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**Republic of Latvia**
**Cabinet**
**Regulation No. 401**
Adopted 22 April 2004

# Procedures for Monitoring of Adverse Reactions Caused by Veterinary Medicinal Products

*Issued pursuant to*
*Section 5, Clause 6*
*of the Pharmaceutical Law*

## I. General Provisions

1. These Regulations prescribe the procedures by which the monitoring of possible adverse reactions caused by veterinary medicinal products shall be performed.

2. These Regulations apply to the adverse reactions caused to:

2.1. animals:

2.1.1. by the use of veterinary medicinal products (also medical treatment pre-mixture added to medicated feed);

2.1.2. by the medicinal products, which are intended for humans, used in veterinary medicine; and

2.1.3. by the use of veterinary medicinal products in a manner incompatible with the information indicated on a labelling and package leaflet;

2.2. humans - by the incidental use of veterinary medicinal products or their use for animals;

2.3. possible, - by the veterinary medicinal products getting into the environment (pollution);

2.4. by the inefficiency of veterinary medicinal products; and

2.5. by the changes during withdrawal period of the veterinary medicinal products from the organism;

## II. Procedures by which Persons Involved in the Use of Veterinary Medicinal Products shall Notify regarding Adverse Reactions Observed

3. A veterinary practitioner, animal owner or other person involved in the use of medicinal products (hereinafter - reporter) may notify:

3.1. regarding the unexpected adverse reactions (unintended adverse reaction which arise when ingesting medicinal products for animals in the dosages indicated in the medicinal product's instruction for preventive purposes, diagnosis or treatment of the disease, or for the modification of the physiological functions of the organism) whereof he or she learns, in administering to animals the veterinary medicinal products or medicinal products intended for humans or in performing his or her occupational duties, including the information regarding:

3.1.1. possible serious adverse reactions (an adverse reaction which results in death or results in significant disability, poses threat to the life of an animal, is a congenital anomaly, or which results in prolonged signs in the animals treated);

3.1.2. possible adverse reactions (an adverse reaction, the nature, severity or outcome of which is not consistent with the product characteristics);

3.2. regarding the expected adverse reactions (an adverse reaction, the nature, severity or outcome of which is consistent with the product characteristics), whereof he or she learns in administering to animals the veterinary medicinal products or medicinal products intended for humans or performing his or her occupational duties. In evaluating the reports received, the Food and Veterinary Service shall determine the frequency of adverse reactions indicated in the instruction of medicinal products;

3.3. regarding any possible adverse human reactions (unintended reaction of the human organism which occurs in a human being following exposure to a veterinary medicinal product) which possibly have been caused by the veterinary medicinal products;.

3.4. if negative effects on the environment have been determined;

3.5. if inefficacy of the veterinary medicinal products has been determined; and

3.6. if changes have been determined during the withdrawal period of the veterinary medicinal products from the organism.

4. If a reporter has determined:

4.1. the adverse reactions referred to in Sub-paragraph 3.1 and 3.2 of these Regulations in animal or group of animals, he or she shall fill in a report form (Annex 1) and send such form to the Food and Veterinary Service;

4.2. inefficacy of the veterinary medicinal products, he or she shall fill in a report form (Annex 1) and send it to the Food and Veterinary Service;

4.3. the adverse reactions referred to in Sub-paragraph 3.3 these Regulations in human or group of humans, he or she shall fill in a report form (Annex 2) and send it to the Food and Veterinary Service;

4.4. negative effects of the veterinary medicinal products on the environment, he or she shall fill in a report form (Annex 3) and send such form to the Food and Veterinary Service;

4.5. presence of residues from the antibiotics in milk, he or she shall fill in a report form (Annex 4) and send such form to the Food and Veterinary Service.

## III. Duties of the Holder (Owner) of the Veterinary Medicinal Product Registration Certificate

5. The holder (owner) of the veterinary medicinal product registration certificate shall notify the responsible official regarding the adverse reactions in human or animal which have been observed using veterinary medicinal products registered by the holder (owner) of the veterinary medicinal product registration certificate.

6. The holder (owner) of the veterinary medicinal product registration certificate shall assign the responsible official, who has the appropriate qualification and who shall be responsible for the supervision of the side effects from the registered veterinary medicinal products.

