

# FEDERAL LAW GAZETTE

## FOR THE REPUBLIC OF AUSTRIA

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**434. Regulation:        Veterinary Health Service Regulation 2009 – TGD-VO 2009**

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**434. Regulation by the Federal Minister of Health on the Recognition and Operation of Veterinary Health Services (Veterinary Health Service Regulation 2009 – TGD-VO 2009)**

Based on § 7 Par. 2 and 3 of the Veterinary Medicines Control Act (TAKG), Fed. Law Gazette I No. 28/2002, last amended by Federal Law Gazette I No. 36/2008, it is herewith decreed:

**Section 1****General****Scope**

§ 1. (1) This Regulation regulates the recognition and operation of veterinary health services within the scope of application of the Veterinary Medicines Control Act, as well as the rights and obligations of the participating vets and agriculturists.

(2) A veterinary health service (VHS) within the meaning of this Regulation is a permanently established institution in which the vets and the animal husbandmen are represented, the objective of which is to advise agricultural animal husbandmen and to care for livestock to minimise the use of veterinary medicines and deficiencies in animal production due to husbandry conditions. The members of this institution shall be obliged, contractually or on the basis of existing provincial regulations, to comply with the regulations of this organisation. Collaboration within the veterinary health service must comply with uniform rules, in order to preserve the health of animals intended for food production through systematic, prophylactic and therapeutic measures, and thus to guarantee the safety, the flawless condition as well as high quality of foods of animal origin in the interest of the best possible consumer protection.

**Definitions**

§ 2. In this Regulation, the following terms shall mean:

1. Treatment register: Part of the livestock register for documentation of the treatment of animals as set out in § 12 of the Residues Control Regulation 2006, Fed. Law Gazette II No. 110/2006 as amended;
2. VHS care contract: care contract between a VHS animal husbandman and an attending VHS vet that has been declared valid by the VHS office;
3. VHS membership contract: membership contract between the animal husbandman or vet and the veterinary health service that is valid as of the registration of the commencement of membership by the VHS office;
4. VHS medicine user: a person who has the qualifications required for the administration of medicines as set out in this Regulation and is either
  - a) a VHS animal husbandman (natural person) or
  - b) a caregiver named by the same in writing for the relevant VHS operation within the meaning of § 14 of the Animal Welfare Act, Fed. Law Gazette I No. 118/2004, last amended by Federal Act Fed. Law Gazette I No. 35/2008, who is
    - ba) a family member living in the relevant VHS facility, or
    - bb) a person in the service of the VHS animal husbandman with a valid employment contract or contractual relationship with the same;
5. Attending VHS vet: a self-employed VHS vet in Austria with access to a home pharmacy, who has concluded a care contract with a VHS animal husbandman;

6. VHS facility: an animal husbandry facility identified by a facility number (facility number in accordance with the Agriculture and Forestry Facility Information System [*LFBIS*] pursuant to the *LFBIS* Act, Fed. Law Gazette No. 448/1980, last amended by Federal Act Fed. Law Gazette No. 505/1994), in which livestock intended for the production of foods or other products intended for use in or on humans is kept and the VHS animal husbandman of which has concluded a care contract for this facility;
7. VHS member: VHS animal husbandmen and VHS vets;
8. VHS vet: a vet licensed to practise in Austria who is a member of the VHS;
9. VHS animal husbandman: a natural person or legal entity who is the owner (= manager) of a VHS facility and a member of the VHS;
10. Livestock: group of animals of the same species kept in the same VHS facility within an epidemiological unit.

## Section 2

### Organisation and Duties of the Veterinary Health Services

#### Recognition of Veterinary Health Services

§ 3. (1) The Provincial Governor shall approve an application for recognition of a veterinary health service as set out in § 7 Par. 2 *TAKG*, if:

