quality of Medicines;

111.1 2. in a national registration procedure which is not a mutual recognition procedure and decentralised procedure, if the samples for testing are taken or sent on the basis of the agreement entered into on 13 October 2011 by and between the State Agency of Medicines and the relevant competent authorities of Estonia and Lithuania regarding a joint procedure in testing of medicinal products in the field of supervising the quality of medicinal products for ensuring the supervision and control of medicinal products, including upon request of the relevant competent authorities of Lithuania and Estonia, as well as within the scope of market surveillance which is co-ordinated by the European Directorate for the Quality of Medicines.

*[11 September 2012]*

**XI. Action in Emergency Situations and the Procedures for Recall of Medicinal Products**

112. The supply of medicinal products is prohibited and the medicinal products shall be recalled from the market, if:

112.1. the medicinal products are harmful;

112.2. the medicinal products do not have a therapeutic efficacy;

112.3. the risk-benefit ratio is unfavourable;

112.4. the qualitative and quantitative composition of the medicinal product does not conform with that declared in the registration documentation;

112.5. the control of the medicinal product or starting materials thereof and the intermediate stage control of the manufacturing process has not been carried out, or any other requirement or duty related to the granting of the special authorisation (licence) for manufacture/import of medicinal products has not been fulfilled.

*[8 October 2013]*

112.1 Upon taking a decision to suspend the distribution of medicinal products or to recall medicinal products from the market, the Health Inspectorate shall indicate a specific date from which distribution of medicinal products must be suspended or the medicinal products must be recalled from the market, as well as shall indicate the level of suspension or recall of the medicinal products (for example, wholesale trade of medicinal products, retail trade of medicinal products, users of medicinal products) and the batch numbers of the medicinal products to be recalled, if individual batches are being recalled.

*[27 July 2010; 2 February 2016]*

112.2 The Health Inspectorate may take the decision referred to in Paragraph 112.1 of this Regulation also regarding potentially counterfeit medicinal products and suspicions regarding quality defects of medicinal products.

*[8 October 2013]*

113. A prohibition regarding supply or recall of medicinal products from the market may also be applied to such batches of medicinal products regarding which there are suspicions of a potential counterfeit or quality defect.

*[8 October 2013]*

113.1 In relation to medicinal products the supply of which is prohibited or which have been recalled from the market in accordance with Paragraphs 112 and 113 of this Regulation, the Health Inspectorate together with the State Agency of Medicines, in emergency circumstances in a transitional period, are entitled to supply the medicinal products to patients who are already being treated with them (shall not apply to counterfeit medicinal products).

*[8 October 2013; see Paragraph 171.6]*

114. The recall of medicinal products may be partial, if the medicinal product batch is withdrawn from selected particular distributors or users.

115. A registration owner shall notify the State Agency of Medicines and the Health Inspectorate:

115.1. without delay – regarding any activity which he or she executes in order to suspend distribution of medicinal products, to request recall of medicinal products from the market, to request cancellation of registration or not to apply for re-registration of medicinal products, and regarding a justification for the relevant activity. The registration owner shall particularly indicate whether the activity performed is based on any of the criteria referred to in Paragraph 112 of this Regulation when the supplies of medicinal products are prohibited and the medicinal products are recalled from the market, or on the criteria for taking the decision referred to in the laws and regulations regarding the procedures for registering medicinal products in relation to suspending or cancelling registration or re-registration of medicinal products or in relation to amending registration of medicinal products (shall apply to the cases, if it is recognised that the medicinal products are harmful, medicinal products do not have therapeutic efficacy, the risk-benefit ratio is unfavourable, the qualitative or quantitative composition of the medicinal product does not conform with that declared in the registration documentation, the data indicated in relation to the registration or re-registration submission are not accurate or complete, or amendments have not been made thereto, the duties specified for the registration owner have not been fulfilled in relation to pharmacovigilance, or the medicinal products have not been manufactured according to the description of the manufacturing method, or control is not performed according to the description of control methods). If the action is based on any of the abovementioned criteria, the registration owner shall inform the Health Inspectorate and the State Agency of Medicines also in cases, if the activity has been carried out in a third country. The registration owners shall also inform the European Medicines Agency, if the action is based on any of the abovementioned criteria;

115.2. regarding each established quality defect of medicinal products in conformity with their class in accordance with Annex 9 to this Regulation if, due to the quality defect, a recall of the medicinal products might follow, and shall indicate the state which received the defective product.

*[21 October 2008; 8 October 2013; 2 February 2016]*

115.1 Paragraph 115 of this Regulation shall be applied in relation to medicinal products registered in Latvia. The registration owner shall submit information regarding medicinal products registered in centralised registration procedure to the European Medicines Agency.

*[2 February 2016]*

115.2 The information referred to in Sub-paragraph 115.1 of this Regulation shall be submitted electronically together with an accompanying letter (drawn up in *MS Word* format) in accordance with Annex 8.1 to this Regulation to which the following information is appended (in *MS Excel* format according to the template approved by the European Medicines Agency):

115.2 1. the reporter – given name, surname, electronic mail address, telephone number;

115.2 2. the owner of the registration certificate – name, address;

115.2 3. regarding the medicinal product – the registered name of the medicinal product in the European Economic Area state, active substance, registration procedure;

115.2 4. the activities carried out involving medicinal products – activity of the owner of the registration certificate (intended activity), cause, explanation of the cause of the activity (intended activity);

115.2 5. the state in which activity is carried out – it shall be indicated whether the activity has been carried out in a European Economic Area state. If the answer is “yes”, the state shall be indicated. It shall be indicated if the activity has been carried out in a third country. If the answer is “yes”, the state and the name of the medicinal product in such state shall be indicated;

115.2 6. the foreseeable date beginning from which the medicinal product will not be available on the market due to the intended activity. The foreseeable date beginning from which it is anticipated that the medicinal product will be available again on the market after the activity which had taken place;

115.2 7. additional information regarding the medicinal product – registration number, date of the first registration and re-registration, name of the medicinal product, strength or concentration, form of the medicinal product, way of administration. It shall be indicated whether the medicinal product is currently on the market. If the medicinal product is not currently available on the market, the reason shall be indicated.

*[2 February 2016]*

115.3 If a notification is submitted to the European Medicines Agency, it shall be completed in English.

*[2 February 2016]*

115.4 The website of the State Agency of Medicines shall contain a link to the website of the European Medicines Agency in which a sample notification (in English) to be sent to the competent authorities and the European Medicines Agency which is referred to in Paragraph 115.2 of this Regulation, is published.

*[2 February 2016]*

116. If there are suspicions regarding potentially counterfeit medicinal products or medicinal products of potentially poor quality, the persons referred to in Paragraphs 11 and 13 of this Regulation, the merchant or performer of economic activity who has been issued a special authorisation (licence) for opening (operation) of a pharmacy, medical treatment institutions, social care institutions, practising veterinarians, institutions engaged in veterinary medical care or other persons shall notify the Health Inspectorate thereof. The following shall be indicated in the notification:

116.1. the name of the medicinal product, strength or concentration, and form of the medicinal product;

116.2. the manufacturer indicated on the labelling and in the package leaflet of the medicinal product and the registration owner;

116.3. the batch number of the medicinal product;

116.4. the person from which the medicinal product has been acquired.

*[8 October 2013]*

116.1 If there are suspicions that the medicinal product significantly endangers public health, the Health Inspectorate in co-operation with the State Agency of Medicines shall evaluate the situation, immediately send a rapid alert notification to all other European Union Member States and ensure sending of notifications to all existing participants of the supply chain, in conformity with the proceedings and procedures laid down in Chapter XII of this Regulation and the time periods specified in Paragraph 122 of this Regulation. If it is assumed that such medicinal products have reached patients, urgent public notifications are provided within 24 hours in accordance with Paragraphs 117 and 118 of this Regulation to patients on recall of the abovementioned medicinal products. The abovementioned notifications shall contain sufficient information regarding potential quality defects or counterfeit of medicinal products and the risk related thereto.

*[8 October 2013]*

116.2 The responsible official referred to in Sections 52 and 52.1 of the Pharmaceutical Law shall be responsible for fulfilment of Paragraph 116 of this Regulation.

*[2 February 2016]*

116.3 Notifications on suspicions regarding a defect or counterfeit in accordance with Paragraph 116 of this Regulation shall be submitted to the Health Inspectorate also by the owner of registration of medicinal products.

*[2 February 2016]*

116.4 The State Agency of Medicines and other testing laboratories may report to the Health Inspectorate regarding the results which arise from testing the medicinal products on the market and which require further research.

*[2 February 2016]*

116.5 If the Health Inspectorate, upon receipt of a notification, suspects counterfeit of medicinal products or raw materials, the Health Inspectorate shall inform the law enforcement authorities.

*[2 February 2016]*

116.6 The notification referred to in Paragraph 116 of this Regulation shall also apply to a potential fraud in manufacture, deterioration of the product quality or any other serious quality problem related to medicinal products.

*[2 February 2016]*

117. The Health Inspectorate, where necessary, in co-operation with local governments shall ensure that the report on quality control or on the recall of medicinal products is published in periodicals and other mass media (for example, television and radio).

*[21 October 2008]*

118. In emergency situations, when a medicinal product is found to be dangerous to consumers’ life or may pose a risk to consumers’ health, the Ministry of Health shall, on the basis of the report from the Health Inspectorate and the opinion of the State Operational Medical Commission, take a decision and on the same day shall notify the National Radio and Television Council regarding the statement to be announced to the public of Latvia.

*[21 October 2008]*

119. If there has been a decision taken to suspend distribution of medicinal product and to recall medicinal products from the market, the relevant registration owner or the manufacturer/importer of the medicinal products shall notify the persons, to which the medicinal products have been distributed regarding the taken decision, by telephone or fax, or using other means of communication. If the decision is communicated orally, the notification in writing shall be submitted concurrently. The following shall be indicated in the notification:

119.1. the name, strength, form and, where necessary, the batch number of such medicinal products to which the report regarding the suspension of medicinal product distribution and the recall of medicinal products from the market applies. The date from which, according to the decision on the suspension of the medicinal product distribution and recall of the medicinal products from the market, the distribution of the medicinal products is to be suspended and the medicinal products are to be recalled from the market;

119.2. the registration owner and the manufacturer/importer;

119.3. the reason for the suspension of medicinal product distribution and recalling of medicinal products from the market;

119.4. the class of quality defect (first, second or third) and a description;

119.5. the level of urgency of the relevant recall (time in hours at which the persons to whom the medicinal products have been distributed shall be notified) in accordance with Paragraph 122 of this Regulation;

119.6. whether all the clients are to be notified regarding the recall of medicinal products or only those who have received the batch to be recalled;

119.7. whether the medicinal products are to be recalled from the retail trade network or from the whole market of medicinal products;

119.8. further action regarding these medicinal products;

119.9. the procedures for returning the medicinal products to the supplier or registration owner;

119.10. the procedures for the collection and disposal of the medicinal products;

119.11. the procedures for covering the loss.

*[27 July 2010]*

120. A person who receives the notification referred to in Paragraph 119 or 126 of this Regulation and which is responsible for the suspension of medicinal product distribution and recall of the medicinal products from the market shall:

120.1. register the following information:

120.1.1. the date and time when the notification regarding the suspension of medicinal product distribution and recall of the medicinal products from the market was received, as well as the mode of receipt (for example, by telephone, by fax or electronic means);

120.1.2. the notification provider (the name, given name, surname, position, telephone number, fax number, electronic mail address);

120.1.3. the name, strength, form, batch number, manufacturer and registration owner of such medicinal products, to which the notification regarding the suspension of medicinal product distribution and recall of the medicinal products from the market, applies, as well as the class of quality defect of these medicinal products and quality defect description (Annex 9);

120.1.4. regarding the person (given name, surname, position) responsible for the suspension of the distribution of the medicinal products and recall of the medicinal products from the market;

120.1.5. the date and time for commencing the suspension of the distribution of the medicinal products and recall of the medicinal products from the market.

120.2. ensure suspending the distribution of the medicinal products specified in the notification and recall of the medicinal products, notifying the persons thereof to whom the medicinal products have been supplied, as soon as possible, but not later than within a day after receipt of the notification;

120.3. inform the notification provider regarding the recalled medicinal products (Annex 10).

*[2 February 2016]*

121. The persons referred to in Paragraph 119 of this Regulation shall, within 10 days after recall of the medicinal products from the market is completed, submit to the Health Inspectorate a report on the recall of medicinal products (Annex 10). The Health Inspectorate has the right to reduce the time period for report submission, if the medicinal products are recalled in the case referred to in Paragraph 118 of this Regulation.

*[21 October 2008]*

122. If a quality defect (Annex 9) or counterfeit has been detected for medicinal products, the Health Inspectorate in co-operation with the State Agency of Medicines shall evaluate the situation, as well as further action on the basis of public health considerations, as well as shall send the rapid alert notification (Annex 12) to the relevant distributors of medicinal products electronically, and, if necessary, inform them also orally (by telephone):

122.1. as soon as possible, but not later than within 12 hours, if a first class quality defect (Paragraph 1 of Annex 9) is detected for the medicinal products or counterfeit medicinal products are detected;

122.2. within 24 hours, if a second class quality defect (Paragraph 2 of Annex 9) is detected for the medicinal products;

122.3. within 48 hours, if a third class quality defect (Paragraph 3 of Annex 9) is detected for the medicinal products. In such case the requirement regarding recall of medicinal products need not be included in the notification.

*[2 February 2016]*

123. If a quality defect has been detected to medicinal products exported and supplied to a European Economic Area state, the registration owner and the wholesaler of medicinal products shall, within four hours after establishing the fact, notify the consignee of the medicinal products in foreign states and the Health Inspectorate in writing regarding the product defect.

*[21 October 2008; 3 December 2013]*

124. The wholesaler of medicinal products, a pharmacy, as well as a social care institution shall appoint a contact person who may be contacted at any time of the day on issues regarding defects and recall of medicinal products. If variations to data have taken place, they shall be notified without delay, but not later than within three days after making of variations. Data regarding the contact person, indicating the given name, surname, telephone number and electronic mail address, shall be provided:

124.1. by the wholesaler of medicinal products and the pharmacy to the State Agency of Medicines, indicating them in the submission for receipt of the relevant special authorisation (licence) which is referred to in the laws and regulations regarding the procedures for the licensing of pharmaceutical activity. The contact person for the manufacturer of medicinal products may be the responsible person referred to in Paragraph 52 of the Pharmaceutical Law, for the importer of medicinal products – the responsible person referred to in Sub-paragraph 52.1 of the Pharmaceutical Law, in the wholesaler of medicinal products – the responsible person referred to in Sub-paragraph 46.1 of the Pharmaceutical Law, but in the pharmacy – the manager of the pharmacy or the deputy manager of the pharmacy;

124.2. by the medical treatment institution and social care institution by registering with the register of medical treatment institutions or the register of social care institutions in accordance with the laws and regulations regarding registration of medical treatment institutions or the laws and regulations regarding registration of social care institutions.