7. The responsible person referred to in Paragraph 6 of these Regulations shall be responsible for the maintaining of that data system in which all the information provided for the personnel of a merchant, representatives or distributors regarding the possible adverse reactions in humans or animals caused by the veterinary medicinal products registered by the holder (owner) of the veterinary medicinal products registration certificate and which has become known from the reports of the veterinary practitioners or other persons involved in the movement of veterinary medicinal products or from the post-marketing studies is compiled.

8. The responsible official referred to in Paragraph 6 of these Regulations shall:

8.1. immediately register the information received regarding the possible adverse reactions in the data system referred to in Paragraph 7 of these Regulations;

8.2. immediately notify the Food and Veterinary Service regarding the adverse reactions determined and send the information thereof in writing not less than within 15 days;

8.3. prepare periodic safety report (Annex 5) indicating the latest data regarding the safety of medicinal products, which shall also include the scientific validation regarding the usefulness or risk caused by veterinary medicinal products;

8.4. submit the periodic safety report referred to in Sub-paragraph 8.3 of these Regulations to the Food and Veterinary Service:

8.4.1. once in six months, if the period of time from the issue of the veterinary medicinal product registration certificate is less than two years;

8.4.2. once a year, if the period of time from the issue of the veterinary medicinal product registration certificate is more than two years;

8.4.3. together with the documents for renewal (extension) of the registration certificate; and

8.4.4. upon the request of the Food and Veterinary Service, if the medicinal products have been registered (re-registered) more than five years ago, or together with an application for the extension of the term of validity of the veterinary medicinal product registration certificate.

9. Upon the request of the Food and Veterinary Service the holder (owner) of the veterinary medicinal product registration certificate shall provide immediately the following additional information:

9.1. regarding the sales volume of veterinary medicinal products and amount of prescriptions written out;

9.2. regarding the post-marketing safety studies;

9.3. regarding the adverse reactions caused by veterinary medicinal products or the inefficacy thereof;

9.4. regarding the compliance or the withdrawal period with the information indicated in the registration documentation of medicinal products;

9.5. regarding the assessment of adverse reactions by A, B, O and N code (hereinafter - ABON code), where:

9.5.1. the A code is used in a report to indicate an adverse reaction when the indicated adverse reaction may be caused by the use of the medicinal products indicated in the report;

9.5.2. the B code is used in a report to indicate an adverse reaction if several medicinal products were administered to an animal and it is not possible to specify which of the medicinal product indicated in the report causes the adverse reactions. The medicinal product, regarding which a report is provided, shall be considered as the medicinal product, which is a potential cause of the adverse reaction, but other medicinal products, which were also used during the treatment, shall be indicated as the potential factor causing the adverse reactions;

9.5.3. the O code is used in a report to indicate an adverse reaction if the report does not contain sufficient information regarding the medicinal products used or the physiological status of an animal at the moment of the administration of the medicinal products and, therefore, it is not possible to assess the cause of the adverse reaction;

9.5.4. the N code is used in a report to indicate an adverse reaction if the tests (trials) carried out on an animal attest that the use of the veterinary medicinal products is not a cause of an adverse reactions, or it is hardly possible that the medicinal products indicated in the report could have caused an adverse reaction.

10. If the veterinary medicinal products are distributed in and also outside of Latvia , the holder (owner) of veterinary medicinal product registration certificate shall:

10.1. maintain the data system referred to in Paragraph 7 of these Regulations and compile the information regarding the possible adverse reactions determined in Latvia and other states. The data system shall be available at least at one location in the territory of the European Union;

10.2. indicate the information regarding all adverse reaction registered outside of Latvia in the periodic safety report referred to in Sub-paragraph 8.3 of these Regulations; and

10.3. shall immediately notify the European Agency for Evaluation of Medicinal Products, the Food and Veterinary Service and the competent authorities of other states where the veterinary medicinal products have been registered regarding the potential serious adverse reactions determined in animals or humans and shall send a report in writing with the detailed information not later than within 15 days.

11. If the veterinary medicinal product has been registered:

11.1. under the centralised procedure for the registration of medicinal products, the holder (owner) of the veterinary medicinal product registration certificate shall immediately notify the European Agency for the Evaluation of Medicinal Products (established in accordance with the Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products) regarding any serious unexpected adverse reaction determined and send a report in writing with the detailed information thereof not later than within 15 days; and

11.2. by using a mutual recognition procedure, the holder (owner) of the veterinary medicinal product registration certificate shall agree with the competent authority of the relevant state and the Food and veterinary Service regarding the time intervals within which any serious unexpected adverse reactions have been determined in animals.