1. the applicant can prove that the personal and material prerequisites for achievement of the objectives set out in § 1 Par. 2 and for fulfilment of the duties set out in **Annex 1** (9) and, in the case of a poultry health service, as set out in **Annex 2** (13) are fulfilled, and
2. the organisation meets the standards set out in **Annex 1** (1) to (7) respectively **Annex 2** (1) to (11), and
3. it is ensured that membership in the veterinary health service is available to all vets and agriculturists who undertake to meet the requirements of this Regulation, and
4. it is ensured, in terms of the personal, technical and organisational prerequisites, that the following duties can be fulfilled:
  - a) implementation of nationwide standards for veterinary health programs;
  - b) registration of the participating animal husbandmen and vets;
  - c) registration of the VHS facilities, the VHS medicine users, the attending VHS vets, their deputies, as well as VHS vets acting on behalf of the attending VHS vets;
  - d) transmission of the data required for monitoring of due and proper compliance with the provisions of this Regulation to the Provincial Governor;
  - e) definition of corrective actions and, if necessary, sanctions in the case of breaches by VHS members;
  - f) central clearing of the facility surveys as set out in Annex 3 (7) in order to ensure fulfilment of the documentation duty;
  - g) annual transmission of the data required in order to be able to make a statement regarding the further development and for evaluation of the veterinary health services to the Federal Ministry of Health.

The Vorarlberg Veterinary Health Service established under provincial laws is exempted from the requirement set out in par. (2), and the provincial regulations applicable to the same shall be deemed equivalent in this respect.

(2) The Federal Minister of Health shall be notified of the recognition of a veterinary health service pursuant to § 7 Par. 2 *TAKG*, whereby copies of the recognition notice and the documents underlying the decision shall be provided.

(3) The recognition notice must specify at least the following:

1. the area of activity of the veterinary health service, in particular the animal species involved, as well as a description of the anticipated activities;
2. the obligation to ensure and monitor the demands on the vets and animal husbandmen involved in accordance with this Regulation;

3. the obligation to keep an up-to-date register of all persons and facilities named in Par. 1 (4) lit. b and c;
4. the demands with regard to the persons involved and their qualification, as well as the demands with regard to premises, equipment and other materials;
5. the internal controls to be carried out within the scope of the veterinary health service, in particular with regard to the use of veterinary medicines and hygiene, as well as the obligation to comply with the tariffs agreement as set out in Annex 1 (9) lit. e.

(4) In the recognition notice the Provincial Governor may define further stipulations, conditions and restrictions in accordance with the relevant veterinary or sanitary police regulations and the state of the art, veterinary medicine and animal welfare standards

(5) On lapse of the prerequisites for recognition, the Provincial Governor shall withdraw the recognition by notice.

#### **Code of Procedure and Operation of Veterinary Health Services**

§ 4. (1) The veterinary health service shall adopt a code of procedure to be approved by the Provincial Governor. Approval must be granted, if it guarantees fulfilment of the duties as set out in this Regulation.

(2) The animal health service must be operated in such a manner that it does not give rise to any concerns in veterinary, sanitary and food policing terms.

#### **Office**

§ 5. In order to ensure the function and to organise the duties of the veterinary health service, every veterinary health service must establish an office as the administrative centre.

#### **Membership in the Veterinary Health Service**

§ 6. (1) Every vet licensed to practise freely in Austria under the Vets Act, and every agriculturist with livestock, whose facility is located within the geographical territory of the respective veterinary health service, shall be entitled to become a member of the veterinary health services.

(2) Membership in the respective veterinary health service shall be established by a written membership contract between the animal husbandman or the vet licensed to practise freely in Austria and the respective veterinary health service.

(3) Within the respective veterinary health service, VHS vets with access to a home pharmacy can conclude a VHS care contract with a VHS animal husbandman. The VHS vet thus becomes the attending VHS vet for the respective facility.

(4) VHS animal husbandmen may only conclude one care contract with one VHS vet per animal species and VHS facility.

(5) All members of the veterinary health service must be notified to the responsible district administration authority by the office of the veterinary health service.

#### **Contracts**

§ 7. (1) A membership contract must be concluded with the VHS animal husbandman for every VHS facility. This must be drafted by the respective veterinary health service in accordance with the standards of this Regulation and must include at least the following:

1. name of the veterinary health service,
2. name, address and contact details of the VHS animal husbandman (phone, fax, e-mail address),
3. name and address of the facility (if not identical to the animal husbandman),
4. facility number (*LFBIS* number of the facility),
5. terms of payment for contributions,
6. declaration of undertaking,
7. termination clause, and
8. beginning of membership.

