Procedure of Import and Export of Medicinal Products

Republic of Latvia

Cabinet Regulation No.436
Riga, June 26, 2007 (Prot. No.37 35.§)

Issued pursuant to Section 5, Clause 3 of the Pharmaceutical Law
And Section 28 of the Law "On the Order of Legal Turnover
of Medicinal Products, Narcotic and Psychotropic Substances"

I.General Provisions

1.The present Regulations determine procedures, according to which medicinal products (except veterinary medicine) are brought into the customs territory of the European Union (further in the text as import of medicinal products) and taken out of the customs territory of the European Union (further in the text as export of medicinal products), as well as customs control offices through which the permitted import and export of narcotic and psychotropic substances and medicinal products and substances included into the II-nd and III-rd class list of precursors.
2.The present Regulations refer to:
2.1.Imports of medicinal products registered in the Medicinal Products Register of the Republic of Latvia or under the centralized registration procedure according to European Parliament and Council Regulation from March 31, 2004, No. 726/2004 stating Community registration and supervision procedures for human and veterinary medicinal products and establishing the European Agency of Medicines (further in the text as European Parliament and Council Regulation No. 726/2004);
2.2.Imports of medicinal products not registered at the Medicinal Products Register of the Republic of Latvia or under the centralized registration procedure according to European Parliament and Council Regulation No. 726/2004, but registered in the third countries (further in the text as non-registered medicinal products from the third countries);
2.3. Imports of medicinal products performed by the state budget institutions or the public benefit organisations according to the Council Regulation (EEC) from March 28, 1983 No. 918/83, according to which a Community System of relief of customs duties is established (further in the text as Council Regulation No. 918/83);
2.4. Imports of samples of medicinal products, including such substances that are used as comparable substances in trials of medicinal products (hereinafter

referred to as ‘standard samples’);
2.5. Exports of medicinal products;
2.6. Imports and exports of medicinal products under investigation.
3. The present Regulations don’ t refer to:
3.1. Imports of medicinal products from the European Economic Area countries as well as exports of medicinal products to the European Economic Area countries;
3.2. Imports of medicinal products performed by a physical person (traveller);
3.3. Imports and exports of medicinal products in mail consignments.
4. Imports and exports of medicinal products mentioned in paragraph 2 of the present Regulations (including medicines containing narcotic and psychotropic substances and medicinal products and substances included into the II-nd class list of precursors (narcotic drugs) and the III-rd class list of precursors (psychotropic drugs)) is allowed through customs control offices mentioned in normative acts on determination of locations for crossing the state border and border control of the state border of the Republic of Latvia where imports and exports of non-alimentary goods subjected to control of Sanitary Border Inspection of the Food and Veterinary Service (further in the text as Sanitary Border Inspection).
5.Customs institutions control imports and exports of medicinal products according to the Customs Law and the appropriate normative acts regulating customs clearance and customs control order.
6.The Sanitary Border Inspection performs its functions in compliance with:
6.1.Council Regulation (EEC) from February 8, 1993, No. 229/93 on the control of products’ compliance with safety regulations imported from the third countries, paragraph 2 (further in the text as Council Regulation No. 339/93);
6.2.Council Regulation (EEC) from May 26, 2003, No. 953/2003, section 8 on evasion of direction of trade of some important medicinal products to the European Union (further in the text as the Council Regulation No. 953/2003);
6.3. Council Regulation (EEC) from May 17, 2006, No. 816/2006, section 14 on the forced licensing related to manufacturing of pharmaceutical products to be exported to countries experiencing public health care problems (further in the text as the Council Regulation No. 816/2006).
7.To store medicinal products in the customs warehouse a permit issued by the State Revenue Service Chief Customs Board is required. The permit to store medicinal products is issued by the State Revenue Service Chief Customs Board if the appropriate ad judgement is received from the Healthcare Inspection.
8.Owner or administrator of the cargo of medicinal products (further in the text administrator of medicinal products):
8.1.submits and instruction to the holder of customs warehouse stating storage requirements for medicinal products. Holder of the customs warehouse grants the necessary storage conditions for medicinal products in compliance with instructions of administrator of medicinal products and requirements applied to distribution and storage of medicinal products by normative acts;
8.2.covers expenses related to granting of storage conditions of medicinal

