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Regulations Regarding Restrictions in the Use of Medicinal Products on Animals and the Requirements for the Circulation of Animals and Products of Animal Origin if Medicinal Products are Used on Animals

Issued pursuant to Section 5, Clause 11 of the Pharmaceutical Law and Section 25, Clause 1 of the Veterinary Medicine Law

I. General Provisions

1. These Regulations prescribe the restrictions in the use of medicinal products on animals and the requirements for the circulation of animals and products of animal origin, if animals have been administered medicinal products, for the use of which restrictions have been specified.

2. The following terms are used in these Regulations:

2.1. therapeutic purpose of use of medicinal products - the administering of medicinal products containing an authorised substance (testosterone, progesterone and derivatives thereof, allyl trenbolone, beta-agonists) in the treatment of reproductive (fertility) problems of farm animals, the termination of unwanted gestation, the use of beta-agonists to induce tocolysis in cows when calving and the use of beta-agonists for the treatment of respiratory problems, navicular disease (navicular syndrome and laminitis and to induce tocolysis in equine animals (hereinafter - horses);

2.2. zootechnical purpose of use of medicinal products - the administering of medicinal products containing a hormonal substance (substances having an oestrogenic (excluding 17β-estradiol and the ester-type derivatives thereof), androgenic or gestagenic action) on farm animals in order to synchronise oestrus and to prepare the recipients and donors of ovaries or to perform sex inversion in aquaculture animals;

2.3. prohibited use of medicinal products - the administering of medicinal products prohibited under the regulatory enactments regulating the circulation of veterinary medicinal products to animals or the administering of medicinal products authorised under the regulatory enactments regulating the circulation of veterinary medicinal products in non-conformity with the conditions specified in the registration documentation of the medicinal products; and

2.4. prohibited medicinal products - medicinal products which contain thyrostatic substances, stilbenes and their salts and esters, derivatives of stilbenes, 17β-estradiol and the ester-type derivatives thereof.

3. The manufacturers of medicinal products, wholesalers and pharmacies, which have received a special permit (licence) in accordance with the procedures specified in the regulatory enactments regulating the circulation of medicinal products, for pharmaceutical or veterinary pharmaceutical activities, or practising veterinarians are entitled to distribute the medicinal products referred to in these Regulations for the treatment of animals.

4. It is prohibited to use the prohibited medicinal products on farm animals.

5. The implementation of the requirements of these Regulations and the justification for the use of the medicinal products referred to in these Regulations shall be supervised and controlled by the Food and Veterinary Service (hereinafter - Service).

II. Use of Medicinal Products for Therapeutic and Zootechnical Purposes

6. It shall be permitted to use medicinal products for therapeutic or zootechnical purposes, if:

6.1. the relevant medicinal products have been registered and distributed in accordance with the regulatory enactments regulating the circulation of medicinal products;

6.2. the animal has been marked and registered in accordance with the regulatory enactments regulating the registration of animals, herds and holdings and the marking of animals;

6.3. the animal is kept in a holding which has been registered in accordance with the regulatory enactments regulating the registration of animals, herds and holdings and the marking of animals and is under the supervision of an authorised veterinarian or an inspector of the Service; and

6.4. prior to the use of medicinal products the animal has been examined by a practising veterinarian, except the case referred to in Sub-paragraph 9.1 of these Regulations.

7. The use of medicinal products for therapeutic and zootechnical purposes shall not be authorised on animals from which food products of animal origin are acquired (hereinafter - food-producing animals) or animals of little reproductive value, which are being fattened, except medicinal products containing beta-agonists in the form of an injection, in order to induce tocolysis for cows when calving.

8. It shall be permitted to administer such medicinal products to farm animals for therapeutic purposes, which contain:

8.1. testosterone, progesterone and derivatives thereof, parent compounds of which are easily absorbed in the application site after hydrolysis. The referred to medicinal products shall be administered to a farm animal by a practising veterinarian in the form of an injection or a vaginal coil for the treatment of ovarian dysfunction. It is prohibited to administer the medicinal products in the form of implants;

8.2. allyl trenbolone (internally) or beta-agonists to horses in accordance with the instructions for use. The medicinal products shall be administered by a practising veterinarian or the animal owner (keeper) under the supervision of a practising veterinarian; and

8.3. beta-agonists in the form of an injection in order to induce tocolysis in cows when calving. The medicinal products shall be administered by a practising veterinarian.

9. For zootechnical purposes:

9.1. medicinal products, which contain substances having a hormonal action, shall be administered to farm animals by a practising veterinarian, but the synchronisation of oestrus and the preparation of donors and recipients for the implantation of embryos may also be performed by another person under the supervision of a practising veterinarian; and

9.2. it shall be permitted to administer medicinal products having a androgenous action to aquaculture animals in order to perform sex inversion during the first three months of life. The medicinal products shall be administered by a practising veterinarian or another person under the supervision of a practising veterinarian.

