Draft Law of the Federal Ministry of Agriculture, Food and Regional Identity

Ordinance Amending the Veterinary In-House Dispensary Regulation and Other Provisions*

Dated ...

The Federal Ministry of Agriculture, Food and Regional Identity, acting in conjunction with Section 1, Paragraph 2, of the Federal Recognition Act, of 16 August 2002 (BGBI. I, p. 3165), amended by Article 7 of the Ordinance, of 31 August 2015, (BGBI. I p. 1474) and the Organisational Chart, of 6 May 2025 (BGBI. 2025 I no. 131), pursuant to:

– Section 61, Paragraphs 1 and 2, Sentences 1 and 2, Point 2, and Sentence 3, as well as Paragraph 3, Point 1, and Section 84, of the Veterinary Medicinal Products Act, in the version of the notice, of 21 May 2026 (BGBl. 2026 I No. 160), in agreement with the Federal Ministry of Health, and

– Section 62, Paragraph 1, Sentence 1, Points 2 and 3, Paragraph 2, Sentence 1, Points 1, 4 and 5, and Sentence 2, Points 1 to 3 and 6, and Paragraphs 3 and 4, and Section 84 of the Veterinary Medicinal Products Act, in agreement with the Federal Ministry of Health and the Federal Ministry for Economic Affairs and Energy:

Artikel 1

Amendment to the Veterinary In-House Dispensary Regulation

The Veterinary In-House Dispensary Regulation, of 1 November 2024 (BGBI. 2024 I No 343), is amended as follows:

1. Section 12 is deleted.

2. Section 13 is replaced by the following Section 13:

§ 1"

Antibiogram obligation

(1) When treating groups of animals of the species cattle, pigs, chickens, or turkeys, which are kept in an animal stall or an enclosed outdoor area, with a veterinary or human medicinal product possessing antibiotic activity, the veterinarian must, subject to Article 2 of Implementing Regulation (EU) 2024/1973, of 18 July 2024, carry out or arrange for the carrying out of an antibiogram without delay and in accordance with Section 14 in the cases referred to in Sentence 2. The antibiogram pursuant to Sentence 1 must be carried out:

1. in the case of a change of the antibiotic veterinary or human medicinal product during the course of treatment,

* Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council, of 9 September 2015, laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241 of 17 September 2015, p. 1).

2. in the case of treatment with an antibiotic veterinary or human medicinal product that takes place more than once during specific age or production stages,

3. in the case of combined administration of antibiotic veterinary medicinal products or human medicinal products for one indication, excluding an authorised veterinary medicinal product containing a combination of antibiotic active substances, or

4. in the case of treatment, in accordance with the conditions of authorisation under Article 106(1) of Regulation (EU) 2019/6 of 23 November 2022, with veterinary medicinal products containing third- or fourth-generation cephalosporins, fluoroquinolones, or colistin.

(2) When treating individual animals of the species cattle, pigs, horses, dogs, or cats, excluding stray cats, with an antibiotic veterinary medicinal product, the veterinarian must, subject to Article 2 of Implementing Regulation (EU) 2024/1973 (as of 18 July 2024) and in the cases specified in Sentence 2, immediately carry out or arrange for the carrying out of an antibiogram in accordance with Section 14. The antibiogram referred to in Sentence 1 must be carried out when treating animals, in accordance with the conditions of authorisation set out in Article 106(1) of Regulation (EU) 2019/6 (as of 23 November 2022), with veterinary medicinal products containing third- or fourth-generation cephalosporins, fluoroquinolones, or colistin. Sentence 2 does not apply if, within the scope of veterinary herd health management, meaningful and representative data on the resistance situation are available for the individual animals to be treated, justifying the need to use veterinary medicinal products containing third- or fourth-generation cephalosporins, fluoroquinolones, or colistin.

