Republic of Latvia

Cabinet
Regulation No. 327
Adopted 31 May 2016

Procedures for Importing and Exporting Veterinary Medicinal Products

Issued pursuant to
Section 5, Clause 3 of the Pharmaceutical Law and Section 28 of the law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products

I. General Provisions

1. This Regulation prescribes:
1.1. the procedures for importing and exporting veterinary medicinal products;
1.2. the border crossing points through which it is permitted to import and export veterinary medicinal products that contain the substances included in the Register II or III of the laws and regulations regarding narcotic substances, psychotropic substances and precursors controlled in Latvia (hereinafter – the veterinary narcotic and psychotropic medicinal products).

2. This Regulation shall not apply to:
2.1. medicated feedingstuffs;
2.2. veterinary medicinal products that contain radioactive isotopes;
2.3. additives of feedingstuffs which, in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition have been published on the website of the European Commission in the Register of Feed Additives;
2.4. biocidal products;
2.5. products for animal care.

3. In addition to the requirements laid down in this Regulation, the veterinary narcotic and psychotropic medicinal products shall be imported and exported in conformity with the requirements specified in the law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products.

II. Import of Veterinary Medicinal Products from Third Countries

4. Veterinary medicinal products may be imported (hereinafter – to import) from a country which is not a European Union Member State or State of the European Economic Area (hereinafter – the third country) by a merchant who has received a special permit (licence) for the manufacturing of veterinary medicinal products if the licence specifies the field of activity – import of veterinary medicinal products, or a special permit (licence) for the manufacturing of medicinal products if the licence specifies the field of activity – import of veterinary medicinal products (hereinafter – the importer). This requirement shall not apply to veterinary medicinal products that are transported from the third country through the territory of Latvia in transit (also placed in a customs warehouse for storage) on the basis of a special permit (licence) for the manufacturing or import of veterinary medicinal products issued by the competent

authority of another European Union Member State or State of the European Economic Area (hereinafter – the Member State).

5. The importer is entitled to:

5.1. perform the activities indicated in the special permit (licence) referred to in Paragraph 4 of this Regulation;

5.2. import veterinary medicinal products with regard to which a veterinary medicinal product marketing authorisation has been issued in accordance with the laws and regulations regarding the procedures for authorising veterinary medicinal products. It shall be permitted in an exceptional case to import veterinary medicinal products with regard to which a permit for the import and use of veterinary medicinal products has been issued for exceptional cases in compliance with the requirements laid down in the laws and regulations regarding the distribution and control of veterinary medicinal products.

6. The importer shall ensure that the following requirements are conformed to:

6.1. the importer imports veterinary medicinal products the manufacturer of which has been issued a permit for the manufacturing of veterinary medicinal products in the relevant third country and in the manufacturing of which good manufacturing practice guidelines are followed which are equal to or higher than the requirements laid down in the laws and regulations regarding the manufacturing and control of veterinary medicinal products, regarding the procedures for issuing a certificate of good manufacturing practice to a manufacturer of veterinary medicinal products, and regarding the requirements for the qualification and professional experience of the official responsible for the manufacturing of veterinary medicinal products (hereinafter – the laws and regulations regarding the manufacturing and control of veterinary medicinal products);

6.2. the importer has, at its disposal, properly qualified personnel, and also permanently and constantly at least one responsible official whose qualification and professional experience correspond to the criteria for the qualification and professional experience of the responsible official (hereinafter – the qualified person) which have been established in the laws and regulations regarding the manufacturing and control of veterinary medicinal products;

6.3. for the purpose of ensuring quality of the imported veterinary medicinal products the importer complies with the requirements laid down in the laws and regulations regarding the manufacturing and control of veterinary medicinal products;

6.4. for the purpose of quality control of the imported veterinary medicinal products the importer follows the principles and guidelines of good manufacturing practice laid down in the laws and regulations regarding the manufacturing and control of veterinary medicinal products;

6.5. the importer facilitates the fulfilment of the obligations of the qualified person referred to in Sub-paragraph 6.2 of this Regulation by handing over the necessary equipment at the disposal thereof and ensuring that the qualified person:

6.5.1. for each batch of veterinary medicinal products imported from the third country, even if these medicinal products have been manufactured in the Member State and then exported and reimported back, performs a full qualitative analysis, quantitative analysis of all active substances, and also tests and inspections necessary for ensuring the quality of veterinary medicinal products in accordance with the conditions of the authorisation dossier of veterinary medicinal products. The abovementioned inspections shall not be performed for batches of veterinary medicinal products with regard to which such inspections have been performed in another Member State and which have been supplied from another Member State together with a proper control report signed by the qualified person. Quality control of immunological veterinary medicinal products imported from the third countries shall be performed at the official laboratory for the quality control of medicinal products of any Member State;

6.5.2. makes accurate entries in the book of records or another document intended for this purpose, and certifies with a signature that each batch of the imported medicinal products conforms to the conditions referred to in Sub-paragraphs 6.4 and 6.5.1 of this Regulation. When performing subsequent import operations of veterinary medicinal products, the book of records or the relevant document shall be supplemented and kept by the undertaking for at least five years from the day of the last entry, ensuring that the book of records is made available to officials of the Food and Veterinary Service (hereinafter – the Service);

6.5.3. may decide not to perform the control of each batch of medicinal products referred to in Sub-paragraph 6.5.1 of this Regulation for veterinary medicinal products that are imported from the third countries which have entered into a contract with the Member States for mutual recognition of conformity assessment of good manufacturing practice. In such case each batch of the imported veterinary medicinal products shall have a batch certificate of veterinary medicinal products appended by the manufacturer which conforms to the sample specified and published in the European Commission's Compilation of Community Procedures on Inspections and Exchange of Information.

III. Export of Veterinary Medicinal Products to Third Countries

7. The following persons are entitled to export veterinary medicinal products to the third country (hereinafter – to export):

7.1. a merchant which has received a special permit (licence) for the manufacturing of veterinary medicinal products or a special permit (licence) for the manufacturing of medicinal products if the licence specifies the field of activity – manufacturing of veterinary medicinal products (hereinafter – the manufacturer of veterinary medicinal products) and which only exports self-manufactured veterinary medicinal products;

7.2. an importer which only exports veterinary medicinal products imported by the importer itself;

7.3. a merchant which has received a special permit (licence) for the opening (operation) of a veterinary medicinal product wholesaler or a special permit (licence) for the opening of a medicinal product wholesaler which specifies the distribution of veterinary medicinal products as a condition for special activity (hereinafter – the wholesaler).

8. It shall be permitted to export veterinary medicinal products if the manufacturer of veterinary medicinal products has manufactured them in accordance with the good manufacturing practice guidelines for veterinary medicinal products laid down in the laws and regulations regarding the manufacturing and control of veterinary medicinal products.

9. The person referred to in Paragraph 7 of this Regulation (hereinafter – the exporter) may export veterinary medicinal products with regard to which the Service has not issued a veterinary medicinal product marketing authorisation in the following cases:

9.1. the manufacturer or importer of veterinary medicinal products manufactures or imports only the veterinary medicinal products that are intended for export and contain active substances and excipients the use of which is permitted in the relevant third country (importing country or recipient country);

9.2. the composition of veterinary medicinal products is changed in order to correspond to the requirements of the relevant third country.

10. The exporter shall ensure that:

10.1. the veterinary medicinal products referred to in Paragraph 9 of this Regulation are not distributed in the market of the Member States;

10.2. veterinary medicinal products are supplied to a consignee in the third country who is entitled to import veterinary medicinal products in the relevant country.

11. The Service shall issue:

11.1. a certificate for the product (veterinary medicinal product) (hereinafter – the product certificate) which certifies the status of marketing authorisation of the veterinary medicinal products intended for export, the conformity of manufacturing thereof with the good manufacturing practice guidelines, and the status of the exporter of veterinary medicinal products in Latvia (Annex 1);

11.2. a product (veterinary medicinal product) certificate in short form or a certificate for free trade (hereinafter – the certificate for free trade) which certifies the status of marketing authorisation of the veterinary medicinal products intended for export, and the status of the exporter of veterinary medicinal products in Latvia;

11.3. a notification regarding the status of marketing authorisation of veterinary medicinal products (hereinafter – the notification) which certifies the status of marketing authorisation of veterinary medicinal products in Latvia (Annex 2).

12. The marketing authorisation holder of the relevant veterinary medicinal product or an authorised representative thereof, and also the manufacturer, exporter or the person to whom the supply of veterinary medicinal products is intended in the relevant third country upon fulfilment of the conditions referred to in Paragraph 13, 14, or 15 of this Regulation may receive the certificate referred to in Sub-paragraphs 11.1 and 11.2 and the notification referred to in Sub-paragraph 11.3 of this Regulation.

13. In order to receive the product certificate, an applicant for it shall submit an application to the Service for the receipt of the certificate for the product (veterinary medicinal product) (Annex 3).

14. In order to receive the certificate for free trade, an applicant for the certificate shall submit an application to the Service for the receipt of the certificate for free trade. The application shall be drawn up in accordance with the following requirements:

14.1. at least the following information shall be indicated in the application:

14.1.1. the given name, surname or name and legal address of the applicant for the certificate for free trade, and also the contact information (telephone number, fax number, and electronic mail address);

14.1.2. the third country to which it is intended to export veterinary medicinal products and the name and contact information (telephone number, electronic mail address) of the competent authority of the relevant third country;

14.1.3. the requirements for the information to be indicated in the certificate for free trade, and also the requirements of the third country for the validity of the certificate of good manufacturing practice of veterinary medicinal products, if any;

14.1.4. the information referred to in Sub-paragraphs 16.2, 16.3, 16.4, 16.5, 16.6, 16.7, 16.8, and 16.9 of this Regulation, where applicable. If veterinary medicinal products are in the marketing authorisation process, the country or countries where an application for the marketing authorisation has been submitted shall be indicated;

14.2. the quality specifications for veterinary medicinal products shall be appended to the application if the information referred to in Sub-paragraph 16.9 of this Regulation should be indicated in the certificate for free trade.

15. In order to receive the notification referred to in Sub-paragraph 11.3 of this Regulation, an applicant for the notification shall submit an application to the Service for the receipt of the notification, indicating at least the following information in the application:

15.1. the given name and surname or name, address, and contact information (telephone number, fax number, and electronic mail address) of the applicant for the notification;

15.2. the third country to which it is intended to export veterinary medicinal products and the name and contact information (telephone number, electronic mail address) of the competent authority of the relevant third country;

15.3. the name of the veterinary medicinal product, the name of the active substance (the international non-proprietary name shall be used), the pharmaceutical form, strength and dose thereof;

15.4. the number of the veterinary medicinal product marketing authorisation. If the veterinary medicinal product does not have a valid marketing authorisation, the following shall be indicated respectively: "not required", "not requested", "in the marketing authorisation process", or "marketing authorisation has been refused", and also the grounds for the absence of a valid veterinary medicinal product marketing authorisation.

