Ministerial draft of the Federal Ministry of Food and Agriculture

Draft Act amending the Veterinary Medicinal Products Act and the Pharmacies Act[1), 2)]

Of [date]

The Bundestag, with the approval of the Bundesrat, has passed the following Act:

Article 1

Amendment of the Veterinary Medicinal Products Act

The Veterinary Medicinal Products Act of 27 September 2021 (Federal Law Gazette (BGBl.) I p. 4530), as last amended by Article 1 of the Ordinance of 14 March 2024 (Federal Law Gazette (BGBl.) 2024 I No. 97), is amended as follows:

1. The table of contents is amended as follows:

   a) After the entry regarding § 44, the following entry regarding § 44a is inserted:

   ‘§ 44a Dispatch of veterinary medicinal products subject to veterinary prescription’.

   b) After the entry regarding § 61, the following entries regarding Subsection 6 are inserted:

   ‘Subsection 6

   Provisions on veterinary notifications on the use of antimicrobial medicinal products in accordance with Delegated Regulation (EU) 2021/578

   § 61a Veterinary notifications on the use of antimicrobial medicinal products in accordance with Delegated Regulation (EU) 2021/578

   § 61b Processing and transmission of data collected in accordance with § 61a’.

   c) The entries regarding the current section 4, subsections 6 to 11 become the entries regarding section 4, subsections 7 to 12.

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1) This Act serves to implement
- Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals (OJ L 123, 9.4.2021, p. 7) and
- Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 35, 17.2.2022, p. 7; L 125, 28.4.2022, p. 4).

2) 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, 17.9.2015, p. 1).

d) The words ‘and amending further provisions’ are added to the entry regarding § 94.

e) The entry regarding § 95 is replaced by the following entries regarding §§ 95 and 96:

‘§ 95 Transitional provision on the occasion of the Act amending the Veterinary Medicinal Products Act and the Pharmacies Act

§ 96 Evaluation’.

2. In § 26, first sentence, the words ‘veterinary medicinal’ are replaced by the words ‘veterinary medicinal technology’.

3. After § 44, the following § 44a is inserted:

‘§ 44a

Dispatch of veterinary medicinal products subject to veterinary prescription

(1) The dispatch of veterinary medicinal products and veterinary medicinal technology products subject to veterinary prescription shall not be allowed unless otherwise provided for in paragraphs 2 to 5.

(2) Pharmacies may, within the scope of this Act, make available on the market, by dispatch, veterinary medicinal technology products subject to veterinary prescription and, with official authorisation for dispatch, veterinary medicinal products subject to veterinary prescription, which are authorised exclusively for use in animals that are not used for the production of foodstuffs; the detailed provisions shall be laid down by the Pharmacies Act.

(3) In the context of the operation of a veterinary dispensing station, the veterinarian may, in individual cases, send veterinary medicinal products and veterinary medicinal technology products subject to veterinary prescription within the scope of this Act to the keeper of animals treated by the veterinarian which are not used for the production of foodstuffs, by transport service providers. Dispatch shall be limited to the quantity required for short-term further treatment.

(4) The veterinary prescription must have been issued in advance by the dispatching veterinarian himself or herself. Article 105(3) of Regulation (EU) 2019/6 shall remain unaffected.

(5) The veterinarian shall ensure that:

1. a suitable transport service provider is selected;

2. the transport and supply of the veterinary medicinal product are carried out as indicated by the manufacturer or on the outer packaging and under the conditions laid down for that purpose in the marketing authorisation for the veterinary medicinal product;

3. the veterinary medicinal product is packaged, transported and supplied in such a way as to maintain its quality and efficacy, in particular ensuring that the temperature requirements applicable to the veterinary medicinal product are complied with during transport until it is supplied to the recipient; in the case of veterinary medicinal products which are particularly sensitive to temperature, compliance

must be verifiable by means of temperature controls carried by the transport service provider; and

4. a track and trace system is maintained by the transport service provider.'