products in the customs warehouse;
8.3.guarantees free access to the storage place of medicinal product within the customs clearance zone for Sanitary Border Inspection, Healthcare Inspection and Customs authorities. The responsible authority of administrator of medicinal products is obliged to present medicinal products to the Sanitary Border Inspection control.
9.The administrator of medicinal products shall attach a supplementing document to the cargo of medicinal products stating the following information:
9.1.date of delivery of medicinal products, title of products, form of products, strength of medicinal products and series number and amount of each consignment, the firm title and address of the supplier (consignor), the manufacturing company of medicinal products, title of the country of production and the title and address of the consignee of medicinal products;
9.2.sales price stated for the consignee.
10.If the administrator of medicinal products uses transportation services rendered by another person on the basis of a signed agreement (further in the text commercial conveyor), then the commercial conveyor in addition to requirements stated in paragraph 9 of the present Regulations, shall submit an agreement to the Customs Authority signed by administrator of medicinal products and commercial conveyor on rendering of transportation services or an authorisation to perform the appropriate activity issued by the administrator of medicinal products.

II Imports of Medicinal Products

11.Products registered at the Latvian Medicinal Product Register, may be imported from the third countries by a person, which according to the normative acts stating the order of issuing , termination, re-registration and annulling of special permits (licences) for pharmaceutical activity, has received a special permit (licence) to manufacture /import medicinal products with a remark, that import activities related to medicinal products are allowed, as well as the name of person authorised to represent the licence holder. The medicine under examination may be imported by a person the special permit (licence) of which states, that the medicinal products under investigation are allowed to be imported. For the cargo of medicinal products imported from the third countries on the basis of manufacturing / imports licence issued by the member state’ s competent institution and transported in transit via the territory of Latvia (including placement into the cargo warehouse), the special permit (licence) for manufacturing /import of medicinal products, issued by the State Agency of Medicines, isn’ t required.
12.The person involved in activities the performance of which requires special permit (licence) for manufacturing /import of medicinal products, mentioned in paragraph 11 of the present Regulations (further in the text as importer of medicinal products), guarantees fulfilment of the following requirements:

12.1. imported medicinal products and those under investigation are manufactured in conformity with requirements equal or higher, than those applied in the European Union to the good manufacturing practice requirements;
12.2. the manufacturer of medicinal products possesses an appropriate permit in the country for manufacturing of medicinal products. Regarding the products under investigation, the importer of medicinal products guarantees timely notification of the appropriate competent state authorities on the manufacturer of products to be investigated and the manufacturer has to be acknowledged compliant with manufacturing medicine under investigation;
12.3. there must permanently be at least one responsible adequately educated and professionally experienced person (further in the text qualified person). On the replacement of the qualified person the State Agency of Medicines should be notified immediately or in five days', at the latest;
12.4. there are personnel complying with requirements stated by normative acts regulating manufacturing and control of medicinal products at the disposal of the person;
12.5. the State Agency of Medicines' authorities shall have the access to the importer's premises around the clock;
12.6. the person guarantees the possibilities for the authorities to fulfil their obligations stipulated by paragraphs 14,15,and 16 of the preset Regulations (regarding the medicinal products under investigation - activities stipulated by paragraphs 21. and 22.), for example., by passing over all the necessary equipment at their disposal;
12.7. observes principles of good manufacturing practice, stated by normative acts on manufacturing and control in the process of quality control and series procession of the imported medicinal products;
12.8. in distribution of medicinal products observes good distribution practice principles stated in normative acts regarding the order of distribution and control of medicinal products. Regarding medicinal products under investigation, requirements stated by normative acts on clinical investigation should be observed.
13. Education and professional experience of the qualified person shall comply with qualification and professional experience criteria stated by normative acts regulating manufacturing and control of medicinal products.
14. The qualified person, without limiting its relations to the importer of medicinal products, is responsible, that each series of imported medicinal products (including the cases, where medicine is produced in the EU (the EU states and EFTA states), exported to the third countries and imported back) is subjected to a complete qualitative analysis and quantitative analysis of all the active substances, as well as all the other tests and examinations required to guarantee the quality of medicinal products following the requirements of registration documents of products. The quality control of medicinal products shall not be applied to series of imported medicinal products already examined in any other EU member state and delivered from another EU member state with a control report signed by a qualified person.

