Explanatory notes

A. General part

I. Objective of and need for the provisions

The rules laid down in Article 57 of Regulation (EU) 2019/6 on veterinary medicinal products require Member States to submit annually comprehensive data on the use of antimicrobial medicinal products in animals to the European Medicines Agency (EMA). Details of data collection are set out in Delegated Regulation (EU) 2021/578 and Implementing Regulation (EU) 2022/209.

Member States shall comply with the following timetable for the submission of data on the use of antibiotics in different animal species to the European Medicines Agency:

(a) within two years from 28 January 2022, data for at least the species and categories listed in Commission Implementing Decision 2013/652/EU in the version in force on 11 December 2018;

(b) within five years from 28 January 2022, data for all other food-producing animal species; and

(c) within eight years from 28 January 2022, data for as fur animals kept foxes and minks.

Section 45(10) of the Veterinary Medicinal Products Act (Tierarzneimittelgesetz – TAMG) also requires veterinarians to notify the competent higher federal authority electronically, for the first time by 28 January 2026, of the type and quantity of medicinal products containing substances with an antibacterial effect they used on dogs and cats during the previous calendar year.

The legislative amendments to (a) were transposed into the TAMG by the Act of 21 December 2022 (Federal Law Gazette (BGBl.) I p. 2852).

II. Main content of the draft

Section 4, Subsection 6 introduces rules for the use of medicinal products with antibiotic effect in food-producing animal species not previously covered, as well as dogs, cats and as fur animals kept foxes and minks, in order to comply with the EU uniform antibiotic data collection obligations under Article 57 of Regulation (EU) 2019/6 on veterinary medicinal products.

III. Alternatives

None. Other solutions, such as sub-statutory rules, are not possible for reasons of legal clarity and legal certainty.

IV. Legislative powers

The provisions in Articles 1 and 2 of the Act are based on the Federal Government's legislative powers in the field of pharmacy law and medicinal products law pursuant to Arti-

cle 74(1)(19) of the Basic Law (Grundgesetz – GG) and the legislative powers for criminal law under Article 74(1)(1) of the GG.

V. Compatibility with European Union law and international treaties

The draft Act is compatible with the law of the European Union and the international treaties concluded by the Federal Republic of Germany. The Act implements Article 57 of Regulation (EU) 2019/6 and the implementing acts adopted on the basis thereof.

VI. Impact of the legislation

1. Legal and administrative simplification

Since the amending law in Article 1 essentially creates the necessary implementing provisions required for the implementation of directly applicable EU law, further legal and administrative simplification cannot be achieved.

The introduction of veterinary medicinal products subject to veterinary prescription for the keepers of non-food-producing animals by veterinary dispensing stations has been simplified compared to the requirements laid down for their dispatch by pharmacies.

2. Sustainability aspects

A sustainability assessment has been carried out in accordance with § 44(1)(4), of the Joint Rules of Procedure of the Federal Ministries (GGO). The regulations contained herein are sustainable in line with the German Sustainability Strategy and support the 3rd Sustainable Development Goal ‘Ensure healthy lives and promote well-being for all at all ages’. The regulations contribute to achieving the objectives of sustainability indicators 3.1.a and 3.1.b while maintaining the profitability of livestock farming, as they maintain the existing high level of protection and incorporate it into the new European legal framework. Furthermore, the principle of sustainable development points 3b and 4c) is taken into account, as the law lays down rules to record data on the antibiotic consumption in animals and thus to the EU’s long-term objective of minimising the use of antibiotics in livestock farming.

3. Budgetary expenditure exclusive of compliance costs

By commissioning the HI-Tier-Länder database[1)] to expand the veterinary medicinal products database, the Federal Government is ensuring that veterinarians can report all three levels of notification via a single reporting portal or database. As the EU-related data collection for stages 2 and 3 is not enforcement data for the monitoring activities of the Länder, it is to be provided exclusively by the Federal Government as the controller and thus also financed.

