Republic of Latvia

Cabinet

Regulation No. 405

Adopted 22 June 2021

**Regulations Regarding Activities with Narcotic and Psychotropic Substances and Medicinal Products at Veterinary Medical Practice Institutions**

*Issued pursuant to*

*Section 37.1 of the Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors*

**I. General Provisions**

1. The Regulation prescribes:

1.1. the requirements for a veterinary medical practice institution to obtain the right to the activities with the substances and medicinal products included in Schedules II and III;

1.2. the conditions and procedures for granting, refusing, suspending, and cancelling the right of a veterinary medical practice institution to the activities with the substances and medicinal products included in Schedules II and III;

1.3. the conditions and procedures for purchasing, receiving, handing over for use, storing, recording, and disposing the substances and medicinal products included in Schedules II and III (hereinafter – the activities with the substances and medicinal products of Schedules II and III) by a veterinary medical practice institution.

2. A veterinary medical practice institution is entitled to carry out the activities with the substances and medicinal products included in Schedule II of the narcotic substances, psychotropic substances, and precursors to be controlled in Latvia (hereinafter – the substances and medicinal products of Schedule II) and the substances and medicinal products included in Schedule III of the narcotic substances, psychotropic substances, and precursors to be controlled in Latvia (hereinafter – the substances and medicinal products of Schedule III) whereto the Food and Veterinary Service (hereinafter – the Service) has granted the right to the activities with the substances and medicinal products of Schedules II and III and which has been included thereby in the list of those veterinary medical practice institutions whereto the right to the activities with the substances and medicinal products of Schedules II and III has been granted (hereinafter – the list of institutions).

3. In order to obtain the right to the activities with the substances of Schedules II and III, a veterinary medical practice institution shall meet the following requirements:

3.1. no violations of the laws and regulations governing the circulation of veterinary medicinal products have been registered during the last two years due to which human or animal health would have been threatened and there is no court ruling in force on the prohibition to be engaged in the field of veterinary medicine;

3.2. in respect of a practising veterinarian working at the institution who is responsible for the activities with the substances and medicinal products of Schedules II and III (hereinafter – the responsible veterinarian), no violations of the laws and regulations governing the circulation of the veterinary medicinal products have been registered during the last two years due to which human or animal health would have been threatened and there is no court ruling in force on the prohibition to be engaged in the field of veterinary medicine.

**II. Conditions and Procedures for Granting and Refusing the Right of a Veterinary Medical Practice Institution to the Activities with the Substances and Medicinal Products of Schedules II and III**

4. A veterinary medicinal practice institution shall appoint at least one responsible veterinarian.

5. A veterinary medicinal practice institution shall develop internal rules of procedure. The internal rules of procedure shall determine:

5.1. the obligations and responsibility of each responsible veterinarian;

5.2. the internal rules of procedure for the circulation of the substances and medicinal products of Schedule II or III and recording thereof at the veterinary medical practice institution.

6. A veterinary medical practice institution shall submit the submission to the Service for the activities with the substances and medicinal products of Schedules II and III (hereinafter – the submission). The submission shall include the following:

6.1. the name of the veterinary medical practice institution;

6.2. the registration number in the Commercial Register or the Enterprise Register, but for a natural person – the personal identity number or taxpayer registration number;

6.3. the given name, surname of each responsible veterinarian and certificate number of the veterinary medical practice;

6.4. such list (Schedule II or III of the narcotic substances, psychotropic substances, and precursors to be controlled in Latvia) that includes the substances and medicinal products wherewith the activities are planned to be implemented at the veterinary medical practice institution;

6.5. the phone number of the veterinary medical practice institution and electronic mail address if an official electronic address has not been registered.

7. The Service shall, within five days, after receipt of the submission, verify the information indicated in the submission. If the submission meets the requirements of this Regulation, the Service shall assess (inspect) a veterinary medical practice institution within 10 working days.

8. If the information indicated in the submission is incomplete or incorrect, the Service shall ask a veterinary medical practice institution in writing to submit additional information within five working days. If the veterinary medical practice institution fails to submit the relevant information within the time period laid down by the Service, the Service shall take the decision to refuse to grant the veterinary medical practice institution the right to the activities with the substances and medicinal products of Schedules II and III and notify the veterinary medicinal practice institution thereof within three working days.