16. The Service shall draw up the certificate for free trade, taking into account the requirements of the third country to which it is intended to export the veterinary medicinal product and indicating at least the following information:

16.1. the title of the certificate "Product (Veterinary Medicinal Product) Certificate in a Short Form" or "Certificate for Free Trade" in accordance with the requirements of the third country;

16.2. with regard to the veterinary medicinal product:

16.2.1. the name;

16.2.2. the pharmaceutical form;

16.2.3. the composition. The international non-proprietary name shall be indicated for the active substance or, where there is none, the chemical name;

16.2.4. the strength – the quantity of the active substance in one unit of dosage, volume, or mass;

16.3. the number, date of issue, and period of validity of the veterinary medicinal product marketing authorisation (this applies to the veterinary medicinal products authorised in Latvia);

16.4. the name, registration number in the Commercial Register, legal address of the manufacturer, the title, number, issuer, date of issue, period of validity of the special permit (licence) for the manufacturing of veterinary medicinal products (if any), and the address of the manufacturing unit;

16.5. the given name, surname or name and legal address of the person responsible for the marketing of veterinary medicinal products (this applies to the veterinary medicinal products authorised in Latvia);

16.6. the given name, surname or name and legal address of the person in whose name it is intended to authorise the veterinary medicinal product, and also indicate that the veterinary medicinal product is in the process of marketing authorisation (this applies to the veterinary medicinal products submitted for marketing authorisation in Latvia);

16.7. the indication "not intended to be authorised for the marketing in Latvia" or "only intended for export" if it is not intended to authorise the veterinary medicinal product in Latvia. If it is not permitted to distribute the veterinary medicinal product or the active substance in Latvia, a proper reason, for example "marketing authorisation suspended", "marketing authorisation cancelled", or "marketing authorisation refused", or any other reason shall be indicated;

16.8. an attestation that the responsibility for the quality of the abovementioned veterinary medicinal product lies with the specific manufacturer which is subject to regular inspections of good manufacturing practice and certification procedures of veterinary medicinal products or active substances, indicating the frequency of inspections;

16.9. an indication that the quality specification of the corresponding veterinary medicinal products conforms to the quality indicators of the European Pharmacopoeia and to the quality specification of the manufacturer of the active substance if the applicant for the certificate for free trade has mentioned in the application the need for such information on the basis of the requirements of the country to which it is intended to export the veterinary medicinal product.

17. The Service shall issue the certificate for free trade by appending a copy of the summary of product characteristics, package leaflet, and labelling of the veterinary medicinal products.

18. The Service shall assess the application referred to in Paragraphs 13, 14, and 15 of this Regulation and the appended documents, contacting the competent authority of the relevant third country, if necessary, and take one of the following decisions:

18.1. to issue the export certificate, the certificate for free trade, or the notification, specifying the period of validity thereof if:

18.1.1. the information indicated in the application referred to in Paragraphs 13, 14, and 15 of this Regulation and the documents appended thereto conform to the requirements of this Regulation;

18.1.2. the information provided by the applicant for the certificate or notification is complete and true;

18.1.3. the veterinary medicinal products do not pose a threat to the animal health and welfare, human health, or the environment;

18.2. to refuse to issue the export certificate, the certificate for free trade, or the notification if:

18.2.1. the information indicated in the application referred to in Paragraphs 13, 14, and 15 of this Regulation and the documents appended thereto fail to conform to the requirements of this Regulation;

18.2.2. the applicant for the export certificate, the certificate for free trade, or the notification has provided incomplete or false information;

18.2.3. the veterinary medicinal products may pose a threat to the animal health and welfare, human health, or the environment.

19. A person shall cover expenses of the Service related to the activities referred to in Paragraph 18 of this Regulation in accordance with the laws and regulations regarding the procedures for making payments to the Food and Veterinary Service for the State supervision and control operations and paid services thereof. If the Service takes a decision to refuse to issue the export certificate, the certificate for free trade, or the notification, the person shall not be reimbursed the expenses paid and related to the assessment of the application.

IV. Import of Samples of Veterinary Medicinal Products

20. A person who has received a permit for the import of samples of veterinary medicinal products (Annex 4) from the Service is entitled to import samples of veterinary medicinal products from the third countries if the import of samples is necessary for the following:

20.1. ensuring of the process of marketing authorisation of veterinary medicinal products;

20.2. training or scientific studies;

20.3. testing of veterinary medicinal products (standard sample);

20.4. clinical studies of veterinary medicinal products.

21. A person to whom the State Agency of Medicines has issued the single-use permit referred to in Section 18 of the law On Procedures for the Legal Trade of Narcotic and Psychotropic

Substances and Medicinal Products is entitled to import samples of veterinary narcotic and psychotropic medicinal products from the third countries. In such case the permit referred to in Paragraph 20 of this Regulation need not be received.

22. In order to receive the permit referred to in Paragraph 20 of this Regulation for the import of samples of veterinary medicinal products, a person shall submit an application to the Service for the receipt of the permit for the import of samples of veterinary medicinal products(Annex 5).

23. The Service shall assess the application referred to in Paragraph 22 of this Regulation and the appended documents, contacting the competent authority of the relevant third country, if necessary, and take one of the following decisions:

23.1. to issue a permit for the import of samples of veterinary medicinal products, specifying the period of validity thereof if:

23.1.1. the information indicated in the application referred to in Paragraph 22 of this Regulation and the documents appended thereto correspond to the requirements of this Regulation;

23.1.2. the information provided by the applicant is complete and true;

23.1.3. the veterinary medicinal products do not pose a threat to the animal health and welfare, human health, or the environment;

23.2. to refuse a permit for the import of samples of veterinary medicinal products if:

23.2.1. the information indicated in the application referred to in Paragraph 22 of this Regulation and the documents appended thereto fail to correspond to the requirements of this Regulation;

23.2.2. the information indicated in the application is incomplete or misleading;

23.2.3. the veterinary medicinal products may pose a threat to the animal health and welfare, human health, or the environment.

24. A person who wishes to receive a permit for the import of samples of veterinary medicinal products shall cover expenses of the Service related to the activities referred to in Paragraph 23 of this Regulation in accordance with the laws and regulations regarding the procedures for making payments to the Food and Veterinary Service for the State supervision and control operations and paid services thereof. If the Service takes a decision not to issue the permit for the import of samples of veterinary medicinal products, the person shall not be reimbursed the expenses paid and related to the assessment of the application.

V. Import and Export of Veterinary Narcotic and Psychotropic Veterinary Medicinal Products

25. The manufacturer, the importer, or the wholesaler shall import or export veterinary narcotic and psychotropic medicinal products in accordance with the law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products in conformity with the following requirements:

25.1. the specific medicinal products have been included in the special permit (licence) for the manufacturing of medicinal products or the special permit (licence) for the manufacturing of narcotic and psychotropic veterinary medicinal products which includes an indication that the import operations involving veterinary narcotic and psychotropic medicinal products are permitted, or the wholesaler has received the special permit (licence) for the wholesale distribution of veterinary narcotic and psychotropic medicinal products or the special permit (licence) for the opening (operation) of a wholesaler which includes an indication that the operation involving veterinary narcotic and psychotropic medicinal products is permitted;

25.2. upon issuing the special permits (licences) referred to in Sub-paragraph 25.1 of this Regulation in accordance with the laws and regulations regarding the procedures for issuing, suspending, re-registering, and revoking special permits (licences) for pharmaceutical and veterinary pharmaceutical activities, the State Agency of Medicines has included the specific medicinal products in the database and issued the single-use permit with regard thereto referred to in Section 18 of the law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products.

26. The person referred to in Paragraph 25 of this Regulation shall import veterinary narcotic and psychotropic medicinal products from and export to the third countries through border crossing points where customs authorities perform customs control for the movement of narcotic and psychotropic substances, medicinal products and precursors across the external border and the Service performs veterinary, phytosanitary, food safety and non-food product safety, quality and classification control in accordance with the laws and regulations regarding border crossing points and controls to be performed at them.

VI. Control of Import of Veterinary Medicinal Products

27. It shall be permitted to import veterinary medicinal products through border crossing points where the Service performs veterinary, phytosanitary, food safety and non-food product safety, quality and classification control in accordance with the laws and regulations regarding border crossing points and controls to be performed at them.

28. The owner of a cargo of veterinary medicinal products or an authorised person thereof shall:

28.1. upon request, ensure that officials of the Service may access veterinary medicinal products, and shall present the documents accompanying the cargo to the Service for control;

28.2. attach to the cargo of veterinary medicinal products an accompanying document issued by the exporting country in which the name, pharmaceutical form, strength, quantity, batch number assigned by the manufacturer, the country of manufacture, the name of the manufacturer, the name and address of the consignor, the name and address of the consignee of the relevant medicinal products are indicated.

29. The Service is entitled to suspend the import of a specific batch of veterinary medicinal products or all veterinary medicinal products if it is established during control of the cargo of veterinary medicinal products that:

29.1. the owner of the cargo or an authorised person thereof fails to present the data and documents referred to in Paragraph 28 of this Regulation;

29.2. the veterinary medicinal product is unidentifiable;

29.3. the requirements for the storage and transportation of veterinary medicinal products laid down in the laws and regulations regarding distribution and control of veterinary medicinal products have been violated;

29.4. the consignor or consignee of the cargo of veterinary medicinal products is unidentifiable;

29.5. the permit referred to in Paragraph 25 of this Regulation has not been attached to the cargo of veterinary narcotic and psychotropic medicinal products.

30. The Service shall control the conformity of the importer with the requirements of this Regulation in accordance with the procedures laid down in the laws and regulations regarding the manufacturing and control of veterinary medicinal products.

31. During control the importer of veterinary medicinal products shall, upon request, provide the following information and documents to officials of the Service:

31.1. regarding control of the batch release of veterinary medicinal products performed in a Member State – according to the conditions of the authorisation dossier of veterinary medicinal products;

31.2. regarding immunological veterinary medicinal products – copies of all batch certificates (control reports) approved by the qualified person.

32. The Service is entitled to prohibit the import of a specific batch of veterinary medicinal products or all medicinal products if it is established during control of the importer that:

32.1. the manufacturer, importer, quality control or batch release of veterinary medicinal products fails to correspond to the requirements of this Regulation;

32.2. the importer does not have the qualified person at its disposal or this person has failed to fulfil the obligations referred to in Paragraph 6 of this Regulation;

32.3. the requirements for the storage and transportation of veterinary medicinal products laid down in the laws and regulations regarding distribution and control of veterinary medicinal products have been violated, thus affecting the quality and safety of veterinary medicinal products;

32.4. the period of validity of the veterinary medicinal product has expired;

32.5. the veterinary medicinal product is falsified;

32.6. the rapid alert notification regarding recall from the market refers to the veterinary medicinal product in accordance with the laws and regulations regarding the distribution and control of veterinary medicinal products.

33. The Service shall, immediately, but not later than within three working days, inform the Health Inspectorate of the established violations in the import of veterinary narcotic and psychotropic medicinal products.

34. The importer shall place the veterinary medicinal products with regard to which the decision referred to in Paragraph 29 of this Regulation has been taken for storage in a customs warehouse, if necessary, ensuring that the relevant veterinary medicinal products are transported and stored in accordance with the package leaflet and the laws and regulations regarding the distribution and control of veterinary medicinal products.

35. The Service shall take a decision to withdraw suspension of the import of veterinary medicinal products if the importer has eliminated the non-conformities referred to in Paragraph 29 of this Regulation. The Service shall inform the importer of the taken decision on the day of taking thereof.