For the one-off extension of the data structures for the implementation of stage 3 (dog, cat) at the beginning of 2025, around EUR 100,000 are assumed in personnel and operating costs (one-off expenditure). EUR 100,000 is also assumed for the extension of the HIT database in 2025 for level 2 (cash-effective only in the 2026 financial year). The estimated costs consist mainly of personnel costs (for approximately 2 full-time equivalents) for programming as well as for technical preparations, coordination, organisation, testing and preparation of assistance texts and guidance. In addition, further operating costs (includ-

[1]) The traceability and information system for animals (abbreviated to HI-Tier or HIT) is an official German database in which keepers of sheep, goats, pigs and cattle and their stock changes, in particular movements between holdings, must be reported. The database is operated on behalf of the Länder and is located at the Bavarian State Ministry of Food, Agriculture and Forestry.

ing one-off acquisition of additional server capacity) arise as part of the database extension.

In day-to-day operations, i.e. in the well-established reporting behaviour or in 'normal operation', which may only occur after several reporting cycles, around EUR 40,000 for each of the stages 3 (cash-effective from the 2026 financial year) and 2 (cash-effective from the 2027 financial year) are assumed in ongoing personnel and operating costs for system administration, system support and use, and for the service desk. Here too, the actual amount depends to a large extent on the personnel required to deal with user requests and technical assistance.

In addition, the Federal Government must bear the costs incurred by the Länder for issuing registration numbers and personal identification numbers to veterinarians for the use of the HIT database, provided that these costs were incurred solely as a result of the use of the database for the purposes of reporting antibiotic consumption quantities. One-off budget expenditure of around EUR 13,900 (cash-effective in the 2025 financial year) and annual budget expenditure of around EUR 8,800 from the 2026 financial year are expected. These are included in the household expenditure on dogs and cats.

Further details can be found in the following table:

Financial years (cash-effective expenditure) [in thousand euros]					
	2025	**2026**	**2027**	**2028**	**2029**
advanced stage 3 (dog/cat) from 1.1.2025					
- one-off expenditure (establishment of databases, allocation of registration numbers)	114				
- ongoing expenditure (normal operation, allocation of registration numbers)		49	49	49	49
Stage 2 (sheep/goats) from 1.1.2026					
- one-off expenditure (establishment of database)		100			
- ongoing expenditure (normal operation)			40	40	40
Total budgetary expenditure	**114**	**149**	**89**	**89**	**89**

In addition, the Federal Government and the Länder do not incur any further budgetary expenditure in excess of the compliance costs set out in point 4. The additional need for material and human resources is to be compensated financially and in accordance with Section 10 (Federal Ministry of Food and Agriculture).

4. Compliance costs

4.1 Citizens

The net compliance costs for citizens are around EUR 799,000.

Requirement (EU/ national)	**§; description of the requirement; type of requirement**	**Justification for annual cost change**	**Annual compliance costs (in thousand EUR)**	**Justification for one-time costs**	**One-time compliance costs (in thousand EUR)**
1a	Dispatch of veterinary medicinal products subject to veterinary prescription –	Travel and material costs: -108000 Transit operations x EUR 2.60	-281		

Requirement (EU/ national)	§; description of the requirement; type of requirement	Justification for annual cost change	Annual compliance costs (in thousand EUR)	Justification for one-time costs	One-time compliance costs (in thousand EUR)
	elimination of the repeat visit to the practice (§ 44a, as amended)				
(1b)	Dispatch of veterinary medicinal products subject to veterinary prescription – dispatch costs for animal keepers (§ 44a, as amended)	Material costs: 108000 Transit operations x EUR 10.00	+1080		
Total (in thousand EUR)			+799		

Requirement 1: Dispatch of veterinary medicinal products subject to veterinary prescription – elimination of the repeat visit to the practice by animal keepers (1a) and the dispatch costs (1b) (§ 44a, as amended).

The dispatch of veterinary medicinal products subject to veterinary prescription is in principle prohibited. Dispatch shall be permitted only if the conditions laid down in paragraphs 2 to 4 are fulfilled. This allows veterinarians to dispatch veterinary medicinal products and veterinary medicinal technology products subject to veterinary prescription to keepers of treated animals that are not used for the production of food. However, dispatch shall be limited to the quantity required for short-term further treatment.

As a result of the dispatch of veterinary medicinal products subject to veterinary prescription, the current path to veterinary practice has been removed for citizens or for commercial animal keepers (business). According to the guidance paper on the quantification of compliance costs, an average travel time of 20 minutes or average travel and material costs of EUR 2.60 are assumed. Based on the estimation of some countries and associations, it is assumed that an average of 12 transit operations per practice can be expected per year.[2)] With a total number of veterinary practices of around 11,000, minus around 1,000 practices with a pure focus on farmed animals not affected by the dispatch system, the number of potentially affected practices is around 10,000. It is therefore assumed that around 120,000 transit operations per year will be carried out.