*[2 February 2016]*

**XII. Duties of the Competent Authority and the Procedures for Rapid Alert**

125. Having received the notification referred to in Paragraphs 115 and 116 of this Regulation or the rapid alert notification referred to in this Chapter, the Health Inspectorate shall submit it to the State Agency of Medicines. The State Agency of Medicines shall evaluate whether the defect indicated in the notification is related to the side effects of the medicinal products. The Health Inspectorate together with the State Agency of Medicines and, if the medicinal products are intended to be used by animals – with the Food and Veterinary Service, shall organise the assessment of the notification in respect of the type, amount and urgency of the risk. The following information shall be specified in the assessment:

125.1. if the defect actually exists, what risk there is to human health and, if the medicinal products are intended to be used by animals, to the health of an animal:

125.1.1. a risk to patients and to patients of particular risk groups;

125.1.2. a risk of receiving inappropriate medical treatment;

125.1.3. a risk from inappropriate dosage (the therapeutic index shall be considered);

125.1.4. an immediate risk or a long-term risk;

125.2. a possibility that the risk actually exists and occurs in the medicinal products supplied by the manufacturer of the medicinal products;

125.3. a risk to distort national programmes that are designated for restriction of diseases caused by various viruses, if a suspicion regarding a vaccine defect arises (mutual contamination by virus);

125.4. whether the potential threat to human health and, if the medicinal products are intended to be used by animals, to the health of an animal, is such that there is a need to perform emergency activities. When negotiating with the manufacturer of the medicinal products such observations shall be evaluated and included in the notification which concern:

125.4.1. other related notifications;

125.4.2. batch distribution (for example, distributed to known inpatient medical treatment institutions, widely distributed in the wholesale network);

125.4.3. the date when the first distribution was performed and the date when the last distribution was performed;

125.4.4. the remaining stock of the medicinal products located at the manufacturer of the medicinal products;

125.4.5. the possibility that other batches of the medicinal products may have the same defect, and that they will be distributed;

125.5. the characterisation of the situation if no other stocks of the medicinal products and alternative products are available, as well as the clinic effect caused by interruption in supply;

125.6. whether further activities and assessments for other batches of the same product or other products are needed, and whether further investigation of the problem is necessary;

125.7. a temporary or permanent prohibition to sell the remaining stocks;

125.8. the necessity for good manufacturing practice inspection in order to prevent the recurrence of a similar situation;

125.9. whether the notification of a medicinal product recall shall be announced to all or specific medical care professionals or the notification shall be broadcasted on television, radio and in other mass media, and whether information shall be publicized on the websites of the competent authorities, press publications or elsewhere.

*[21 October 2008; 27 July 2010]*

126. The Health Inspectorate shall examine each case individually and in co-operation with the State Agency of Medicines shall evaluate the seriousness of the defect, its possible harm to the consumer, the parties involved and the environment, as well as the possible distribution of the defective batch. On the basis of the assessment referred to in Paragraph 125 of this Regulation, the Health Inspectorate shall draw up:

126.1. a rapid alert notification of a quality defect/recall (Annex 12);

126.2. a notification of follow-up activities and activities which are not urgent, as well as provide information about the quality defects (Annex 13).

*[21 October 2008]*

127. The rapid alert procedure is transmission of information by rapid alert means regarding the recall of medicinal products, if they have a quality defect, they are counterfeit medicinal products and emergency activity is needed in order to protect the health of human beings and animals.

*[2 February 2016]*

128. Transmission of information shall take place between the competent authorities which are responsible for the medicinal products for human use and for veterinary medicinal products in the European Economic Area states, the states which are preparing for joining the European Union, and the states with which the European Community has entered into a mutual recognition contract, the institutions which participate in the Pharmaceutical Inspection Cooperation Scheme, as well as between the European Commission and international organisations – the European Council, the European Directorate for the Quality of Medicines and the World Health Organisation. The rapid alert procedure shall be used:

128.1. to notify the competent authorities regarding the presence of potential counterfeit in a legal distribution network or regarding products which are related to fraudulent activities in manufacture, packaging, distribution or advertising, as well as regarding products which contain counterfeit raw materials;

128.2. in transmission of other information, for example, warnings regarding the use and recall of medicinal products due to safety considerations, or notifying regarding further activities;

128.3. to notify regarding quality defects, counterfeit or active substances or trial medicinal products obtained by means of fraud, if the relevant competent authority deems it essential.

*[2 February 2016]*

129. The Health Inspectorate shall ensure the implementation of the rapid alert procedure at any time of day or night.

*[2 February 2016]*

130. Within the scope of the rapid alert procedure the Health Inspectorate, using the rapid alert system, shall send such information electronically the urgency and seriousness of which precludes any delay. It shall be a rapid alert notification regarding:

130.1. a first class defect (Paragraph 1 of Annex 9) and counterfeit which is sent to all contact persons in the list of the rapid alert notification list of the European Medicines Agency regardless of whether the particular batch of medicinal products has or has not been exported to such state. If it is necessary to warn the authorities of states in different time zones, they shall be contacted by telephone. The notifications shall be sent in accordance with the requirements referred to in Sub-paragraph 122.1 of this Regulation;

130.2. a second class defect which may cause disease or incorrect medical treatment (Paragraph 2 of Annex 9), which is sent to all contact persons in the list of the rapid alert notification list of the European Medicines Agency. If there is information regarding specific states in which the medicinal products have been distributed, the notification shall be sent only to the contact persons of the relevant states. If possible, the notification shall be sent in accordance with the requirement referred to in Sub-paragraph 122.2 of this Regulation, but not later than within 24 hours from provision of the notification in Latvia;

130.3. a third class defect (Paragraph 3 of Annex 9) is not usually sent.

*[2 February 2016]*

131. The rapid alert procedure shall be used also in notifying the relevant authorities regarding a recall of products or determination of a prohibition to sell the medicinal products, in case of suspending or cancelling a manufacture or wholesale trade licence.

*[2 February 2016]*

132. The rapid alert notification shall be sent to the institutions referred to in Paragraph 128 of this Regulation and to the State Agency of Medicines in English. The list of addressees shall be appended to the notification, and the notification shall be sent in the form of an electronic document to the electronic mail address of the particular institution.

*[2 February 2016]*

133. The Health Inspectorate shall:

133.1. draw up the following internal regulatory enactments:

133.1.1. the procedures by which a rapid alert notification is received;

133.1.2. the procedures by which the rapid alert notification is evaluated;

133.1.3. the procedures by which the rapid alert notification is issued and sent:

133.1.3.1. to persons who are included in the rapid alert list of the European Medicines Agency;

133.1.3.2. to the third countries with which Latvia has concluded a bilateral co-operation contract in the field of health care (to the competent authorities);

133.1.3.3. to distributors and consumers in the Republic of Latvia;

133.1.4. the procedures by which the rapid alert notification regarding follow-up activities is issued and by which non-urgent information regarding quality defect is distributed (Annex 13);

133.2. issue an order regarding the official who is responsible for transmission of the rapid alert notification, and shall notify the European Medicines Agency thereof, indicating the given name, surname of the official and means of communication during and outside working hours, as well as notify the European Medicines Agency regarding variations in these data;

133.3. support the registration owner in the process of medicinal product recall and shall monitor the effectiveness of the process of medicinal product recall;

133.4. ensure that information regarding the recall of medicinal products is being notified to the persons referred to in Paragraph 128 of this Regulation as soon as possible, if the quality defect causes a serious risk to public health;

133.5. monitor the conduct of the implementation of the medicinal product recall process;

133.6. investigate the circumstances that led to the distribution of the defective product and ensure that any necessary corrective action is taken by the manufacturer of the medicinal products and, where necessary, also by the registration owner;

133.7. perform those follow-up activities which are not urgent, and provide information regarding quality defect in accordance with Annex 13 to this Regulation.

*[21 October 2008]*

134. The Health Inspectorate shall examine each case individually and in co-operation with the State Agency of Medicines shall assess the seriousness of the defect, its possible harm to the consumer, parties involved and the environment, and the possible distribution of the defective batch.

*[21 October 2008]*

135. If the defective medicinal products (including parallel imported medicinal products and parallel distributed medicinal products) are first identified in Latvia, the Health Inspectorate together with the State Agency of Medicines shall:

135.1. examine the quality defect and issue an order regarding rapid alert notification (for medicinal products which have been registered in the national registration procedure);

135.2. conduct the examination of the quality defect and issue an order regarding rapid alert notification (for medicinal products which have been registered in the centralised registration procedure, or medicinal products which have been registered both in the centralised and national registration procedure). The notification to all the involved competent authorities shall include all the recommended activities.

*[21 October 2008]*

136. The Health Inspectorate (in co-operation with the State Agency of Medicines) may come to an agreement with the European Medicines Agency and the representative of the Committee for Medicinal Products of the European Medicines Agency who is the rapporteur on medicinal products in the Committee for Medicinal Products, on the activities to be performed.

*[21 October 2008]*

137. The rapid alert notification shall include a description of the different packaging of the medicinal product in which the product may be packed (if information has been received from the European Medicines Agency).

138. In case if medicinal products have been re-packaged in parallel distribution, but the defect is not related to re-packaging and resulted from the manufacture of the medicinal products, a description of the different packages in which the product is distributed (if information from the European Medicines Agency is available) shall be indicated in the rapid alert notification.

139. The states and authorities referred to in Sub-paragraphs 128.1 and 128.2 of this Regulation shall, within the scope of the Rapid Alert System, be also notified regarding the fact of medicinal product distribution by sending information regarding:

139.1. possible counterfeit medicinal products;

139.2. medicinal products resulting from fraud in manufacture, packaging, distribution or promotion;

139.3. a product containing counterfeit starting materials.

140. The Health Inspectorate shall establish and maintain a system that would ensure receipt of a relevant notification in case suspicion regarding defective products shall arise, and draw up, maintain and update the list of medicinal products to be recalled, in accordance with the European Commission’s Compilation of Community Procedures on Inspections and Exchange of Information.

*[21 October 2008]*

141. The Health Inspectorate shall submit the decision to suspend the distribution of medicinal products and to recall medicinal products, on the date of issue thereof, to the Food and Veterinary Service, the State Agency of Medicines and the Ministry of Health. The Health Inspectorate shall ensure and supervise the execution of the decision, including the follow-up activities.

*[21 October 2008; 22 September 2009]*

142. If medicinal products are being withdrawn from circulation, the registration owner or the manufacturer of medicinal products shall compensate the losses caused to consumers of the medicinal products, as well as expenses arisen to persons because of collection, transportation to the place of disposal, and disposal of such medicinal products.

*[27 July 2010]*

143. If poor-quality medicinal products have been established and they are withdrawn from circulation, the person due to whose fault the medicinal products lost their quality shall cover the losses and expenses referred to in Paragraph 142 of this Regulation.

144. Medicinal products unusable for distribution shall be destroyed in accordance with the laws and regulations governing the circulation of hazardous waste.

**XIII. Supervision**

145. The Health Inspectorate shall:

145.1. monitor and check the distribution of parallel distributed medicinal products and the conformity thereof with the medicinal product marketing authorisation of the European Union and amendments made thereto;

145.2. ensure, according to the competence, implementation of conditions or restrictions of such European Commission decision which has been taken in accordance with Regulation No 726/2004 of the European Parliament and of the Council and the opinion of the Scientific Committee (referring to recommended conditions or restrictions with regard to the safe and effective use of the medicinal product as specified in Article 9(4)(c) of Regulation No 726/2004 of the European Parliament and of the Council);

145.3. notify the Food and Veterinary Service regarding poor-quality and counterfeit medicinal products found in third countries;

145.4. notify the World Health Organisation regarding the activity commenced (suspension of distribution of medicinal products or recall of medicinal products from the market) in relation to the poor-quality or counterfeit medicinal products detected, as well as regarding suspicions of those which may affect public health protection in the third countries. A copy of the notification shall be submitted to the European Medicines Agency.