10. In the cases referred to in Paragraph 9 of these Regulations a practising veterinarian is entitled to issue a veterinary prescription for one-time receipt of medicinal products. The use and quantity of the medicinal product shall be specified in the prescription.

11. The activities referred to in Paragraphs 8, 9 and 10 of these Regulations shall be registered by a practising veterinarian, indicating at least the following:

11.1. the type of use of the medicinal product;

11.2. the name and active substance of the medicinal product;

11.3. the date of treatment; and

11.4. the species and identification number of the specific animal (except aquaculture animals for which the number or conventional unit shall be indicated).

12. The information referred to in Paragraph 11 of these Regulations shall be stored by a practising veterinarian for not less than five years and shall be presented to an inspector of the Service upon a request.

III. Restrictions in the Use of Medicinal Products

13. It is prohibited to distribute medicinal products containing beta-agonists if they are intended for the treatment of food-producing animals, except if the medicinal products are meant to be used for therapeutic purposes in accordance with Paragraph 8 of these Regulations.

14. It is prohibited to administer medicinal products containing beta-agonists or hormonal substances to farm animals, except if the medicinal products are meant to be used for therapeutic or zootechnical purposes in accordance with Paragraphs 8 and 9 of these Regulations.

15. It is prohibited for the owners (keepers) of farm animals to keep and store medicinal-products containing beta-agonists, which may be used for the inducement of tocolysis.

16. It is prohibited to administer to farm animals:

16.1. medicinal products containing substances having a hormonal action, if:

16.1.1. the medicinal products have a long-term effect on the organism (depositing);

16.1.2. the withdrawal period of the medicinal product from the organism of an animal exceeds 15 days after the last administration;

16.1.3. the conditions for use of the medicinal product are not known;

16.1.4. the laboratory for the control of residues does not have the reagents or equipment required for the determination of residues of medicinal products;

16.1.5. the activities connected to the registration of the medicinal product in the European Union were performed up to 1 January 1995; or

16.2. medicinal products containing beta-agonists, if the withdrawal period of these medicinal products from the organism of the animal exceeds 28 days after the last administration.

IV. Requirements for the Circulation of Animals and Products of Animal Origin

17. It is prohibited to:

17.1. distribute or slaughter farm animals, which have been administered medicinal products containing prohibited substances, beta-agonists or substances having a hormonal action, and farm animals in whose organism the referred to substances have been detected, except if the medicinal products are meant to be used for therapeutic or zootechnical purposes in accordance with Paragraphs 8 and 9 of these Regulations;

17.2. distribute or process the meat and products of animal origin referred to in Sub-paragraph 17.1 of these Regulations; or

17.3. distribute aquaculture animals or food products of aquaculture animal origin, if the animals have been administered medicinal products containing the prohibited substances, beta-agonists or substances having a hormonal action.

18. It shall be permitted to distribute meat and other food products of animal origin for human consumption which have been obtained from farm animals that have been administered medicinal products having a hormonal action or beta-agonists, if a practising veterinarian or an inspector of the Service establishes that:

18.1. the animals have been treated in accordance with the requirements specified in Paragraphs 8 and 9 of these Regulations;

18.2. the medicinal products which have been used in the treatment of animals conform with the requirements specified in Paragraphs 6 and 16 of these Regulations; and

18.3. prior to the slaughter of the animal the withdrawal period of the medicinal product from the organism of the animal has expired.

19. It shall be permitted to distribute breeding animals or breeding animals past reproductive age, if during reproductive age medicinal products were used on them for therapeutic or zootechnical purposes or to distribute and process the meat of such animals if the requirements referred to in Paragraphs 8 and 9 of these Regulations have been fulfilled and the withdrawal period of the medicinal product from the organism of the animal has expired.

20. The Service shall allow the sale of horses of high value, especially sport horses, racing horses, circus horses or horses intended for breeding or displays, to which medicinal products containing allyl trenbolone or beta-agonists have been administered for therapeutic purposes and the withdrawal period of these medicinal products from the organism of the animal has not expired, if the conditions regulating the use of medicinal products for therapeutic purposes have

been observed and the treatment method and date has been written in the horse certificate or passport in accordance with regulatory enactments regarding the identification of horses.

21. It is prohibited to import farm animals or food products of animal origin to the Republic of Latvia from countries which are not European Economic Area countries (hereinafter - third countries) and in which it is permitted to distribute and administer such medicinal products to farm animals, which contain prohibited substances.