This results in a reduction in time of 2.4 million minutes or 40 000 hours. The travel and material costs are therefore reduced by a total of EUR 312,000 (relief). Assuming that around 90 % of the 120,000 transit operations are accounted for by citizens' animals and only 10 % for commercial animal keepers, this results in a differentiated relief of around EUR 281,000 for citizens and around EUR 31,000 for commercial animal keepers (business). On the other hand, citizens are charged an average dispatch cost of EUR 10.00 per transit operation (with/without cooling). For around 108,000 transit operations, the additional material expenditure is therefore 1.08 million euro.

[2]) Due to insufficient data and lack of experience, the few relevant opinions from the Länder and associations in this regard have been used. Feedback on the number of future annual transit operations per practice ranges from one to two or eight, up to six to twelve dispatch operations. It is therefore reasonable to assume that the dispatch will take place at least once a month and that twelve transit operations per year will take place per practice.

In Germany, veterinary medicinal products subject to veterinary prescription are obtained from pharmacies only to a very limited extent, as a result of veterinary dispensing legislation. In order to obtain veterinary medicinal products subject to veterinary prescription in the pharmacy, the animal keeper must present a veterinary prescription in the pharmacy. Since, as a general rule, animal keepers are handed over to veterinary medicinal products subject to veterinary prescription in person in the pharmacy, the dispatch of veterinary medicinal products subject to veterinary prescription by pharmacies plays a very limited role and can be disregarded in the calculation of compliance costs.

4.2 Business

For businesses, there is a change in the annual compliance costs in the form of a burden of around EUR 24.567 million and a one-off total conversion effort of around EUR 1 million. Of these, EUR 586,000 are to be allocated to the category of introduction or adaptation of digital process sequences, EUR 304,000 to the category of acquisition or retrofitting of machinery, equipment, buildings and infrastructure, and EUR 119,000 to the category of training costs.

Of which administrative costs arising from information obligations

A new obligation to provide information has been introduced, resulting in a burden of EUR 23.81 million in red tape resulting from information obligations.

Below is an estimate of the compliance costs of the business (veterinarians, commercial animal keepers) for the individual requirements.

Requirement (EU/ national)	**§; description of the requirement; type of requirement**	**Justification for annual cost change**	**Annual compliance costs (in thousand EUR)**	**Justification for one-time costs**	**One-time compliance costs (in thousand EUR)**
1a (national)	Dispatch of veterinary medicinal products subject to veterinary prescription – elimination of the new practice visit by commercial animal keepers (§ 44a, as amended); additional requirement	Travel and material costs: -12000 Transit operations x EUR 2.60	-31		
1b (national)	Dispatch of veterinary medicinal products subject to veterinary prescription – dispatch costs for commercial animal keepers (§ 44a, as amended); additional requirement	Material costs: 12000 Transit operations x EUR 10.00	+120		
1c (national)	Dispatch of veterinary medicinal	Personnel costs: 10000	+92		

Requirement (EU/ national)	§; description of the requirement; type of requirement	Justification for annual cost change	Annual compliance costs (in thousand EUR)	Justification for one-time costs	One-time compliance costs (in thousand EUR)
	products subject to veterinary prescription by veterinarians to animal keepers – transit operation by veterinary practice (§ 44a, as amended); additional requirement	Practices x 12 transit operations per year per practice x 2 min/60 min x EUR 22.90			
2a (national)	Veterinary notifications on the use of antimicrobial medicinal products in accordance with Delegated Regulation (EU) 2021/578 (§ 61a in conjunction with § 95, as amended) for dogs and cats (advanced stage 3); Information obligation	732500 Notifications x 33 min/60 min x EUR 59.10	+23810	(a) Personnel costs: 75 % of 4,950 practices x 44 min/ 60 min x EUR 59.10 + Material costs: 75 % of 4,950 x EUR 75,00 (b) Personnel costs: 75 % of 550 practices x 54 min/ 60 min x EUR 59.10 + Material costs: 75 % of 550 x EUR 500,00 (c) Personnel costs: 75 % of 5,500 practices x 22 min/ 60 min x EUR 59.10	+756
2b (EU)	Veterinary notifications on the use of antimicrobial medicinal products in accordance with Delegated Regulation (EU) 2021/578 (§ 61a in conjunction with § 95, as amended) for ducks, geese, sheep, goats, horses, etc. (stage 2); Information obligation	17710 Notifications x 33 min/ 60 min x EUR 59.10	+576	(a) Personnel costs: 25 % of 4,950 practices x 44 min/ 60 min x EUR 59.10 + Material costs: 25 % of 4,950 x EUR 75,00 (b) Personnel costs: 25 % of 550 practices x 54 min/ 60 min x EUR 59.10 + Material costs: 25 % of 550 x EUR 500,00 (c) Personnel costs: 25 % of 5,500 practices x 22 min/ 60 min x EUR 59.10	+253