## IV. Information which the Holder (Owner) of Veterinary Medicinal Product Registration Certificate shall Send to the Food and Veterinary Service, if the Adverse Reaction is Determined during the Use of the Medicinal Product Registered by Him or Her

12. If the holder (owner) of the veterinary medicinal product registration certificate has received a report from a reporter or when the adverse reactions have been determined, in performing post-marketing tests of veterinary medicinal products, he or she shall send a periodic safety report (Annex 5) to the Food and Veterinary Service and in addition to the information specified in a report shall indicate (in a free form) the information in six sections in accordance with Paragraphs 13, 14, 15, 16, 17, 18 and 19 of these Regulations.

13. In the first section of the report referred to in Paragraph 12 of these Regulations shall indicate:

13.1. the given name and surname of such an official who is responsible for the supervision of the adverse reactions of the medicinal products registered by the holder (owner) of the veterinary medicinal product registration certificate;

13.2. the address, phone number and fax number of the responsible official;

13.3. the report number which has been assigned by the responsible official;

13.4. the date when the official has received the report;

13.5. the source of the report (clinical or post-marketing studies, the adverse reaction determined by the distributors of the veterinary medicinal products, veterinary practitioners or any other persons involved in the movement of veterinary medicinal products);

13.6. the given name, surname, address, profession of a reporter, as well as, if possible, copy of the sent report;

13.7. the state where an adverse reaction was determined; and

13.8. the country importing the veterinary medicinal products.

14. In the second section of the report referred to in Paragraph 12 of these Regulations shall indicate:

14.1. the number of animals treated;

14.2. the species, variety, age, sex and weight of the animals;

14.3. the symptoms observed.

15. The information regarding the medicinal products that may be the possible cause of an adverse reaction shall be indicated in the third section of the report referred to in Paragraph 12 of these Regulations, as well as the following information:

15.1. the name of the medicinal product;

15.2. the veterinary medicinal product registration certificate number;

15.3. ATC vet code (code in the anatomic- therapeutic- chemical codification);

15.4. a pharmaceutical form;

15.5. the series number and term of validity of the medicinal product; and

15.6. instructions for storage of the medicinal product.

16. The information regarding the treatment of an animal shall be indicated in the fourth section of the report referred to in Paragraph 12 of these Regulations:

16.1. the given name, surname, occupation or qualification of such a person who has administered the medicinal product to the animal;

16.2. the reason for the use of the medicinal product and diagnosis;

16.3. the dose and interval (if the medicinal product was administered several times) of administration of the medicinal product , the type and place of the administration;

16.4. the first date of administration of the medicinal product;

16.5. the date when the medicinal product were administered for the last time, as well as the duration of use of the medicinal product;

16.6. the symptoms during the time interval between the administrations of the medicinal product (if any were observed);

16.7. the course of action after the determination of the unforeseen symptoms (for example, reduction of the dose of the medicinal product or administration of another medicinal product);

16.8. indication, whether such symptoms have been determined previously. If the symptoms have been determined previously, the following

information shall be indicated:

16.8.1. the date when such medicinal product was administered to the animal ; and

16.8.2. .description of symptoms

16.8.3. the result of treatment

17. The information regarding other medicinal products used during this period of time (regarding the medicinal products used at the same time with such medicinal products regarding which the report has been submitted) in the fifth section of the report referred to in Paragraph 12 of these Regulations. The medicinal products used during the week when the adverse reaction has been observed shall also be indicated in this section. The following information shall be indicated regarding each medicinal product used parallel:

17.1. the name of the medicinal product, the ACTvet code (code in anatomic-therapeutic-chemical codification) and the pharmaceutical form;

17.2. the series number (if the medicinal product has not been prepared in a dispensing pharmacy), term of validity and instructions for storage of the medicinal product;

17.3. information regarding:

17.3.1. the person who has administered the medicinal product to an animal;

17.3.2. the dose of the medicinal product and the time interval between the administrations of doses, the type and place of administration; and

17.3.3. the date when the medicinal product has started and terminated to be administered to the animal.