In the case of a poultry health service (PHS), the declaration of membership shall replace the membership contract.

(2) The membership contract between the respective veterinary health service and the vet must include at least the following:

1. name of the veterinary health service,
2. name of the vet,

3. number of the vet ID,
4. address and contact details (phone, fax, e-mail address) at the vet's place of work/office,
5. details regarding the home pharmacy, membership in a firm of vets or shared practice,
6. terms of payment for contributions,
7. declaration of undertaking,
8. termination clause, and
9. beginning of membership.

In the case of a poultry health service (PHS), the declaration of membership shall replace the membership contract.

(3) The care contract pursuant to § 6 Par. 3 between the VHS animal husbandman and the VHS vet must include at least the following:

1. name of the veterinary health service,
2. name, address and *LFBIS* number of the VHS animal husbandman,
3. name and address of the attending VHS vet,
4. species of animals to be cared for,
5. terms of settlement,
6. termination clause,
7. validity clause, and
8. obligation by the contractual partners to comply with the provisions of the Veterinary Health Service Regulation.

The office of the respective veterinary health service must be sent a copy of the care contract. The period of notice for a care contract is two months. Termination of the care contract by mutual agreement is possible at any time. Any termination of the care contract must be in writing.

(4) The contracts must be drafted by the respective veterinary health service in accordance with the standards of this Regulation. If recommendations for a uniform nationwide design of the contracts pursuant to par. 1, 2 and 3 are made by the advisory council "Tiergesundheitsdienst Österreich", these may be promulgated in the "*Amtliche Veterinärnachrichten*" (Official Veterinary Gazette). If the Federal Ministry of Health promulgates a form that has been recommended by the advisory council "*Tiergesundheitsdienst Österreich*", this form or a form of the same content by the respective veterinary health service must be used.

(5) The termination of contractual relationships as well as any amendments to contracts or contractual elements must be notified forthwith, but not later than within four weeks, to the office of the respective veterinary health service by the contractual partners in writing. Moreover, any changes within the sphere of the respective VHS member that have retroactive effects on contracts must be notified in writing to the relevant contractual partners and the VHS office forthwith, but not later than within four weeks.

### **Section 3**

#### **Rights and Obligations of the Members**

##### **VHS Vets**

§ 8. (1) All VHS vets must fulfil the following requirements:

1. The veterinary practice must be run with the due diligence of a proper vet; in particular, acute and emergency care for the contractual livestock must be guaranteed.
2. They must ensure the necessary treatments, taking the objective of minimising the use of medicines as well as the profitability and sustainability of the measures into consideration.
3. When visiting facilities, they shall wear the clean protective clothing to be provided by the animal husbandman.
4. They shall be obliged to undergo continuing education as specified in § 10.
5. When acting on behalf of or as deputy for an attending VHS vet, they must comply with the latter's obligations under this Regulation.

(2) An attending VHS vet shall work primarily at the location of his practice. If a vet plans to become active as an attending VHS vet in another province and if a relevant VHS already exists at the planned place

of work prior to the start of such work in the other province, reciprocal written notification of the relevant veterinary health services about the number of planned care contracts is required. The VHS vets concerned must be members of the respective VHS.

(3) Attending VHS vets may employ VHS vets to fulfil their duties; such VHS vets shall then be acting on their behalf. In this case the attending VHS vet shall be responsible for compliance with the provisions of this Regulation. VHS vets acting on behalf of an attending VHS vet must be notified by the same to the VHS office in writing. An entry in a suitable electronic system shall replace such notification.

(4) Only other VHS vets with access to a home pharmacy shall be permitted to deputise for an attending VHS vet. The deputy himself shall be responsible for compliance with the provisions of this Regulation. The deputies must be named to the VHS animal husbandman and the VHS office in writing by the attending VHS vet. An entry in a suitable electronic system shall replace such notification.