Requirement (EU/ national)	§; description of the requirement; type of requirement	Justification for annual cost change	Annual compliance costs (in thousand EUR)	Justification for one-time costs	One-time compliance costs (in thousand EUR)
2c (EU)	Veterinary notifications on the use of antimicrobial medicinal products in accordance with Delegated Regulation (EU) 2021/578 (§ 61a in conjunction with § 95, as amended) for fur animals (stage 3); Information obligation	No commercial fur farming in Germany since 2019	0		
Total (in thousand EUR)			+24567		+1009
of which arising from information obligations (in thousand EUR)			+23810		+756
Total, transposition of EU law (in thousand EUR)			+576		+253
Number of requirements			2		
of which information obligations			1		

Requirement 1: Dispatch of veterinary medicinal products subject to veterinary prescription – elimination of the new practice (1a) and payment of dispatch costs (1b) by commercial animal keepers, as well as personnel costs for the transit operation (1c) (§ 44a, as amended)

See information on requirement 1 for citizens. The elimination of the repeat visit to the practice (1a) and thus the elimination of travel time results in a relief of around EUR 31,000 for commercial animal keepers (business).

However, commercial animal keepers are charged the dispatch costs (1b) of EUR 10.00 per transit operation. On the assumption above that out of the 120,000 transit operations around 90 % are accounted for by citizens' animals and only 10 % for commercial animal keepers, there are therefore 12,000 transit operations and an additional material expenditure of EUR 120,000.

The additional time spent per transit operation (1c) by a veterinary officer is estimated to be around two minutes for documentation and dispatch. A low qualification level according to the wage cost table (Q health and social services) of EUR 22.90 per hour results in personnel expenditure of around EUR 92,000.

Requirement 2: Veterinary notifications on the use of antimicrobial medicinal products in accordance with Delegated Regulation (EU) 2021/578 (§ 61a in conjunction with § 95, as amended)

The requirement states that in future all antibiotic applications, in line with the requirements of Article 57 of Regulation (EU) 2019/6, per pack size and animal species and year for the treatment of dogs and cats (nationally advanced stage 3, from 2025), 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 (stage 2, from 2026) and as fur animals kept foxes and minks (stage 3, from 2029)[3)] must be recorded and reported by veterinarians to the HIT database. The notification shall be made by electronic means.

According to statistics from the Federal Chamber of Veterinary Surgeons (Bundestierärztekammer (BTK)), there are around 11,000 veterinary practices and clinics in Germany. According to the veterinary associations, around 70 % of the total 11,000 veterinary practices treat dogs and cats, around 5 % sheep, around 2 % goats, ducks, geese, rabbits and fish and around 13 % horses. The pack sizes per animal species required for the aggregated reporting, as well as the number of notifications to be made, can be found in the table below.