36. Any expenses related to destruction of a specific cargo of veterinary medicinal products or re-export thereof to the country of origin shall be covered by the importer.

VII. Import or Export of Veterinary Medicinal Products if Implemented by a Veterinary Medical Practice Institution or a Natural Person

37. It shall be permitted for a veterinary medical practice institution to export veterinary medicinal products to another Member State in such quantities that do not exceed the quantity of veterinary medicinal products to be used in one day, and to use them on animals (except for immunological veterinary medicinal products the use of which is prohibited in the Member State of destination) if:

37.1. a marketing authorisation has been issued, in accordance with the laws and regulations regarding the procedures for authorising veterinary medicinal products, for the veterinary medicinal products in the Member State where the practising veterinarian who works

in the veterinary medical practice institution has registered his or her professional activities and has received a certificate for the performance of veterinary practice;

37.2. the veterinary medicinal products are transported in the original packaging of the manufacturer;

37.3. the qualitative and quantitative composition of the active substances of the veterinary medicinal products that are intended for use in food-producing animals is equivalent to the composition of the veterinary medicinal products that may be used in food-producing animals in the Member State of destination;

37.4. the practising veterinarian who works in the veterinary medical practice institution becomes acquainted with the good veterinarian practice of the Member State of destination and ensures that the withdrawal period of veterinary medicinal products indicated on the labelling of the veterinary medicinal products (information indicated on the primary or secondary packaging) is observed. If a longer withdrawal period is prescribed for equivalent veterinary medicinal products in the Member State of destination according to the principles of good veterinarian practice of the Member State of destination, the veterinarian shall observe it.

38. In the case referred to in Section 37 of this Regulation, the veterinary medical practice institution shall:

38.1. not dispense veterinary medicinal products to the owner or keeper of the animals treated in the Member State of destination, except for the minimum quantity necessary for the completion of the course of treatment for the specific animal;

38.2. register the following information on the veterinary medicinal products used in the animal in the Member State of destination;

38.2.1. the species and age of the animal, and also the identification number thereof, where applicable;

38.2.2. the diagnosis made with regard to the animal;

38.2.3. the veterinary medicinal products used and the doses and quantities thereof;

38.2.4. the duration of care of the animal;

28.2.5. the specified withdrawal period of the veterinary medicinal products, if necessary;

38.3. the registered information shall be kept for at least three years and presented to an official of the Service upon request.

39. A veterinary medical practice institution may import veterinary medicinal products from another Member State in order to provide its veterinary medical practice if it has received a permit for the import and use of the relevant veterinary medicinal products for exceptional cases in accordance with the laws and regulations regarding the distribution and control of veterinary medicinal products. A single-use permit issued by the State Agency of Medicines in accordance with the requirements of Section 18 of the law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products must be received with regard to veterinary narcotic and psychotropic veterinary medicinal products.

40. It shall be permitted for a natural person crossing the border of Latvia together with an animal to import and export the veterinary medicinal products necessary for the animal, except for medicinal products the composition of which includes the substances included in the Register II of the narcotic substances and psychotropic substances (hereinafter – the narcotic medicinal products) and the substances included in the Register III (hereinafter – the psychotropic medicinal products) controlled in Latvia, for a course of treatment which does not exceed two months. If continued availability of medicinal products is necessary for the animal due to medical indications, it shall be permitted for the natural person to import and export the narcotic medicinal products necessary for the animal for a course of treatment not exceeding

14 days, or the psychotropic medicinal products for a course of treatment not exceeding 30 days. The need for veterinary medicinal products shall be confirmed by a prescription issued by a practising veterinarian or a copy of the prescription signed and approved by a practising veterinarian using the stamp of the seal of the veterinary medical practice, or another document certifying this fact.

VIII. Parallel Import of Veterinary Medicinal Products

41. Veterinary medicinal products imported in parallel shall include veterinary medicinal products authorised in another Member State and imported to Latvia by a wholesaler which is not the manufacturer, the marketing authorisation holder or an authorised representative thereof of these veterinary medicinal products (hereinafter – the parallel importer) if identical or equivalent veterinary medicinal products are authorised in Latvia (hereinafter – the veterinary medicinal products authorised in Latvia).

42. Prior to commencing the import, the parallel importers which import veterinary medicinal products to Latvia from another Member State shall notify their intention to import veterinary medicinal products to the marketing authorisation holder and, where applicable, the proprietor of the trade mark of the relevant veterinary medicinal products. This condition shall not refer to the veterinary medicinal products authorised in the centralised authorisation procedure in accordance with 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.

43. The parallel import of veterinary medicinal products shall be permitted if the Service has issued to the parallel importer a permit for the distribution of the veterinary medicinal products imported in parallel in Latvia (Annex 6).

44. If the parallel importer re-packages the veterinary medicinal products imported in parallel, the proprietor of the trade mark of veterinary medicinal products is entitled to request that the parallel importer supplies a sample of the re-packaged product.

45. The proprietor of the trade mark of veterinary medicinal products may not exercise the trade mark right in order to prohibit re-packaging if:

45.1. the trade mark right exercised by the proprietor of the trade mark with regard to the trading system established by it contributes to an artificial partitioning of the market among Member States;

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

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

45.4. the proprietor of the trade mark has received a prior notification before marketing of the re-packaged product.

46. In order to receive the permit referred to in Paragraph 43 of this Regulation, an applicant for the permit shall submit to the Service an application for the receipt of the permit for the distribution of the veterinary medicinal products imported in parallel (Annex 7). The information indicated in the application shall be accurate, truthful, and not misleading. If a single veterinary medicinal product has different pharmaceutical forms or strengths, a separate application shall be submitted for each pharmaceutical form and strength of the medicinal product.

47. The veterinary medicinal products with regard to which the application referred to in Paragraph 46 of this Regulation has been submitted shall correspond to the following requirements:

47.1. they have been authorised and released for free circulation in the Member State from which it is intended to import the veterinary medicinal products imported in parallel;

47.2. the manufacturer (re-packager) thereof has a special permit (licence) for the manufacturing of the relevant veterinary medicinal products, and the manufacturing corresponds to the requirements of good manufacturing practice;

47.3. the package leaflet and labelling thereof correspond to the requirements laid down in the laws and regulations regarding the labelling of veterinary medicinal products;

47.4. they are identical or equivalent to the veterinary medicinal products authorised in Latvia;

47.5. if the veterinary medicinal products are not identical to the veterinary medicinal products authorised in Latvia, permitted variations of equivalent veterinary medicinal products from the veterinary medicinal products authorised in Latvia shall correspond to the following conditions:

47.5.1. the variations do not pose a threat to the animal and human health or the environment, and do not affect the therapeutic effect of the veterinary medical products imported in parallel;

47.5.2. the veterinary medicinal products imported in parallel and the veterinary medicinal products authorised in Latvia contain the same active substances and have the same therapeutic effect, and also they have been manufactured by using the same manufacturing methods;

47.5.3. the method of administration, dose, and target species specified by the manufacturer of the veterinary medicinal products imported in parallel correspond to the method of administration, dose, and target species indicated in the summary of product characteristics, labelling, and package leaflet of the relevant veterinary medicinal products authorised in Latvia;

47.5.4. the difference (if any) in the colouring is small (another colour code);

47.6. on the labelling of the veterinary medicinal products imported in parallel:

47.6.1. the therapeutic indications or any other information approved by another Member State but not approved for the veterinary medicinal products authorised in Latvia (where applicable) are covered (for example, with a label);

47.6.2. the owner of the permit for the distribution of the veterinary medicinal products imported in parallel is indicated;

47.7. if the veterinary medicinal products imported in parallel are re-packaged (re-labelled), they shall correspond to the following additional conditions:

47.7.1. the name of the re-packager (re-labeller) of the veterinary medicinal products is indicated on the labelling;

47.7.2. the composition of the veterinary medicinal products has not been changed;

47.7.3. the product remains untouched;

47.7.4. the primary packaging is not opened;

47.7.5. the manufacturing batch number is indicated on the labelling of the re-packaged veterinary medicinal products separately from or together with the re-packaging batch number.

48. After registration of the application the Service shall verify the provided information and inform the submitter of the application in writing if any additional information is necessary or if incomplete or erroneous information has been submitted. After verification of the information the Service shall, if necessary, request the following information and documents regarding the

veterinary medicinal products imported in parallel from the competent authority of the Member State which has authorised and evaluated the veterinary medicinal products imported in parallel:

48.1. the number, date of granting, and period of validity of the marketing authorisation;

48.2. whether the medicinal products imported in parallel have been released for free circulation;

48.3. the name, legal address, and address of the site of operation (if different) of the veterinary medicinal product marketing authorisation holder;

48.4. the name, legal address and address of the site of operation of the undertaking of the manufacturer of veterinary medicinal products, and also information on the fact whether the special permit (licence) for the manufacturing of veterinary medicinal products is valid;

48.5. the qualitative and quantitative composition of the veterinary medicinal products;

48.6. the shelf life of the veterinary medicinal products and the recommended storage conditions;

48.7. the description of the manufacturing method (if there is a variation between the veterinary medicinal products imported in parallel and the veterinary medicinal products authorised in Latvia).

49. The Service shall verify the received information and documents, taking into account the information received from another Member State, and compare it with the relevant information on the veterinary medicinal products authorised in Latvia.

50. The Service shall evaluate the conformity of the veterinary medicinal products imported in parallel with the requirements laid down in this Chapter and prepare an assessment report. The Service shall inform the submitter of the application in writing if additional information is necessary in order to evaluate whether the veterinary medicinal products imported in parallel and the relevant veterinary medicinal products included in the Register of Veterinary Medicinal Products of Latvia have been manufactured, using the same manufacturing methods.

51. After preparation of the assessment report the Service shall take:

51.1. one of the following decisions:

51.1.1. to issue a permit for the distribution of the veterinary medicinal products imported in parallel in Latvia if the veterinary medicinal products and submitted documents correspond to the requirements of this Regulation;

51.1.2. to refuse to issue a permit for the distribution of the veterinary medicinal products imported in parallel in Latvia if:

51.1.2.1. the veterinary medicinal products and the provided information fail to correspond to the requirements laid down in this Regulation

51.1.2.2. false or misleading information has been provided in the application referred to in Paragraph 46 of this Regulation;

51.1.2.3. for the purpose of protection of the animal and human health (due to the safety, efficacy, and quality of the medicinal products) the distribution of the relevant veterinary medicinal products authorised in Latvia has been prohibited or suspended or the veterinary medicinal products have been recalled from the market in Latvia or in another Member State;

51.2. a decision on belonging of the veterinary medicinal products imported in parallel to the classification group of veterinary medicinal products according to the veterinary medicinal products authorised in Latvia if the decision referred to in Sub-paragraph 51.1.1 of this Regulation is taken.

52. If the decision referred to in Sub-paragraph 51.1.1 of this Regulation is taken, the Service shall issue to the applicant for the permit the permit for the distribution of the veterinary

medicinal products imported in parallel in Latvia, and it shall be valid for five years from the day of issue of the permit.