*[21 October 2008; 22 September 2009; 27 July 2010; 2 February 2016]*

146. The State Agency of Medicines shall:

146.1. shall perform the duties of the competent supervisory authority referred to in Articles 18 and 19 of Regulation No 726/2004 of the European Parliament and of the Council regarding medicinal products which in accordance with the abovementioned Regulation have been registered within the centralised registration procedure (including in pharmacovigilance) in accordance with Regulation No 726/2004 of the European Parliament and of the Council;

146.2. ensure, according to the competence, implementation of conditions or restrictions of such European Commission decision which has been taken in accordance with Regulation No 726/2004 of the European Parliament and of the Council and the opinion of the Scientific Committee (abovementioned recommended conditions or restrictions with regard to the safe and effective use of the medicinal product as specified in Article 9(4)(c) of Regulation No 726/2004 of the European Parliament and of the Council);

146.3. shall notify the Food and Veterinary Service:

146.3.1. regarding the decision of the State Agency of Medicines that is taken in accordance with the laws and regulations regarding the procedures for registering medicinal products, regarding determination of the conformity of the product with the definition of the medicinal product specified in the Pharmaceutical Law and subjecting of the product to registration with the State Agency of Medicines, as well as indicate a term period by which the decision shall be executed;

146.3.2. regarding cancelled authorisations for distribution of unregistered medicinal products;

146.4. shall ensure analysis of medicinal product consumption, summarisation and publication of the results;

146.5. is entitled to issue the authorisation referred to Paragraphs 34, 86 and 94 of this Regulation, if a medicinal product, registered in Latvia and included in the Medicinal Product Register of Latvia, cannot be used for treatment of a patient or a specific disease, or for performance of a treatment manipulation because the medicinal product is not available to the consumer on the market. In such case:

146.5.1. Paragraph 86 of this Regulation shall be applied after commencement of distribution of such medicinal products;

146.5.2. the authorisation referred to in Paragraph 34 of this Regulation shall be received within one year after commencement of distribution of such medicinal products;

146.5.3. the requirement regarding the submission of the pharmacy and medical treatment institution request referred to in Paragraph 94 of this Regulation shall not be applied for obtaining of the authorisation;

146.6. shall notify the Health Inspectorate regarding the batches of medicinal products which are not safe and of good quality or may be dangerous to human health or life not later than within one day after establishing the fact;

146.7. shall perform inspections regarding conformity of distribution of medicinal products with good distribution practice not less than once in five years and, if necessary, perform unannounced inspections. If unannounced inspections are not performed, an agreement shall be reached with the wholesaler of medicinal products and the person who performs transactions with medicinal products, regarding the time when an inspection is to be commenced, and shall notify the wholesaler of medicinal products and the person who performs transactions with medicinal products thereof in writing. If necessary, the State Agency of Medicines has the right to request the Official Control Authority Batch Release of a European Economic Area state or a laboratory of the State Agency of Medicines to perform a sample test;

146.8. may perform the inspections of wholesalers of medicinal products referred to in Sub-paragraph 146.7 of this Regulation upon request of a European Union Member State, the European Commission or the European Medicines Agency also in the third countries. The inspections may also be performed in the premises of such persons who perform brokering of medicinal products;

146.9. shall prepare a control report after each inspection referred to in Sub-paragraphs 146.7 and 146.8 of this Regulation in accordance with Annex 13.1 to this Regulation. It shall be indicated in the control report whether the relevant wholesaler of medicinal products and the person who performs transactions with medicinal products conform to the requirements of good distribution practice. Prior to approval of the control report the State Agency of Medicines shall, within three working days after drawing up the report, send it to the inspected person in the form of an electronic document to his or her electronic mail address or – upon request – in the form of a printed document, and shall ensure a possibility of providing comments. If necessary, the control report shall be sent to the institution which requested the performance of the inspection;

146.10. shall issue a certificate of good distribution practice conformity of medicinal products which conforms to the sample of the good distribution practice certificate of the European Union (Annex 14), if the activity of the inspected person conforms to the requirements of good distribution practice. The authorisation shall be issued in the form of an electronic document by sending it to the electronic mail address of the submitter of the submission within three working days after the relevant parallel importer has paid the specified charge for assessment of the documents according to the price list of paid services of the State Agency of Medicines. If conformity assessment of good distribution practice is related to a trip, the wholesaler of medicinal products shall cover the travel (transport) expenses of the State Agency of Medicines to the object to be inspected and back, hotel (accommodation) expenses, health insurance expenses, and daily allowance in accordance with the laws and regulations regarding the procedures for reimbursing the expenses related to official travels and work trips of employees. The certificate in the form of a printed document shall be issued within three working days after receipt of a request and for an additional charge for such service according to the price list of paid services of the State Agency of Medicines;

146.11. shall enter information regarding the issued certificates of good manufacturing practice in the European Union database on manufacturing and import authorisations and good manufacturing practice certificates (hereinafter – the Eudra GMDP database) within three working days after taking a decision to issue the certificate;

146.12. if the result of the inspection referred to in Sub-paragraph 146.7 of this Regulation shows that the wholesaler of medicinal products does not conform to the requirements laid down in the Pharmaceutical Law and this Regulation and the requirement of good distribution practice is not conformed to in the activity thereof, shall enter information in the Eudra GMDP database within three working days after taking of the decision;

146.13. is entitled to issue information to the requester regarding the wholesale data of exported medicinal products, including parallel imported and parallel distributed medicinal products, (including veterinary medicinal products) (excluding references to specific pharmacies, wholesalers of medicinal products, manufacturers and importers of medicinal products and without indicating other identifying data) which is necessary for analysing the access to medicinal products, in the following division:

146.13.1. a standard report on sales data of medicinal products (quarter in division by months, six months, year) – shall include the anatomically-therapeutic chemical classification number (ATC code), the international nonproprietary name (INN), the form, strength or concentration, the number in the packaging, the number of packagings sold, the turnover in euros;

146.13.2. an expanded report on sales data of medicinal products (quarter in division by months, six months, year) – shall include the information included in the standard report and the recipient group of medicinal products in accordance with Sub-paragraph 18.4 of this Regulation or belonging of the medicinal products to a classification group;

146.13.3. a full report on sales data of medicinal products (quarter in division by months, six months, year) – shall include the information included in the standard report, the recipient group of medicinal products in accordance with Sub-paragraph 18.4 of this Regulation and belonging of the medicinal products to a classification group;

146.13.4. an individual report on sales data of medicinal products which is issued only to the owner of registration certificate of medicinal products for his or her registered medicinal products – shall include the international nonproprietary name (INN), the registration number of medicinal products, the anatomically-therapeutic chemical classification number (ATC code), the form, strength or concentration of medicinal products, the number in the packaging, the number of packagings sold;

146.14. shall enter into a contract with the requester of information regarding the service of providing wholesale data of medicinal products, including exported, parallel imported and parallel distributed medicinal products (except veterinary medicinal products), in the cases referred to in Sub-paragraph 146.13 of this Regulation according to the price list of paid services of the State Agency of Medicines;

146.15. shall ensure the conformity of the website referred to in Paragraph 103.1 of this Regulation with the requirements referred to in Sub-paragraph 103.1 5 of this Regulation and in Articles 2, 3 and 4 of Implementation Regulation No 699/2014;

146.16. shall follow the availability of medicinal products and analyse it, forecast tendencies and public health risks;

146.17. shall post the data received on distribution of particular medicinal products which is referred to in Paragraph 60.2 and Sub-paragraphs 153.3.1 and 153.3.2 of this Regulation without delay on the website of the State Agency of Medicines, indicating the date of commencing or discontinuing distribution of the relevant medicinal products, as well as regarding the fact of availability of medicinal products;

146.18. is entitled to request data from the wholesalers of medicinal products and pharmacies regarding the remaining stock of the particular medicinal product.

*[21 October 2008; 22 September 2009; 27 July 2010; 8 October 2013; 2 February 2016; 20 December 2016]*

146.1 The State Agency of Medicines shall authorise officials for the performance of the inspection referred to in Sub-paragraphs 146.7 and 146.8 of this Regulation who are entitled:

146.1 1. to inspect the wholesalers of medicinal products and the persons carrying out brokering of medicinal products;

146.1 2. to take samples in order to perform independent testing at the Official Control Authority Batch Release of a European Economic Area state or a laboratory of the State Agency of Medicines.

*[8 October 2013]*

147. If in the case referred to in Paragraph 43 or Paragraphs 1, 2 and 3 of Annex 8 to this Regulation testing of medicinal products is performed by another testing laboratory which is accredited by the State Agency “Latvian National Accreditation Bureau” in conformity with the LVS EN ISO/IEC 17025:2005 standard “General Requirements for the Competence of Testing and Calibration Laboratories” regarding which the Ministry of Economics has published a notification in the newspaper *Latvijas Vēstnesis* [the official Gazette of the Government of Latvia], it has a duty to notify the State Agency of Medicines regarding the test results without delay (on the day of establishing the fact).

148. The Health Inspectorate shall place the following information regarding recalled medicinal products on the website of the Health Inspectorate:

148.1. the name, strength, form, batch number of the medicinal product, firm name and country of manufacture of the medicinal product, but regarding registered medicinal products – also the registration number;

148.2. the reason of recall and a description of the medicinal product defect.

*[21 October 2008; 27 July 2010; 8 October 2013]*

149. The State Agency of Medicines shall ensure the following information on the website of the State Agency of Medicines:

149.1. the labelling and approved package leaflets for parallel imported medicinal products. If parallel imported medicinal products differ from registered medicinal products, the difference shall be indicated;

149.2. the parallel importers and parallel imported medicinal products. The information shall be prepared in accordance with the laws and regulations regarding the procedures for registering medicinal products specifying the information regarding parallel imported medicinal products to be published in the Medicinal Product Register of Latvia on the website of the State Agency of Medicines;

149.3. the parallel distributors and the medicinal products for parallel distribution in Latvia according to the information published on the website of the European Medicines Agency;

149.4. the authorisations for selling of the remaining medicinal product stock;

149.5. the addresses of the websites of the wholesalers of the medicinal products and manufacturers of the medicinal products;

149.6. a sample of the submission in Latvian for the notification referred to in Paragraph 63 of this Regulation of parallel distribution of the centrally registered medicinal products;

149.7. the unregistered medicinal products regarding which the authorisation referred to in Paragraph 86 of this Regulation for distribution of unregistered medicinal products has been issued, indicating:

149.7.1. the name of the medicinal products, strength or concentration and the form of the medicinal products;

149.7.2. international name of the active ingredient;

149.7.3. the name, address of the authorisation owner (marketing authorisation owner or marketing authorisation requester) and the name of the European Economic Area state which has granted the marketing authorisation or in which a request for the marketing authorisation has been submitted;

149.7.4. the name of the manufacturer of the medicinal products and the name of the state of manufacture;

149.7.5. the code of the anatomical therapeutic chemical classification and defined daily dose;

149.7.6. the identification number of the medicinal products granted by the State Agency of Medicines;

149.7.7. the designation of the classification group for prescription medicinal products. The designation shall not be indicated for medicinal products not subject to medical prescription;

149.8. the wholesaler (name, licence number, address) of medicinal products which distributes unregistered medicinal products regarding which the authorisation referred to in Paragraph 86 of this Regulation has been issued;

149.9. the licensed pharmacies, wholesalers of medicinal products, manufacturers of medicinal products and importers of medicinal products (licence number, name, registration number, legal address, and address of the site of pharmaceutical activity, contact information and types of special activity). In addition at least the manager of the pharmacy, the term of validity of the licence and the conditions of special activity shall be indicated for pharmacies. In addition at least the responsible official shall be indicated for wholesalers of medicinal products. In addition at least the qualified person and the date of granting the licence shall be indicated for manufacturers of medicinal products and importers of medicinal products;

149.10. the data on the authorisations issued in accordance with Section 48, Paragraph one of the Pharmaceutical Law.

*[27 July 2010; 11 September 2012; 3 December 2013]*

150. The State Agency of Medicines shall fulfil all the necessary procedures in order to ensure that officials and employees who are responsible and are involved in the taking of decisions in relation to the issuance of the authorisations specified in this Regulation, as well as developers (rapporteurs) of reports and experts, are not financially or otherwise interested in the field of pharmacy and their impartiality is not influenced. The abovementioned persons, in entering into a contract with the State Agency of Medicines regarding the fulfilment of the particular work, shall submit to the State Agency of Medicines the annual declaration of financial interest. The declaration shall be appended to the contract.

151. The Health Inspectorate and the State Agency of Medicines:

151.1. shall not disclose information related to commercial secrets of the medicinal product distributor which has become known to them in the course of enforcing this Regulation;

151.2. shall, according to the competence, ensure prompt mutual information exchange and information exchange with other authorities, as well as, in order to prevent direction of medicinal products to illegal circulation, provide information to the law enforcement authorities and the Ministry of Health regarding facts that have come to their knowledge;

151.3. shall determine the procedures for receiving and processing the notifications referred to in Paragraphs 115 and 116 of this Regulation in relation to the medicinal products which are suspected of a potential counterfeit or quality defect, and the procedures for recalling batches of medicinal products both during the working hours and outside working hours.

*[21 October 2008;8 October 2013]*

152. In order to ensure prompt exchange of information in accordance with the requirements of this Regulation, the medicinal product manufacturer, wholesaler of medicinal products, pharmacy, medical treatment institution and social care institution shall have:

152.1. telecommunications;

152.2. a fax machine (that does not apply to the pharmacy, medical treatment institution (the practice of a physician), as well as social care institution, in which the receipt and sending of information is ensured by other technical means);

152.3. a computer with the necessary software (that does not apply to the medical treatment institution and social care institution, in which the receipt and sending of information is ensured by other technical means).

153. The registration owner shall:

153.1. be responsible for advancement of the medicinal products in the market, including planning the registration and re-registration process and the time periods so that the stock of medicinal products referred to in Paragraph 78 of this Regulation would not increase. The registration owner may appoint a person – a local representative of the owner of registration in the State of the European Economic Area, who represents him or her in the relevant Member State (hereinafter – representative);

153.2. be legally located in the European Economic Area (registered firm name, central administration or actual location of operation);

153.3. after the State Agency of Medicines has taken a decision to register medicinal products or in relation to medicinal products registered in centralised registration procedure – after entering into effect of the relevant decision of the European Commission, shall submit a notification to the State Agency in writing:

153.3.1. regarding the actual date of commencing the distribution (sale) of medicinal products in Latvia, indicating for medicinal products registered in Latvia and for parallel imported medicinal products – the product number in the Medicinal Product Register of Latvia. For medicinal products registered in centralised registration procedure and parallel distributed medicinal products – the European Union number assigned by the European Medicines Agency for each size of the packaging of the form of registered medicinal product;

153.3.2. regarding registered medicinal products which are permanently or temporarily not placed on the market of Latvia. Such notification shall be provided at least two months (except emergency circumstances) before placing on the market of the medicinal products is discontinued. The registration owner shall inform the State Agency of Medicines regarding the reasons for such action in accordance with Sub-paragraph 115.1 of this Regulation;

153.3.3. regarding all incidents in relation to the administration of medicinal products and executed or executable activities (in Latvia or another state);

153.4. ensure fulfilment of the requirements laid down in Sub-paragraph 12.8 of this Regulation;

153.5. ensure urgent fulfilment of the restrictions related to the safety of medicinal products to be distributed which are specified in accordance with the laws and regulations regarding the procedures for registering medicinal products.

*[11 September 2012; 8 October 2013; 2 February 2016]*

154. Appointing of the representative shall not release the registration owner from the obligations which are specified in Paragraph 153 of this Regulation. The representative shall ensure fulfilment of the duties specified in Paragraph 20 and Sub-paragraphs 153.3, 153.4 and 153.5 of this Regulation.

155. If the manufacturer of medicinal products, wholesaler of medicinal products, pharmacy, medical treatment institution, practising veterinarian, institution engaged in veterinary medical care or social care institution terminates activity, it is re-organized or liquidated, the person who is responsible for the re-organisation or liquidation shall transfer for sale the remaining stock of medicinal products to persons who have the right to distribute the medicinal products, or shall destroy the medicinal product stock in accordance with the requirements laid down in Paragraph 144 of this Regulation and submit to the Health Inspectorate information:

155.1. to co-ordinate the utilisation, distribution or disposal of the remaining stock of medicinal products;

155.2. regarding administration or distribution of the remaining stock of medicinal products, indicating the legal person to whom medicinal products are distributed or information regarding disposal of medicinal products and a certification that the medicinal product stocks are liquidated.