Legislative Provision	**Animal species**	**Veterinary practices**	**Number of antibiotic preparations/pack sizes[4)]**	**Number of notifications**
(1)	(2)	(3)	(4)	(5) = (3) x (4)
Section 61a(1)(1)	Dogs	7,325 (= 70 % of 11,000)	100	732,500
	Cats			
Section 61a(1)(2)	Sheep[5)]	550 (= 5 % of 11,000)	5	2,750
	Goats	220 (= 2% of 11,000)	3	660
	Ducks			
	Goose			
	Rabbits			
	Fishes			
	Horses	1430 (= 13 % of 11,000)	10	14,300
			Total number of notifications	**750,210**

On the basis of the standard activities in the guidance paper on the quantification of compliance costs and according to the assessment of the veterinary associations, there is an estimated additional ongoing time due to the new veterinary reporting obligations for veterinarians to aggregate and transmit the data to be reported of 33 minutes.[6)] With a wage cost rate (high qualification level) of EUR 59.10, the additional annual compliance costs

[3)] There will be no compliance costs for as fur animals kept foxes and minks (§ 61a(1)(3) TAMG, as amended), as the closure of the last fur farm in Germany in 2019 means that there is no longer any economic fur farming in Germany (cf. Animal Welfare Report (2023), p. 40; cf. URL: https://www.tierschutzbund.de/tiere-themen/tierschutz-im-alltag/pelz [accessed on 19.3.2024]).

[4)] Data are based on estimates provided by the veterinary associations.

[5)] According to information from the veterinary associations, a differentiation was made here, as the use of antibiotics in sheep is somewhat higher than in goats, ducks, geese, etc.

[6)] 3 Minutes ‘Familiarisation with the information obligation’ (simple complexity); 10 Minutes ‘Procurement of data’ (medium complexity); 5 Minutes ‘Filling out forms, labelling, marking’ (medium complexity); 10 Minutes ‘Verification of data’ (medium complexity); 3 Minutes ‘Processing of data’ (simple complexity); 1 Minute ‘Transmission and publication of data’ (simple complexity); 1 Minute ‘Copying, archiving, distributing’ (simple complexity).

for stage 2 animal species are around EUR 576,000 (2a (EU); 17710 Notifications x 33 min/60 min x EUR 59.10) and for stage 3 animal species (dog, cat) approximately EUR 23.81 million (2b (national); 732500 Notifications x 33 min/60 min x EUR 59.10).

As a result of the implementation of stage 1 with the 2022 Act amending the Veterinary Medicinal Products Act regarding collection of data on medicinal products with antibiotic effect and amending other provisions, according to the Federal Statistical Office, 5,500 predominantly user-advising but also small-scale animal care practices, which take care of livestock due to the lack of livestock practitioners of small livestock populations (e.g. private chicken farms), are already affected by the data collection. It is therefore assumed that the remaining approximately 5,500 practices will be added through the implementation of stages 2 and 3 (mainly small animal practices focusing on dog/coat, horses), which have not yet been required to report to the HIT database.[7)]

In view of the comments received from some Länder and associations, it is likely that ten per cent of the above veterinary practices (about 550 veterinary practices in particular from rural areas) will have to switch to an electronic system as a result of this requirement, thus procuring the necessary terminal equipment and interfaces and, if necessary, access to the HIT database. For 90 % of veterinary practices (around 4,950 practices), the material costs are based exclusively on the extension of their respective modules for processing and transferring data. This procurement measure should be approximately EUR 75 by analogy with the calculations of the Federal Statistical Office for the implementation of stage 1. In addition, a time expenditure of 44 minutes[8)] can be assumed for the procurement. The costs are higher for around 550 veterinary practices, as terminal equipment and a complete IT program or interfaces to process and transmit the data have to be purchased. It is assumed that the procurement will cost around EUR 500, plus an additional ten minutes, resulting in a total time expenditure of 54 minutes.

An additional one-off time expenditure of around 22 minutes (medium complexity) is assumed for the 5,500 practices for participation in further education and training measures based on the standard activities in the guidance paper. With a wage cost rate of EUR 59.10, this results in a one-off compliance expenditure of EUR 119,000.

This together results in a one-off compliance expenditure of around EUR 1.009 million. Of these, EUR 586,000 are to be allocated to the category of introduction or adaptation of digital process sequences, EUR 304,000 to the category of acquisition or retrofitting of machinery, equipment, buildings and infrastructure, and EUR 119,000 to the category of training costs. Broken down according to national target 2a (approx. 75 %) and EU-related target 2b (approx. 25 %), the following differentiated conversion burden is thus obtained.

The one-off implementation costs are therefore calculated as follows:

(a) for 90 % of the practices affected (IT upgrade):

Personnel expenditure: 4,950 Practices x 44 min/60 min x EUR 59.10 = EUR 215,000. 75 % of which advanced stage 3 (national) amounting to EUR 161,000 and 25 % stage 2 (EU) amounting to EUR 54,000.