4. § 45 is amended as follows:

a) The following sentence is added to paragraph (8):

'The evidence of expertise shall not be required in the case of veterinary medicinal products exempted under § 4.'

b) Paragraphs (10) and (11) are repealed.

5. In § 49(7), the word 'in' is replaced by the word 'of'.

6. In § 53(4), the introductory part of the sentence is worded as follows:

'The Federal Ministry of Food and Agriculture shall also be authorised, by means of an order in council, with the consent of the Bundesrat, to fix as follows:'.

7. After § 61, the following subsection 6 is inserted:

'Subsection 6

Provisions on veterinary notifications on the use of antimicrobial medicinal products in accordance with Delegated Regulation (EU) 2021/578

§ 61a

Veterinary notifications on the use of antimicrobial medicinal products in accordance with Delegated Regulation (EU) 2021/578

(1) Veterinarians who treat:

1. dogs and cats;

2. ducks, geese, sheep, goats, fish of the species Atlantic salmon, rainbow trout, sea bream, sea bass and carp, horses and rabbits used for the production of foodstuffs; and

3. as fur animals kept foxes and minks

with the medicinal products with antibiotic effect referred to in points 3, 4(1) to (5) and (10) of the Annex to Delegated Regulation (EU) 2021/578, shall notify the competent higher federal authority for the purposes referred to in Article 57 of Regulation (EU) 2019/6 and in Section 61b(2), sentence 1 in accordance with paragraph (2).

(2) The following are to be notified:

1. the information on the prescribed, used or supplied medicinal product referred to in points 4 to 6 and 9 of Annex II to Regulation (EU) 2022/209;

2. the name of the attending veterinarian and the practice address;

3. the total quantity of those prescribed, used or supplied medicinal products; and

4. the respective species of animals treated.

The indication of the name referred to in point 2 of the first sentence may be replaced by the indication of the practice name. The notification referred to in paragraph (1) shall be made for each half-year by 14 January of the following year.

(3) The notification referred to in paragraph (1) shall be made electronically to the competent higher federal authority. The prescribed notification may be made by third parties, provided that the veterinarian has notified the competent higher federal authority electronically, mentioning the third party.

(4) The competent higher federal authority shall have the power to collect, store and use the data referred to in paragraph (2) for the purposes referred to in paragraph (1).

§ 61b

Processing of data collected in accordance with § 61a

(1) Without prejudice to Article 57 of Regulation (EU) 2019/6, the data collected in accordance with § 61a may be processed in accordance with paragraphs (2) and (3).

(2) By 15 February of the year following the reporting period, the Federal Office for Consumer Protection and Food Safety shall notify the Federal Institute for Risk Assessment, in pseudonymised form, of the annually collected data referred to in point 9 of Annex 2 for the purpose of risk assessment in the field of antimicrobial resistance. The Federal Office for Consumer Protection and Food Safety shall determine the procedure for establishing the pseudonym. The procedure shall be designed in such a way that the Federal Institute for Risk Assessment cannot restore the personal references to the data reported to it. On the basis of the data submitted to it, the Federal Institute for Risk Assessment shall carry out the risk assessment. The Federal Institute for Risk Assessment shall draw up an annual non-personal report on the results of the risk assessment on the data of the previous year referred to in the first sentence. The reporting period shall be a calendar year. The Federal Institute for Risk Assessment shall publish the report by 31 August of the year following the reporting period.

(3) The Federal Institute for Risk Assessment shall be authorised to collect, store and use the data referred to in the first sentence of paragraph (2) in pseudonymised form for the purpose referred to in the fourth sentence of paragraph (2). The data may also be used for scientific purposes by the Federal Institute for Risk Assessment in pseudonymised form.’

8. The current subsections 6 to 11 become subsections 7 to 12.

9. In § 68(4) second and third sentences are worded as follows:

‘In addition, pursuant to Article 104 of Regulation (EU) 2019/6, the federal higher authority shall provide information on the retail sale of veterinary medicinal products at a distance via a publicly accessible Internet portal. That Internet portal shall be connected to the Internet portal operated by the European Medicines Agency containing information on the retail sale of veterinary medicinal products at a distance and on the common logo referred to in Article 104(9) of Regulation (EU) 2019/6.’