*[21 October 2008; 27 July 2010; 11 October 2013]*

156. Registration owners, manufacturers of medicinal products, medical care practitioners and officials and employees of the State Agency of Medicines shall not be subject to civil or administrative liability for any consequences caused by the administration of medicinal products, which does not correspond to the registered indications, or consequences caused by the administration of unregistered medicinal products, if such administration has been suggested or requested by the competent authority (medical treatment institution), having considered any possible or already ascertained spread of pathogens, toxins, chemical substances or nuclear radiation. Any of the abovementioned cases may cause harm irrespective of whether the authorisation has been granted in the European Community or medicinal products have been registered in accordance with this Regulation.

156.1 The Health Inspectorate shall notify the State Police and the customs regarding distribution of counterfeit and potentially counterfeit medicinal products in Latvia, also on the basis of information which has been obtained in the rapid alert system.

*[2 February 2016]*

156.2 The Health Inspectorate, the State Police, the customs and investigatory institutions shall mutually co-operate in detecting counterfeit medicinal products, also in cases if the medicinal products have been obtained by fraud (upon manufacturing, packaging, distributing or advertising) or using counterfeit raw materials.

*[2 February 2016]*

156.3 The State Police shall inform the State Agency of Medicines and the Health Inspectorate regarding illegal use of medicinal products in order to create a specific condition for any person, including illegal sale and administration of medicinal products against the person's will for the purpose of violence.

*[2 February 2016]*

156.4 The Health Inspectorate in co-operation with the State Agency of Medicines shall, according to the competence, inform the professional organisation of the field of pharmacy, merchants and public regarding the danger of distributing counterfeit medicinal products and the measures to be taken in order to restrict their becoming part of illegal distribution chain of medicinal products.

*[2 February 2016]*

156.5 In order to make public information regarding preventive and taken measures in the field related to falsification of medicinal products, the Ministry of Health in co-operation with the Health Inspectorate, the State Agency of Medicines, the State Police and the customs shall organise meetings in which patient and consumer organisations and, if necessary, officials of other competent authorities participate.

*[2 February 2016]*

**XIV. Closing Provisions**

157. Cabinet Regulation No. 88 of 27 February 2001, Regulations Regarding the Import, Export and Distribution of Medicinal Products and Requirements for the Opening and Operation of Medicinal Product Wholesalers (*Latvijas Vēstnesis*, 2001, No. 88, 35, 52; 2003, No. 114; 2004, No. 69), is repealed.

158. [2 February 2016]

159. Until the date when the special authorisation (licence) for manufacturing or import of medicinal products referred to in Sub-paragraph 11.2 of this Regulation is received, such merchants and performers of economic activity are entitled to distribute in wholesale medicinal products manufactured thereby to whom, on the day of coming into force of this Regulation, the special authorisation (licence) has been issued for:

159.1. the opening (operation) of a medicinal product manufacturing undertaking;

159.2. the manufacture (re-packaging and re-dividing up) of medicinal products at a medicinal product wholesaler;

159.3. the manufacture of medicinal products in a pharmacy.

*[11 September 2012]*

160. Medicinal product wholesalers to which, on the day of coming into force of this Regulation, the special authorisation (licence) for the opening of a medicinal product wholesaler with a condition of special activity – import of medicinal products into Latvia from a state which is not located in the European Economic Area and the authorisation for import of the relevant medicinal products into the Republic of Latvia from the third countries issued by the State Agency of Medicines has been issued, are entitled to distribute in wholesale the imported medicinal products up to the receipt of the special authorisation (licence) for the manufacture or import of medicinal products.

161. The authorisation for distribution of unregistered medicinal products which has been issued by the State Agency of Medicines until the day of coming into force of this Regulation, shall be valid. After importation of the quantity of medicinal product indicated in the authorisation, the authorisation for distribution shall not be valid for repeated importation of medicinal products.

162. The authorisation for distribution of parallel imported medicinal products in the Republic of Latvia, which has been issued by the State Agency of Medicines until the day of coming into force of this Regulation, shall be valid until the expiry date indicated therein.

162.1 Parallel importers which have received the authorisation for distribution of parallel imported medicinal products in the Republic of Latvia and distribute parallel imported medicinal products in Latvia, shall, by 1 October 2010, submit to the State Agency of Medicines a certification that the notification regarding the intention to commence distribution of the particular medicinal products indicated in the authorisation in the Republic of Latvia has been provided to the relevant medicinal product registration owner (marketing authorisation owner) and to the medicinal product trademark owner. The information referred to in Paragraph 25 of Annex 1 to this Regulation shall be included in the notification.

*[27 July 2010]*

163. The State Agency of Medicines is entitled to re-register the authorisation for distribution of parallel imported medicinal products on the basis of the submission of the holder (owner) of the authorisation for distribution of parallel imported medicinal products. The submission shall be submitted to the State Agency of Medicines not later than 60 days prior to the expiration date of the authorisation for distribution of parallel imported medicinal products. Information indicated in Annex 1 shall be appended to the submission.

164. Authorisation for distribution of the remaining stock of medicinal products, which has been issued by the State Agency of Medicines until the day of coming into force of this Regulation, shall be valid until the expiry date indicated therein.

165. The submission for issuance of the authorisation for distribution of parallel imported medicinal products in the Republic of Latvia, which has been submitted to the State Agency of Medicines until the day of coming into force of this Regulation, shall be considered valid.

166. The submission for issuance of the authorisation for distribution of unregistered medicinal products in the Republic of Latvia, which has been submitted to the State Agency of Medicines until the day of coming into force of this Regulation, shall be considered valid.

167. The fulfilment of the requirements specified in Paragraph 17 of this Regulation shall be ensured until 1 January 2008.

168. The requirement regarding submission of the pharmacy request specified in Paragraph 94 of this Regulation to the State Agency of Medicines, when an authorisation for distribution of unregistered medicinal products is being submitted, and Sub-paragraph 72.3 of this Regulation shall come into force on 30 December 2007.

169. [27 July 2010]

170. Such pharmacies which distribute medicinal products in retail trade by means of the web and the websites of which are being reconstructed or developed anew, shall observe the requirements specified in Paragraphs 100, 101, 102 and 103 of this Regulation. Other pharmacies to which a website has been constructed shall:

170.1. within one month from the day of coming into force of this Regulation, notify the State Agency of Medicines and the Health Inspectorate regarding the domain name, electronic mail address, as well as regarding amendments thereto;

170.2. correct the content of the website in accordance with the requirements of this Regulation within five months from the day of coming into force of this Regulation.

*[21 October 2008; 27 July 2010]*

171. For the medicinal products which are registered within the centralised registration procedure (the labelling and package leaflet thereof in Latvian has been approved in the European Union) in accordance with Regulation No 726/2004 of the European Parliament and of the Council and which are also registered within the national registration procedure in the State Agency of Medicines, the distribution of the remaining stock of medicinal products registered within the national registration procedure shall be allowed only in the medical treatment institution or social care institution until the remaining stock of medicinal products in such institution has finished.

171.1 Paragraph 67.1 of this Regulation shall come into force on 1 September 2009.

*[4 August 2009]*

171.2 Parallel importers which distribute medicinal products for parallel distribution in the Republic of Latvia, regarding which a certification that the parallel distributor has notified the relevant medicinal product registration owner (marketing authorisation owner) and the medicinal product trademark owner regarding the intention to commence distribution of the medicinal products for parallel distribution in the Republic of Latvia has not been submitted to the State Agency of Medicines, shall, by 1 October 2010, submit the abovementioned certification to the State Agency of Medicines where the particular addressee who has been notified and the date of providing the notification shall be indicated.

*[27 July 2010]*

171.3 Sub-paragraph 12.10 of this Regulation shall come into force from 1 January 2011.

*[27 July 2010]*

171.4 The authorisation issued by the State Agency of Medicines:

171.4 1. for distribution of medicinal products registered in a European Economic Area state, but not registered in the Republic of Latvia which has been issued by the State Agency of Medicines until 1 October 2012, shall be valid until expiry of the term of validity indicated therein;

171.4 2. for distribution of unregistered medicinal products for individually granted medicinal products which has been issued by the State Agency of Medicines until 1 October 2012 with an indicated term of validity, shall be valid until expiry of the term of validity indicated therein;

171.4 3. for distribution of the remaining stock of medicinal products which has been issued by the State Agency of Medicines until 1 October 2012, shall be valid until expiry of the term of validity indicated therein.

*[11 September 2012]*

171.5 A submission regarding receipt of an authorisation for distribution of medicinal products registered in a European Economic Area state, but not registered in the Republic of Latvia, and a submission regarding receipt of an authorisation for distribution of individually granted unregistered medicinal products which has been submitted to the State Agency of Medicines by 1 October 2012 shall be deemed valid.

*[11 September 2012]*

171.6 Sub-paragraph 12.3 1, Paragraphs 12.4 and 113.1 and Sub-paragraph 151.3 of this Regulation shall come into force on 28 October 2013.

*[8 October 2013]*

171.7 Paragraph 66.5 of this Regulation in relation to the issuance of a registration certificate to a person carrying out brokering of medicinal products, and Sub-paragraph 146.10 of this Regulation in relation to the issuance of a certificate of good distribution practice compliance of medicinal products in the form of a printed document for additional charge shall come into force on 1 July 2014.

*[8 October 2013]*

171.8 The turnover specified in Sub-paragraph 146.13.1 of this Regulation until 31 December 2013 shall be indicated in lats.

*[8 October 2013]*

171.9 Paragraph 53 of this Regulation in relation to the issuance of an authorisation for distribution of parallel imported medicinal products, Sub-paragraph 79.1 in relation to the issuance of an authorisation for distribution of the remaining stock of medicinal products, and Paragraph 97 which determines the issuance of an authorisation for distribution of unregistered medicinal products in the form of a printed document for additional charge, shall come into force on 1 July 2014.

*[3 December 2013]*

171.10 The holder of a special authorisation (licence) for the opening (operation) of a pharmacy shall submit a report on retail sales data of medicinal products to the State Agency of Medicines in accordance with Paragraph 76 of this Regulation, starting from 1 January 2018. The holder of a special authorisation (licence) for the opening (operation) of a pharmacy shall submit the sales data of medicinal products in 2016 by 20 February 2017, but sales data of medicinal products in 2017 – by 20 February 2018. The number, name of the product, the distributed quantity of the medicinal product, the price at which the medicinal product is sold, and the group of consumers of the product shall be indicated in the notification.

*[20 December 2016]*

172. This Regulation shall come into force on 1 August 2007.

**Informative Reference to European Union Directives**

*[8 October 2013; 3 December 2013]*

This Regulation contains legal norms arising from:

1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;

2) Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (text with EEA relevance);

3) Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use;

4) Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use;

5) Directive 2011/62/EU of the European Union and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products;

6) Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use;

7) Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance;

8) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare; and

9) Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.

Prime Minister A. Kalvītis

Acting for the Minister for Health, Minister for Welfare D. Staķe

**Annex 1**

Cabinet Regulation No. 416

26 June 2007

*[2 February 2016]*

**Submission Regarding Parallel Imported Medicinal Products**

(Mark with an “x” as appropriate)

|  |  |
| --- | --- |
| 1. For granting an authorisation for distribution of parallel imported medicinal products | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF yes |
| A request to the State Agency of Medicines for the issuance of an authorisation for distribution of parallel imported medicinal products in the Republic of Latvia to the applicant indicated in Part I for the medicinal products indicated in Part I. |
| We wish to receive the authorisation in the form of a printed document | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes |
| 2. For approving variations | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes |

**Part I**

**Administrative data**

|  |
| --- |
| 1. Applicant: |
| 1.1. holder (owner) of a special authorisation (licence): |
| 1.1.1. registration number |   |
| 1.1.2. name |   |
| 1.1.3. legal address |   |
| 1.1.4. number of the special authorisation (licence) for the operation of a wholesaler of medicinal products |   |
| 1.1.5. address of the place of pharmaceutical operation |   |
| 1.1.6. telephone number |   |
| 1.1.7. fax number |   |
| 1.1.8. electronic mail address |   |
| 2. Number and date of the previous authorisation (if there has been such) |   |
| 3. Contact person in relation to the submission: |   |
| 3.1. given name, surname |   |
| 3.2. position |   |
| 3.3. address of the place of employment |   |
| 3.4. telephone by which a contact person is available twenty-four hours |   |
| 3.5. fax |   |
| 3.6. electronic mail address |   |

**Part II**

**Information regarding medicinal products**

|  |
| --- |
| 4. Information regarding the parallel imported medicinal products: |
| 4.1. name, strength or concentration |   |
| 4.2. type of packaging |   |
| 4.3. medicinal product composition |   |
| 4.4. package size |   |
| 4.5. route of administration |   |
| 5. State of origin of parallel imported medicinal products (the state in which the medicinal products are registered – a marketing authorisation issued for them) |   |
| 6. Name of the medicinal product in the state of origin |   |
| 7. Manufacturer of the parallel imported medicinal products: |   |
| 7.1. name |   |
| 7.2. legal address and address of the workplace of the undertaking |   |
| 7.3. postal code |   |
| 7.4. city |   |
| 7.5. state |   |
| 7.6. telephone number |   |
| 8. The registration owner of medicinal products in the state of origin: |   |
| 8.1. name |   |
| 8.2. legal address and address of the workplace of the undertaking |   |
| 8.3. postal code |   |
| 8.4. city |   |
| 8.5. state |   |
| 8.6. telephone number |   |
| 9. Registration number of medicinal products in the state of origin |   |
| 10. Registration number for medicinal products registered in Latvia in relation to which parallel import has been performed, and name of the medicinal products, as well as registration owner and manufacturer of medicinal products |   |
| 11. Information regarding distribution of the medicinal products (mark with “X” as appropriate): |
| 11.1. distribution of parallel imported medicinal products is intended for wholesale –for a wholesaler of medicinal products or for storage in order to export to other European Economic Area states or third countries | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes |
| 11.2. distribution of parallel imported medicinal products is intended for retail – for a pharmacy, medical treatment institution, social care institutions, practising veterinarians, practitioners and institutions engaged in veterinary medical care | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes |

**Part II.A**

**Information regarding the supplier**

|  |
| --- |
| 12. Supply: |
| 12.1. the state from which the parallel imported medicinal products are supplied |   |
| 12.2. the supplier of medicinal products in foreign states (name, address, licence number, contact information) |   |
|   |
|   |
| 12.3. the supplier of medicinal products in Latvia (name, address, licence number, contact information) |   |
|   |
|   |