53. As to the veterinary medicinal products imported in parallel, the Service shall include the following in the Register of Veterinary Medicinal Products of Latvia:

53.1. the mock-up of the labelling and the package leaflet. If the veterinary medicinal products imported in parallel vary from the veterinary medicinal products authorised in Latvia, the variation shall be indicated;

53.2. the information on the parallel importers and the veterinary medicinal products imported in parallel by them. Information shall be prepared in accordance with the laws and regulations regarding the procedures for authorising veterinary medicinal products.

54. The parallel importer shall:

54.1. maintain a register indicating information therein on the performed activities in relation to the import of the veterinary medicinal products imported in parallel. The name, the country of manufacture, the batch number of the veterinary medicinal products, and the amount of the imported batch shall be indicated in the register;

54.2. inform the relevant marketing authorisation holder of the veterinary medicinal products authorised in Latvia and the Service of the commencement of the distribution of the veterinary medicinal products imported in parallel in Latvia;

54.3. within two weeks after receipt of a request from the Service, provide information on activities involving the veterinary medicinal products imported in parallel;

54.4. within two weeks after implementation of changes, provide information to the Service if any information indicated in the application referred to in Paragraph 46 of this Regulation has changed;

54.5. provide information on the veterinary medicinal products imported in parallel and distributed in the State in accordance with the laws and regulations regarding the procedures for gathering information and producing statistics in the field of circulation of veterinary medicinal products;

54.6. provide information on adverse reactions caused by the use of the veterinary medicinal products imported in parallel and distributed in the State in accordance with the laws and regulations regarding the supervision of adverse reactions, and also ensure recall of veterinary medicinal products from the market, if necessary;

54.7. if the secondary packaging is opened when re-packaging (re-labelling) veterinary medicinal products, for example, in order to change the packaging or package leaflet, one sample for comparison shall be kept for each re-packaging operation (for example, a veterinary medicinal product, a packaging material, and a package leaflet). It shall be ensured that it is possible to identify the person responsible for the mistakes made during re-packaging (the original manufacturer or the parallel importer, the re-packager) if such mistakes may affect the quantities of the product recalled;

54.8. if the secondary packaging is not opened when re-packaging (re-labelling) veterinary medicinal products, only the packaging material shall be kept.

55. The marketing authorisation holder of veterinary medicinal products authorised in Latvia shall inform the parallel importer of any variations in the authorisation dossier of the veterinary medicinal products and concurrently submit an application to the Service for variations in the authorisation dossier of the veterinary medicinal products.

56. If the Service has, 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,

approved the variations in the authorisation dossier of the veterinary medicinal products authorised in Latvia, it shall:

56.1. inform in writing the owner of the permit for the distribution of the veterinary medicinal products imported in parallel or the submitter of the application of the approved variations in the summary of product characteristics, package leaflet, or labelling of the relevant veterinary medicinal products authorised in Latvia, and of the change of classification of medicinal products, where applicable;

56.2. issue the summary of product characteristics of medicinal products (a copy thereof) which include variations approved by the Service regarding the relevant veterinary medicinal products authorised in Latvia to the owner of the permit for the distribution of the veterinary medicinal products imported in parallel or the submitter of the application.

57. In the case referred to in Paragraph 56 of this Regulation the owner of the permit for the distribution of the veterinary medicinal products imported in parallel shall:

57.1. suspend the parallel import of veterinary medicinal products and, within 10 working days from receipt of the information referred to in Sub-paragraph 56.1 of this Regulation, submit an application to the Service for the approval of variations in the permit for the distribution of the veterinary medicinal products imported in parallel. The application shall be accompanied by information confirming the relevant variations. The distribution of the veterinary medicinal products imported in parallel shall be resumed after receipt of the decision of the Service to approve variations in the permit for the distribution of the veterinary medicinal products imported in parallel;

57.2. ensure implementation of the relevant variations in the package leaflet and labelling of the veterinary medicinal products imported in parallel in accordance with the laws and regulations regarding the labelling of veterinary medicinal products;

57.3. distribute the remaining stocks of the veterinary medicinal products imported in parallel the labelling and package leaflet of which do not contain any variations in accordance with the laws and regulations regarding the distribution and control of veterinary medicinal products.

58. The owner of the permit for the distribution of the veterinary medicinal products imported in parallel shall suspend the import of veterinary medicinal products and, within 10 working days from taking of the decision to approve variations, submit an application to the Service for the approval of variations in the permit for the distribution of the veterinary medicinal products imported in parallel if a decision has been taken in the country issuing the marketing authorisation of the veterinary medicinal products imported in parallel on variations in the summary of product characteristics, package leaflet, labelling of the veterinary medicinal products, or in classification of medicinal products. The application shall be accompanied by information confirming the relevant variations. The distribution of the veterinary medicinal products imported in parallel shall be resumed after receipt of the decision of the Service to approve variations in the permit for the distribution of the veterinary medicinal products imported in parallel. The remaining stocks of the veterinary medicinal products imported in parallel the labelling and package leaflet of which do not contain any variations shall be distributed in accordance with the requirements laid down in the laws and regulations regarding the distribution and control of veterinary medicinal products.

59. If legal details of the owner of the permit for the distribution of the veterinary medicinal products imported in parallel change, the owner shall notify the Service thereof in writing. The Service shall take the decision to grant a new permit for the distribution of the veterinary medicinal products imported in parallel.

60. The applicant shall, in accordance with the laws and regulations regarding the procedures for making payments to the Food and Veterinary Service for the State supervision and control operations and paid services thereof, cover expenses related to the assessment of the application for the receipt of the permit for the distribution of the veterinary medicinal products imported in parallel. If the Service does not issue the permit for the distribution of the veterinary medicinal products imported in parallel or revokes it, the expenses paid and related to the assessment of the application shall not be reimbursed.

61. The Service shall take a decision to revoke the permit for the distribution of the veterinary medicinal products imported in parallel if:

61.1. the marketing authorisation of the veterinary medicinal products imported in parallel in the country of manufacture, the Member State from which the medicinal products are supplied or of the veterinary medicinal products authorised in Latvia has been revoked for reasons related to a threat to human and animal health or the environment (safety, quality, or efficacy of the medicinal products), or distribution of the veterinary medicinal products is prohibited and they are removed from the market;

61.2. the information indicated in the application referred to in Paragraph 46 of this Regulation has changed but the parallel importer has failed to inform the Service thereof in accordance with the procedures laid down in this Regulation;

61.3. the manufacturing of the veterinary medicinal products imported in parallel is prohibited;

61.4. the re-registration for the distribution of the veterinary medicinal products imported in parallel in Latvia has been refused;

61.5. it is established that the parallel importer has provided false information.

62. The Service shall take the decision to suspend the permit for the distribution of the medicinal products imported in parallel if:

62.1. the operation of the marketing authorisation of the veterinary medicinal products imported in parallel in the country of manufacture, supplying country or of the relevant veterinary medicinal products authorised in Latvia has been suspended for reasons related to a threat to human and animal health (safety, quality, or efficacy of the medicinal products);

62.2. the owner of the permit for the distribution of the veterinary medicinal products imported in parallel in Latvia has failed to provide data and documents regarding variations in the marketing authorisation or the legal name of the relevant veterinary medicinal products or has failed to implement the variations in accordance with the procedures laid down in this Regulation;

62.3. the manufacturing of the veterinary medicinal products imported in parallel does not correspond to the requirements of good manufacturing practice;

62.4. the permit for the distribution of the veterinary medicinal products imported in parallel in Latvia has not been re-registered.

63. The Service shall inform the owner of the permit for the distribution of the veterinary medicinal products imported in parallel of the decision referred to in Paragraphs 61 and 62 of this Regulation.

64. The Service shall revoke the decision to suspend the permit for the distribution of the veterinary medicinal products imported in parallel on the basis of an application of the owner of the relevant permit if the reasons for suspending the operation of the permit have been eliminated.

65. The Service shall, upon request, provide information to the competent authority of another Member State on the veterinary medicinal products imported in parallel.

IX. Import of the Veterinary Medicinal Products Intended for Parallel Distribution

66. Parallel distribution of veterinary medicinal products is the supply of veterinary medicinal products authorised under the centralised procedure for the authorisation of medicinal products from one Member State to another Member State if it is performed by a wholesaler of veterinary medicinal products who is not the manufacturer of these veterinary medicinal products, a marketing authorisation holder or an authorised representative thereof (hereinafter – the parallel distributor).

67. The parallel distributor shall notify its intention of distributing veterinary medicinal products authorised centrally to the following:

67.1. the veterinary medicinal product marketing authorisation holder and the Service but if medicinal products are supplied to another Member State – to the competent authority of the relevant Member State;

67.2. the proprietor of the trade mark of the veterinary medicinal product prior to marketing the re-packaged product and, upon request of the proprietor of the trade mark of the veterinary medicinal product, shall supply him or her with a sample of the re-packaged product;

67.3. the European Medicines Agency in accordance with Paragraphs 69 and 70 of this Regulation.

68. Parallel distribution of veterinary medicinal products shall also be permitted if the marketing authorisation holder of the veterinary medicinal products authorised centrally has not commenced the distribution of such medicinal products in Latvia.

69. The parallel distributor shall, according to a model specified by the European Medicines Agency (Annex 8) and published on the website of the Service, submit a notification to the European Medicines Agency regarding the parallel distribution of the medicinal products authorised centrally.

70. If amendments are made to annexes of the marketing authorisation of the veterinary medicinal products authorised centrally or if data change in the information indicated by the parallel distributor in the notification referred to in Paragraph 69 of this Regulation (for example, data regarding the re-packager or the parallel distributor), the parallel distributor shall notify of the changes in the parallel distribution of the medicinal products authorised centrally according to the sample specified by the European Medicines Agency and referred to in Paragraph 69 of this Regulation which has been published on the website of the Service. This notification must also be submitted if the Member State in which it is intended to distribute the veterinary medicinal products authorised centrally changes.

71. The parallel distributor is entitled to implement only the following variations related to the packaging of the veterinary medicinal products authorised centrally:

71.1. the provision of information on the labelling and in the package leaflet in the language of the country in which the veterinary medicinal products are offered on the market, moreover, the information on the labelling and in the package leaflet is identical in all languages used;

71.2. variations in the size of the packaging, provided that the offered size of the packaging corresponds to the size of the packaging indicated in the authorisation dossier of the veterinary medicinal products registered under the centralised authorisation procedure.

X. Closing Provisions

72. The permits for the distribution of the veterinary medicinal products imported in parallel which have been issued until the day of coming into force of this Regulation shall be valid until expiry of the period of validity indicated therein.