15.The quality control mentioned in paragraph 14 of the present Regulations may be omitted, if medicinal products are imported from countries, which have previously signed with the EU the good manufacturing practice compliance evaluation and mutual recognition agreements (Australia, Canada, New Zealand, Switzerland) and the mentioned agreements foresee testing each series of the particular medicinal products in the exporting country (qualitative and quantitative analysis). In that case a certificate mentioned in paragraph 34 of the present Regulations should be attached to each series of the imported medicinal products.
16.The qualified person in all the cases certifies series of medicinal products, making precise inscriptions into the registry log-book or another equal document meant for that purpose, confirming it with his signature, that each series of medicinal products is manufactured and controlled in compliance with requirements stipulated by paragraphs 14 and 15 of the present Regulations. Following the definite activities, the registry log-book or the appropriate document is complemented and kept by the enterprise for at least five years since the time of the last inscription, granting free access for the authorities of the State Agency of Medicines to the mentioned log-book or document.
17.To perform the quality control mentioned in paragraph 14 of the present Regulations, another person' s (further in the text contractual work performer' s) quality control laboratory, if the importer and the contractual work performer have signed a written agreement, observing conditions mentioned in paragraphs 18., 19.and 20 of the present Regulations.
The agreement shall precisely determine obligations of the parties, especially emphasizing the obligation of the contractual work performer to observe the good manufacturing practice principles and general directives, as well as the manner, how the qualified person responsible for certification of each series of products, really fulfils his or her obligations.
19.The contractual work performer guarantees fulfilment of the following requirements:
19.1.in case no written permission of importer of medicinal products is received, sub-contract with the third person on work performance, which following the paragraph 17 of the present Regulations are to be performed by the contractual work performer, may not be signed;
19.2.observing of good manufacturing general guidelines and principles stated by normative acts regulating manufacturing and control of medicinal products, as well as subjecting to control of the State Agency of Medicines.
20. Prior to signing of the agreement on provision of quality control, the importer of medicinal products guarantees acknowledgement issued by the State Agency of Medicines on the compliance of the laboratory with good manufacturing practice requirements as provided by the European Commission' s directives on the good manufacturing practice regarding medicinal products and medicines under investigation.

21. Regarding medicinal products manufactured in the third countries to be investigated, the qualified person is responsible for manufacturing and control of each series of products according to good manufacturing practice principles and guidelines (which are at least equal to those acting in the EU), as well as specification and information stated by the sponsor in his application to the State Agency of Medicines to obtain the permit to clinical trial of medicinal products. The medicinal product to be investigated, which is the preparation to be investigated from the third country and which is registered, but without any documented certification for each series regarding production conditions conforming with good manufacturing practice principles and guidelines, the qualified person has to guarantee performance of analyses, tests and control for each series of preparation to confirm the compliance of the quality to the information rendered by the sponsor to the State Agency of Medicines to obtain the permit for clinical investigation of medicinal products.

22.Regarding the medicinal products to be investigated, the qualified person in all cases makes precise records in the registry log-book or another equal document meant for that purpose and confirms with his signature, that each series of medicinal products complies with requirements stated by paragraph 21 of the present Regulations. The log-book or the appropriate document is complemented following the definite activities and kept by the enterprise for at least five years since the time of the last record, granting free access for authorities of the State Agency of Medicines to the mentioned log-book or document.

23.For preparations imported from the third countries to be investigated, analytical control (qualitative and quantitative analysis) is not required.

24.Special permit (licence) mentioned by paragraph 11 of the present Regulations in relation to manufacturing/imports of medicinal products refers just to the products (types and forms of medicinal products to be investigated) indicated by the importer of medicinal products in his application to obtain special permit (licence) for manufacturing/import of medicinal products included by the State Agency of Medicines into the database following the normative acts stating the order of issuing, termination, re-registration and annulment of special permits(licences) for pharmaceutical activities.