(5) Attending VHS vets must fulfil the following standards and comply with the following provisions:

1. They shall be obliged to carry out and document facility surveys as set out in Annex 3; the attending VHS vet shall be responsible for scheduling such surveys and must provenly notify the VHS animal husbandman thereof within good time.
2. They shall be obliged to demand that the VHS animal husbandman rectify any defects identified in the facility survey within a reasonable period of time.
3. They may involve the VHS medicine users of the respective VHS facility in auxiliary services that go beyond the scope of work required in ordinary animal husbandry and animal care, as well as in the administration of veterinary medicines to such agricultural livestock as is covered by the care contract, whereby this shall be carried out in accordance with precise instructions, under supervision and with written documentation as set out in Section 4 of this Regulation.
4. They may also dispense medications, the dispensation of which is permitted within the scope of the VHS on the basis of the regulation pursuant to § 7 Par. 1 TAKG, to VHS medicine users.
5. They shall be obliged to comply with program instructions when participating in veterinary health programs within the scope of the VHS.
6. They must
  - a) take receipt of the veterinary medicines and remains of veterinary medicines (i.e. opened medicines, the effectiveness of which is no longer guaranteed according to the manufacturer's data) that are returned to them pursuant to § 9 Par. 3 (9), that are no longer required or have expired not later than on the next visit following the end of the respective treatment, or arrange for their due and proper disposal, and
  - b) check the empty containers of veterinary medicines presented to them pursuant to § 9 Par. 3 (9) in the case of veterinary medicines intended for instillation and injection – with the exception of veterinary medicines pursuant to § 13 Par. 1 – not later than on the next visit following the end of the respective treatment.
7. The receipts for medicine dispensations, medicine returns and administration issued by them must comply with the specifications promulgated in the "*Amtliche Veterinärnachrichten*".
8. They must keep the documentation as set out in (1) as well as any other contracts and records to be kept on the basis of this Regulation for at least five years even after withdrawal from the VHS, and they must present the same to the official control bodies in an orderly and easily auditable form for inspection on demand.
9. They must report any breaches of the regulations in accordance with § 7 Par. 1 and 2 TAKG that could present a risk to the health of consumers, or facts that give justified reason to suspect cruelty to animals pursuant to § 222 of the Austrian Penal Code to the VHS office forthwith. The VHS office must notify the responsible authority forthwith.
10. They must provenly inform the VHS facility about any apparent breaches of animal welfare provisions not included in (9) and resulting in a serious impairment of animal health, and must define a goal with a reasonable period of time for the remediation or elimination of observed defects together with the VHS animal husbandman. If the defined goal is not reached within the specified period of time, the responsible bodies of the VHS must be notified.

#### **VHS Animal Husbandmen**

§ 9. (1) VHS animal husbandmen must fulfil the following requirements:

1. In addition to membership in the VHS they are not permitted to enter into any other permanent care relationships within the meaning of § 24 Par. 3 of the Veterinary Surgeons Act, Fed. Law Gazette

No. 16/1975, last amended by Federal Act Fed. Law Gazette I No. 135/2006, for animals of the species covered by the veterinary health service.

2. They must ensure that the continuing education requirements as set out in § 10 are fulfilled.
3. They must conduct the animal husbandry as well as the production and storage of own feeds with the due diligence of a proper agriculturist.
4. The stock register including the treatment register must be kept in an orderly and easily auditable form (documentation of dispensation, use and return of veterinary medicines) and must be kept at the facility for at least five years - even after withdrawal from the VHS - and presented to the official control bodies for inspection on demand.
5. All animals kept in the facility or operation must be tagged in accordance with the statutory requirements. In the event of disease, it must be organisationally possible to segregate animals in groups or individually. It must be possible to identify the individual treated animals. This identification must be made possible on the basis of a barn plan listing all bays or boxes, as well as through group allocation of the individual animals. These records must be enclosed with the stock register.
6. The animal husbandman must guarantee traceable documentation of animal movements in his facility.
7. The VHS animal husbandman must provide proper protective clothing for the vet and his helpers.
8. The animal husbandman must ensure the necessary assistance during examinations and treatments, in particular the necessary fixation of animals.
9. The VHS animal husbandman must apply the provisions regarding to the attending VHS vet that fall under his responsibility also to VHS vets acting on behalf of or as deputy for the attending VHS vet.
10. In addition to the documentation set out in (4) they must also keep any other contracts and records to be kept on the basis of this Regulation for at least five years even after withdrawal from the VHS, and they must present the same to the official control bodies in an orderly and easily auditable form for inspection on demand.