**Differences from the medicinal products registered in Latvia**

|  |
| --- |
| 13. Are the parallel imported medicinal products different from the relevant medicinal products registered in Latvia(mark with an “x” as appropriate)https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyeshttps://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno14. If the answer is “yes”, the following shall be indicated: |
| 14.1. trade name |   |
| 14.2. manufacturer of parallel imported medicinal products and manufacturer of medicinal products for the relevant medicinal products registered in Latvia is an undertaking within the scope of the same group of undertakings | yeshttps://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 14.3. manufacturer of parallel imported medicinal products and manufacturer of medicinal products for the relevant medicinal products registered in Latvia are independent undertakings | yeshttps://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 14.4. term of storage |   |
| 14.5. most visible differences, for example, in appearance, colour, size and splitting lines and division lines which are intended for division of medicinal products in doses |   |
| 14.6. therapeutic indications which are in parallel imported medicinal products but which are not in medicinal products registered in Latvia |   |

**Chapter III**

**Information regarding re-packaging (re-labelling) in relation to the parallel imported medicinal products**

|  |
| --- |
| 15. The following shall be indicated regarding re-packaging (re-labelling) (mark with an “x” as appropriate): |
| 15.1. the medicinal products are or will be re-packaged | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 15.2. the medicinal products are or will be re-labelled | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 15.3. indicate variations (mark with an “x” as appropriate): |   |   |
| 15.3.1. secondary packaging changed (re-packaging) | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 15.3.2. package leaflet placed or attached in the packaging (re-packaging) | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 15.3.3. adhesive label on the packaging (re-labelling) | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 15.3.4. other information indicated on the packaging | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 15.4. description of specifications and quality control (testing methods) |   |
| 15.5. full description of new secondary packaging if in re-packaging the secondary packaging has changed |   |
| 15.6. person who has performed the re-packaging (re-labelling) of the medicinal product |   |
| 15.6.1. name |   |
| 15.6.2. address of the place of employment |   |
| 15.6.3. means of communication |   |
| 15.6.4. medicinal product manufacturing licence number |   |
| 15.7. contracts (if re-packaging (re-labelling) of parallel imported medicinal products has been performed) |   |
| 15.8. any other information in relation to re-labelling, printed materials, transportation, storage and any devices added |   |

**Chapter IV**

**Information added**

(Mark with an “x” as appropriate),

indicate the number of pages appended

|  |
| --- |
| 16. The package leaflet of the medicinal products in Latvian: |
| 16.1. must be submitted, if there is none in Latvian |   |
| 16.2. need not be submitted, if: |   |
| 16.2.1. the registration owner of medicinal products (manufacturer of medicinal products) has included (inserted, attached) the package leaflet in the packaging of medicinal products for parallel imported medicinal products |   |
| 16.2.2. the State Agency of Medicines has granted an exemption from the duty to ensure the package leaflet of the medicinal products in the official language in accordance with the laws and regulations regarding the procedures for labelling medicinal products and the requirements to be brought forward for the package leaflet of medicinal products |   |
| 17. Copy of the package leaflet in the original language |   |
| 18. Draft translation of the package leaflet in Latvian (shall not apply to the case referred to in Sub-paragraph 16.2 of this Regulation) |   |
| 19. Digital photograph of the size of each packaging (secondary and, if any, primary) of the medicinal products (to be submitted electronically) in which all information printed on the packaging is clearly visible, if:*Note. Applicable if secondary packaging is not opened in re-packaging for parallel imported medicinal products* |   |
| 19.1. the registration owner of medicinal products (manufacturer of medicinal products) has ensured information on the packaging in the official language (which is not a sticker) |   |
| 19.2. the State Agency of Medicines has granted an exemption from the duty to ensure the package leaflet of the medicinal products in the official language in accordance with the requirements to be brought forward in the laws and regulations regarding the procedures for labelling medicinal products and for the package leaflet of medicinal products |   |
| 20. The sample sticker with information on the labelling in the official language.*Note. Not applicable:**1) to the cases referred to in Sub-paragraphs 19.1 and 19.2 of this Annex;**2) to the exception specified in the laws and regulations regarding the procedures for labelling medicinal products and the requirements to be brought forward for the package leaflet of medicinal products when the medicinal products are distributed to a medical treatment institution* |   |
| 21. Mock-up (copy) of the packaging (primary, secondary) of the medicinal products*Note. Not applicable to the cases referred to in Paragraph 19 of this Annex* |   |
| 22. Documents in relation to the raw materials, traceability and reporting systems regarding adverse effects in relation to a potential risk of infection, if the parallel imported medicinal products are immunological preparations or medicinal products obtained from human blood and plasma |   |
| 23. Certification that the following persons have been notified regarding the intention to commence distribution of parallel imported medicinal products in the Republic of Latvia:

|  |  |  |
| --- | --- | --- |
| 23.1. |   | medicinal product registration owner (marketing authorisation owner) |
|   | (date) |   |
|   |
| (name and address) |

  |   |
|

|  |  |  |  |
| --- | --- | --- | --- |
| 23.2. |   | medicinal product trademark (brand) owner |   |
|   | (date) |   | (name and address) |

  |   |

|  |  |  |
| --- | --- | --- |
| I, |   | , |
|   | (given name, surname, position of the responsible official, applicant or his or her authorised representative) |   |
| certify that the information provided is true. |
|  |

|  |
| --- |
| Responsible official (authorised representative of the applicant) |
|   |
| (position, given name, surname) |
|  |   |
| (signature) |   |
|  |   |
| (date) |   |

|  |  |
| --- | --- |
| Date of receipt of the submission in the State Agency of Medicines |   |

Notes.

1. In a column or row, which is not completed, draw a dash. Part III shall be filled in, if re-packaging is performed.

2. If information regarding several medicinal products of the same name with different types of packaging is indicated in one submission, Parts II, II.A and III shall be prepared separately for each type of packaging.

3. If the submission is submitted for approving variations, only the variations shall be indicated in the relevant box.

4. If the authorisation is drawn up on several pages, the responsible official shall sign each page.

5. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

**Annex 2**

Cabinet Regulation No. 416

26 June 2007

*[2 February 2016]*

**Authorisation for Distribution of Parallel Imported Medicinal Products in the Republic of Latvia**

**REPUBLIC OF LATVIA**

**STATE AGENCY OF MEDICINES**

|  |
| --- |
|   |
| (address, registration number, telephone and fax number) |

|  |  |
| --- | --- |
| Authorisation number and date of issuance |   |

|  |  |
| --- | --- |
| Authorisation owner |   |
|   | (name of the legal person, type, |
|   |
| registration number in the Enterprise Register, number of the special authorisation (licence)) |

|  |  |  |  |
| --- | --- | --- | --- |
| (submission for receipt of permit No. |   | , |   |
|   | (registration number in the State Agency of Medicines, date of submission and registration)) |

**Distribution of parallel imported medicinal products is permitted:**

|  |  |  |  |
| --- | --- | --- | --- |
| Name, form, strength and packaging size of the parallel imported medicinal product | Number of the authorisation for distribution of parallel imported medicinal products in the Medicinal Product Register of Latvia | Holder (owner) of the medicinal product registration certificate (in a European Economic Area state from which they are supplied), the state from which the medicinal products are supplied, and the registration number of the medicinal products therein | Manufacturer of the parallel imported medicinal products |
| 1 | 2 | 3 | 4 |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| Name, form and strength of medicinal products registered in Latvia in relation to medicinal products for which parallel importation has been performed | Registration number of the medicinal product registered in Latvia, within the Medicinal Product Register of Latvia | Holder (owner) of the medicinal product registration certificate in Latvia |
| 5 | 6 | 7 |
|  |  |  |

The parallel imported medicinal products have been re-packaged (mark with an “x” as appropriate):

yes

no



|  |  |
| --- | --- |
| Variations performed |   |

|  |
| --- |
| Information regarding permissible differences of parallel imported medicinal products from medicinal products registered in Latvia (if there are no differences, a line shall be drawn): |
| 1. Name of the manufacturer of medicinal products |   |
| 2. Trade name of medicinal products |   |
| 3. Colour (colour code), appearance, size, splitting lines and division lines which are intended for division of medicinal products in doses, storage time |
|   |

|  |  |
| --- | --- |
| Information regarding storage time of medicinal products |   |

|  |  |
| --- | --- |
| Decision to issue an authorisation for distribution of parallel imported medicinal products |   |
|   | (number, date) |

|  |  |  |
| --- | --- | --- |
| Director of the State Agency of Medicines |   |   |
|   | (signature) |   |

Place for stamp

|  |  |  |
| --- | --- | --- |
| Date |   |   |

Notes.

1. In a column or row, which is not completed, draw a dash.

2. The details of the document “signature” and “place for a seal”shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

**Annex 2.1**

Cabinet Regulation No. 416

26 June 2007

**Submission for Registration of a Person Carrying out Brokering of Medicinal Products**

*[8 October 2013]*

To the State Agency of Medicines

(mark with an “x” as appropriate)

for registration

for variations

**1. Information on the submitter:**

|  |  |
| --- | --- |
| 1.1. firm name (name) |  |
| 1.2. legal address |  |
| 1.3. registration numberor registration number of the firm name of the branch of the foreign merchant in the Commercial Register |  |
| 1.4. address of the actual place of operation in the Republic of Latvia |  |
| 1.5. number of the special authorisation (licence) for pharmaceutical activity (if any) |  |
| 1.6. contact information:telephone |  |
| fax |  |
| electronic mail address |  |
|  |  |
| website |  |
| contact person |  |
|  | (given name, surname, position) |

Information regarding the working hours of such undertaking which performs brokering of medicinal products

(the beginning and end of working hours shall be indicated)

|  |  |
| --- | --- |
| Monday |  |
| Tuesday |  |
| Wednesday |  |
| Thursday |  |
| Friday |  |
| Saturday |  |
| Sunday |  |

**2. I request to register variations** (mark with an “x” as appropriate):

|  |  |
| --- | --- |
| https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF3.1. in the name or firm name of the registered person |  |
| https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF3.2. in the legal address |  |
| https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF3.3. in the place of actual operation |  |
| https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF3.4. in the contact information |  |
|  | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFtelephone |  |
|  | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFfax |  |
|  | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFelectronic mail address |  |
|  | https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFcontact person |  |

Appended:

1. Description of the system for brokering of medicinal products (regarding quality system) on \_\_\_\_\_\_ pages.

2. Document by which the merchant or performer of economic activity authorises the contact person referred to in Sub-paragraph 1.6 of this submission to submit a submission and documents to the State Agency of Medicines, on \_\_\_\_\_\_\_ pages.

I certify that the information indicated in the submission is complete and true and it conforms to the requirements laid down in Cabinet Regulation No. 416 of 26 June 2007, Distribution and Quality Control of Medicinal Products.

|  |  |
| --- | --- |
| Contact information of the person responsible for registrationgiven name and surname |  |
| position |  |
| address |  |
| telephone, fax, e-mail |  |
|  |  |
| (place, date) |  | (signature)(signature of the person with the right of representation) |

Notes.

1. If an undertaking has several sites of activity, the information referred to in Sub-paragraph 1.4 of this Annex regarding other sites and responsible persons shall be indicated on a separate page and appended to the submission.

2. The performer of economic activity who needs not register with the Commercial Register shall indicate the given name, surname and personal identity number in Sub-paragraph 1.1 of this submission, the address of the declared place of residence – in Sub-paragraph 1.2, Sub-paragraph 1.3 need not be completed.

3. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

4. Upon submitting a submission regarding variations, such parts of the form shall be completed to which data regarding variations apply.

**Annex 2.2**

Cabinet Regulation No. 416

26 June 2007

*[8 October 2013]*

|  |  |  |
| --- | --- | --- |
| **LATVIJAS REPUBLIKA****ZĀĻU VALSTS AĢENTŪRA** |  | ***REPUBLIC OF LATVIA******STATE AGENCY OF MEDICINES*** |
| (juridiskā adrese, reģistrācijas numurs, tālruņa numurs,faksa numurs, e-pasta adrese) |  | *(legal address, registration number, phone,**fax number, e-mail)* |

**Personas, kas veic starpniecības darījumus ar zālēm,**

**REĢISTRĀCIJAS APLIECĪBA**

***Person engaged in brokering of medicinal products***

***REGISTRATION CERTIFICATE***

|  |  |
| --- | --- |
| 1. Reģistrācijas numurs  |   |
| *Registration number* |   |

|  |  |
| --- | --- |
| 2. Reģistrētās personas firma (nosaukums) |   |
| *Name or corporate name of registrant* |   |

|  |  |
| --- | --- |
| 3. Reģistrētās personas juridiskā adrese |   |
| *Permanent or legal address of registrant* |   |
| 4. Faktiskās darbības norises vietas |
| adrese |   |
| *Address of a site where registered activities take place* |

|  |  |
| --- | --- |
| 5. Reģistrācijas juridiskais pamatojums  |   |
| *National legal basis of registration* |   |

Šī reģistrācijas apliecība ir derīga tikai pilnā apjomā, iekļaujot visas lapas.

*This registration form is only valid in full, including all the pages.*

Šīs reģistrācijas apliecības 2.punktā minētā persona par jebkurām izmaiņām ziņo nekavējoties.

*The registered person referred to in Paragraph 2 should report immediately of any changes.*

|  |  |  |  |
| --- | --- | --- | --- |
| Zāļu valsts aģentūras atbildīgā amatpersona*Name of the authorised person of the State Agency of Medicines* |   |   |   |
|  | (paraksts/*signature*) | (amats, vārds, uzvārds/*position, name, surname*) |

Piezīme. Dokumenta rekvizītu "paraksts" neaizpilda, ja elektroniskais dokuments ir sagatavots atbilstoši normatīvajiem aktiem par elektronisko dokumentu noformēšanu.