25.Importer of medicinal products is allowed to import narcotic and psychotropic medicinal products stated in application to obtain special permit (licence) for manufacturing/import of medicinal products included by the State Agency of Medicines into the database following the normative acts stating the order of issuing, termination, re-registration and annulment of special permits(licences) for pharmaceutical activities , if imports of the particular products is certified according to the definite order by the State Agency of Medicines by a permit following the law “ On the Legal Turnover of Narcotic and Psychotropic Substances and Medicinal Products”. In addition to requirements stipulated by the present Regulations , imports of narcotic and

psychotropic substances is guided by the law “ On the Legal Turnover of Narcotic and Psychotropic Substances and Medicinal Products”.
26.The state budget institution or the public benefit organization mentioned in sub-paragraph 2.3.of the present Regulations is allowed to import from the third countries non-prescription medicinal products included into the State Registry of Medicines or registered centrally following the European Parliament and Council Regulation No.726/2004.

III.Imports of Samples and Non-registered Medicinal Products from the Third Countries

27. Non-registered medicinal products may be imported from the third countries by a person possessing a definite permit issued by the State Agency of Medicines to distribute the particular medicinal products, following the normative acts on distribution and quality control of medicinal products.
28.Samples of medicinal products may be imported by a person possessing a definite permit issued by the State Agency of Medicines to import samples of medicines into the Republic of Latvia (further in the text- sample imports permit) (Annex 1), in the following cases:
28.1.for registration of medicinal products;
28.2.for scientific investigations;
28.3.for educational purposes;
28.4.standard samples for testing of medicinal products.
29.To obtain sample imports permit , the applicant shall submit to the State Agency of Medicines an application in conformity with requirements defined in Annex 2 to the present Regulations, confirming the necessity of medicinal products’ sample imports.
30.The State Agency of Medicines in five business day time period since the receipt of application mentioned in paragraph 29 of the present Regulations checks if the information rendered complies with requirements of the present Regulations. If the information is incomplete or erroneous, the State Agency of Medicines demands additional information in writing.
31.The State Agency of Medicines takes the decision to reject permit the sample imports permit if in one month time since the demand of additional information mentioned in paragraph 29 of the present Regulations such information (substation) isn’ t received.
32.The State Agency of Medicines takes decision to issue the sample imports permit according to the order stipulated by the Administrative Process Law.

IV.Exports of Medicinal Products

33.Medicinal products, including those to be investigated may be exported by a person, which according to the normative acts stating the order of issuing,

termination, re-registration and annulment of special permits(licences) for pharmaceutical activities, has obtained special permit (licence) for manufacturing / imports of medicinal products or a special permit (licence) for opening (operation) of a wholesale enterprise , as well as a person authorised to represent the licence holder. The cargo of medicinal products exported to the third countries on the basis of a manufacturing/import licence issued by a competent authority of another EU member state and transported via territory of Latvia in transit (including placement into the customs warehouse) doesn' t require special permit (licence) issued by the State Agency of Medicines for manufacturing/imports of medicinal products.

34. If the manufacturer of medicinal products registered in Latvia exports products to a country , which have previously signed with the EU the good manufacturing practice compliance evaluation and mutual recognition agreement, a certificate signed by the qualified person should be attached to each series of the imported medicinal products stating information mentioned in Annex 3 to the present Regulations.

35. the State Agency of Medicines, following the application of manufacturer of medicinal products or the competent authority of the exporting or importing country, issues:

35.1. a product certificate (Annex 4). The product, according the understanding of the present paragraph, appears to be a medicinal product meant for humans in its final medicinal form and active substances to be used in those forms, which are subject to pharmaceutical control according to normative acts in the exporting, as well as importing country. The product certificate complies with the form suggested by the World Health Organisation and determines the status of product, as well as the applicant in the exporting country. The certificate is meant exclusively for one type of products;

35.2. notification on the product registration status (Annex 5). The notification is meant for importer of medicinal products participating in international tenders following regulations of tender invitations. The notification means, that the particular medicinal products are registered and allowed to be distributed in the Republic of Latvia (exporting country). Following the demand of applicant and the holder of registration certificate (owner, if the persons are different) the State Agency of Medicines issues the product certificate mentioned in sub-paragraph 35.1.for each product, mentioned in the notification.