(2) In collaboration with the attending VHS vet, the VHS animal husbandman must comply with the following provisions:

1. VHS animal husbandmen who enter into care contracts for multiple animal species must keep the records separately for each species in the stock register including the treatment register.
2. If another vet is consulted, the VHS animal husbandman must notify the attending VHS vet thereof forthwith without demand. All measures taken must be documented in the treatment register.
3. The animal husbandmen must make the facility surveys to be performed annually possible, and must collaborate within the scope of the VHS membership obligations. The facility surveys must be documented as set out in Annex 3 and records must be duly kept in the stock register, and they must be handed over or made available to the attending VHS vet at every facility survey.
4. Additional records of production data that are relevant for the assessment of animal health must be made available to the attending VHS vet.
5. In the case of animal health problems, the attending VHS vet must be notified within good time. If a disease within the meaning of the Animal Diseases Act is suspected, the authority must be notified forthwith in accordance with the relevant statutory provisions.
6. If the treatment fails, new cases of disease occur, or an animal perishes (increased mortality rate that exceeds the normal level for the relevant facility under the prevailing conditions in the case of poultry, aquaculture animals or suckling pigs), the VHS animal husbandman must – notwithstanding other reporting duties under veterinary law – inform the attending VHS vet forthwith and determine the further procedure in consultation with the same.
7. Investigative material required for diagnostics must be made available by the animal husbandman if required.
8. The instructions of the attending VHS vet for the remediation of assessed defects must be followed.

(3) If VHS animal husbandmen are involved in the administration of medicines as set out in Section 4 of this Regulation, they shall have the following obligations – notwithstanding further provisions contained in this Regulation or other statutory provisions:

1. Prior to involvement in the administration of medicines they must complete training as set out in § 10 or ensure that a VHS medicine user named by them has completed this training.

2. When preparing medicated feeds in the facility, they must complete the required additional training as set out in § 16 or ensure that a VHS medicine user named by them has completed this training.
3. They must name the VHS medicine user in consultation with the attending VHS vet and notify the VHS office thereof, thereby specifying the name (first and last name), date of birth and, if applicable, employment/contractual relationship within the scope of the facility survey on the cover sheet of the facility survey report or, in the case of short-term changes, using a form published in the “*Amtliche Veterinärnachrichten*”.
4. They must take responsibility for the actions of the VHS medicine users in their facility.
5. They must ensure that the VHS medicine user obtains the medicines prescribed for use within the scope of the VHS only from the attending VHS vet or, on his prescription, from a public pharmacy and from the manufacturer in the case of medicated feeds as set out in § 6 Par. 4 *TAKG*. The medicine dispensation, return and administration document must be kept by the VHS animal husbandman as set out in Par. 1 (4). When taking over the medicine, the VHS medicine user must check that the medicine dispensation, return and administration document has been completed legibly.
6. They must ensure that the medicines provided to the VHS medicine user by the attending VHS vet are kept separate from food and feeds, as well as sufficiently refrigerated, and that they are always kept out of reach of unauthorised persons.
7. They must ensure that the animal medicines provided to the VHS medicine user by the attending VHS vet are administered only in accordance with the vet’s instructions at the relevant facility, and that this administration is documented in writing in the treatment register.
8. They must provide the other auxiliary services required of them within the meaning of § 8 Par. 5 (3) only as instructed by the attending VHS vet.
9. They must
  - a) return veterinary medicines that are no longer required or have expired or veterinary medicine residues (i.e. opened medicines, the effectiveness of which is no longer guaranteed according to the manufacturer’s data) to the attending VHS vet not later than on the next visit following the end of the respective treatment, and
  - b) provenly present the empty containers of veterinary medicines intended for instillation and injection – with the exception of veterinary medicines pursuant to § 13 Par. 1 – to the attending VHS vet not later than on the next visit following the end of the respective treatment.
10. Before starting to prepare medicated feeds within the meaning of § 6 Par. 6 second sentence *TAKG*, they must notify the responsible district administration authority of the intended activity. The certification of completed training as VHS medicine user for the relevant VHS facility as set out in Annex 4 Art. 1 (1) must be enclosed with this notification. The VHS advisory council may define further details regarding the preparation of medicated feeds by promulgation in the “*Amtliche Veterinärnachrichten*”.