(3) When treating individual horses with an antibiotic veterinary medicinal product or human medicinal product, the veterinarian must, in the cases specified in Sentence 2, immediately carry out or arrange for the carrying out of an antibiogram in accordance with Section 14. The antibiogram referred to in Sentence 1 must be carried out in the event of off-label use (redirection), provided the medicinal product contains an active substance belonging to the following groups:

1. aminopenicillins in combination with beta-lactamase inhibitors,

2. amphenicols,

3. third- and fourth-generation cephalosporins,

4. quinolones (including fluoroquinolones),

5. polymyxins,

6. pseudomonic acids, or

7. rifamycins.

Sentence 2 does not apply if, during treatment with a veterinary medicinal product authorised for horses, there is a change in the field of application specified in the conditions of authorisation.

(4) Notwithstanding Paragraphs 1 to 3, an antibiogram need not be prepared if, according to the state of veterinary medical knowledge,

1. sampling would entail a risk of further compromising the health of the animal to be treated,

2. the pathogen cannot be cultured using cell-free artificial media, or

3. no suitable method is available for determining the pathogen's susceptibility.

In such a case, the veterinarian must keep a record stating the reasons why no antibiogram was prepared."

3. In Section 14, Paragraph 1, Sentence 1, the phrase "pursuant to Article 2, Paragraph 1, of Implementing Regulation (EU) 2024/1973, as amended on 18 July 2024" is inserted after the phrase "Section 13, Paragraph 1, Sentence 2, Paragraph 2, Sentence 2, and Paragraph 3, Sentence 2".

4. Section 20 is amended as follows:

a) In the entry preceding Point 1, the reference "Point 15" is replaced by the reference "Point 16".

b) Points 7 and 8 are replaced by the following Point 7:

"7. contrary to Section 13, Paragraph 1, Sentence 1, Paragraph 2, Sentence 1, or Paragraph 3, Sentence 1, fails to carry out or have carried out an antibiogram, or fails to do so correctly, completely or in due time,".

c) Point 9 becomes Point 8, and the reference "Section 12, Paragraph 3, Sentence 2," is deleted.

d) Points 10 to 12 become Points 9 to 11.

Artikel 2

Amendment to the Ordinance on the Manufacture of Veterinary Medicinal Products and Active Substances

The Ordinance on the Manufacture of Veterinary Medicinal Products and Active Substances, of 9 March 2023 (BGBI. [BGBl. 2023 I No. 66, p. 2), is amended as follows:

1. Section 1 is replaced by the following Section 1:

§ 1"

Scope of application

(1) This Ordinance governs the requirements regarding Good Manufacturing Practice for:

1. veterinary medicinal products exempted from the authorisation requirement pursuant to Section 4, Paragraph 1, of the Veterinary Medicinal Products Act,

2. veterinary medicinal products and veterinary-medical technical products subject to authorisation pursuant to Section 22, Paragraph 1, of the Veterinary Medicinal Products Act,

3. inactivated immunological veterinary medicinal products pursuant to Article 2, Paragraph 3, of Regulation (EU) 2019/6, in the version of 23 November 2022, and

4. active substances serving as starting materials for veterinary medicinal products and veterinary-medical technical products referred to in Point 2.

(2) This Ordinance is applicable to:

1. persons, establishments, and facilities manufacturing veterinary medicinal products and veterinary-medical technical products referred to in Paragraph 1, Points 1 to 3, and

2. the manufacture and importation of active substances serving as starting materials for veterinary medicinal products referred to in Paragraph 1, Point 2.

(3) The requirements of this Ordinance shall not apply to:

1. veterinary medicinal products that have not been prepared commercially and in the preparation of which no industrial process has been used,

2. substances listed in the Homoeopathic Pharmacopoeia (Section 3 of the Pharmacopoeia), of 25 July 1978 (BGBl. I p. 1112), as last amended by the notice of 16 June 2025 (BAnz AT 01.07.2025 B6), which are used for the manufacture of homoeopathic preparations serving as starting materials for homoeopathic veterinary medicinal products, and

3. active substances for veterinary medicinal products exempted from authorisation pursuant to Section 4, Paragraph 1, of the Veterinary Medicinal Products Act.

Compliance with comparable standards and procedures shall ensure that the quality of manufacturing and testing is equivalent to the requirements laid down in this Ordinance.

(4) This Ordinance does not apply to the collection and disposal of veterinary medicinal product waste."