18. The information regarding the determined adverse reaction shall be indicated in the sixth section of the report referred to in Paragraph 12 of these Regulations:

18.1. the description of an adverse reaction;

18.2. the date and time of determination of the adverse reaction;

18.3. the date and time of disappearance of the adverse reaction (symptoms caused); and

18.4. the treatment performed, in order to avoid the adverse reaction.

19. The information regarding tests and investigations performed in order to research the causes of an adverse reaction shall be indicated in the seventh section of the report referred to in Paragraph 12 of these Regulations:

19.1. if death has occurred, all the possible causes of the death. If laboratory or other post-mortem investigations have been performed, the results of tests and investigations shall be attached to the documents to be sent to the Food and Veterinary Service;

19.2. if tests for the investigation of the medicinal product samples has been performed, the results thereof shall be attached to the documents to be sent to the Food and Veterinary Service; and

19.3. if investigations referred to in Sub-paragraph 19.1 and 19.2 of these Regulations have not been performed, the type of the investigation of the case notified shall be indicated.

## V. Duties of the Food and Veterinary Service

20. The Food and Veterinary Service shall perform the duties, in order to facilitate the reporting regarding the possible adverse reactions caused by the use of veterinary medicinal products or use of human medicinal products in animals.

21. The Food and Veterinary Service shall co-operate with the European Agency for the Evaluation of Medicinal Products, in order to:

21.1. promote the exchange of information regarding the determined possible adverse reactions caused by veterinary medicinal products and the supervision thereof;

21.2. establish single uniform data processing network regarding the veterinary medicinal products registered in the European Union;

21.3. facilitate the exchange of information regarding the supervision of adverse reactions caused by the veterinary medicinal products in the European Union, as well as participate in the development of the guidelines regarding:

21.3.1. the procedures by which the reports shall be compiled, examined and submitted regarding the adverse reactions caused by the veterinary medicinal products;

21.3.2. the technical requirements to be observed, in performing the exchange of information, as well as the procedures by which the electronic information means shall be used, if the information is provided using the internationally adopted terminology.

22. The Food and Veterinary Service shall establish and maintain the supervisory system of adverse reactions caused by the veterinary medicinal products and:

22.1. compile the information regarding the adverse reactions caused to humans and animals, assess such information scientifically, then compare this with the data regarding the sales amounts of veterinary medicinal products and the amount of prescriptions written out;

22.2. compile the information regarding :

22.2.1. inefficacy of medicinal products;

22.2.2. administration of medicinal products in a manner incompatible with the information indicated on the labelling of medicinal product and in the package leaflet;

22.2.3. test or results performed in order to check the compliance of the withdrawal period (withdrawal from the organism) indicated in the registration documentation of the medicinal product with the information indicated on the labelling and package leaflet;

22.2.4. the possible (potential) impact on the environment;

22.3. evaluate the information sent by the holder (owner) of the veterinary medicinal product registration certificate (also regarding the usefulness or the risk caused by the registered veterinary medicinal product);

22.4. evaluate the reports regarding adverse reactions using ABON code.

23. The Food and Veterinary Service shall ensure:

23.1. the operation of the supervisory system referred to in Paragraph 22 of these Regulations;

23.2. processing of the information indicated in the report forms in accordance with regulatory enactments regarding the nature protection;

23.3. the notification of the holder (owner) of the veterinary medicinal product registration certificate regarding the adverse reaction which have been determined using the medicinal product registered by him or her not later than within 15 days after the receipt of a report, as well as the exchange of data (if necessary), if the adverse reactions which have been determined after the administration of the veterinary medicinal products registered by the holder (owner) of the veterinary medicinal product registration certificate were indicated in the report;

23.4. non-disclosure of reporter's personal data, if a reporter has indicated this on the standard report form;

23.5. exchange of necessary data, using the data exchange network referred to in Paragraph 22 of these Regulations, with other Latvian and international competent authorities, as well as, if serious adverse reactions have been determined in humans or animals, sending of a detailed report to the European Agency for the Evaluation of Medicinal Products and competent authorities of other states, where the veterinary medicinal products have been registered, not later than within 15 days after the receipt of the report;