36. To receive the product certificate mentioned in sub-paragraph 35.1, the manufacturer of medicinal products shall submit an application to the State Agency of Medicines, indicating:

36.1. name, surname, company title and address of the certificate applicant;

36.2. status of the certificate applicant:

36.2.1. manufacturing the forms of medicine;

36.2.2. packaging and labelling forms of medicine manufactured by another independent producer;

36.2.3.not involved in activities mentioned in sub-paragraphs 36.2.1. and 36.2.2.;
3.3.in case certificate applicant isn’ t manufacturer of medicine forms, it shall indicate the title and address of the manufacturing company;
36.4.product title, dosage and form of medicine:
36.4.1.in Latvia;
36.4.2.in other countries;
36.5.active substances (using international non-patented title (INN) or the national non-patented title) and the amount per dose;
36.6.complete composition of the product, including additional substances (including quantitative composition, if co-ordination is added with registration certificate holder (owner));
36.7.if the product is registered in Latvia;
36.8.if product is distributed in Latvia;
36.9.product registration certificate number and date of assignment (if necessary, it has to be noted, if the registration certificate is temporary, or if the product hadn’ t yet been certified);
36.10.title and address of the product registration certificate holder (owner);
36.11.status of the product registration certificate holder (owner) in relation to sub-paragraphs 36.2.1., 36.2.2. and 36.2.3. of the present Regulations;
36.12.if the product registration certificate holder (owner) isn’ t the manufacturer of the medicine form, the title and address of the manufacturer should be mentioned and the attached document should certify, that the registration certificate holder agrees to make the present information public;
36.13.if the registration certificate for the product is not required, one of the reasons should be mentioned, why it isn’ t necessary;
36.13.1.the product is produced exclusively for special treatment conditions, mainly for treatment of tropical diseases without endemic character under Latvian conditions;
36.13.2.the product is revised to improve its stability under tropical conditions;
36.13.3.the product is revised in order to exclude additives from its contents the application of which in the importing country is forbidden;
36.13.4.the product is revised to for another maximum possible dose of active substance;
36.13.5.another reasons (should be indicated);
36.14.in case the status of the product registration certificate holder (owner) or the certificate applicant complies with the status mentioned in sub-paragraphs 36.2.2. or 36.2.3. (especially, if a foreign producer is involved in manufacturing of the product), the certificate applicant shall submit information to the State Agency of Medicines stating responsibility of each party involved in production regarding each period of the process and the

final product, as well as type and volume of control provided by each party involved.
37.To obtain the notification mentioned in sub-paragraph 35.2.of the present Regulations on the product registration status, the person shall submit an application to the State Agency of Medicines, stating:
37.1.name, surname of the certificate applicant, or the firm title and address;
37.2.the importing country;
37.3.product title, dosage and form of medicine, titles of active substances (using international non-patented titles (INN) or national non-patented titles) and their amounts per dose, registration certificate number and date of assignment. If the product isn't registered, the remark should be "not required", or "not demanded", or "is in the process of registration", or "registration is refused".
38. The State Agency of Medicines issues the product certificate mentioned in paragraph 35 of the present Regulations and the notification on the product registration status in 30 days' time following the receipt of application. Expenses related to product certificate issuing shall be covered by applicant according to the public paid services' pricelist of the State Agency of Medicines
39. If the issue of such a certificate as mentioned in Paragraph 35.1 hereof for a product, which is an active substance used in a officinal form, requires inspection of the relevant production facilities and assessment of the conformity to the good manufacturing practice requirements to production of active substances, the Applicant for the certificate shall request from the State Agency of Medicines to carry out an inspection of the conformance of the active substances production facilities. The State Agency of Medicines shall carry out the aforesaid inspection and issue of a good manufacturing practice certificate by such procedure as provided for in the normative acts regulating production and control of medicinal products.

V. Supervision and Sanctions

40. Sanitary Border Inspection:
40.1.controls conformity of medicinal products' imports with requirements included in paragraphs 6., 8., 9., 10., 11., 24.,and 25. of the present Regulations;
40.2. conformity of medicinal products' transportation and storage conditions with normative acts on the order of control of medicinal products' distribution and quality control is checked in customs control zones;
40.3. renders information to the Healthcare Inspection on violations of requirements stated in the present Regulations.
41. The Sanitary Border Inspection, on the basis of the Act drafted by the authority of the Sanitary Border Inspection, has the right to take a decision