9. The Service shall assess (inspect) the conformity of the premises and equipment of a veterinary medical practice institution with the requirements of this Regulation and draw up a statement. The following shall be indicated in the statement:

9.1. the name of the veterinary medical practice institution, registration number in the Commercial Register or the Enterprise Register, but for a natural person – the personal identity number or taxpayer registration number, the given name, surname of the responsible veterinarian and certificate number of the veterinary medical practice;

9.2. the facts established during the assessment (inspection);

9.3. the information on the conformity of the facts established with the information indicated in the submission and also the conformity with the requirements of this Regulation. If the non-conformity with the requirements laid down in laws and regulations has been established, the name of the specific law or regulation and the relevant Section, its Paragraph, Clause or Sub-clause shall be indicated;

9.4. the information on the conformity of the veterinary medical practice institution with the laid down requirements and proposal to grant the right to the activities with the substances and medicinal products of Schedules II and III;

9.5. the given name, surname, and position of the official of the Service who has carried out the assessment (inspection);

9.6. the date of the assessment (inspection).

10. If the premises, equipment and internal rules of procedure of a veterinary medical practice institution meet the requirements of this Regulation, the Service shall take the decision to grant the veterinary medical practice institution the right to the activities with the substances and medicinal products of Schedules II and III, include it in the list of institutions, grant the registration number in the list of institutions and notify the decision to the veterinary medical practice institution within three working days.

11. If the premises, equipment and internal rules of procedure of a veterinary medical practice institution fail to meet the requirements of this Regulation, the Service shall take the decision to refuse to grant the veterinary medical practice institution the right to the activities with the substances and medicinal products of Schedules II and III and notify the veterinary medicinal practice institution thereof within three working days.

12. The Service shall maintain the list of institutions and enter the following information on a veterinary medical practice institution therein:

12.1. the name, registration number in the Commercial Register or the Enterprise Register, but for a natural person – the personal identity number or taxpayer registration number, official electronic mail address (if none, the electronic mail address indicated in the submission), and the phone number;

12.2. the given name, surname of each responsible veterinarian and certificate number of the veterinary medical practice;

12.3. such list (Schedule II or III of the narcotic substances, psychotropic substances, and precursors to be controlled in Latvia) that includes the substances and medicinal products wherewith the activities are planned to be implemented at the veterinary medical practice institution;

12.4. the date on which the veterinary medical practice institution was included in the list of institutions and the registration number thereof in the list of institutions;

12.5. the date from which the right to the activities with the substances and medicinal products of Schedules II and III has been suspended for the veterinary medical practice institution and the time period for the suspension of the right;

12.6. the date on which the responsible veterinarian has been changed.

13. A veterinary medical practice institution shall notify of any changes in the information indicated in the submission to the Service within one working day.

14. The Service shall, within one working day after receipt of the information referred to in Paragraph 13 of this Regulation, update data in the list of institutions.

15. The Service shall, within one working day, send the information included and updated in the list of institutions to the following entities:

15.1. the Health Inspectorate;

15.2. the State Agency of Medicines;

15.3. medicinal product wholesalers and veterinary medicinal products wholesalers which are entitled to distribute the substances and medicinal products of Schedules II and III.

16. If the right to the activities with the substances and medicinal products of Schedules II and III has been suspended for a veterinary medical practice institution in accordance with Paragraph 41 of this Regulation and it wants to renew such right, it shall submit to the Service a submission written in free form with the request to renew the right to the activities with the substances and medicinal products of Schedules II and III.

17. The Service shall carry out the assessment (inspection) within five working days upon receipt of the submission referred to in Paragraph 16 of this Regulation. If a veterinary medical practice institution has not rectified the non-conformities indicated in the decision referred to in Paragraph 41 of this Regulation, the Service shall take the decision to renew the right to the activities with the substances and medicinal products of Schedules II and III, update the list of institutions within one working day and notify the decision to the veterinary medical practice institution within three working days.

18. If the right to the activities with the substances and medicinal products of Schedules II and III has been cancelled for a veterinary medical practice institution in accordance with Paragraph 42 of this Regulation and it wants to resume the activities with the substances and medicinal products of Schedules II and III, it shall submit to the Service the submission referred to in Paragraph 6 of this Regulation. The Service shall act in conformity with the procedures laid down in Paragraphs 7, 8, 9, 10, and 11 of this Regulation.

19. The Service shall ensure the storage of the data on the granted right to the activities of a veterinary medical practice institution with the substances and medicinal products of Schedules II and III for at least five years after exclusion thereof from the list of institutions.

**III. Purchase, Receipt, and Handing Over for Use of the Substances and Medicinal Products of Schedules II and III**

20. A veterinary medical practice institution shall purchase the substances and medicinal products of Schedule II or III from medicinal product wholesalers and veterinary medicinal product wholesalers which are entitled to distribute the substances and medicinal products of Schedules II and III. The veterinary medical practice institution shall submit a written request of the responsible veterinarian for the purchase of the aforementioned substances and medicinal products.