73. The Regulation shall come into force on 15 June 2016.

Informative Reference to European Union Directives

This Regulation contains legal norms arising from:

1) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products;

2) Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

Prime Minister Māris Kučinskis

Minister for Agriculture Jānis Dūklavs

Annex 1
Cabinet Regulation No. 327
31 May 2016

Produkta (veterināro zāļu) sertifikāts[1]
Certificate of a Pharmaceutical product[1]

Šis sertifikāts atbilst Pasaules Veselības organizācijas ieteiktajam paraugam
This certificate conforms to the format recommended by the World Health Organization

Sertifikāta numurs *No. of certificate*	
Eksportētājvalsts (sertifikāta izsniedzēja) *Exporting (certifying country)*	Latvijas Republika Republic of Latvia
Importētājvalsts (sertifikāta pieprasītāja) *Importing (requesting country)*	
1. Veterināro zāļu nosaukums, deva un forma *Name and dosage form of the product*	
1.1. Aktīvā(-s) viela(-s)[2] un daudzums devas vienībā[3] *Active ingredient(s)[2] and amount(s) per unit dose[3]*	
Pilns sastāvs, iekļaujot palīgvielas (skat. piezīmes)[4] *For complete composition including excipients, see attached[4]*	
1.2. Vai veterinārās zāles ir reģistrētas eksportētājvalstī[5] (Vajadzīgo atzīmēt ar x) *Is this product licensed to be placed on the market for use in the exporting country[5]*	☐ jā/yes ☐ nē/no
1.3. Vai veterinārās zāles tiek izplatītas eksportētājvalstī *Is this product actually on the market in the exporting country?*	☐ jā/yes ☐ nē/no
Ja 1.2. apakšpunktā atbilde ir "jā", aizpildiet 2.A punktu, neaizpildot 2.B punktu Ja 1.2. apakšpunktā atbilde ir "nē", aizpildiet 2.B punktu, neaizpildot 2.A punktu[6] *If the answer to 1.2.is yes, continue with section 2A and omit section 2B* *If the answer to 1.2.is no, omit section 2A and continue with section 2B[(6)]*	
2.A. 1. Veterināro zāļu reģistrācijas apliecības numurs[7] un izsniegšanas datums *Number of product licence[(7)] and date of issue*	
2.A. 2. Reģistrācijas apliecības īpašnieks (turētājs) (nosaukums un adrese) *Product licence holder (name and address)*	
2.A. 3. Reģistrācijas apliecības īpašnieka (turētāja) statuss[8] (Vajadzīgo atzīmēt ar x) *Status of product licence holders[8] (key in appropriate category)*	a ☐zāļu formas ražošana *manufactures the dosage form*
	b ☐iepako un (vai) marķē zāļu formu, ko ražo cits neatkarīgs ražotājs

	packages and/or labels a dosage form manufactured by an independent company
	c ☐nav iesaistīts ražošanā, iepakošanā un (vai) marķēšanā, bet ir atbildīgs par produkta kvalitāti un sērijas izlaišanu *not involved in manufacturing, packaging and/or labeling, but is responsible for quality and batch release*
	d ☐nav iesaistīts iepriekš minētajās darbībās *is involved in none of the above*
2.A. 3.1. Ja atzīmēta "b", "c" un "d" atbilde, norāda zāļu formas ražotāja nosaukumu un adresi[9] *For categories "b", "c" and "d" the name and address of the manufacturer producing the dosage form[(9)]:*	
2.A. 4. Vai kopsavilkums pamatots ar pievienoto novērtējumu[10] (Vajadzīgo atzīmēt ar x) *Is a summary basis for approval appended?[10]*	☐ jā/*yes* ☐ nē/*no*
2.A. 5. Vai pievienotā oficiāli apstiprinātā informācija par veterinārajām zālēm ir pilnīga un atbilst reģistrācijas dokumentācijai[11] (Vajadzīgo atzīmēt ar x) *Is the attached, officially approved product information complete and consonant with the licence?[11]*	☐ jā/yes ☐ nē/no ☐ nav nodrošināta/*no provided*
2.A. 6. Sertifikāta pretendenta nosaukums (vai vārds, uzvārds) un adrese, ja atšķiras no veterināro zāļu reģistrācijas apliecības īpašnieka (turētāja) *Applicant for certificate, if different from licence holder (name and address)*	
2.B. 1. Sertifikāta pretendenta nosaukums (vai vārds, uzvārds) un adrese *Applicant for certificate (name and address*)	
2.B. 2. Sertifikāta pretendenta statuss[8] (Atzīmēt ar X attiecīgo atbildi) *Status of applicant[8] (key in appropriate category)*	a ☐zāļu formas ražošana *manufactures the dosage form*
	b ☐iepako un (vai) marķē zāļu formu, ko ražo cits neatkarīgs ražotājs *packages and/or labels a dosage form manufactured by an independent company*
	c ☐nav iesaistīts iepriekš minētajās darbībās *is involved in none of the above*
2.B. 2.1. Ja atzīmēta "b" un "c" atbilde, norāda zāļu formas ražotāja nosaukumu un adresi[9] *For categories b and c the name and address of the manufacturer producing the dosage form is[9]*	
2.B. 3. Kādēļ nav reģistrācijas apliecības (Vajadzīgo atzīmēt ar x)	☐ netiek prasīta/*not required* ☐ nav pieprasīta/*not requested*

Why is marketing authorisation lacking? (key as appropriate)	☐ reģistrācijas procesā/*under consideration* ☐ atteikta/*refused*
2.B. 4. Piezīmes[13] *Remarks[13]*	
3. Vai kompetentā iestāde regulāri pārbauda zāļu formu ražošanas vietu[14] (Vajadzīgo atzīmēt ar x) *Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?*	☐ jā/*yes* ☐ nē/*no* ☐ nepiemēro/*not applicable*
Ja atbilde ir "nē" vai "nepiemēro", aizpildīt 4. sadaļu. *If „no" or „not applicable", proceed to question 4*	
3.1. Kārtējo pārbaužu biežums (gadi) *Periodicity of routine inspections (years):*	
3.2. Vai attiecīgā tipa zāļu formas ražošana ir inspicēta (Vajadzīgo atzīmēt ar x) *Has the manufacture of this type of dosage form been inspected? (key as appropriate)*	☐ jā/*yes* ☐ nē/*no*
3.3. Vai ražotnes aprīkojums un darbības atbilst labas ražošanas prakses prasībām[15] (Vajadzīgo atzīmēt ar x) *Do the facilities and operations confirm to GMP? (15) (key as appropriate)*	☐ jā/*yes* ☐ nē/*no* ☐ nepiemēro/*not applicable*
4. Vai iesniegtā informācija par visiem produkta ražošanas aspektiem ir pietiekama sertifikāta izsniedzējiestādei[16] (Vajadzīgo atzīmēt ar x) *Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16] (key as appropriate)*	☐ jā/*yes* ☐ nē/*no*
Ja "nē", paskaidro *If "no", explain*	
(sertifikāta izsniedzēja kompetentā iestāde) (*certifying authority)*	
Adrese *Address*	
Tālruņa numurs *Telephone*	
Faksa numurs *Fax*	

Sertifikāta izsniedzējiestādes atbildīgā amatpersona/
Responsible person of the certifying authority

(amats, vārds, uzvārds, paraksts*/*position, name, surname, signature*)

Z.v.*/*Stamp* Datums*/*Date* _____

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

Notes.

[1] Sertifikāts, kas ir noformēts atbilstoši Pasaules Veselības organizācijas paraugam, apliecina veterināro zāļu statusu un sertifikāta iesniedzēja statusu eksportētājvalstī un apstiprina informāciju. Sertifikāts paredzēts viena veida veterinārajām zālēm, jo dažādām zāļu formām un stiprumiem var atšķirties ražošanas nosacījumi un apstiprinātā informācija.
This certificate, which is in the format recommended by WHO, establishes the status of pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
[2] Izmanto starptautisko nepatentēto nosaukumu (*INN*), ja tāds ir noteikts, vai nacionālo nepatentēto nosaukumu.
Whenever possible, use International Nonproprietary Names (INNs) or national nonproprietary names.
[3] Sertifikātā norāda zāļu formas pilnu sastāvu vai šo informāciju pievieno sertifikāta pielikumā.
The formula (complete composition) of the dosage form should be given on the certificate or be appended.
[4] Ieteicams detalizēts kvantitatīvais sastāvs, bet šāda norāde jāsaskaņo ar veterināro zāļu reģistrācijas apliecības īpašnieku (turētāju).
Details of quantitative composition are preferred but their provision is subject to the agreement of the product licence holder.
[5] Ja nepieciešams, pielikumā pievieno visus veterināro zāļu pārdošanas, izplatīšanas vai lietošanas ierobežojumus, kas ir norādīti veterināro zāļu reģistrācijas apliecībā.
When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
[6] 2.A un 2.B punkts savstarpēji viens otru izslēdz.
Section 2.A. and 2.B. are mutually exclusive.
[7] Ja nepieciešams, norāda, vai izsniegta veterināro zāļu pagaidu reģistrācijas apliecība vai arī reģistrācija nav vēl apstiprināta.
Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
[8] Norāda par veterināro zāļu laišanu tirgū atbildīgo personu.
Specify whether the person responsible for placing the product on the market.
[9] Šo informāciju var norādīt tikai ar veterināro zāļu reģistrācijas apliecības īpašnieka (turētāja) piekrišanu vai, ja veterinārās zāles nav reģistrētas, – ar veterināro zāļu reģistrācijas iesnieguma iesniedzēja piekrišanu. Ja informācija šajā punktā nav iekļauta, tas nozīmē, ka iesaistītās puses nav vienojušās par informācijas iekļaušanu. Informācija par ražošanas vietu ir veterināro zāļu reģistrācijas apliecības sastāvdaļa. Ja ražošanas vieta ir mainīta, reģistrācijas apliecību attiecīgi aktualizē vai arī tā vairs nav spēkā.
This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
[10] Attiecas uz tās kompetentās iestādes izstrādāto dokumentu, kura apkopo tehnisko pamatojumu attiecīgo veterināro zāļu reģistrācijai.

This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

[11] Attiecas uz veterināro zāļu aprakstu, kuru kompetentā iestāde ir apstiprinājusi kā veterināro zāļu kopsavilkumu.

This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC).

[12] Šajos apstākļos ir nepieciešama veterināro zāļu reģistrācijas apliecības īpašnieka (turētāja) atļauja sertifikāta izsniegšanai, ko sertifikāta pretendents iesniedz Pārtikas un veterinārajā dienestā.

In this circumstance, permission for issuing the certificate is required from the product – licence holder. This permission has to be provided to the authority by the applicant.

[13] Norāda iemeslu, kādēļ veterināro zāļu reģistrācija nav pieprasīta:

a) veterinārās zāles ir izstrādātas ekskluzīvi tādu slimību ārstēšanai, kas nav izplatītas eksportētājvalstī;

b) veterinārās zāles ir pārveidotas, lai uzlabotu to stabilitāti (noturīgumu) atšķirīgos apkārtējās vides (piemēram, tropu) apstākļos;

c) veterinārās zāles ir pārveidotas, lai no tām izņemtu palīgvielas, ko aizliegts lietot importētājvalstī;

d) veterinārās zāles ir pārveidotas, lai atbilstu atšķirīgai aktīvās vielas maksimālās devas robežai;

e) citi iemesli (norādīt).

Please indicate the reason that the applicant has provided for not requesting registration.

a. the product has been developed exclusively for the treatment of conditions-particularly tropical diseases- not endemic in the country of export;

b. the product has been reformulated with a view to improving its stability under tropical conditions;

c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;

d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;

e. any other reason, please specify.

[14] "Nepiemēro" nozīmē, ka veterinārās zāles neražo sertifikāta izsniedzējvalstī un ražošanas vietas pārbaudes veic veterināro zāļu ražotājvalsts kompetentā institūcija.