and to terminate further imports of medicinal products:
41.1. following the paragraph 2 of the Council Regulation No.339/93, if it is revealed, that:
41.1.1. cargo documents don’ t comply with requirements mentioned in paragraph 9 of the present Regulations, or the medicinal products can’ t be identified (no labelling);
41.1.2. the imported products aren’ t included into the database of the State Agency of Medicines according to normative acts regarding the order of issuing, termination, re-registration and annulment of special permits(licences) for pharmaceutical activities;
41.1.3.the medicinal products possess no appropriate importing permits according to paragraphs 27.and 28.of the preset Regulations;
41.1.4.there are violations in fulfilment of storage and transportation requirements regulated by normative acts on the order of distribution and quality control of medicinal products;
41.1.5.the shelf-life of medicinal products is out-dated;
41.1.6.the consignor and the consignee of medicinal products’ cargo can’ t be identified;
41.2.following the Section 8 of the Council Regulation No. 953/2003, if it is stated, that the imported medicinal products appear to be products of different prices included into Annex I of the Council Regulation No. 953/2003;
41.3.following the Section 15 of the Council Regulation No. 816/2006, if there are grounded doubts on violation of the special import prohibition foreseen by Section 13, p.1 of the Council Regulation No. 816/2006 regarding medicinal products manufactured according to forced licence;
41.4.if the special permit (licence) issued to the businessman importing medicinal products mentioned in the sub-paragraph 41.1.2.of the present Regulations is invalid;
41.5.if the imported medicinal products, following normative acts regulating order of distribution and quality control of medicinal products, can be related to rapid reaction notification of the Healthcare Inspection on the quality defect and exemption of products from the market.
42.The Sanitary Border Inspection informs the Healthcare Inspection in writing on the decision taken on the day of decision or in three business days time, at the latest.
43.Medicinal products, on which the decision is taken following paragraph 41 of the present Regulations, are to be placed in the customs warehouse possessing the acknowledgement of the Healthcare Inspection mentioned in sub-paragraph 51.2of the present Regulation (if the customs warehouse storage conditions comply with specifications of medicinal products).
44.If the Sanitary Border Inspection has taken decision mentioned in paragraph 41.of the present Regulations, following the final clarification of circumstances, the Healthcare Inspection takes the decision on annulment of previous cancellation of imports of medicinal products or on prohibition of that import and notifies the Sanitary Border Inspection and the State Agency

of Medicines on the decision on the day the decision is taken. If the Healthcare Inspection' s decision is to annul the previous decision on cancellation of imports, the Sanitary Border Inspection on the day of receipt of the mentioned decision informs the customs authority that it is allowed to apply customs clearance procedure to let the products in free turnover.
45.If the Healthcare Inspection takes decision on prohibition of imports of products due to violation of requirements mentioned in the present Regulations, it informs the customs authority and it may initiate elimination of medicinal products or return products which are not allowed to be let in free turnover, nor used in other ways. The appropriate customs institution and the Sanitary Border Inspection is notified on the decision taken on the same day. In that case, all the accompanying documents shall include appropriate remarks in conformity with Council Regulation No. 339/93/EK, Section 6, p.4.
46. Expenses related to elimination or returning of the particular cargo of medicinal products shall be covered by the person to whom the mentioned decision of the paragraph 45 of the present Regulations is related to (administrator of products).
47.The State Agency of Medicines controls the compliance of the importer of medicinal products with requirements stated in paragraphs 12., 14., 15., 16., 17., 18., 19., 20., 21., 22. and 23 following the order of manufacturing and control of medicinal products stated in normative acts.
47.The importer of medicinal products during the control renders the following data to the responsible persons of the State Agency of Medicines:
48.1.data on the quality control of each series of medicinal products (performed in the country of European Economic Area) in conformity with registration documentation of products;
48.2.on the immunologic preparations and remedies produced from human blood and plasma all the copies of control reports confirmed by qualified persons.
49.The Healthcare Inspection, on the basis of control report of the State Agency of Medicines, has the right to terminate imports of particular remedies or all the medicinal products mentioned in the application to receive special permit (licence) to manufacture/import products included into the database of the State Agency of Medicines according to normative acts stating the order of issuing, termination, re-registration and annulment of special permits(licences) for pharmaceutical activities, if the State Agency of Medicines in the course of examination at the importer reveals and documents in the control report, that:
49.1.the quality control and the series delivery isn' t in conformity with requirements stated in paragraphs 14., 15. and 16 of the present Regulations;
49.2.the qualified person doesn' t fulfil its obligations in conformity with requirements stated in paragraphs 14., 15. and 16 of the present Regulations (regarding products to be investigated in paragraphs 21., and 22);
49.3.the importer of medicinal products can' t present definite data and documentation during the control, mentioned in paragraph 48 of the present