#### **Training and Continuing Education of the Members**

§ 10. (1) The VHS vets must complete adequate specialised continuing education as set out in Annex 4 Art. 2 regularly and report completion of the same to the Austrian Veterinary Surgeons’ Council.

(2) The specialised continuing education for vets must be evaluated and recognised and its completion must be documented by the Austrian Veterinary Surgeons’ Council free of charge as set out in the Training Code of the Veterinary Surgeons’ Council. This documentation must be transmitted to the veterinary health services in electronic form without demand and free of charge once per year at the end of the calendar year. Fulfilment of the continuing education requirements for VHS vets must be verified by the office of the respective veterinary health service.

(3) VHS animal husbandmen or family members living in the respective VHS facility or persons in the service of the VHS animal husbandman with a valid employment contract or contractual relationship with the same, who in any case also fulfil the provisions for carers within the meaning of § 14 *TSchG* [Animal Welfare Act], must provenly attend VHS continuing education courses as set out in Annex 4 Art. 1 (2).

(4) VHS animal husbandmen must ensure that VHS medicine users provenly complete the theoretical and practical training set out in the provisions of Annex 4 Art. 1 (1) prior to first administration of veterinary medicines (including vaccinations) in the respective facility.

(5) Fulfilment of the training and continuing education requirements for VHS animal husbandmen and VHS medicine users must be verified by the respective attending VHS vet – in any case within the scope of the facility survey. Thereby the office must support the attending vet. It must be ensured that completion of

the training as VHS medicine user and continuing education is documented on the facility survey cover sheet at the VHS facility.

(6) The respectively necessary documents to prove fulfilment of the requirements set out in Annex 4 Art. 1 must be presented to the attending VHS vet and to the control bodies on demand.

#### **Implementation of Training and Continuing Education**

§ 11. (1) The training and continuing education events can be implemented by the Vienna University of Veterinary Medicine, *Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES)*, the Agricultural Training Institute (*LFI*), *ARGE Huhn & Co*, *VETAK* – the Academy of the Austrian Veterinary Surgeons' Council, any comparable adult education organisation or any other organisation offering training and continuing education events in coordination with the VHS offices. Thereby the veterinary health service may also use its own human and material resources and involve other VHSs.

(2) The provisions of Annex 4 apply with regard to the content of the training and continuing education courses and the number of hours. When determining the content of training and continuing education events, it must be ensured that the provisions of the *TAKG*, the provisions of this Regulation as well as any other provisions relating to animal husbandry and animal health are taken into account.

### **Section 4**

#### **VHS Medicine Administration**

##### **Principles of Dispensation of Veterinary Medicines**

§ 12. (1) Veterinary medicines may be dispensed in accordance with the provisions of the Veterinary Medicines Administration Regulation, Fed. Law Gazette II No. 266/2006 as amended within the scope of the VHS in the following cases:

1. within the scope treatment or continued therapy (follow-up treatment) of a disease,
2. as a medical measure to prevent animal diseases (prophylaxis),
3. in the case of a disease within the scope of treatment of previously unobtrusive animals within the same epidemiological unit, if the occurrence of similar clinical signs and symptoms is to be expected (metaphylaxis).

If the use of veterinary medicines appears to be expedient, the attending VHS vet must in any case visit the facility prior to their use in order to diagnose the animals and segregate them appropriately if necessary, and to determine the therapy as well as any necessary prophylactic or metaphylactic measures.

(2) Attending VHS vets may hand over veterinary medicines within the scope of involvement as set out in § 8 Par. 5 (3). This is subject to completion of the training set out in § 10 Par. 4 by the VHS medicine user. The VHS vet named in the dispensation bill shall be responsible for the dispensation of a medicine.