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7) It is not possible to further differentiate the veterinary practices or the number of cases according to the above animal species, as several animal species are often treated in one practice and this could lead to incorrect case numbers and calculations. For this reason, the total number of new veterinary practices (the vast majority of which are small animal practices focusing on dogs/cats) is expected to increase.

8) 5 Minutes ‘Familiarisation with the information obligation’ (medium complexity); 10 Minutes ‘Procurement of data’ (medium complexity); 5 Minutes ‘Filling out forms, labelling, marking’ (medium complexity); 22 Minutes ‘Training and further education attendance’ (medium complexity); 1 Minute ‘Verification of data’ and 1 minute ‘Execution of payment orders’ (simple complexity in each case).

Material expenditure: 4,950 Practices x EUR 75.00 = EUR 371,000. 75 % of which advanced stage 3 (national) amounting to EUR 278,000 and 25 % stage 2 (EU) amounting to EUR 93,000.

(b) for 10 % of the practices affected (IT procurement):

Personnel expenditure: 550 Practices x 54 min/60 min x EUR 59.10 = EUR 29,000. 75 % of which advanced stage 3 (national) amounting to EUR 22,000 and 25 % stage 2 (EU) amounting to EUR 7,000.

Material expenditure: 550 Practices x EUR 500.00 = EUR 275,000. 75 % of which advanced stage 3 (national) amounting to EUR 206,000 and 25 % stage 2 (EU) amounting to EUR 69,000.

(c) for 100 % of the practices affected (training/further education):

Personnel expenditure: 5,500 Practices x 22 min/60 min x EUR 59.10 = EUR 119,000. 75 % of which advanced stage 3 (national) amounting to EUR 89,000 and 25 % stage 2 (EU) amounting to EUR 30,000.

No costs arising from mail order sales of veterinary medicinal products by pharmacies (Section 44a(2) and Article 2) are incurred by pharmacies, as no separate applications for authorisation of such mail order are required. A mail order authorisation issued by a pharmacy applies equally to medicinal products for human use and veterinary medicinal products on the basis of identical requirements.

In accordance with the ‘one in, one out’ rule, the proposed regulation results in an ‘in’ of EUR 23.991 million. Compensation is sought from an exculpatory project within the scope of the Federal Ministry of Food and Agriculture during the legislative period.

4.3 Administration

For the administration (Länder, including municipalities), the annual compliance costs change by around EUR 207,000 (burden). One-off compliance expenditure amount to approximately EUR 56,000. The Federal Government will incur annual compliance expenditure of around EUR 512,000 and one-off compliance expenditure of around EUR 688,000.

Requirement	**§; description of the requirement; type of requirement**	**Justification for annual cost change**	**Annual compliance costs (in thousand EUR)**	**Justification for one-time costs**	**One-time compliance costs (in thousand EUR)**
1a	Recording of antibiotic consumption quantities by the BVL (§ 61a(1)(1) (dog/cat), as amended); Federal Government	Personnel costs: 198985 min/60 min x EUR 70.50 Material costs: 1500 Euro SAS licences + EUR 10 000 public relations, publications	+245	Personnel costs: 276878 min/60 min x EUR 70.50	+325
(1b)	Recording of	Personnel	+238	Personnel	+303

Requirement	§; description of the requirement; type of requirement	Justification for annual cost change	Annual compliance costs (in thousand EUR)	Justification for one-time costs	One-time compliance costs (in thousand EUR)
	antibiotic consumption quantities by the BVL (§ 61a(1)(2) (ducks, geese), as amended); Federal Government	costs: 192955 min/60 min x EUR 70.50 Material costs: 1500 Euro SAS licences + EUR 10 000 public relations, publications		costs: 258051 min/60 min x EUR 70.50	
(1c)	Recording of antibiotic consumption quantities by the BVL (§ 61a(1)(3) (fur animals), as amended); Federal Government	Personnel costs: 630 min/60 min x EUR 70.50	+0.7	Personnel costs: 1140 min/60 min x EUR 70.50	+1
2	Training costs for the monitoring authorities (§ 61a in conjunction with § 61b TAMG, as amended); Land			16 Länder x 10 persons x 8 hours x EUR 43.80	+56
3	Supervision by the competent authorities of the Länder (§ 61a TAMG, as amended); Land	6000 Controls x 45 min/60 min x EUR 43.80	+197		
4	Performance of risk assessment by BfR and publication of the report (§ 61b(2), as amended); Federal Gov-	400 hours x EUR 70.50	+28	840 hours x EUR 70.50	+59