23.6. that the European Agency for the Evaluation of Medicinal Products, the competent authorities of other states where the veterinary medicinal products have been registered and the holder (owner) of the veterinary medicinal product registration certificate are immediately informed, if, after the evaluation of the veterinary medicinal product supervision data, the Food and Veterinary Service considers it necessary to stop or withdraw the veterinary medicinal product registration certificate or that the information regarding the indication, doses (posology), animal species or breeds indicated in the registration documents of the veterinary medicinal products must be amended, or the information regarding contra-indications or safety measures to be performed using the veterinary medicinal products in animals must be supplemented;

23.7. in the case that is considered as an emergency, the taking of the decision regarding the suspension of the operation of the medicinal product registration permit . The European Agency for the Evaluation of Medicinal Products, competent authorities of other states, where the veterinary medicinal products have been registered, and the holder (owner) of the veterinary medicinal product registration certificate shall be informed regarding the decision taken not later than on the following day.

24. The Food and Veterinary Service shall:

24.1. examine, whether the holder (owner) of the veterinary medicinal product registration certificate and reporter have not provided the information regarding the same case (or whether duplication of the information has occurred);

24.2. ensure the availability of the forms indicated in Annexes of these Regulations;

24.3. classify the adverse reactions determined. In order to classify the adverse reaction as a serious unexpected adverse reaction, the animal species in which the medicinal product is used shall be taken into account:

24.3.1. for swine, birds, fish, bees and other animal species, if animals are kept and treated in the group, the mortality ratio shall be assessed. If the mortality ratio has been exceeded, the adverse reaction shall be classified as a serious unexpected adverse reaction; and

24.3.2. for horses, dogs, cats and other animal species, if the animal is kept and treated individually, the death of each animal shall be classified as a serious unexpected adverse reaction; and

24.4. ensure that the report forms referred to in Annex 1 and 2 of these Regulations are in yellow colour, the report form referred to in Annex 3 - in green colour and the report form referred to in Annex 4 is in pink colour.

## Informative Reference to European Union Directives

These Regulations contain legal norms arising from 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.

Prime Minister I. Emsis

Minister for Agriculture M. Roze

**Annex 1**
Cabinet Regulation No. 401
22 April 2004

| | Shall be filled in only by employees of VFS |
|---|---|
| Adverse reaction number | |
| Date of receipt | |
| Adverse Reaction file | |

**Report regarding adverse reactions in animal(-s)**

| **Information regarding the reporter** | | | |
|---|---|---|---|
| Given name, surname and address of the reporter | | | |
| The address where adverse reactions have been determined | | | |
| Given name, surname and address of the veterinary practitioner involved | | | |
| Full name of the veterinary (or human) medicinal product | | | |
| Medicinal product number (on labelling) | | Batch number | |
| The copy of this form will be handed over to the holder of the veterinary medicinal product registration certificate, if any adverse reactions have arisen in using the medicinal products registered by him or her. The holder of the veterinary medicinal product registration certificate may contact you in order to get more detailed information. | | | |
| If you do not wish to disclose the indicated addresses to the holder of the veterinary medicinal product registration certificate, mark up this box | | | |
| Has the holder (manufacturer) of the veterinary medicinal product registration certificate been informed already? | Yes | | No |
| **Detailed information regarding adverse reaction(-s)** | | | |

| | | | | | |
|---|---|---|---|---|---|
| Purpose of utilising the medicinal product | | | | | |
| Number of animals treated | | Number of animals in which the adverse reaction (-s) has been observed | | Number of cases of death | |
| Amount of the administered medicinal product 0} | | Method/rout of administration of medicinal product | | Duration of the course of treatment | |
| Date when the medicinal product was administered for the first time | | medicinal product was administered by (occupational sector) | | | |
| Date when a reaction (-s) was (were) determined | | Animal weight (kg) | | | |
| Species and breed of the animal | | Age and sex of the animal | | | |
| The type of adverse reactions and time, for how long the symptoms have been observed | | | | | |
| Was the animal also administered with other medicinal products? Which ones? | | | | | |
| What emergency assistance has been provided, what medicinal products have been administered (if administered) | | | | | |
| Vaccination history (if an immunological product has been involved in the instigation of the adverse reactions) The series number, registration number (shall be indicated by FVS) | | | | | |
| Posthumous *(Post mortem)* examinations and/or laboratory tests | | have been performed | | have not been performed | |
| **If examinations and tests HAVE BEEN PERFORMED, please attach the copies thereof**<br>If there are any comments or additional information, please attach them on a separate page | | | | | |