(3) If the treatment fails, new cases of disease occur, or an animal perishes (increased mortality rate that exceeds the normal level for the relevant facility under the prevailing conditions in the case of poultry, aquaculture animals or suckling pigs), the VHS animal husbandman must – notwithstanding other reporting duties under veterinary law – inform the attending VHS vet forthwith and determine the further procedure in consultation with the same.

(4) After completion of every treatment, but not later than after four weeks, the administration of medicines pursuant to § 9 Par. 3 (7) as well as the success of therapy must be checked by the attending VHS vet. If only one single animal in the stock was treated, the medicine administration and success of therapy shall be checked by the attending VHS vet within the scope of the next routine veterinary visit after completion of the treatment.

(5) Veterinary medicines for continuation of the therapy (follow-up treatment) may only be provided to the VHS animal husbandman or VHS medicine user in the amount required for successful treatment and only in such amount at most as is expected to be required within one month for the animals to be treated.

(6) In the case of pour-on preparations for the treatment of parasites, the dispensation quantity may be defined for the duration of one treatment cycle, even if the monthly demand is thus exceeded.

(7) The dispensation, administration and return of veterinary medicines must be documented as set out in Annex 5.

##### **Special Provisions within the Scope of Prophylaxis**

§ 13. (1) Veterinary medicines for use within the scope of prophylaxis, which contain exclusively vitamins, vital elements or trace elements as active substances, as well as pure iron injection preparations are so-called “management preparations” and may be provided to the VHS animal husbandman or VHS



medicine user by the attending VHS vet in a maximum amount equivalent to the two-month demand for the animals to be treated. Other management preparations may be promulgated by the Federal Minister of Health in the “*Amtliche Veterinärnachrichten*” on recommendation by the advisory council.

(2) If vaccines are used within the scope of prophylactic measures, they may only be provided in a quantity equivalent to the one-month demand for the animals to be vaccinated.

#### **Special Provisions within the Scope of Metaphylaxis**

§ 14. (1) Within the scope of metaphylaxis, a written action plan or a written instruction – supplementary to the medicine dispensation, return and administration document – must be prepared on the day of occurrence of the acute case for the anticipated duration of the stock problem, but not longer than for the duration of one year. Veterinary medicines may be provided in a quantity not higher than the anticipated one-month demand for the animals to be treated.

(2) The action plan/instruction must in any case include details of the disease concerned (diagnosis), the unit to be treated (animal groups, age groups, box number, ear tag number in the case of individual animal tagging, barn units, etc.), the date of creation, as well as the date until which the written action plan/instruction is valid.

(3) The use of these veterinary medicines by the VHS medicine user shall be permitted only in proven consultation with the attending VHS vet even during the period specified in the action plan/written instruction. Thereby the VHS animal husbandman must inform the attending VHS vet about the following and document the same in writing:

1. date on which the attending VHS vet is informed,
2. beginning of treatment of further animals in accordance with the action plan or written instruction,
3. number and identity of newly diseased animals in the action plan or written instruction.

(4) Compliance with and the success of the action plan or written instruction must be verified by the attending VHS vet at the next facility visit as set out in § 12 Par. 4 provenly by copying the documentation of the treatment provided in accordance with the action plan or written instruction.

(5) When taking back veterinary medicines as set out in § 8 Par. 5 (6), the attending VHS vet must make sure in particular that any veterinary medicines that were not required for the treatment are provenly taken back. Proof of completeness of the return must be provided in the form of a plausible comparison of quantities (dispensed quantity minus quantity of veterinary medicine that was administered).

#### **Administration of Medicines within the Scope of Animal Health Programs**

§ 15. (1) Special veterinary medicines that may be provided to the VHS medicine user exclusively within the scope of animal health programs must be promulgated by the Federal Minister of Health – on recommendation by the advisory council – in the “*Amtliche Veterinärnachrichten*” as set out in § 7 Par. 1 TAKG, together with detailed regulations for their use.

(2) Animal husbandmen participating in animal health programs pursuant to Par. 1 must in any case be registered by the veterinary health service and notified to the respective Provincial Governor by the VHS office. A withdrawal from participation in animal health programs must be reported to the responsible district administration authority by the office of the veterinary health service without delay.