*Remark. Document property* "*Signature*" *is not filled in if the document is prepared in accordance with the laws of electronic documents.*

**Annex 3**

Cabinet Regulation No. 416

26 June 2007

**Distribution Authorisation for Selling of the Remaining Stock of Medicinal Products**

[2 February 2016]

**Annex 4**

Cabinet Regulation No. 416

26 June 2007

*[11 September 2012; 8 October 2013]*

**REPUBLIC OF LATVIA**

**STATE AGENCY OF MEDICINES**

|  |
| --- |
|   |
| (legal address, registration number, telephone and fax number) |

**Authorisation for Distribution of Medicinal Products Registered in a European Economic Area State, but Unregistered in the Republic of Latvia**

Rīga

|  |  |  |  |
| --- | --- | --- | --- |
|   |   | No. |   |
| (date) |   |   |   |

|  |  |  |  |
| --- | --- | --- | --- |
| On the basis of decision No. |   | of the State Agency of Medicines |   |
|   | (date) |   |   |

on the issuance of the authorisation for medicinal products registered in a European Economic Area State, but unregistered in the Republic of Latvia, for the purpose of protection of public health it is permitted to distribute the following medicinal products in the Republic of Latvia:

|  |  |  |  |
| --- | --- | --- | --- |
| Submission No. |   | Received |   |
|   | (registration number in the State Agency of Medicines) |  | (registration date in the State Agency of Medicines) |

|  |  |
| --- | --- |
| 1. Name of the medicinal product, form, strength or concentration and quantity in the packaging unit |   |
| 2. International name of the active ingredient(s) |   |
| 3. Marketing authorisation owner (name, legal address, state) |   |
| 4. European Union Member State or European Economic Area state which has granted the marketing authorisation (registration certificate) and registration number |   |
| 5. Manufacturer of the medicinal products (name, address, state) |   |
| 6. ATC code and DDD code |   |
| 7. Identification number |   |
| 8. Distribution condition |   |

Bringing in of medicinal products from European Economic Area states is permitted.

|  |  |
| --- | --- |
| The authorisation is valid until |   |
|   | (date) |
| Director of the State Agency of Medicines |  |
|   | (signature) |

Place for a seal

Notes.

1. In column 3 of the Table the registration certificate owner or the submitter of the submission for registration of the medicinal product shall be indicated in accordance with the laws and regulations regarding the procedures for registering medicinal products.

2. In column 6 of the Table the anatomical therapeutic chemical classification code (ATC code) and the defined daily dose code (DDD code) shall be indicated.

3. In column 7 of the Table the identification number of medicinal products assigned by the State Agency of Medicines for each size of the packaging of the form of medicinal products shall be indicated.

4. In column 8 of the Table the classification group which has been granted in accordance with the laws and regulations regarding the procedures for classification of medicinal products, and the designation thereof shall be indicated. The designation shall not be indicated for medicinal products not subject to medical prescription.

5. In a column or row, which is not completed, a dash shall be drawn.

6. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

**Annex 5**

Cabinet Regulation No. 416

26 June 2007

*[11 September 2012; 8 October 2013; 2 February 2016]*

**Submission for Receipt of an Authorisation for Distribution of Medicinal Products Registered in a European Economic Area State, but Unregistered in the Republic of Latvia**

(Mark with an “x” as appropriate)

Submission for granting an authorisation 

Submission regarding variations in documentation 

We request the State Agency of Medicines to issue an authorisation for distribution of the unregistered medicinal products indicated in Part I of the submission in the Republic of Latvia

We wish to receive the authorisation in the form of a printed document

(mark with an “x” as appropriate)

yes

no

**Part I**

**Information regarding the applicant and medicinal products**

|  |
| --- |
| 1. Applicant: |
| 1.1. name of the legal person, type |
| 1.2. registration number |
| 1.3. telephone number | fax number |
| 1.4. electronic mail address |
| 2. Medicinal products: |
| 2.1. name |
| 2.2. form of the medicinal product |
| 2.3. strength or concentration |
| 2.4. package size |
| 2.5. international name of the active ingredient |
| 3. Holder of the registration certificate (registration owner) (name, state, legal address) |
| 4. European Union Member State or European Economic Area state which has granted the marketing authorisation (registration certificate), and the registration number of the medicinal products in such state |
| 5. Medicinal product manufacturer: |
| 5.1. name |
| 5.2. legal address and fixed establishment address |
| 5.3. telephone number | fax number | electronic mail address |
| 6. Contact person regarding the submission (given name, surname, telephone number, fax number, electronic mail address) |

**Part II**

**Appended Documents**

(mark with an “x” as appropriate, indicate the number of pages appended)

|  |  |
| --- | --- |
| 1. Labelling of the medicinal products: |  |
| 1.1. mock-up of the primary and secondary packaging in the original language |  |
| 1.2. mock-up of the labelling in which the location of the sticker is indicated |  |
| 1.3. certified translation of the text of the labelling in accordance with the laws and regulations regarding the certification of translations into the official language |  |
| 1.4. information regarding the re-labeller (re-packer) – the name, legal address and address of activity, number of the licence for manufacture of medicinal products |  |
| 2. Package leaflet of medicinal products and description of medicinal products: |  |
| 2.1. in the original language |  |
| 2.2. certified translation of the package leaflet in accordance with the laws and regulations regarding the certification of translations into the official language |  |
| 3. Statement of a professional association of doctors regarding the medicinal products with a justification of public health considerations |  |
| 4. [2 February 2016] |  |

|  |  |
| --- | --- |
| I, | , |
|  | (given name, surname, position of the responsible official, applicant or his or her authorised representative) |

certify that the information provided by me is true.

|  |
| --- |
| Responsible official (authorised representative of the applicant): |
| given name, surname, position |  |
| signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Place \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Date of the receipt of the submission at the State Agency of Medicines \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Notes.

1. In a column or row, which is not completed, a dash shall be drawn.

2. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

**Annex 6**

Cabinet Regulation No. 416

26 June 2007

*[11 September 2012; 8 October 2013; 2 February 2016]*

**REPUBLIC OF LATVIA**

**STATE AGENCY OF MEDICINES**

|  |
| --- |
|  |
| (legal address, registration number, telephone and fax number) |

**Authorisation for Distribution of Unregistered Medicinal Products for Individually Granted Medicinal Products**

Rīga

|  |  |  |
| --- | --- | --- |
|  |  | No.\_\_\_\_\_\_\_\_\_ |
| (date) |  |  |

On the basis of the decision No.\_\_ of the State Agency of Medicines on the issuance of the authorisation for distribution of unregistered medicinal products in the Republic of Latvia, the distribution of medicinal products in the Republic of Latvia is permitted to

|  |
| --- |
|  |
| (name, type, registration number of the legal person) |

|  |  |  |  |
| --- | --- | --- | --- |
| Submission No. |  | Received |  |
|  | (registration number in the State Agency of Medicines) |  | (registration date in the State Agency of Medicines) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Identification number | Name of the medicinal product, form, strength or concentration and quantity in the packaging unit | Quantity of packaging units | Medicinal product may be distributed to | Medicinal product manufacturer, state |
| 1 | 2 | 3 | 4 | 5 |
|  |  |  |  |  |
|  |  |  |  |  |

|  |
| --- |
| Bringing in of medicinal products is permitted from:(mark with an “x” as appropriate): |
| https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFthe European Economic Area states |
| https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFthe third countries |

|  |  |
| --- | --- |
| The authorisation is valid until |  |
|  | (date) |
| Director of the State Agency of Medicines |  |
|  | (signature) |

Place for a seal

If the quantity of the packaging units of medicinal products is indicated in the authorisation, a new authorisation for distribution of unregistered medicinal products is necessary for repeated distribution of the medicinal products according to the quantity of packaging units of medicinal products indicated in the authorisation.

Notes.

1. In a column or row, which is not completed, a dash shall be drawn.

2. In the Table the section “Bringing in of medicinal products is permitted from:” shall be filled in according to the information indicated in the submission for the receipt of an authorisation for distribution of individually granted unregistered medicinal products.

3. In column 4 of the Table the person to whom the authorisation owner is entitled to distribute the medicinal products indicated in the authorisation (shall not apply to the authorisation referred to in Notes 4 and 5) shall be indicated, by including an indication:

3.1. “to the pharmacy”, and indicate its name and licence number;

3.2. “to the medical treatment institution”, and indicate its name and registration number in the Register of Medical Treatment Institutions;

3.3. “to the social care institution”, and indicate its name, number of the taxpayer certificate of the State Revenue Service in the Register of Taxpayers of the State Revenue Service;

3.4. “to the practising veterinarian”, and indicate its given name, surname and registration number in the Register of Enterprises Subject to Monitoring by the Food and Veterinary Service;

3.5. “to the institution engaged in veterinary medical care”, and indicate its name and registration number in the Register of Enterprises Subject to Monitoring by the Food and Veterinary Service.

4. In the authorisation for unregistered medicinal products which conform to the list of usable medicinal products or which are distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment (shall not apply to the authorisation referred to in Note 3):

4.1. column 3 of the Table shall not be completed;

4.2. in column 4 of the Table the relevant indication shall be included:

4.2.1. “Medicinal products conform to the list of medicinal products usable in hospitals”;

4.2.2. “Medicinal products are distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment”. The name of a specific pharmacy and medical treatment institution need not be indicated.

5. For medicinal products for compassionate use:

5.1. in column 4 “Medicinal product may be distributed to” of the Table the following shall be included:

5.1.1. the indication “Medicinal product is available for compassionate reasons” pursuant to Article 83 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

5.1.2. the given name and surname of the clearly known patient or the indication “group of patients”;

5.1.3. the medical treatment institution where the medicinal product is being assigned to the patient;

5.2. in column 5 of the Table the following shall be indicated:

5.2.1. the name, address of the manufacturer of the medicinal product, contact persons (given name, surname, position, telephone, fax, electronic mail address (if any));

5.2.2. the name of the state of manufacture;

5.2.3. the name, address of the authorisation requester, and contact persons (given name and surname, position, telephone, fax, electronic mail address (if any));

5.3. the following shall be appended to the authorisation:

5.3.1. the programme for the use of the medicinal product referred to in Sub-paragraph 94.33.3 of this Regulation (except the draft of the medicinal product labelling and package leaflet);

5.3.2. the medicinal product labelling and package leaflet in the official language;

5.3.3. the opinion of the Committee for Medicinal Products of the European Medicines Agency regarding the conditions for the use and distribution of the medicinal product and the target group patients (if any).

6. In the introductory part of the authorisation, after the entry regarding the name and type of the legal person, the number of the special authorisation (licence) shall be indicated for the wholesaler of the medicinal products and medicinal product manufacturer instead of the registration number. If the authorisation regarding medicinal products for compassionate use is issued to a medical treatment institution, the registration number of the medical treatment institution in the Register of Medical Treatment Institutions shall be indicated.

7. In column 1 of the Table the identification number of the medicinal product granted by the State Agency of Medicines shall be indicated.

8. The indication “The authorisation is valid until” shall be included in the authorisation, if the authorisation is issued regarding:

8.1. medicinal products conforming to the list of usable medicinal products;

8.2. medicinal products distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment;

8.3. medicinal products for compassionate use, if the term of validity of the authorisation is determined.

9. The indication “After distribution of the quantity of the medicinal products indicated in the authorisation, a new authorisation for distribution of unregistered medicinal products is necessary for repeated distribution (importation) of the medicinal products” shall be included in the authorisation, if the quantity of the packaging units is indicated in the authorisation.

10. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

**Annex 7**

Cabinet Regulation No. 416

26 June 2007

*[27 July 2010; 11 September 2012; 8 October 2013; 2 February 2016]*

**Submission for Obtaining an Authorisation for Distribution of Individually Granted Unregistered Medicinal Products**

We request the State Agency of Medicines to issue an authorisation for the distribution of individually granted unregistered medicinal products in the Republic of Latvia for the medicinal products indicated in Part I.

We wish to receive the authorisation in the form of a printed document

(mark with an “x” as appropriate)

yes

no

**Part I**

**Information regarding the applicant and medicinal product**

|  |
| --- |
| 1. Authorisation requester |
| 1.1. name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Licence No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1.2. telephone number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ fax number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1.3. electronic mail address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1.4. address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2. Medicinal product |
| 2.1. name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2.2. form of the medicinal product \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2.3. active ingredient and strength or concentration \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2.4. packaging unit size and quantity of the packaging units (shall not apply, if the medicinal product conforms to the list of usable medicinal products or the medicinal product is distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2.4.1 it is intended to bring in the medicinal products from a European Economic Area state (mark with an “x” as appropriate):https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFnoIf the answer is “yes”, the state shall be indicated\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| it is intended to bring in the medicinal products from a third country (mark with an “x” as appropriate):https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFnoIf the answer is “yes”, the state shall be indicated\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2.5. the medicinal product is distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment (mark with an “x” as appropriate):https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 2.6. conforms to the list of the usable medicinal products of the hospital (mark with an “x” as appropriate):https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 2.7. conforms to the medicinal products for compassionate use in accordance with Article 83(2) of Regulation (EC) No 726/2004 of the European Parliament and of the Council (mark with an “x” as appropriate):https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 2.7.1. a programme for the use of the medicinal product has been drawn up (mark with an “x” as appropriate):https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFno |
| 2.7.2. the medicinal product for compassionate use has been used or is used in the European Union (mark with an “x” as appropriate):https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFnoIf the answer is “yes”, the state shall be indicated\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2.7.3. the person responsible for registration and notification of adverse effects, as is stipulated in Article 24(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council (given name, surname, contact address, telephone, fax, electronic mail address) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2.7.4. whether, when using the medicinal product for compassionate use, any adverse effects referred to in Article 24(1)of Regulation (EC) No 726/2004 of the European Parliament and of the Council were determined (mark with an “x” as appropriate):https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFyes https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFnoIf the answer is “yes”, the state shall be indicated\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2.8. the state in which the medicinal products are registered, and the registration number of the medicinal products therein\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 3. Medicinal product manufacturer: |
| 3.1. name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 3.2. legal address and fixed establishment address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 3.3. telephone number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ fax number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4. Person to be contacted regarding the application (given name and surname, position, telephone, fax, electronic mail address) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 5. Supplier of the medicinal products (name, legal address and address of activity)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Part II**

**Appended Documents**

Mark as appropriate with an “x” and indicate the number of pages appended

|  |
| --- |
| 1. [2 February 2016] |
| 2. [2 February 2016] |
| 3. The request of the pharmacy, medical treatment institution, social care institution, practising veterinarian and the merchant engaged in veterinary medical care.Note. The column need not be completed regarding medicinal products included in the list of usable medicinal products, which are distributed within the scope of the system for reimbursement of expenses for the acquisition of medicinal products intended for out-patient medical treatment, as well as regarding medicinal products for compassionate use |  |
| 4. Regarding medicinal products for compassionate use: |  |
| 4.1. the reasoned substantiation of the medical treatment institution for the use of the medicinal product for a clearly known group of patients and for the conformity of use in respect of the chronic or seriously debilitating disease specified in Article 83(2) of Regulation (EC) No 726/2004 of the European Parliament and of the Council or a disease, which is considered to be life-threatening and for which a satisfactory medical treatment result cannot be achieved by using medicinal products registered in Latvia or the European Union |  |
| 4.2. the certification of the authorisation requester: |  |
| 4.2.1. that the submission for registration has been submitted to the European Medicines Agency pursuant to Article 6 of Regulation (EC) No 726/2004 of the European Parliament and of the Council |  |
| 4.2.2. that the medicinal product is undergoing a clinical trial |  |
| 4.3. the programme for the use of the medicinal product |  |
| 4.4. the description of the product, the draft of the medicinal product labelling and package leaflet in the official language |  |
| 4.5. the copy of the submission for registration submitted to the European Medicines Agency and the data and documents appended thereto |  |
| 4.6. the opinion (scientific recommendation) of the Committee for Medicinal Products of the European Medicines Agency or a competent authority of another European Union Member State |  |
| 5. [2 February 2016] |

|  |  |  |
| --- | --- | --- |
| I, |  | , |
|  | (given name, surname, position of the responsible official, applicant or his or her authorised representative) |  |

certify that the information provided is true.

|  |
| --- |
| Responsible official (authorised representative of the applicant): |
| given name, surname, position \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |
| (place, date) |  | (signature) |

Date of the receipt of the submission at the State Agency of Medicines \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Notes.