10. § 69 is amended as follows:

    a) Paragraph (3) is repealed.

    b) Paragraphs (4) to (8) become paragraphs (3) to (7).

    c) In new paragraph (7), the reference ‘Paragraph 7’ is replaced by the reference ‘Paragraph 6’.

11. In § 76(1), third sentence, and (2), the entry ‘131’ is replaced by ‘134’.

12. In § 88 the point 4 is worded as follows:

    4. ‘ contrary to § 38(1)(2) or (3), manufactures or makes available on the market a veterinary medicinal product, an active substance or a veterinary medicinal technology product, or’.

13. § 89 Paragraph (2) is amended as follows:

    a) After point 7, the following point 8 is inserted:

        8. ‘ contrary to § 44a(1), dispatches a veterinary medicinal product or a veterinary medicinal technology product,’.

    b) The current points 8 to 10 become points 9 to 11.

    c) The current point 11 becomes point 12 and the words ‘§ 56(1), first sentence, fails to notify, fails to notify correctly, completely’ are replaced by the words ‘§ 56(1), first sentence or ‘§ 61a(1), first sentence fails to notify, fails to notify correctly, completely or in the prescribed manner’.

    d) The current points 12 to 17 become points 13 to 18.

14. The words ‘and amending further provisions’ shall be added to the entry regarding § 94.

15. After § 94, the following § 95 is inserted:

§ 2‘

Transitional provision on the occasion of the Act amending the Veterinary Medicinal Products Act and the Pharmacies Act

By way of derogation from § 61a (2) third sentence, the first notification shall be made for

1. dogs and cats until 28 January 2026;

2. ducks, geese, sheep, goats, fish of the species Atlantic salmon, rainbow trout, sea bream, sea bass and carp, horses and rabbits used for the production of foodstuffs until 14 January 2027; and

3. as fur animals kept foxes and minks until 14 January 2030.’

16. The current § 95 becomes § 96.

17. Annex 2 is amended as follows:

a) In point 8, the full stop at the end is replaced by a comma.

b) The following point 9 is added:

9. ‘ Information in accordance with § 61a (2) first and second sentences:

a) the information on the prescribed, used or supplied medicinal product referred to in points 4 to 6 and 9 of Annex II to Regulation (EU) 2022/209;

b) pseudonymised indication of the name of the attending veterinarian or the name of the practice and the practice address;

c) the date of prescription or first use or the date of dispensing of the medicinal product;

d) the total quantity of those prescribed, used or supplied medicinal products;

e) the respective species of animals treated;

f) the number of animals treated; and

g) the number of days of treatment.’

Article 2

Amendment of the Pharmacies Act

The Pharmacies Act in the version published on 15 October 1980 (Federal Law Gazette (BGBl.) I p. 1993), as last amended by Article 3 of the Act of 19 July 2023 (Federal Law Gazette (BGBl.) 2023 I No. 197), is amended as follows:

18. § 11a is amended as follows:

a) In the first sentence, the words in the part of the sentence before point 1 ‘§ 43(1) first sentence of the Medicinal Products Act’ is replaced by the words ‘§ 43(1) first sentence of the Medicinal Products Act and in accordance with §§ 43 and 44a(2) of the Veterinary Medicinal Products Act’.

b) In the second sentence, the words ‘medicinal products obtainable only in pharmacies’ are replaced by the words ‘medicinal products obtainable only in pharmacies intended for human use as well as non-prescription veterinary medicinal products’.

19. § 28a is amended as follows:

‘§ 28a

A licence issued in the period from 28 January 2022 to 31 December 2025 for the dispatch of medicinal products obtainable only in pharmacies pursuant to § 43 (1) first sen-

tence of the Medicinal Products Act shall also be deemed to be a licence for the dispatch of veterinary medicinal products obtainable only in pharmacies pursuant to §§ 43 and 44a (2) of the Veterinary Medicinal Products Act.'

Article 3

Entry into force

This Act shall enter into force on 1 January 2026.