#### **Preparation of Medicated Feed**

§ 16. Based on § 6 Par. 6 second sentence TAKG, medicated feeds may be prepared within the scope of a veterinary health service under the supervision of the attending VHS vet for animal production in the VHS facility, if the VHS medicine user proves his qualification to do so after having completed the training as set out in Annex 4 Art. 1 (1.1) and the VHS animal husbandman has fulfilled his reporting duty as set out in § 6 Par. 7 TAKG.

### **Section 5**

#### **Controls and Sanctions in the VHS**

##### **Controls in the Veterinary Health Service**

§ 17. (1) The veterinary health service must set up a system of regular internal controls and thus ensure that the veterinary health service is operated in accordance with the statutory provisions and the terms and conditions of the recognition notice. The internal controls must be implemented as set out in Annex 6 Art. 1 (I).

(2) The implementation of external controls of the VHS offices as well as the members of the veterinary health services by an appropriately accredited agency shall be ensured by the Federal Ministry of Health on

the basis of a risk-based control plan that guarantees statistically confirmed statements with regard to the controlled areas. The Federal Ministry of Health may charge the office of a veterinary health service to contract and organise such controls. The costs of contracting, organisation and implementation of these controls shall be borne by the Federal Ministry of Health. The external controls must be implemented as set out in Annex 6 Art. 1 (II).

(3) Control bodies within the meaning of par. 1 must

1. report any breaches of the regulations in accordance with § 7 Par. 1 and 2 *TAKG* that could present a risk to the health of consumers, or facts that give justified reason to suspect cruelty to animals pursuant to § 222 of the Austrian Penal Code to the VHS office forthwith. The VHS office must notify the responsible authority forthwith; and
2. notify the VHS facility provenly of any apparent breaches of animal welfare provisions that are not included in (1) and result in a serious impairment of animal health. The attending VHS vet or the control body, together with the VHS animal husbandman, must define a goal and a reasonable period of time for the remediation or elimination of identified defects. If the defined goal is not reached within the specified period of time, the responsible bodies of the VHS must be notified. They must notify the district administration authority.

#### **Official Controls**

§ 18. The veterinary health service, the attending VHS vets or the VHS vets acting on their behalf or as their deputy, as well as the VHS animal husbandmen shall be subjected to official controls at regular intervals as set out in Annex 6 Art. 5.

#### **Sanctions**

§ 19. (1) If members fail to comply with provisions of this Regulation, at least the following measures must be provided for and implemented in accordance with Annex 6 Art. 6 by the veterinary health service:

1. written demand to rectify defects;
2. written demand to rectify defects with warning;
3. exclusion from VHS medicine use;
4. exclusion from participation in animal health programs for a specified time;
5. exclusion from animal health programs;
6. exclusion from VHS support programs;
7. follow-up control with costs;
8. fines;
9. exclusion from membership in the VHS.

(2) All sanctions as set out in Par. 1 (3) to (5) and (9) must be reported to the responsible district administration authority by the office of the veterinary health service.

### **Section 6**

#### **Final and Transitional Provisions**

##### **Gender-related Terms**

§ 20. The gender-related terms used in this Ordinance shall apply to both genders.

##### **Entry into Force and Transitional Provisions**

§ 21. (1) This Regulation shall enter into force as of 1 January 2010.

(2) As of the end of 31 December 2009,

1. the Veterinary Health Service Regulation 2005, Fed. Law Gazette II No. 443/2005, last amended by Fed. Law Gazette II No. 281/2008, and
2. *TAKG* Training Regulation, Fed. Law Gazette II No. 194/2002

shall cease to be in force.

(3) Legal acts that are valid prior to this Regulation coming into force on the basis of the Veterinary Health Service Regulation 2005 shall, notwithstanding par. 4 and 5, remain valid until according new legal acts are issued. References to the Veterinary Health Regulation 2005 shall be construed as references to this Regulation.

(4) The promulgation file ref. 74200/24-IV/B/5/07, AVN 11/2007 of 18 December 2007, “Promulgation of a Clarification with Regard to the Dispensation of Veterinary Medicines for the Further Treatment of Acute Cases as well as for Metaphylaxis pursuant to § 8 *TGD-VO*” shall be cancelled upon publication of this Regulation.

**Stöger**