2. Section 2 is replaced by the following Section 2:

§ 1"

Manufacturing requirements

(1) For persons, establishments, and facilities referred to in Section 1, Paragraph 2, Point 1, Articles 3 to 45 of Implementing Regulation (EU) 2025/2091, as amended on 16 April 2026, apply accordingly regarding compliance with Good Manufacturing Practice. For the manufacture and importation of active substances referred to in Section 1, Paragraph 2, Point 2, Articles 3 to 76 of Implementing Regulation (EU) 2025/2154, as amended on 17 October 2025, apply accordingly regarding compliance with Good Manufacturing Practice.

(2) Notwithstanding Paragraph 1, the following requirements apply to persons, establishments, and facilities referred to in Section 1, Paragraph 2, Point 1, that manufacture inactivated immunological veterinary medicinal products pursuant to Article 2(3) of Regulation (EU) 2019/6, as amended on 23 November 2022:

1. When producing inactivated immunological veterinary medicinal products in accordance with Article 2(3) of Regulation (EU) 2019/6, in the version dated 12 November 2022, it must be ensured that only standard procedures that are adequately described in the specialist literature are used.

2. The holder of a manufacturing license in accordance with Section 35b, Paragraph 1, of the Veterinary Medicinal Products Act must ensure that the production and testing of the inactivated immunological veterinary medicinal products in accordance with Article 2(3) of Regulation (EU) 2019/6, in the version dated 23 November 2022, is validated according to the current state of science and technology. By derogation from Sentence 1, the validation of the production of individual inactivated immunological veterinary medicinal products in accordance with Article 2(3) of Regulation (EU) 2019/6, in the version of 23 November 2022, can be carried out jointly for several veterinary medicinal products prepared in the same way."

3. Sections 3 and 4 are deleted.

Artikel 3

Amendment to the Ordinance on the Use of Antibiotics in Veterinary Medicine

The Ordinance on the Use of Antibiotics in Veterinary Medicine, of 2 January 2023 (BGBl. 2023 I No 3), is amended as follows:

1. In Section 2, Sentence 1, the term “calendar half-year” is replaced by the term “calendar year”.

2. The Annex is amended as follows:

a) Point 1 is amended as follows:

a%6) In Sentence 1, the term “half-yearly” is replaced by the term “annual”.

b%6) Sentence 2 is amended as follows:

a%7%7) In the information before Letter a, the word “semi-annual” is replaced by the word “annual”.

b%7%7) In Letter b, Double Letters aa and bb, the word “semi-annual” is replaced by the word “annual”.

b) In Point 2, Sentences 1 and 2, the word “six-monthly” is replaced by the word “annual”.

Artikel 4

Entry into force

Articles 2 and 3 shall enter into force on 1 February 2027. Otherwise, the Regulation enters into force on the day following its publication.

Approved by the Federal Council.

EU legal acts:

1. Regulation (EU) 2019/6 of the European Parliament and of the Council, of 11 December 2018, on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43; L 163, 20.6.2019, p. 112; L 326, 8.10.2020, p. 15; L 241, 8.7.2021, p. 17; L 151, 2.6.2022, p. 74), which was last amended by Delegated Regulation (EU) 2023/183, of 23 November 2022, (OJ L 26, 30.1.2023, p. 7)

2. Commission Implementing Regulation (EU) 2024/1973, of 18 July 2024, establishing a list of antimicrobial medicinal products which are not to be used in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 of the European Parliament and of the Council or which are to be used in accordance with those Articles only under certain conditions (OJ L, 2024/1973, 19.7.2024)

3. Commission Implementing Regulation (EU) 2025/2091, of 17 October 2025, establishing good manufacturing practices for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L, 2025/2091, 27.10.2025), most recently amended by Implementing Regulation (EU) 2026/857, of 16 April 2026 (OJ L, 2026/857, 17 April 2026), has been amended,

4. Commission Implementing Regulation (EU) 2025/2154, of 17 October 2025, establishing good manufacturing practices for active substances used as starting materials for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L, 2025/2154, 27.10.2025)