21. The following information shall be indicated in the request:

21.1. the name, address, phone number, and electronic mail address of a veterinary medical practice institution;

21.2. the name, pharmaceutical form, strength, and amount of the substances and medicinal products of Schedule II or III;

21.3. the given name, surname of the responsible veterinarian and certificate number of the veterinary medical practice;

21.4. the date and also the signature and imprint of the personal stamp of the responsible veterinarian if the request is not drawn up in the form of an electronic document.

22. A veterinary medical practice institution shall store the purchase documents of the substances and medicinal products of Schedule II or III for not less than five years and present the documents to the Service upon request thereof.

23. The responsible veterinarian has the right to receive the substances and medicinal products of Schedule II or III from a medicinal product wholesaler and a veterinary medicinal product wholesaler.

24. The obligation of the responsible veterinarian is to ensure handing over of the substances and medicinal products of Schedule II or III for use to practising veterinarians of a veterinary medical practice institution for the treatment of animals at the veterinary medical practice institution where several practising veterinarians are employed.

25. The obligation of the practising veterinarian referred to in Paragraph 24 of this Regulation is to prevent access of an unauthorised person to the substances and medicinal products of Schedule II or III which are received for use for the treatment of an animal in accordance with the internal rules of procedure laid down in Paragraph 5 of this Regulation.

**IV. Storage of the Substances and Medicinal Products of Schedules II and III**

26. The substances and medicinal products of Schedule II shall be stored in a lockable metal cabinet or safe which is attached so as it would not be possible to move such safe or cabinet. The safe or cabinet in which the substances and medicinal products of Schedule II are kept shall be equipped with an alarm system which warns about its opening.

27. The substances and medicinal products of Schedule III shall be kept in a lockable cabinet or safe.

28. A veterinary medical practice institution has the obligation to ensure the premises and equipment for the storage of the substances and medicinal products of Schedule II or III in conformity with the requirements of this Regulation and the laws and regulations governing the circulation veterinary medicinal products.

**V. Recording of the Substances and Medicinal Products of Schedules II and III**

29. A veterinary medical practice institution shall establish the system for recording of the substances and medicinal products of Schedule II or III and ensure traceability of the information on the purchase, handing over for use, use, and disposal of the substances and medicinal products of Schedule II or III (hereinafter – the circulation), and also on the shortage thereof.

30. The responsible veterinarian shall be responsible for:

30.1. the registration of the information in the recording system referred to in Paragraph 29 of this Regulation;

30.2. the comparison of the substances and medicinal products of Schedule II or III with actual remaining quantity at a veterinary medical practice institution.

31. A veterinary medical practice institution shall, when ensuring traceability of the information referred to in Paragraph 29 of this Regulation, present the following information to the Service upon request:

31.1. basic information on the substances and medicinal products of Schedule II or III:

31.1.1. the name of the substances and medicinal products;

31.1.2. the pharmaceutical form of the substances and medicinal products;

31.1.3. the active substances and concentration of the substances and medicinal products;

31.1.4. the serial number granted by the manufacturer;

31.1.5. the packaging;

31.2. the purchase information of the substances and medicinal products of Schedule II or III:

31.2.1. the date of delivery;

31.2.2. the name of a wholesaler;

31.2.3. the number and date of the accompanying document of the goods;

31.2.4. the amount of the substances and medicinal products;

31.3. the information on the handing over of the substances and medicinal products of Schedule II or III for use by the veterinary medical practice institution where there are several practising veterinarians (where applicable):

31.3.1. the date;

31.3.2. the given name, surname, and signature of a practising veterinarian;

31.3.3. the amount of the substances and medicinal products;

31.4. the information on use of the substances and medicinal products of Schedule II or III with an animal:

31.4.1. the date;

31.4.2. the given name, surname, address of the owner of an animal;

31.4.3. the species, name, age, and identification number of the animal (where applicable);

31.4.4. the purpose of administration (use) of the substances and medicinal products;

31.4.5. the amount actually used;

31.4.6. the amount written-off (where applicable);

31.4.7. the restriction period for the use of animal production (for productive animals);

31.5. the control information of the substances and medicinal products of Schedule II or III on:

31.5.1. the comparison of remaining quantity of the substances and medicinal products of Schedule II or III;

31.5.2. the disposal of the substances and medicinal products of Schedule II or III;

31.6. the information on the shortage of the substances and medicinal products of Schedule II or III.

32. A veterinary medical practice institution shall ensure the storage of the information on the circulation of the substances and medicinal products of Schedule II or III for at least five years after making the last entry.