22. It is prohibited to import the following to the Republic of Latvia from the third countries which the European Commission has included in the list of the countries from which the import of farm animals or food products of animal origin is allowed:

22.1. farm animals which have been administered with prohibited substances;

22.2. farm animals which have been administered with medicinal products containing beta-agonists or substances having a hormonal action, except if the medicinal products have been used in accordance with the conditions equivalent to the requirements of these Regulations and the withdrawal period of the medicinal product from the organism of the animal has expired; and

22.3. food products of animal origin which have been acquired from the animals referred to in Sub-paragraphs 22.1 and 22.2 of these Regulations.

23. It is permitted to import farm animals to Latvia from the third countries intended for fattening, farm animals of little reproductive value or the meat thereof, if the third country ensures the health requirements of the animals equivalent to the requirements of these Regulations.

V. Supervision and Control

24. According to the competence thereof, the Service shall perform inspections in order to:

24.1. prevent activities with medicinal products containing prohibited substances, beta-agonists or substances having a hormonal action if it is intended to promote the fattening of food-producing animals with such medicinal products or substances;

24.2. prevent illegal treatment of animals (treatment during which the medicinal products prohibited under these Regulations for treatment purposes are administered to an animal or the restrictions on use of medicinal products specified in these Regulations are violated); or

24.3. to ascertain whether the withdrawal period of medicinal products from the organism of an animal has been observed.

25. In accordance with the regulatory enactments regarding the control of residual substances and the procedures for financing thereof, the Service shall:

25.1. inspect the possible presence of medicinal products in animals, in the drinking water intended for animals and in the places of rearing or keeping animals; and

25.2. inspect the residual substances of medicinal products in animals, their excrements, bodily fluids and tissues, as well as in the products of animal origin.

26. If the following are established during the inspections referred to in Paragraphs 24 and 25 of these Regulations:

26.1. the prohibited medicinal products, the use of medicinal products in non-conformity with the requirements of these Regulations or prohibited residual substances of medicinal products, such medicinal products shall be confiscated and the animals to which they have been administered, as well as the food products of animal origin shall be inspected. If during an inspection the presence of prohibited medicinal products or residual substances thereof is detected in the organism of an animal or in food products of animal origin, the Service shall organise the liquidation of the relevant animals or food products of animal origin;

26.2. that the withdrawal period of medicinal products from the organism of an animal has not been observed or if the animal has been illegally treated, the Service shall impose the relevant administrative punishment on the animal owner (keeper).

27. The manufacturers of medicinal products which distribute or manufacture substances having a hormonal action, prohibited substances and beta-agonists or medicinal products containing such substances, as well as wholesalers and pharmacies which are entitled to distribute such substances or medicinal products manufactured from them, shall keep the following information:

27.1. the date of acquisition or distribution of the medicinal products or substances;

27.2. the amount of the acquired or manufactured substance or medicinal products;

27.3. the amount of the substance sold or used for the manufacture of medicinal products; and

27.4. information regarding the person to which the relevant substances or medicinal products have been sold or from whom they have been purchased (for a natural person - the given name and surname, for a legal person - the name).

28. The information referred to in Paragraph 27 of these Regulations shall be presented, upon a request, to an inspector of the Health Inspectorate or the Service during inspections.

29. The Service shall control practising veterinarians and veterinary medical care institutions which distribute and use the medicinal products referred to in these Regulations.

30. A practising veterinarian and the head of a veterinary medical care institution shall register the purchased and sold amount of medicinal products referred to in these Regulations, indicating the given name and surname of the natural person or the name of the legal person to whom the relevant medicinal products have been sold or from whom they have been purchased. The referred to information shall be presented to an inspector of the Service upon a request.

31. If the results of inspections performed in Latvia confirm the non-conformity of imported animals or food products of animal origin with the requirements of these Regulations, the Service, on the basis of the regulatory enactments regarding the mutual co-operation of the competent authorities of the European Union Member States and institutions of the European Union, shall co-operate with the competent authority of the European Union Member State, from which the animals or food products of animal origin have been imported, and shall determine the further action with these.

32. The observance of the conditions referred to in Paragraph 22 of these Regulations shall be controlled by the Service in accordance with the regulatory enactments regarding the procedures for control which relate to the importing of animals and food products of animal origin from the third countries.

VI. Closing Provision

33. Cabinet Regulation No. 579 of 2 August 2005, *Regulations Regarding Restrictions in the Use of Medicinal Products on Animals and the Circulation of Animals and Food Products of Animal Origin if Animals have been Administered with Medicinal Products Subject to Restrictions on Use* (*Latvijas Vēstnesis*, 2005, No. 122; 2006, No. 90), is repealed.

Informative Reference to European Union Directives

These Regulations contain legal norms arising from:

1) Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC;

2) Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists; and

3) Directive 2008/97/EC of the European Parliament and of the Council of 19 November 2008 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists.

Prime Minister V. Dombrovskis

Minister for Agriculture J. Dūklavs