Minister for Agriculture M. Roze

**Annex 2**
Cabinet Regulation No. 401
22 April 2004

| | |
|---|---|
| | Shall be filled in only by employees of VFS |
| The adverse reaction number | |
| Date of receipt | |
| Adverse Reaction file | |
| Report regarding adverse reactions caused by veterinary medicinal products in human(-s) | |

| | | | |
|---|---|---|---|
| Information regarding the reporter | | | |
| The given name, surname and address of the reporter | | | |
| The address where adverse reactions have been determined | | | |
| The given name, surname and address of the veterinary practitioner involved | | | |
| The full name of the veterinary medicinal products | | | |
| The medicinal product number (on labelling) | | Batch number | |
| The copy of this form will be handed over to the holder of the veterinary medicinal product registration certificate if any adverse reactions have arisen in using the medicinal products registered by him or her. The holder of the veterinary medicinal product registration certificate may contact with you in order to get more detailed information. | | | |
| If you do not want to disclose the indicated addresses to the holder of the veterinary medicinal product registration certificate, colour in this box | | | |
| Has the holder (manufacturer) of veterinary medicinal product registration certificate been already informed ? | Yes | | No |
| Detailed information regarding the person in whom the adverse reaction(-s) has (have) been observed | | | |
| Given name and surname | | Age | |
| Sex | | Profession | |
| Detailed information regarding the adverse reaction(-s) in the human | | | |
| Date when the reaction (-s) was (were) determined | | The number and species of animals treated | |
| Detailed information regarding the use of veterinary medicinal products. If coincidental, indicate how it happened. If the veterinary medicinal product was injected, indicate the amount of the medicinal product injected | | | |
| Type of the adverse reactions and time, for how long the symptoms have been observed, | | | |
| Detailed information regarding the first symptoms | | | |
| Detailed information regarding the symptoms, which were determined later. | | | |
| Were you ill during that period of time (for instance, flu) or did you take some medicine? | Yes | No | If yes, provide detailed information in the Annex |
| Did you look for medical assistance? | Yes | No | Has the doctor approved that the symptoms are connected with use of the veterinary medicinal products? Yes / No |

| | | | | |
|---|---|---|---|---|
| Were the medicinal products administered, the examinations and tests performed? | Yes | | No | |
| If examinations and tests HAVE BEEN PERFORMED, please attach the copies thereof<br>If there are any comments or additional information, please attach them on a separate page | | | | |

Minister for Agriculture M. Roze

**Annex 3**
Cabinet Regulation No. 401
22 April 2004

| | Shall be only be filled in by employees of the VFS |
|---|---|
| Adverse reaction number | |
| Date of receipt | |
| Adverse Reaction file | |
| Report regarding NEGATIVE EFFECTS ON THE ENVIRONMENT OF THE VETERINARY MEDICINAL PRODUCTS | |

| Information regarding the reporter | | | | |
|---|---|---|---|---|
| The given name, surname and address of the reporter | | | | |
| The address where the incident was determined | | | | |
| The given name, surname and address of the veterinary practitioner involved | | | | |
| The full name of the veterinary medicinal products (if such is known) | | | | |
| The series number (if such is known) | | | | |
| The copy of this form will be handed over to the holder of the veterinary medicinal product registration certificate if environmental pollution has arisen in using his or her registered medicinal products in animals. The holder of the veterinary medicinal product registration certificate may contact you in order to get more detailed information. | | | | |
| If you do not wish to disclose the indicated addresses to the holder of the veterinary medicinal product registration certificate, colour in this box | | | | |
| Has the holder (manufacturer) of veterinary medicinal product registration certificate already been informed ? | Yes | | No | |
| Is the regional environment administration informed? | Yes | | No | |

| Detailed information regarding the adverse reaction(-s) in animals that have suffered from the effect of medicinal products due to environmental pollution (if there is a suspicion that the environment is polluted by the veterinary medicinal products) | | | |
|---|---|---|---|
| *animal species (including invertebrates, fish, birds) that have not been treated with the veterinary medicinal products | | | |
| Animal species concerned | Number of animals concerned | number of dead animals | Period of time since medicinal product has come into the environment Detailed information regarding the adverse reaction(-s) |
| | | | |

| Detailed information regarding the adverse reaction(-s) in humans who have suffered from the effect of medicinal products due to environmental pollution (if there is a suspicion that the environment is polluted by the veterinary medicinal products) | | | |
|---|---|---|---|
| Number of humans concerned | | Date when the symptoms appeared | |
| Given name and surname of the human(-s) concerned | Information regarding the pollution by veterinary medicinal products (origin) and adverse reactions caused | | |
| | | | |
| If examinations and tests HAVE BEEN PERFORMED, please, attach the copies thereof<br>If there are any comments or additional information, please attach them on a separate page | | | |