33. A veterinary medical practice institution shall, each year until 30 January, submit electronically to the State Agency of Medicines the following information on the use of the substances and medicinal products of Schedule II or III in the previous year:

33.1. the name, address, phone number, and electronic mail address of the veterinary medical practice;

33.2. the original name of the substances and medicinal products of Schedule II or III;

33.3. the non-proprietary name of the substances and medicinal products of Schedule II or III (the name of the active substances);

33.4. the pharmaceutical form and strength of the substances and medicinal products of Schedule II or III;

33.5. the amount used during the reporting period in recording units (ml, tab, g);

33.6. the date of submission.

34. If the responsible veterinarian establishes shortage of the substances and medicinal products of Schedule II or III, he or she shall inform the veterinary medical practice institution thereof.

35. A veterinary medical practice institution shall immediately notify of the shortage of the substances and medicinal products of Schedule II or III to the Service and indicate the following:

35.1. the name of the substances and medicinal products, active substance and its concentration, the manufacturer of the medicinal products, the serial number granted by the manufacturer and term of validity;

35.2. the amount of shortage of the substances and medicinal products;

35.3. the date when the shortage was established.

36. If a veterinary medical practice institution establishes the shortage of the substances and medicinal products of Schedule II or III has been caused due to a potential criminal offence, it shall immediately notify the State Police and inform the Service thereof.

**VI. Disposal of the Substances and Medicinal Products of Schedules II and III**

37. The responsible veterinarian shall take the decision on transfer of the substances and medicinal products of Schedule II or III for disposal and inform the veterinary medical institution thereof if:

37.1. they have quality defects;

37.2. the term of validity thereof has expired.

38. The responsible veterinarian shall draw up a statement on the substances and medicinal products of Schedule II or III which in accordance with Paragraph 37 of this Regulation have to be transferred for disposal. The following shall be indicated in the statement:

38.1. the date of drawing up the statement;

38.2. the name and amount of the substances and medicinal products;

38.3. the serial number granted by the manufacturer;

38.4. the reason for the disposal;

38.5. the given name, surname, and signature of the responsible veterinarian.

39. The substances and medicinal products of Schedule II or III referred to in Paragraph 37 of this Regulation shall be kept in accordance with the requirements of this Regulation for the storage of the substances and medicinal products of Schedules II and III separately from other substances and medicinal products of Schedule II or II, and transferred for disposal in conformity with the laws and regulations regarding hazardous waste.

40. The statement specified in Paragraph 38 of this Regulation shall be signed by the responsible person of the merchant who is accepting the substances and medicinal products of Schedule II or III for disposal. The statement shall be kept at the veterinary medical practice institution and presented to the Service upon request.

**VII. Procedures for Suspending and Cancelling the Right of a Veterinary Medical Practice Institution to the Activities with the Substances and Medicinal Products of Schedules II and III**

41. The Service shall take the decision to suspend the right of a veterinary medical practice institution to the activities with the substances and medicinal products of Schedules II and III by not excluding it from the list of institutions if:

41.1. the Service establishes violations for the rectification of which time is required;

41.2. the submission of the veterinary medical practice institution is received for the suspension of the right to the activities with the substances and medicinal products of Schedules II and III.

42. The Service shall take the decision to cancel the right of a veterinary medical practice institution to the activities with the substances and medicinal products of Schedules II and III by excluding it from the list of institutions if:

42.1. the veterinary medical practice institution or the responsible veterinarian has been repeatedly punished administratively during a year for the violation of the requirements of the laws and regulations governing the circulation of the medicinal products of Schedules II and III due to which human or animal health has been threatened;

42.2. a court ruling on the prohibition to be engaged in the field of veterinary medicine is in force for the veterinary medical practice institution or the responsible veterinarian;

42.3. the violations of the requirements of the laws and regulations governing the circulation of the medicinal products of Schedules II and III have not been rectified within the time period laid down by the Service;

42.4. the submission of the veterinary medical practice institution for the termination of the activities has been received.

43. The Service shall, within one working day after taking the decision referred to in Paragraphs 41 and 42 of this Regulation, update the list of institutions, notify the decision to a veterinary medical practice institution within three working days, and act in conformity with the procedures laid down in Paragraph 14 of this Regulation.

**VIII. Closing Provision**

44. Cabinet Regulation No. 1456 of 15 December 2009, Procedures by Which a Person Engaged in Veterinary Medical Practice Carries out Activities with Narcotic and Psychotropic Medicinal Products (*Latvijas Vēstnesis*, 2009, No. 200; 2011, No. 56), is repealed.

Prime Minister A. K. Kariņš

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