"Not applicable" means manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

[15] Labas ražošanas prakses prasības zāļu ražošanai un kvalitātes kontrolei, uz ko atsaucas sertifikātā, ir iekļautas normatīvajos aktos par veterināro zāļu ražošanu un kontroli vai Pasaules Veselības organizācijas Farmaceitisko izstrādājumu specifikāciju ekspertu komitejas 32. ziņojumā (PVO Tehnisko ziņojumu sērija, Nr. 823, 1992, 1. pielikums). Ieteikumus attiecībā uz bioloģiskiem produktiem ir noteikusi PVO Bioloģisko standartu ekspertu komiteja (PVO Tehnisko ziņojumu sērija, Nr. 822, 1992, 1. pielikums).

The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

[16] Šo daļu aizpilda, ja veterināro zāļu reģistrācijas apliecības īpašnieks (turētājs) vai sertifikāta pretendents atbilst statusam, kas noteikts 2.A. 3. vai 2.B. 2. punkta "b", "c" vai "d" apakšpunktā. Tas ir īpaši būtiski, ja veterināro zāļu ražošanas procesā ir iesaistīts līgumražotājs citā valstī. Šajā gadījumā sertifikāta pretendents Pārtikas un veterinārajam

dienestam sniedz informāciju, ar ko identificē katra iesaistītā līgumražotāja atbildību par katru galaprodukta ražošanas posmu, kā arī katra līgumražotāja veiktās kontroles apjomu un veidu.
This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in 2.A.3. or 2.B.2. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

Minister for Agriculture Jānis Dūklavs

Annex 2
Cabinet Regulation No. 327
31 May 2016

Paziņojums par veterināro zāļu reģistrācijas statusu
Statement of Licensing Status of Pharmaceutical Product(s)[1]

Šis paziņojums atbilst Pasaules Veselības organizācijas ieteiktajam paraugam
This statement conforms to the format recommended by the World Health Organization

Paziņojuma Nr. *Statement No.*	

Eksportētājvalsts (sertifikāta izsniedzējvalsts) Exporting (certifying) country	Latvijas Republika Republic of Latvia

Importētājvalsts (sertifikāta saņēmējvalsts) *Importing (requesting) country*	

Šis paziņojums apliecina, ka paziņojumā minētās veterinārās zāles ir reģistrētas vai nav reģistrētas eksportētājvalstī – Latvijas Republikā.
This statement indicates only whether or not the following products are licenced to be put on the market in the exporting country – Republic of Latvia.

Pretendents *Applicant*	(vārds un uzvārds vai nosaukums, adrese/*name, address*)

Veterināro zāļu nosaukums *Name of product*	Deva un zāļu forma *Dosage form*	Aktīvā(-s) viela(-s)[2] un to daudzums devas vienībā *Active ingredient(s)[(2)] and amount (s) per unit dose*	Veterināro zāļu reģistrācijas apliecības numurs un izsniegšanas datums[3] *Product-licence No. and date of issue[3]*

Pārtikas un veterinārais dienests pēc paziņojuma pieprasījuma no pretendenta vai veterināro zāļu reģistrācijas apliecības īpašnieka (turētāja), ja tas atšķiras no pretendenta, par katru no iepriekš minētajām veterinārajām zālēm izsniedz atsevišķu produkta (veterināro zāļu) sertifikātu, kas sagatavots atbilstoši Ministru kabineta 2016. gada 31. maija noteikumiem Nr. 327 "Veterināro zāļu ievešanas un izvešanas kārtība".
The certifying authority undertakes to provide, at the request of the applicant (or, if different, the product-licence holder), a separate and complete Certificate of a Pharmaceutical Product in the format recommended by WHO, for each of the products listed above.

Izsniedzējinstitūcija *Certifying authority*	Pārtikas un veterinārais dienests

Adrese *Address of certifying authority*			
Tālruņa numurs *Telephone*		Faksa numurs *Fax number*	

Atbildīgā amatpersona *Name of authorized official*	(amats, vārds un uzvārds/*position, name, surname*)
	(paraksts/*signature*)
(datums/*date*)	(zīmoga vieta/*stamp*)

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

Notes.

[1] Paziņojums paredzēts veterināro zāļu ražotāja vai importētāja pārstāvim, kas piedalās starptautiskos piedāvājumos saskaņā ar uzaicinātāja pieprasījumu. Paziņojums liecina, vai produkts ir reģistrēts laišanai tirgū eksportētājvalstī. Produkta (veterināro zāļu) sertifikāts atbilstoši Pasaules Veselības organizācijas ieteiktajam paraugam tiks izsniegts pēc iesniedzēja un zāļu reģistrācijas apliecības īpašnieka (ja atšķiras) pieprasījuma katram attiecīgajam produktam.
This statement is intended for use by importing agents who are required to screen bids made in response to an international tender and should be requested by the agent as a condition of bidding. The statement indicates that the listed products are authorized to be placed on the market for use in the exporting country. A Certificate of a Pharmaceutical Product in the format recommended by WHO will be provided, at the request of the applicant and, if different, the product-licence holder, for each of the listed products.
[2] Izmanto, ciktāl iespējams, starptautisko nepatentēto nosaukumu vai nacionālo nepatentēto nosaukumu.
Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
[3] Ja veterinārajām zālēm nav reģistrācijas apliecības, norāda atbilstošo: "netiek prasīta", "nav pieprasīta", "izskatīšanas procesā" vai "atsaukta".
If no product licence has been granted, enter "not required", "not requested", "under consideration", or "refused" as appropriate.

Minister for Agriculture Jānis Dūklavs

Annex 3
Cabinet Regulation No. 327
31 May 2016

Application for the Receipt of the Certificate for the Product (Veterinary Medicinal Product)[1]

Country to which it is intended to import the veterinary medicinal product	
1. Information on the veterinary medicinal product	
1.1. the name and pharmaceutical form	
1.2. the name of the active substance (INN or national non-proprietary name), quantity thereof per dose-unit	
1.3. the full composition of the veterinary medicinal product, including excipients[2]	
2. Whether the veterinary medicinal product has been authorised in Latvia	
3. Whether the veterinary medicinal product is distributed in Latvia	
4. The number[3] and date of issue of the veterinary medicinal product marketing authorisation	
5. The name or given name, surname, and address of the veterinary medicinal product marketing authorisation holder	
6. The status of the marketing authorisation holder[4] (Mark as appropriate with an x)	a ☐ the manufacturer of the pharmaceutical form
	b ☐ packages and (or) labels the pharmaceutical form which is manufactured by another independent manufacturer
	c ☐ not involved in the manufacturing, packaging, and (or) labelling but responsible for the product quality and batch release
	d ☐ not involved in the abovementioned activities
6.1. In case of marking the status "b", "c", and "d", indicate the name and address of the manufacturing site of the pharmaceutical form (those indicated in the special permit (licence) for the manufacturing of veterinary medicinal products)[5]	
7. If additional information regarding the veterinary medicinal product is necessary, append an abstract of a summary of product	Has the abstract of a summary of product characteristics of the medicinal product been appended?

characteristics of the medicinal product[6] (Mark as appropriate with an x)	yes ☐ no ☐
8. The name or given name, surname, and address of the applicant for the certificate, if different from the veterinary medicinal product marketing authorisation holder[7]	
9. The status of the applicant for the certificate, if different from the veterinary medicinal product marketing authorisation holder (mark as appropriate with an x)	a ☐the manufacturing of the pharmaceutical form b ☐packages and (or) labels the pharmaceutical form which is manufactured by another independent manufacturer c ☐not involved in the manufacturing, packaging, and (or) labelling but responsible for the product quality and batch release d ☐not involved in the abovementioned activities
9.1. In case of marking the status "a" and "b", indicate the name and address of the manufacturer of the pharmaceutical form	

Point of contact of the applicant for the certificate		
(given name, surname, position)		Address
Telephone number	Fax number	

Date*
Place for a seal* Signature*

* The details of the document "date", "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 the drawing up of electronic documents.

Notes.

[1] The application must be drawn up for one type of the veterinary medicinal product as different pharmaceutical forms and strengths may have various manufacturing conditions and approved information.
[2] Indicate also the quantitative composition of the active substances and excipients if a coordination document with the veterinary medicinal product marketing authorisation holder or the submitter of the application for authorisation if different from the applicant for the certificate has been appended.
[3] Mark if a temporary veterinary medicinal product marketing authorisation has been issued or if the veterinary medicinal product is in the process of marketing authorisation.
If no marketing authorisation has been requested for the veterinary medicinal product, indicate that the marketing authorisation has not been requested, and also specify the reason for it:
a) the veterinary medicinal product has been developed exclusively for the treatment of such diseases which are not common in the exporting country;

b) the veterinary medicinal product has been modified in order to improve stability (persistence) of the veterinary medicinal product under different ambient conditions (for example, tropical);
c) the veterinary medicinal product has been modified in order to remove excipients the use of which is prohibited in the importing country;
d) the veterinary medicinal product has been modified in order to correspond to a different limit of the maximum dose of the active substance;
d) other reasons (indicate).

[4] Indicate information on the person responsible for the marketing of the veterinary medicinal product. Provide information indicating responsibility of each party involved in the manufacturing and quality control for the manufactured veterinary medicinal product, and also the type and scope of control performed by each involved party.

[5] This information shall be indicated if it has been coordinated with the veterinary medicinal product marketing authorisation holder or, if the veterinary medicinal product has not been authorised – with the consent of the submitter of the application for marketing authorisation of the veterinary medicinal product.

[6] Mark "yes" if a summary has been appended indicating additional information (including indications, size of the packaging, period of validity).

[7] In such case consent to issue the certificate must be obtained from the veterinary medicinal product marketing authorisation holder or the submitter of the application for marketing authorisation. The applicant for the certificate shall submit this consent to the Food and Veterinary Service.

Minister for Agriculture Jānis Dūklavs

Annex 4
Cabinet Regulation No. 327
31 May 2016

Permit for the Import of Samples of Veterinary Medicinal Products

Food and Veterinary Service

Permit for the Import of Samples of Veterinary Medicinal Products into the Republic of Latvia
Riga

_____ No._____
(date)

On the basis of the decision No. _____ _____ by the Food and Veterinary Service
(date, month, year)

to issue a permit for the import of samples of veterinary medicinal products into the Republic of Latvia for the purpose of marketing authorisation of the veterinary medicinal products/use of the veterinary medicinal products in scientific studies/ use of the veterinary medicinal products in clinical studies (underline the appropriate),

_____
(name of the legal person, registration number thereof in the Register of Enterprises, name of the merchant involved in the distribution of veterinary medicinal products,

_____
special permit (licence) number)

according to the application No. _____ received _____
(registration number in the Food and Veterinary Service) (registration date in the Food and Veterinary Service)

is permitted to import samples of the following veterinary medicinal products:

Name, pharmaceutical form, strength, size of the packaging of the veterinary medicinal product (indicating a measurement unit)	Number of packages	Purpose for the need to import samples[1]	Consignee[2] (name, registration number, address, telephone number, e-mail address)	Manufacturer of the veterinary medicinal product, country from which samples will be imported, registration number in the exporting country[3]

Official of the Food and Veterinary Service who is responsible for taking of the decision
(given name, surname, position, signature)
Place for a seal

* 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 the drawing up of electronic documents.

Notes.