Regulations.
50.The State Agency of Medicines fulfils the obligations of the competent supervisory institution mentioned in the European Parliament and Council Regulation No. 726/2004. Section 19 regarding medicinal products registered within a centralized registration procedure and imported from the third countries.
The Healthcare Inspection:
51.1.supervises, if the storage and transportation of medicinal products in the customs clearance areas complies with requirements of normative acts relate to distribution of medicinal products;
51.2.examines the location of storage of medicinal products following the demand of the holder (owner) of the customs warehouse and renders acknowledgement to the holder (owner) of the customs warehouse on the conformity of conditions with requirements of good distribution practice stipulated in the normative acts. The holder (owner) of the customs warehouse submits the mentioned acknowledgement to the Sanitary Border Inspection and the State Revenue Service Chief Customs Board;
51.1.3.is entitled to demand and receive information from the State Agency of Medicines, the Sanitary Border Inspection and other competent state institutions related to fulfilment of the present Regulations;
51.4.renders the necessary information to the State Agency of Medicines, the Sanitary Border Inspection and other competent state institutions;
51.5.infroms the European Commission on all the decisions taken in relation to fulfilment of requirements following the Council Regulation No. 953/2003;
51.6.informs the European Commission on any decisions taken regarding confiscation or elimination of products in conformity with European Parliament and Council Regulation No. 816/2006.
52. Competent authorities may not disclose commercial secrets of the controlled person revealed in the course of fulfilment of their duties following the present Regulations.
53.The Healthcare Inspection, the State Agency of Medicines, the Sanitary Border Inspection and customs institutions in the framework of their competence guarantees operative mutual exchange of information, as well as , in order not to allow illegal turnover of medicinal products, renders information to commercial institutions and the Ministry of Health on the revealed facts.

VI. Closing Provisions

54. To invalidate the Cabinet of Ministers Regulations No.88 from February 27, 2001 “ Regulations on Import, Export and Distribution of Medicinal Products and Opening and Operation Requirements Applicable to Wholesale Establishments” (The Latvijas Vēstnesis, 2001, No.35., 52., 2003, No. 114, 2004, No.69.).

55.The wholesale establishments possessing on the day of validation of the present Regulations a special permit (licence) for opening the medicinal product wholesale establishment with a special activity condition imports of products to Latvia from a country outside the European Economic Area and a permit issued by the State Agency of Medicines for imports of such products into the Republic of Latvia from the third countries, have the right to import medicinal products till the term of special permit (licence) determined by normative acts stating the order of issuing, termination, re-registration and annulment of special permits(licences) for pharmaceutical activities, but not later than January 1, 2008.
56. The sponsor possessing on the day of validation of the present Regulations a special permit for imports into the Republic of Latvia of medicinal products for human investigation, has the right to import products to be investigated till the term of special permit (licence) determined by normative acts stating the order of issuing, termination, re-registration and annulment of special permits(licences) for pharmaceutical activities, but not later than January 1, 2008.

Informative Reference to the European Union Directives

The present Regulations include legal norms arising from:
1) Directive 2001/20/EK from April 4, 2001 of the European Parliament and Council on approximation of normative and administrative acts of member states related to introduction of good clinical practice in the clinical investigation with human medicinal products;
2) Directive 2001/83/EK from November 6, 2001 of the European Parliament and Council on the Union Code related to human medicinal products;
3) Directive 2003/94/EK from October 8,2003 of the Commission stating good manufacturing practice principles and guidelines regarding human medicinal products and human medicinal products to be investigated (the document is related to the European Economic Area);
4) Directive 2004/27/EK from March 31, 2004 of the European Parliament and Council, by which regarding the traditionally applied remedies of plant origin altered the Directive 2001/83/EK on the Union Code related to human medicinal products (the document is related to the European Economic Area);
5) Directive 2005/28/EK from April 8, 2005 of the Commission stating the principles of good clinical practice and the specified guidelines regarding human medicinal products to be investigated, as well as requirements related to manufacturing permits or imports of such medicinal products (the document is related to the European Economic Area).

MinisterA.Kalvītis

For the Minister for Health Minister of WelfareA.Stae