Minister for Agriculture M. Roze

**Annex 4**
Cabinet Regulation No. 401
22 April 2004

| | Shall only be filled in by employees of the VFS |
|---|---|
| Adverse reaction number | |
| Date of receipt | |
| Adverse Reaction file | |
| Report regarding PRESENCE OF RESIDUES OF ANTIBIOTICS IN MILK | |

| **Information regarding reporter** | |
|---|---|
| Given name, surname and address of the reporter | |
| Address where the animals are kept | |
| The given name, surname and address of the veterinary practitioner involved | |
| The full name of the veterinary (or human) medicinal product | |
| Series number (if such is known) | |
| A copy of this form will be handed over to the holder of the veterinary medicinal product registration certificate if the period of withdrawal of the medicinal | |

| |
|---|
| product registered by him or her from the organism of an animal fails to comply with the information indicated on the labelling. The holder of the veterinary medicinal product registration certificate may contact you in order to get more detailed information. |

| | | | | |
|---|---|---|---|---|
| If you do not wish to disclose the indicated addresses to the holder of the veterinary medicinal product registration certificate, colour in this box | | | | |
| Has the holder (manufacturer) of veterinary medicinal product registration certificate already been informed ? | Yes | | No | |

| **Animal information** | | | |
|---|---|---|---|
| Identification number | Species | Variety | Age |
| | | | |

| **Information regarding the treatment - for a cow in dry period** | | | |
|---|---|---|---|
| Dry off date | | Calving date | |
| The date and time, when the milk was milked in undesignated milk | | | |

| **Information regarding the treatment - for a cow during LACTATION period** | | | | |
|---|---|---|---|---|
| Date of last calving | | Number of quarters when the cow suffered from mastitis | | |
| The date and time of the first treatment, number of the injectors used | | / / | | |
| The date and period of time of further treatment (if such was performed), number of the injectors used | | / / | | |
| The date and time when the final treatment (the last one) was performed, amount of millilitres administered | | / / | | |
| The date and time when the milking in undesignated milk was began | | / / | | |

| **Information regarding tests performed for a cow (individual investigations) and/or for undesignated cow** | | | | |
|---|---|---|---|---|
| Information regarding the test | First test for a cow or undesignated milk | Second test for a cow or undesignated milk | Third test for a cow or undesignated milk | Fourth test for a cow or undesignated milk |
| The name of the test | | | | |
| Date and place | | | | |
| Results | | | | |

**If examinations HAVE BEEN PERFORMED, please attach the copies thereof**
**If there are any comments or additional information, please, attach them on a separate page**

Minister for Agriculture M. Roze

**Annex 5**
Cabinet Regulation No. 401
22 April 2004

| **PERIODIC SAFETY REPORT**<br>**(SHALL BE FILLED IN BY THE HOLDER (OWNER) OF the VETERINARY MEDICINAL PRODUCT REGISTRATION CERTIFICATE)** |
|---|
| The holder (owner) of the veterinary medicinal product registration certificate |
| Date |
| name of the veterinary medicinal product |
| Period of time since previous report<br>and the date of submission of the previous report |
| The number of medicinal products sold during the period of time<br>from the date of submission of the previous report |
| DOSE-unit |
| Frequency of the adverse reaction |

| Adverse reaction report number and the state where the adverse reaction was observed | Date of treatment/vaccination | Date when adverse reaction was determined | Number of animals treated | Species and age | Animals in which an adverse reaction was observed (number) | Number of dead animals | Were the medicinal products used in accordance with the information indicated on the labelling (yes/no) | Other medicinal product used at the same time together with the indicated medicinal product | Symptoms/diagnosis | Comments and opinion of the holder(owner) of the veterinary medicinal product registration certificate | Assessment in accordance with ABON code |
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Minister for Agriculture M. Roze