[1] Indicate the relevant reason – marketing authorisation of the veterinary medicinal product, scientific research, training, testing of intermediate samples, clinical studies.
[2] Indicate the relevant person for whom samples are intended: an applicant for the receipt of a veterinary medicinal product marketing authorisation or a marketing authorisation holder, a scientific institution, a training institution, a medicines control laboratory, a sponsor (name, address, registration number, telephone number, e-mail address).
[3] If the veterinary medicinal product the samples of which will be imported has not been authorised in the exporting country, the registration number need not be indicated. In such case the submitter of the application must provide a justification explaining why the veterinary medicinal product has not been authorised in the exporting country.

Minister for Agriculture Jānis Dūklavs

Annex 5
Cabinet Regulation No. 327
31 May 2016

Application for the Receipt of a Permit for the Import of Samples of Veterinary Medicinal Products

_____
(place)

No. _____

_____
(date)

We hereby request the Food and Veterinary Service to issue a permit for the import of samples of veterinary medicinal products into the Republic of Latvia with regard to the medicinal products indicated in Part I of this application.

Part I
Information regarding the applicant and samples of veterinary medicinal products

1. Applicant	
1.1. name	
1.2. legal address	
1.3. telephone and fax number	
1.4. electronic mail address	
2. Veterinary medicinal products the samples of which are intended to be imported	
2.1. name	
2.2. active substance(s)	
2.3. pharmaceutical form	
2.4. strength	
2.5. size of the packaging (quantity of medicinal products in the packaging indicating the measurement unit)	
2.6. number of packages and grounds for the necessary quantity	
3. Exporting country	
4. Registration number of the veterinary medicinal products in the country of manufacture (if any)	
5. Manufacturer of the veterinary medicinal products	
5.1. name	

5.2. legal address and address of the site of operation of the undertaking	
5.3. telephone and fax number	
5.4. electronic mail address	
6. Person who can be contacted with regard to the application (given name, surname, telephone number, fax number, electronic mail address)	

Part II
Grounds for the import of samples of veterinary medicinal products
(fill in as necessary)

1. Marketing authorisation of veterinary medicinal products	an applicant for the receipt of a veterinary medicinal product marketing authorisation or a marketing authorisation holder: given name, surname or name and address, telephone number, electronic mail address
2. Scientific study	name of the study and name, address, telephone number, electronic mail address of the site of the study (scientific institution)
3. Training	name and address, telephone number, electronic mail address of the training institution, name of the study programme and speciality
4. Standard samples	name and address, registration number, telephone number, electronic mail address of the laboratory
5. Clinical studies	sponsor: name and address, telephone number, electronic mail address and number and date of issue of the permit of the Food and Veterinary Service to conduct the clinical study or date when the application has been submitted to the Food and Veterinary Service for the receipt of the permit to conduct clinical studies

Part III
Documents appended
(mark as appropriate with an X, indicate the number of pages appended)

1. Attestation that samples of veterinary medicinal products will be received from the manufacturer of the veterinary medicinal products (if samples are intended for the marketing authorisation of veterinary medicinal products) which is entitled to manufacture veterinary medicinal products in the country, or from a person who has the right in the exporting country to distribute veterinary medicinal products	
2. Attestation that samples are intended for the marketing authorisation of veterinary medicinal products	
3. Attestation that samples are intended for the use in a scientific study	
4. Attestation that samples are intended to be used for training purposes	
5. Attestation that samples are intended to be used as standard samples	
6. Attestation that samples are intended to be used in a clinical study	

7. Document which attests to the verification of the information related to the receipt of the permit and the payment of expenses related to examination of the documents	

I, _____ ,

(given name, surname, position of the applicant or an authorised representative thereof)

hereby certify that the information provided by me is true.

Responsible official (authorised representative of the applicant)	
given name, surname, position	_____
signature	_____
	Place for a seal

Date of receipt of the application at the Food and Veterinary Service _____

Notes.

1. Draw a dash in a column or row which is not completed.
2. If the form is sent without using electronic data carriers, the applicant shall sign each page appended to the form.
3. 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 the drawing up of electronic documents.

Minister for Agriculture Jānis Dūklavs

Annex 6
Cabinet Regulation No. 327
31 May 2016

Permit for the Distribution of the Veterinary Medicinal Products Imported in Parallel in the Republic of Latvia

Food and Veterinary Service

(legal address, registration number, telephone number, fax number)

In Riga

_____ No. _____

(date of issue)

_____ No. _____

(date of re-registration)

On the basis of the decision No. ____ by the Food and Veterinary Service to issue (re-register) a permit for the distribution of the veterinary medicinal products imported in parallel in the Republic of Latvia (taken on

_____ _____ _____),

(date, month, year)

the owner of the special permit (licence) for the opening (operation) of a veterinary medicinal product wholesaler

(name, type, registration number of the legal person,

name of the veterinary medicinal product wholesaler, number of the special permit (licence))

is permitted to distribute the veterinary medicinal products imported in parallel.

Application No. for the receipt of permit _____

(registration number in the Food and Veterinary Service)

(date of receipt and registration in the Food and Veterinary Service)

	Registration number of the veterinary medicinal products imported in parallel in the Register of Veterinary	The veterinary medicinal product marketing authorisation holder	Manufacturer of the veterinary medicinal products

	Medicinal Products of Latvia		
Permit for the distribution of the veterinary medicinal products imported in parallel in the Republic of Latvia shall be valid until			
	(date, month, year)		

Name, form, and strength of the veterinary medicinal products authorised in Latvia in relation to the medicinal products for which parallel import has been performed	Registration number of the veterinary medicinal products authorised in Latvia in the Register of Veterinary Medicinal Products of Latvia	The veterinary medicinal product marketing authorisation holder Representative in the Republic of Latvia

The veterinary medicinal products imported in parallel have been (mark as appropriate with an X):
re-packaged ☐yes ☐no
relabelled ☐yes ☐no

Variations performed

Variations between the veterinary medicinal products imported in parallel and the veterinary medicinal products authorised in Latvia:
(if there are no differences, draw a dash)

manufacturer of the medicinal products _____
stability _____
excipients _____
colouring, colour code _____
therapeutic indications _____
size of the packaging _____
package leaflet _____
labelling
withdrawal period of the medicinal products _____

Responsible official of the Food and Veterinary Service

(position, given name, surname, signature)

Place for a seal

Date _____

Notes.

1. Draw a dash in a column or row which is not completed.
2. If the permit is drawn up on several pages without using electronic data carriers, the responsible official shall sign each page.

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

Minister for Agriculture Jānis Dūklavs

Annex 7
Cabinet Regulation No. 327
31 May 2016

Application
for the Issue and Re-Registration of a Permit for the Distribution of the Veterinary Medicinal Products Imported in Parallel in the Republic of Latvia

(mark as appropriate with an X)

For the issue ☐ yes

For the re-registration ☐ yes

We hereby request the Food and Veterinary Service to issue to the applicant indicated in Part I a permit for the distribution of the veterinary medicinal products imported in parallel in the Republic of Latvia with regard to the veterinary medicinal products indicated in Part I.

Part I

1. Applicant	
1.1. holder (owner) of the special permit (licence):	
1.1.1. registration number	
1.1.2. name	
1.1.3. legal address	
1.1.4. number of the special permit (licence)	
1.1.5. address of the site of pharmaceutical activity	
1.1.6. telephone and fax number	
2. Veterinary medicinal products imported in parallel and to be distributed in the Republic of Latvia:	
2.1. name	
2.2. pharmaceutical form	
2.3. strength	
2.4. size of the packaging	
2.5. method of use	
3. Functions of the holder of permit (mark as appropriate with an X):	
3.1. the sale and wholesale supply of the medicinal products imported in parallel	
3.2. the sale and retail supply of the medicinal products imported in parallel	
3.3. the parallel import only	

4. Special permit (licence) of the applicant for the manufacturing of veterinary medicinal products (if any)	
5. Document regarding the payment of expenses (number, date)	
6. Number and date of the previous permit (if any)	
7. Person who can be contacted with regard to the application	

Part II

8. Country from which veterinary medicinal products are imported	
9. Licensed wholesaler in the European Union or a State of the European Economic Area from which the veterinary medicinal products imported in parallel have been purchased:	
9.1. name	
9.2. legal address and address of the site of operation of the undertaking	
9.3. postal code	
9.4. city	
9.5. country	
9.6. telephone number	
10. Information on the movement of the product before it has reached the supplier referred to in Paragraph 9	
11. Name of the veterinary medicinal products in the country from which veterinary medicinal products are imported	
12. Manufacturer of the veterinary medicinal products imported in parallel:	A 12. Veterinary medicinal product marketing authorisation holder in the country from which veterinary medicinal products are imported
12.1. name	A 12.1. name
12.2. legal address and address of the site of operation of the undertaking	A 12.2. legal address and address of the site of operation of the undertaking
12.3. postal code	A 12.3. postal code
12.4. city	A 12.4. city
12.5. country	A 12.5. country
12.6. telephone number	A 12.6. telephone number
13. Registration number for veterinary medicinal products authorised in Latvia in relation to which parallel import has been performed	A 13. Registration number of the veterinary medicinal products in the country from which the veterinary medicinal products imported in parallel are imported

Part III

Information on the veterinary medicinal products authorised in Latvia in relation to which parallel import has been performed

14. Name, pharmaceutical form, and strength

15. Registration number
16. Marketing authorisation holder
17. Do the veterinary medicinal products imported in parallel vary from the relevant veterinary medicinal products authorised in Latvia (mark as appropriate with an X):
☐ yes ☐ no
18. If the answer is “yes”, indicate the variations:
18.1. manufacturer
18.2. stability
18.3. excipients
18.4. colouring, colour code
18.5. indications
18.6. withdrawal period of the medicinal products

Part IV

Information on re-packaging (re-labelling) with regard to the veterinary medicinal products imported in parallel

19. Indicate with regard to the re-packaging (re-labelling): (mark as appropriate with an X) 19.1. re-packaging performed_____ ☐yes_____ ☐no 19.2. re-labelling performed_____ ☐yes_____ ☐no
19.3. indicate variations: (mark as appropriate with an X) change of the secondary packaging (re-packaging) _____ ☐yes_____ ☐no insertion of the package leaflet in the packaging (re-packaging) _____ ☐yes_____ ☐no label on the packaging (re-labelling) _____ ☐yes_____ ☐no other information indicated on the packaging _____ ☐yes_____ ☐no
19.4. full description of the new secondary packaging if the secondary packaging has changed during re-packaging _____
19.5. the person who has performed the re-packaging (re-labelling):
19.5.1. name
19.5.2. address
19.5.3. means of communication
19.5.4. number of the special permit (licence) for the manufacturing of veterinary medicinal products
19.6. contracts (if re-packaging (re-labelling) of the veterinary medicinal products imported in parallel has been performed)

Part V

Documents appended
(mark as appropriate with an X, indicate the number of pages appended)

20. Package leaflet for the veterinary medicinal products imported in parallel in the country of origin thereof and translation thereof into the Latvian language	
21. Attestation to the conformity of the translation of the package leaflet with the package leaflet in the original language	
22. Draft package leaflet of the veterinary medicinal products imported in parallel	
23. Attestation that the specific package leaflet is identical to the medicinal product package leaflet of the veterinary medicinal products authorised in Latvia, except for permissible variations	
24. Mock-up of labelling of the medicinal products which are intended to be distributed in the Republic of Latvia	
25. Number, date of issue of the special permit (licence) for the manufacturing of veterinary medicinal products, and the competent authority of the issuer if the re-packaging (re-labelling) has been performed in another Member State	
26. Certificate of good manufacturing practice (copy) if the re-packaging (re-labelling) has been performed in another Member State	
27. Number and date of issue of the special permit (licence) for the manufacturing of veterinary medicinal products if the re-packaging (re-labelling) of medicinal products has been performed in Latvia	
28. Contract (copy) between the parallel importer and the person who has performed re-packaging (re-labelling) if they are not the same person	
29. Relevant licences and contracts (copies) between the persons who are involved in storage of the product	
30. Samples of the veterinary medicinal products imported in parallel (3 originals)	
31. Document which attests to the payment of the expenses related to the control of veterinary medicinal products	

I, _____ ,

(given name, surname, position of the responsible official, applicant or an authorised representative thereof)

hereby confirm that the information provided by me is true.