1. The licence number shall not be indicated in Sub-paragraph 1.1 of Part I, if the authorisation is requested for medicinal products for compassionate use. In this case, the registration number of the medical treatment institution in the Register of Medical Treatment Institutions shall be indicated in Sub-paragraph 1.1 of Part I.

2. In a column or row, which is not completed, a dash shall be drawn.

3. If the form is sent without using electronic data media, the applicant shall sign each page appended to the form.

4. *[11 September 2012]*

5. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

**Annex 8**

Cabinet Regulation No. 416

26 June 2007

*[11 September 2012]*

**Medicinal products subjected to Quality Control**

The following medicinal products are subject to quality control:

|  |  |
| --- | --- |
| No. | Medicinal product |
| 1. | Eye drops and eye ointments: |
| 1.1. | at least one batch of the medicinal product in the medicinal product wholesaler within a calendar year |
| 1.2. | at least one batch of the medicinal product in the medicinal product manufacturing undertaking within a calendar year |
| 1.3. | in the medicinal product wholesaler each batch of the medicinal product prior to the commencement of distribution, if it is intended to distribute the medicinal product on the basis of a medical treatment institution request, in accordance with Section 10, Clause 7, Sub-clause “b” of the Pharmaceutical Law |
| 2. | Injections and infusion liquids: |
| 2.1. | at least one batch of the medicinal product in the medicinal product wholesaler and medicinal product manufacturing undertaking within a calendar year (this does not apply to the specifications of Paragraphs 4 and 5 of this Annex) |
| 2.2. | in the medicinal product wholesaler each batch of the medicinal product prior to the commencement of distribution, if it is intended to distribute the medicinal product on the basis of a medical treatment institution request, in accordance with Section 10, Clause 7, Sub-clause “b” of the Pharmaceutical Law |
| 3. | Powders in ampoules and vials (except immunological preparations and insulin preparations): |
| 3.1. | at least one batch of the medicinal product in the medicinal product wholesaler and the medicinal product manufacturing undertaking within a calendar year |
| 3.2. | in the medicinal product wholesaler each batch of the medicinal product prior to the commencement of distribution, if it is intended to distribute the medicinal product on the basis of a medical treatment institution request, in accordance with Section 10, Clause 7, Sub-clause “b” of the Pharmaceutical Law |
| 4. | Immunological preparations – packed and unpacked samples of the following preparations from each batch of the medicinal product: |
| 4.1. | live vaccines |
| 4.2. | immunological preparations that are intended for the primary immunisation of infants or other risk groups |
| 4.3. | immunological preparations that are used in public immunisation programmes |
| 4.4. | new immunological preparations or immunological preparations which have been manufactured using new or modified technologies or technologies new to the relevant manufacturer which have been indicated in the registration documentation |
| 5. | Medicinal products derived from human blood and plasma – packed and unpacked samples from each batch of the medicinal product |
| 6. | Non-sterile pharmaceutical forms: |
| 6.1. | at least one batch of the medicinal product from each pharmaceutical form in the medicinal product wholesaler and the medicinal product manufacturing undertaking within a calendar year |
| 6.2. | in the medicinal product wholesaler each batch of the medicinal product prior to the commencement of distribution, if it is intended to distribute the medicinal product on the basis of a medical treatment institution request, in accordance with Section 10, Clause 7, Sub-clause “b” of the Pharmaceutical Law |

Note. The control referred to in Sub-paragraphs 1.1, 2.1 and 3.1, Paragraphs 4 and 5 and Sub-paragraph 6.1 of this Annex shall also be applied to the wholesaler of medicinal products which imports medicinal products (a person who has the special authorisation (licence) referred to in Sub-paragraph 11.2 of this Regulation for the manufacturing or importing medicinal products).

Acting for the Minister for Health, Minister for Welfare D. Staķe

**Annex 8.1**

Cabinet Regulation No. 416

26 June 2007

*[2 February 2016]*

**Notification of a Medicinal Product Registration Owner Regarding Activity Executed Thereby in Order to Suspend Distribution of Medicinal Products, to Request Recall of Medicinal Products from the Market, to Request Cancellation of Registration or not to Apply for Re-registration of Medicinal Products, and Regarding Justification for the Relevant Activity**

*Notification of "withdrawn products" by marketing authorization holders*

|  |  |
| --- | --- |
| Reģistrācijas īpašnieks |  |
| *Marketing authoriation holder* |  |

|  |
| --- |
| 1. Datums*Date* |
| 2. Kompetentās iestādes nosaukums*Name of regulatory authority* |
| 3. Iesniedzam paziņojumu par*Please find herewith enclosed our notification for a*https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFCentrālajā reģistrācijas procedūrā reģistrētajām zālēm saskaņā ar Regulas Nr. 1027/2012 13. un 14.b pantu*Centrally authorized medicinal product in accordance with Article 13 and 14b of Regulation 1027/2012*https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIFNacionālajā reģistrācijas procedūrā reģistrētajām zālēm saskaņā ar Ministru kabineta 2007. gada 26. jūnija noteikumu Nr. 416 "Zāļu izplatīšanas un kvalitātes kontroles kārtība" 115.1. un 153.3.2. apakšpunktu*Nationally Authorized medicinal product in accordance with Article 23a and 123 of Directive 2012/26/EC* |
| 3.1. Zāļu nosaukums, stiprums vai koncentrācija, zāļu forma, daudzums*Dosage form* | 3.2. Starptautiskais nepatentētais nosaukums*INN* | 3.3. Zāļu reģistrācijas numurs*Authorization number* | 3.4. Eudravigilances (EV) kods*EudraVigilance (EV) CODE* |
| 1 | 2 | 3 | 4 |
| 4. Darbības, kuras paredzēts veikt ar minētajām zālēm:*To take the following action(s):*https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF4.1. apturēt zāļu izplatīšanu (pastāvīgi vai uz laiku)*cease the marketing of a medicinal product (permanently or temporarily)*https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF4.2. apturēt zāļu reģistrācijas apliecības darbību*suspend the marketing of a medicinal product*https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF4.3. atsaukt zāles no tirgus*withdraw a medicinal product from the market*https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF4.4. pieprasīt reģistrācijas atsaukšanu;*request the withdrawal of a marketing authorisation*https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF4.5. nepieteikties pārreģistrācijai*not to apply for the renewal of a marketing authorisation* |
| 5. Paziņoju, ka šīs darbības cēloņi (cēlonis):*I declare that the reason(s) for such action(s) are*https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF5.1. attiecas uz Ministru kabineta 2006. gada 9. maija noteikumu Nr. 376 "Zāļu reģistrēšanas kārtība" 114. punktā vai Ministru kabineta 2007. gada 26. jūnija noteikumu Nr. 416 "Zāļu izplatīšanas un kvalitātes kontroles kārtība" 115.1. apakšpunktā noteikto*based on the grounds provided in Articles 116 and 117 of Directive 2001/83/EC*https://likumi.lv/wwwraksti/BILDES/KVADRATS.GIF5.2. neattiecas uz Ministru kabineta 2006. gada 9. maija noteikumu Nr. 376 "Zāļu reģistrēšanas kārtība" 114. punktā vai Ministru kabineta 2007. gada 26. jūnija noteikumu Nr. 416 "Zāļu izplatīšanas un kvalitātes kontroles kārtība" 115.1. apakšpunktā noteikto*not based on the grounds provided in Articles 116 and 117 of Directive 2001/83/EC* |

Apliecinu, ka kopā ar šo pavadvēstuli tiek iesniegta izplatīšanas lapa MS *ExcelM* formātā (veidne *EMA/445787/2013*), nosaukta *<Zāļu reģistrācijas īpašnieka reģistrācijas faila nosaukums>*, kas satur visu nepieciešamo informāciju par attiecīgajām zālēm.

*I herewith confirm that together with this cover letter an Excel spread sheet (template EMA/445787/2013) entitled <MAH file name> is submitted containing all the required information related to the medicinal product(s) concerned.*

Ar cieņu

Yours sincerely

|  |  |
| --- | --- |
| Pilnvarotā persona |  |
| *The authorised person* | (vārds, uzvārds) |

|  |  |  |
| --- | --- | --- |
| Paraksts |  |  |
| *Signature* |  |  |

|  |  |
| --- | --- |
| Zāļu reģistrācijas īpašnieks |  |
| *MAH (name, country)* | (nosaukums, valsts) |

Piezīmes.

1. Paziņojuma pavadvēstuli noformē uz reģistrācijas apliecības īpašnieka veidlapas.

*The cover letter of the notification has to be written on a headed paper.*

2. Dokumenta rekvizītu "paraksts" neaizpilda, ja elektroniskais dokuments ir sagatavots atbilstoši normatīvajiem aktiem par elektronisko dokumentu noformēšanu.

*The document part "Signature" shouldn`t be filled in if the electronic document is prepared in accordance with the normative acts on creation of electronic documents.*

3. Eiropas zāļu aģentūrai paziņojumu nosūta uz elektroniskā pasta adresi: withdrawnproducts@ema.europa.eu.

*European Medicines Agency notice shall be sent to the e-mail address: withdrawnproducts@ema.europa.eu*

**Annex 9**

Cabinet Regulation No. 416

26 June 2007

**Quality Defects of Medicinal Products**

1. Class I defects are potentially life threatening or may cause a serious risk to health, for example:

1.1. wrong medicinal product (label and contents are different products);

1.2. correct medicinal product but wrong strength, with serious medical consequences;

1.3. microbiological contamination of a sterile injectable or ophthalmic medicinal product;

1.4. chemical contamination with serious medical consequences;

1.5. mix-up of some types of products within more than one container; or

1.6. wrong active ingredient in a multi-component medicinal product, with serious medical consequences.

2. Class II defects may cause illness or mistreatment, but are not classified as Class I defects, for example:

2.1. poor labelling, for example, wrong or missing text or figures;

2.2. missing or incorrect information (package leaflet);

2.3. microbiological contamination with medical consequences of a non-injectable liquid, sterile medicinal product which is used in ophthalmology;

2.4. chemical or physical contamination (significant impurities, cross-contamination, particulates);

2.5. mixing in of some products in containers (rogues);

2.6. non-compliance with specifications (for example, assay, stability, fill, weight); or

2.7. insecure closure with serious medical consequences (for example, cytotoxics, child-resistant container, potent medicinal products).

3. Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons, for example:

3.1. faulty packaging (for example, wrong or missing batch number or expiry date);

3.2. faulty closure; or

3.3. contamination of outer packaging (for example, microbiological spoilage, dirt or detritus (dead organic waste) material, particulate matter.

Acting for the Minister for Health, Minister for Welfare D. Staķe

**Annex 10**

Cabinet Regulation No. 416

26 June 2007

*[21 October 2008; 27 July 2010; 8 October 2013]*

**Notification on Recall of Medicinal Products**

**I. Notification provider:**

Name

Licence number

Address

Registration number in the database of the Health Inspectorate

(to be filled in by the Health Inspectorate after the receipt of the notification)

**II. Information regarding recalled medicinal products**

Reference number of the rapid alert notification of a quality defect/recall \_\_\_\_\_\_\_\_\_

Name and prerequisites of the rapid alert notification sender \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the medicinal product, strength and form of the medicinal product \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The medicinal product received from the supplier

(name, address)

Quantity of the medicinal product received from the supplier \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Person to whom the medicinal product is supplied | Quantity of the supplied medicinal product | Return date of the recalled medicinal product | Quantity of the returned medicinal product |
|  |  |  |  |  |

Responsible person for withdrawal of the medicinal product from the market

(position, given name, surname, signature)

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

Acting for the Minister for Health, Minister for Welfare D. Staķe

**Annex 11**

Cabinet Regulation No. 416

26 June 2007

**Notification of Continuous Operation Telephone Number (or Other Means of Communication) Available for Communication Twenty-four Hours a Day and Contact Persons Responsible for the Recall of Medicinal Products**

[2 February 2016]

**Annex 12**

Cabinet Regulation No. 416

26 June 2007

*[21 October 2008; 27 July 2010; 8 October 2013]*

Piezīmes.

1. Ailē vai rindā, kuru neaizpilda, ievelk svītru.

2. Ja atļauju noformē uz vairākām lapām, atbildīgā amatpersona paraksta katru lapu.

3. Ja izdots rīkojums, ka pēc sākotnējās ātrās reaģēšanas sērijai nepieciešama sekojoša ātrā reaģēšana, 18.punktā norāda “Ātra reaģēšana, kas seko sākotnējai ātrai reaģēšanai# references numurs#” (“*Rapid Alert following original rapid alert# ref.no#*”). Aizpilda Veselības inspekcija.

4. Ātrās reaģēšanas paziņojumam ir references numurs, kuru veido valsts kods (valsts, kurā fakts konstatēts pirmo reizi), kompetentās iestādes kods un, ja nepieciešams, klasifikācija un korespondences numurs (piemēram, LV//II/04/07 – norāda otrās klases ātrās reaģēšanas iniciatīvu no Latvijas, ceturto ātro reaģēšanu pēc kārtas, kuru inicējusi Latvija, septīto ātrās reaģēšanas korespondenci) (atbilstoši Ministru kabineta 2007.gada 26.jūnija noteikumu Nr.416 “Zāļu izplatīšanas un kvalitātes kontroles kārtība” XII nodaļas prasībām). Aizpilda Veselības inspekcija.