Responsible official (authorised representative of the applicant)

_____

(position, given name, surname, signature)

Date _____

Place _____

Date of the receipt of the application at the Food and Veterinary Service _____

Notes.

1. Draw a dash in a column or row which is not completed.
2. If the form is sent without using electronic media, the applicant shall sign each page appended to the form.
3. Submit copies of the documents referred to in Paragraphs 26 and 31 of the Regulation if the electronic document has been prepared in accordance with the laws and regulations regarding the drawing up of electronic documents.
4. The details of the document "signature" and "date" shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding the drawing up of electronic documents.
5. A notation of the Food and Veterinary Service shall not be completed, if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

Minister for Agriculture Jānis Dūklavs

Annex 8
Cabinet Regulation No. 327
31 May 2016

Paziņojums par centralizēti reģistrētu veterināro zāļu paralēlo izplatīšanu
Notification of Parallel Distribution of a Centrally Authorised Veterinary Medicinal Product

Lūdzu aizpildīt visas attiecīgās sekcijas veidlapā. Informācijas neiekļaušana var radīt kavēšanos. Punkti, kas atzīmēti ar *, jāaizpilda obligāti.
Please complete all relevant sections in this form. Omissions may lead to a delay. Fields in red are mandatory.

1. Ziņas par paralēlo izplatītāju
Details of the parallel distributor

1.1. Nosaukums* *Business name*			
1.2. Adrese Nr. 1.* *Address line 1*			
1.3. Adrese Nr. 2 *Address line 2*			
1.4. Pasta indekss *Post code*		**1.5. Pilsēta*** *City*	
1.6. Valsts* *Country*			
1.7. Klienta numurs* *Customer number*			

Kontaktpersona
Contact person name

1.8. Amats *Title*			
1.9. Vārds* *Name*		**1.10. Uzvārds*** *Last name:*	
1.11. Elektroniskā pasta adrese* *E-mail*			
1.12. Tālruņa numurs *Phone*			
1.13. Faksa numurs *Fax*			

1.14. Speciālā atļauja (licence) veterināro zāļu vai zāļu lieltirgotavas atvēršanai (darbībai) (pievienot kopiju)
Wholesale Distribution Authorisation (please enclose copy) (within the meaning of Article 77 of Directive 2001/83/EC or Article 65 of Directive 2001/82/EC)

☐Atzīmēt, ja pievienots
Tick if enclosed

1.15. Kontaktpersona kvalitātes problēmu un nekvalitatīvu sēriju gadījumā
Contact person in case of quality problems and defective batches

1.16. Amats *Title*			
1.17. Vārds* *First name*		**1.18. Uzvārds*** *Last name*	
1.19. Elektroniskā pasta adrese* *Email*			
1.20. 24 stundu kontaktu tālruņa numurs* *24 Hour contact number*			
1.21. Faksa numurs *Fax*			

2. Ziņas par veterinārajām zālēm un to reģistrācijas apliecības īpašnieku (turētāju)
Details of the medicinal product and marketing authorisation holder

2.1. ES numurs* *EU number*	
2.2. (Piešķirtais) nosaukums* *(Invented) Name*	
2.3. Stiprums *Strength*	
2.4. Zāļu forma* *Pharmaceutical form*	
2.5. Iepakojums *Packaging*	
2.6. Iepakojuma lielums *Pack size*	
2.7. Reģistrācijas apliecības īpašnieka (turētāja) nosaukums* *MAH name*	

3. Izcelsmes un galamērķa dalībvalstis
Member State(s) of Origin and Destination
3.1. Izcelsmes dalībvalsts* – norādīt vismaz vienu dalībvalsti, kur veterināro zāļu reģistrācijas apliecības īpašnieks (turētājs) veterinārās zāles laidis tirgū pirmo reizi
Member State(s) of Origin – please select at least one MS
(= where the product was put on the market for the first time by the MAH)
3.2. Galamērķa dalībvalstis* – norādīt vismaz vienu dalībvalsti, kur veterinārās zāles paredzēts izplatīt
Member State(s) of Destination – please select at least one MS
(= where the product will be distributed)
Lūdzu ņemt vērā, ka veterināro zāļu izcelsmes dalībvalsts un galamērķa dalībvalsts nevar būt viena un tā pati valsts.

Please be aware that products cannot be sourced and distributed in the same country.
3.3. Atzīmēt attiecīgo*
Please check one of the following buttons below as applicable

☐"Specifiskais mehānisms"[1] ir piemērojams pirms paziņojuma iesniegšanas, un esmu informējis patenta turētāju vai labuma guvēju *The "Specific Mechanism [1]" is applicable to the present notification and I have notified the patent holder or the beneficiary* Norādīt informēšanas datumu (kam jābūt vismaz mēnesi pirms paziņojuma iesniegšanas) (dd./mm./gggg.) *Please insert the date of the notification (which should be at least one month before the date of the notification) DD/MM/YYYY* Informēšanas datums *Date of notification* ☐"Specifiskais mehānisms" nav piemērojams *The "Specific Mechanism" does not apply to the present notification.*

Piezīme. [1] Piemērojams Iestāšanas līgums, trešā daļa, II sadaļa, IV pielikums, 2. sekcija, AA2003/ACT/Annex IV/enp.2499, parakstīts 2003. gada 16. aprīlī Atēnās.
Accession Treaty, Part Three, Title II, Annex IV, Section 2 "Company law", AA2003/ACT/Annex IV/ enp.2499, signed in Athens on 16 April 2003 applicable.

4. Ziņas par pārpakotājiem (vairāki pārpakotāji ir pieļaujami)
Details of the repackager(s) (multiple repackagers are permitted)

4.1. Nosaukums* *Name*			
4.2. Pārpakotāja numurs* *Repackager No*			
4.3. Adrese Nr. 1* *Address line 1*			
4.4. Adrese Nr. 2 *Address line 2*			
4.5. Pasta indekss *Post code*		**4.6. Pilsēta*** *City*	
4.7. Valsts* *Country*			
4.8. Tālruņa numurs *Phone*			
4.9. Faksa numurs *Fax*			

4.10. Speciālā atļauja (licence) veterināro zāļu vai zāļu ražošanai (pievienot kopiju vai izdarīt atsauci uz *EudraGMP*, ja pieejams)
Manufacturing Authorisation (please enclose copy or make reference to EudraGMP, if available)
(within the meaning of Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC)

☐Atzīmēt, ja pievienots *Tick if enclosed*	*EudraGMP* atsauce *EudraGMP reference*

5. Pārpakošanas veids
Nature of the repackaging

5.1. Modifikācijas, ko veic paralēlais izplatītājs oriģinālajam iepakojumam (piemēram, primārā un sekundārā marķējuma pārmarķēšana, sava marķējuma izveide)*
Modifications proposed by the parallel distributor to the original pack (e.g. over labelling outer and inner packaging, creation of own carton etc.)

☐**Pārmarķēšana** *Relabelling*	☐**Pārpakošana** *Reboxing*	☐**Pārmarķēšana un pārpakošana** *Relabelling and reboxing*

5.2. Sīkākas ziņas par pārpakošanu, pārmarķēšanu, ja nepieciešams
Provide details of the repackaging/relabelling process, if necessary:

5.3. Vai paralēlais izplatītājs maina iepakojuma lielumu?
Has the parallel distributor changed the pack-size?
☐Jā
Yes

5.4. Ja 5.3. atbilde ir "Jā", apliecināt, ka attiecīgais iepakojuma lielums ir apstiprināts Eiropas Savienības tirdzniecības atļaujā
If 5.3 is YES, please confirm that the pack-size is authorised within the Community Marketing Authorisation.
☐Jā
Yes

5.5. Vai ir sertificēts, ka oriģinālais produkts netiek tieši vai netieši ietekmēts
It is certified that the original condition of the product has not been directly or indirectly affected.
☐Atzīmēt, lai sertificētu*
Tick to certify

6. Tirdzniecības iepakojuma parauga iesniegšana*
Submission of mock-ups
6.1. To veterināro zāļu, ko paredzēts izplatīt galamērķa dalībvalstī, primārā un sekundārā iepakojuma un lietošanas instrukcijas paraugs ir pievienots (divas krāsainas kopijas) vai, ja pieejams, divas krāsainas pārpakotā parauga kopijas un divas printētas lietošanas instrukcijas. Iesniedzot elektronisku dokumentu, nepieciešama viena elektroniska kopija.
A mock-up of outer and inner packaging and package leaflet of the medicinal product for distribution in the Member State of destination are to be enclosed (in 2 copies, in colour) or, if available, 2 colour copies of the repackaged specimen (including outer and inner packaging) and 2 printed package leaflets. One electronic copy would be necessary in case of a notification using the electronic submission.

7. Maksa

Fee
7.1. Maksa par pakalpojumu pēc Eiropas Zāļu aģentūras rēķina saņemšanas.
A fee is payable after receipt of the invoice from EMA in accordance with the "Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures.

8. Pienākumi pēc paziņošanas
Post-notice obligations
8.1. Ar parakstu apliecinu, ka informācija par veterinārajām zālēm tiks norādīta atbilstoši aktuālajam Eiropas Komisijas lēmumam. Ja informācija par veterinārajām zālēm (iepakojums un lietošanas instrukcija) vai cita informācija tiks grozīta, apņemos iesniegt paziņojumu Eiropas Zāļu aģentūrā par izmaiņām.
I, the undersigned, undertake to ensure that the product information remains in conformity with the latest Commission Decision relating to the medicinal product. Should the product information (labelling and/or package leaflet) and/or any other aspect of this notification be amended, I undertake to submit a notification of a change to the EMA, if applicable.

9. Apliecinu, ka visas ziņas, kas norādītas šajā paziņojumā, ir patiesas un nav noklusētas (ciktāl parakstītājs ir informēts). Piekrītu, ka ziņas tiek uzglabātas elektroniski*.
I confirm that data declared in this notification form is accurate and no material information has been omitted (within the knowledge of the signatory).
I also consent to these details being stored electronically.

9.1. Vārds, uzvārds*
Name _____

9.2. Datums*
Date _____

Minister for Agriculture Jānis Dūklavs