5. Ja paziņojumu sniedz par viltotām zālēm, virsrakstā norāda “Ātrās reaģēšanas paziņojums par viltotām zālēm”.

6. 15.punktā norāda speciālas atļaujas (licences) zāļu ražošanai īpašnieku un kvalificēto personu, kas speciālas atļaujas (licences) īpašnieka vārdā ir izlaidusi sēriju, ja tās ir dažādas personas.

7. Dokumenta rekvizītu "paraksts" neaizpilda, ja elektroniskais dokuments ir sagatavots atbilstoši normatīvajiem aktiem par elektronisko dokumentu noformēšanu.

Veselības ministra vietā – labklājības ministre D.Staķe

Notes.

1. In a column or row, which is not completed, draw a dash.

2. If the authorisation is drawn up on several pages, the responsible official shall sign each page.

3. If an order is issued that after the initial rapid alert the batch needs a following rapid alert, it shall be indicated in Paragraph 18 “Rapid Alert following original rapid alert# ref.no#”. To be filled in by the Health Inspectorate.

4. The rapid alert notification shall have a reference number, which is formed from the state code (state in which the fact is establish the first time), the code of the competent authority, and, where necessary, classification and correspondence number (for example, LV//II/04/07 – indicates Class II rapid alert initiative from Latvia, the fourth alert in succession which has been initiated by Latvia, the seventh rapid alert correspondence (in conformity with the requirements of Chapter XII of Cabinet Regulation No.416 of 26 June 2007, Procedures for the Distribution and Quality Control of Medicinal Products). To be filled in by the Health Inspectorate.

5. If the notification is provided for counterfeit medicinal products, the title shall indicate “Rapid Alert Notification on Counterfeit Medicinal Product”.

6. The owner of the special authorisation (licence) for medicinal product manufacturing and the qualified person who has released the batch in the name of the owner of the special authorisation (licence) shall be indicated in Paragraph 15, if they are not one and the same person.

7. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

Acting for the Minister for Health, Minister for Welfare D. Staķe

**Annex 13**

Cabinet Regulation No. 416

26 June 2007

*[27 July 2010; 8 October 2013]*

Piezīme. Dokumenta rekvizītu "paraksts" neaizpilda, ja elektroniskais dokuments ir sagatavots atbilstoši normatīvajiem aktiem par elektronisko dokumentu noformēšanu.

Veselības ministra vietā – labklājības ministre D.Staķe

Note. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

Acting for the Minister for Health, Minister for Welfare D. Staķe

**Annex 13.1**

Cabinet Regulation No. 416

26 June 2007

*[2 February 2016]*

**Report On Inspection of Good Distribution Practice of Medicinal Products**

Riga

|  |  |  |
| --- | --- | --- |
| Report No. |   |   |
| Site of inspection |   |   |

|  |  |
| --- | --- |
| Firm name of the merchant or given name, surname of the performer of economic activity |   |
| Legal address of the merchant or declared address of the performer of economic activity |   |
| Name of the undertaking of pharmaceutical activity |   |
| Address of the site of pharmaceutical activity, contact information |   |

|  |
| --- |
| Wholesale activities involving medicinal products to be registered/registered |
|   | acquisition |
|   | storage |
|   | supply |
|   | export |
|   | brokering |
|   | others (describe) |

|  |  |
| --- | --- |
| Conditions for special activity |   |
| Other activities |   |

|  |
| --- |
| Conditions for special activity |
|   | acquisition |
|   | storage |
|   | supply |
|   | export |
|   | brokering |
|   | others (describe) |

|  |  |
| --- | --- |
| Other activities |   |
| Date of inspection |   |   |
|   | (day, month, year) |   |
| Inspector and expert |  |   |
| Leading inspector |  |   |
|   | (given name, surname, institution) |   |
| Inspector |  |   |
|   | (given name, surname, institution) |   |

|  |
| --- |
| References: |
| • Number of the special authorisation (licence) for distribution of medicinal products for human use in wholesale |
|   |
| • Number and date of the certificate of good distribution practice compliance of a distributor of medicinal products in relation to medicinal products for human use |
|   |
| • Registration number (for a person carrying out brokering of medicinal products) |
|   |

**1. Introductory part**

1.1. Short description of the undertaking and entrepreneurial activities

*The fields of activity of the undertaking and the types of products distributed shall be indicated.*

1.2. Previous inspection

*Date, given name, surname of the inspector who participated in the previous inspection*

1.3. Variations since the previous inspection

*The most significant variations in the staff, premises, installations and equipment shall be described. If possible, references shall be indicated or information shall be included from documents of the undertaking in which these or future changes are described.*

*The principal text of the report must be written in the past form because the report applies to that observed during inspection. Other verb tense may be used in the description of future plans.*

**2. Short layout of the inspection activities carried out**

2.1. Field of inspection (type and reason)

*Short description of inspection (for example, conformity of distribution activities with good distribution practice). The reason for inspection shall be indicated (for example, repeat (routine) inspection, submission for the receipt of a licence, justified reason for inspection).*

2.2. Purpose of inspection

2.3. Inspected area and activities

*Each activity inspected shall be indicated.*

2.4. Non-inspected areas and activities

*If necessary, the area or activities which were not inspected, shall be indicated.*

2.5. The staff met during the inspection

2.6. The responsible person

*The given name, surname, name of the position of those representative of the managing staff shall be indicated with whom meetings took place during the inspection.*

**3. Observations of inspectors in relation to the inspection and deficiencies detected**

*References to the titles of the relevant chapters of the good distribution practice guidelines shall be indicated.*

*A short description of the relevant activities must be indicated within the scope of the section.*

*The most significant procedures or aspects, as well as future plans which might affect the performance of the next inspection, may be indicated.*

*This section may be linked to the section regarding the deficiencies detected in order to explain their classification.*

Report on the measures detected in the previous inspection and taken for elimination of the deficiencies

Quality management

Staff

Premises and installations

Documentation

Activities

Complaints, return of medicinal products, suspicions regarding counterfeit medicinal products, and recall of medicinal products

Activities transferred to providers of outsourced services

Self-inspection

Transportation

Other specific issues identified

*For example, significant variations in the future notified by the undertaking.*

**4. Various information**

*Samples taken*

*Annexes appended. Information regarding the administrative punishments imposed for violating the specified procedures in pharmaceutical activity or violating the laws and regulations regarding circulation of narcotic and psychotropic substances and medicinal products after the previous inspection, the officials punished, and information regarding payment of a fine shall also be indicated in Annex.*

*List of annexes appended*

*List of deficiencies (critical, significant and other)*

*All deficiencies and a corresponding reference to the requirements of the laws and regulations governing the field of distribution of medicinal products shall be indicated. All deficiencies detected shall be indicated also in case, if they were eliminated at one. The undertaking shall be requested to inform the responsible authorities regarding the deadlines for and progress of measures for elimination of deficiencies.*

*Each deficiency, if possible, shall be indicated in the form of a negation.*

*Deficiencies must be indicated in a short and concise manner, for example, without using the phrase “approach to monitoring of the temperature did not conform to the requirements of good distribution practice”, but: “approach to monitoring of the temperature did not conform to the requirements of good manufacturing practice because:*

*• the devices for measuring temperature were not calibrated;*

*• records of temperature data were not regularly reviewed”.*

*In defining the deficiencies, such words as “non-conforming”, “insufficient”, “inappropriate” must be used.*

**5. Comments of the inspector**

*May be used, for example, to indicate actual information or orally expressed promises received during the inspection, or to indicate whether the answers provided by the undertaking are acceptable.*

**6. Recommendations for further activities**

*Recommendations for the undertaking or institution shall be provided, if any.*

**7. Summary and conclusions**

*The inspector shall indicate whether the distributor is operating in the field inspected according to the guidelines for good distribution practice of medicinal products published by the European Commission.*

*If necessary, he or she shall indicate whether appropriate corrective and preventive action has been carried out, as well as any other information which would attract the attention of the institution which requested the performance of inspection.*

*The report shall be signed and date by all inspectors/experts who participated in the inspection.*

Given name, surname

Signature

Institution

Date

Sending of the report

Notes.

1. Definitions of significant deficiencies:

1.1. critical deficiencies – any deviations from the requirements of the guidelines for good distribution practice due to which the product may become or has become harmful to human or public health.

Critical deficiency is also an aggregate of significant deficiencies which points towards a serious inability of the system to ensure appropriate operation. For example, the following may be a critical deficiency:

1.1.1. acquisition of medicinal products from an undertaking or delivery to an undertaking to which a special authorisation (licence) for wholesale trade of medicinal products has not been issued;

1.1.2. storage of medicinal products at room temperature, if storage at a low temperature has been specified for them;

1.1.3. the rejected or recalled medicinal products are in the stock to be sold;

1.2. significant deficiencies – deficiencies which are not critical deficiencies and:

1.2.1. which point towards large deviations from the guidelines of good distribution practice;

1.2.2. due to which the product does not conform to the documentation, particularly to the storage and transportation circumstances;

1.2.3. which point towards large deviations from the conditions of the special authorisation (licence) for wholesale trade of medicinal products (within the scope of the European Union and the European Economic Area);

1.2.4. combination of various other deficiencies from which each individual deficiency is not significant, but together they may cause significant deficiency, therefore, they must be explained and they should be notified as a significant deficiency;

1.3. other deficiencies – deficiencies which may not be classified as critical or significant, but which point towards deviations from the guidelines of good distribution practice. Deficiencies may be classified as “other deficiencies”, if they are evaluated as non-significant or there is not sufficient information to classify them as significant or critical.

2. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

**Annex 14**

Cabinet Regulation No. 416

26 June 2007

*[2 February 2016]*

|  |  |  |
| --- | --- | --- |
| LATVIJAS REPUBLIKAZĀĻU VALSTS AĢENTŪRA |  | REPUBLIC OF LATVIASTATE AGENCY OF MEDICINES |
| (adrese, reģistrācijas numurs, tālruņa numurs, faksa numurs, e-pasta adrese) |  | *(address, registration number, phone, fax number, e-mail)* |

|  |  |
| --- | --- |
| Sertifikāts Nr. |   |
| *Certificate No.* |   |

**ZĀĻU IZPLATĪTĀJA LABAS IZPLATĪŠANAS PRAKSES ATBILSTĪBAS SERTIFIKĀTS ATTIECĪBĀ UZ CILVĒKIEM PAREDZĒTAJĀM ZĀLĒM**

*CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF MEDICINAL PRODUCTS FOR HUMAN USE*

|  |
| --- |
| Izdots pēc oficiālas pārbaudes (inspekcijas) saskaņā ar Direktīvas 2001/83/EK 111. pantu*Issued following an official inspection in accordance with Art. 111 of Directive 2001/83/EC* |
| Zāļu valsts aģentūra apliecina:*The State Agency of Medicines confirms the following:* |
| Zāļu vairumtirgotājs*Wholesale distributor* |   |
| Izplatīšanas vietas adrese |
| *Site address* |   |
| ir oficiāli pārbaudīts nacionālās uzraudzības programmas ietvaros saistībā ar licenci Nr. \_\_\_\_ saskaņā ar Direktīvas 2001/83/EK 77. panta 1. punktu, kas pārņemts šādos Latvijas Republikas tiesību aktos:*has been inspected* under the national inspection programme in connection with authorization No. \_\_\_\_ *in accordance with* article *77(1) of Directive 2001/83/EC transposed in the following national legislation:* |
|  |

|  |  |  |
| --- | --- | --- |
| Zāļu izplatītāja oficiālajās pārbaudēs, no kurām pēdējā tika veikta |   | , |
|   | (datums) |   |

iegūtā informācija ļauj uzskatīt, ka tas atbilst labas izplatīšanas prakses principiem, kas minēti Direktīvas 2001/83/EK 84. pantā.

*From the knowledge gained during inspection of this distributor, the latest of which was conducted on …../...…/...… [date], it is considered that it complies with the principles of good distribution practice requirements laid down in Article 84 of Directive 2001/83/EC.*

Šis sertifikāts atspoguļo izplatīšanas vietas statusu minētās oficiālās pārbaudes laikā, un tas nevar atspoguļot atbilstības statusu, ja ir pagājuši vairāk nekā pieci gadi kopš oficiālās pārbaudes, kad tika izsniegts šis sertifikāts. Derīguma termiņš var tikt saīsināts, izmantojot riska vadības regulējošos principus un izdarot ierakstu lauciņā, kas atvēlēts ierobežojumu vai paskaidrojumu atzīmēšanai.

*This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of official inspection, after which time the issuing authority should be consulted. This period of validity may be reduced, using regulatory risk management principles by an entry in the "Restrictions" or "Clarifying Remarks" field.*

Šis sertifikāts ir derīgs tikai pilnā apjomā, uzrādot visas lapas.

*This certificate is valid only when presented with all pages.*

Sertifikāta autentiskumu var pārbaudīt Savienības datubāzē. Ja sertifikāta nav datubāzē, lūdzu, sazinieties ar Zāļu valsts aģentūru.

*The authenticity of this certificate may be verified in the Union's database. If it does not appear, please contact the issuing authority.*

Ierobežojumi vai paskaidrojumi saistībā ar šā sertifikāta jomu:

*Any restrictions or clarifying remarks related to the scope of this certificate:*

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(datums/*date*) | Zāļu valsts aģentūras pilnvarotās amatpersonas vārds, uzvārds un paraksts*Name, surname and signature of the authorized person of the Competent Authority of Latvia* |
|  |  |
|   | (vārds, uzvārds, amats, atbildīgā iestāde, tālruņa numurs, e-pasta adrese jautājumiem/*name, surname, position, national authority, phone number, email in case of enquiries*) |

Informācija par licenci pieejama Kopienas datubāzē.

*Details of the authorisation can be found in the Union database.*

Piezīmes.

1. Paraksts, datums un kontaktinformācija ir uz katras sertifikāta lappuses.

*The signature, date and contact details should appear on each page of the certificate.*

2. Dokumenta rekvizītu "paraksts" neaizpilda, ja elektroniskais dokuments ir sagatavots atbilstoši normatīvajiem aktiem par elektronisko dokumentu noformēšanu.

*Document property "Signature" is not filled in if the document is prepared in accordance with the laws of electronic documents.*

3. Šajā sertifikātā minētā Savienības datubāze, kurā pārbauda sertifikāta autentiskumu, ir Eiropas Savienības datubāze par ražošanas un importēšanas licencēm un labas ražošanas prakses sertifikātiem (*Eudra GMDP* datubāze).

*The Union database mentioned in this certificate is the European Union database on the production and import licenses and certificates of good manufacturing practice (Eudra GMDP database).*