Requirement	§; description of the requirement; type of requirement	Justification for annual cost change	Annual compliance costs (in thousand EUR)	Justification for one-time costs	One-time compliance costs (in thousand EUR)
	ernment				
5	Handling of administrative offences (§ 89(2)(8) and (12), as amended); Land	80 procedures x 2 hours x EUR 65,20	+10		0
Total (in thousand EUR)			+719		+744
of which incurred at federal level (in thousand EUR)			+512		+688
of which on the Land level (in thousand EUR)			+207		+56
Number of requirements			5		

The estimate of the enforcement costs for the two requirements is presented below.

Requirement 1: Recording of antibiotic consumption quantities by the BVL (data collection, processing and transmission to the EMA) (§§ 61a, as amended)

The regulations implement the requirements of Article 57 of Regulation (EU) 2019/6, which requires Member States to collect, process and submit to the European Medicines Agency (EMA) data on the consumption of medicinal products containing substances with antibiotic effect in different animal species. The provisions of § 61a(1) to (3) TAMG, as amended, serve to implement the corresponding requirements of Article 57 of Regulation (EU) 2019/6. Following a decision of the German Bundestag as part of the legislative process to enact the Veterinary Medicinal Products Act, the start of data collection for dogs and cats was brought forward from 2029 to 2025. Accordingly, expenditure on compliance for the purpose of accounting is shown below for the four-year national-related advance of the EU legal data collection. The EU-related compliance expenditures for the data collections pursuant to § 61a(1)(2) and (3) are shown but are not included in the accounting framework.

§ 61 Paragraph 1, point 1 (dog/cat, nationally advanced stage 3)

According to the BVL, a one-off implementation costs will be incurred as part of the implementation of the reporting system, data processing, public relations and quality management pursuant to Section 61a(1)(1) TAMG, as amended. The BVL estimates the additional time expenditure to be 276 878 minutes per year. In total, a two-and-a-half-year implementation phase and a corresponding time expenditure of 692,194 minutes are assumed. With a federal wage cost rate of EUR 70.50 (higher civil service), the one-off compliance expenditure for the entire implementation amount to around EUR 813,000 (for two and a half years) or around EUR 325,000 (per year).

On the other hand, an ongoing annual compliance expenditure will also be incurred by the BVL to deal with the task implemented. The BVL estimates the additional time expenditure to be 198,985 minutes per year. The Federal Government’s wage cost rate of EUR 70.50

(higher civil service) results in annual personnel costs of EUR 234,000. In addition, annual material costs of EUR 11,500 are incurred for the SAS licences required for data evaluation (= EUR 1,500) and public relations work (= EUR 10,000, e.g. for organising training courses, for training materials, instructions, publications, etc.).[9)] This results in an annual compliance expenditure of around EUR 245,000 or total compliance expenditure for the four-year nationally advanced data collection of EUR 981,000.

§ 61 Paragraph 1, point 2 (duck, geese; Stage 2)

According to the BVL, a one-off implementation costs will be incurred as part of the implementation of the reporting system, data processing, public relations and quality management pursuant to Section 61a(1) point 2 and point 3 TAMG, as amended. The BVL estimates the additional time expenditure required for the animal species under point 2 to be 258,051 minutes per year. In total, a two-and-a-half-year implementation phase and a corresponding time expenditure of 645127 minutes are assumed. With a federal wage cost rate of EUR 70.50 (higher civil service), the one-off EU-related compliance expenditure for the entire implementation amount to around EUR 758,000 (for two and a half years) or around EUR 303,000 (per year).

On the other hand, an ongoing annual compliance expenditure will also be incurred by the BVL to deal with the task implemented. The BVL estimates the additional time expenditure to be 192955 minutes per year. The Federal Government's wage cost rate of EUR 70.50 (higher civil service) results in annual personnel costs of EUR 227,000. In addition, annual material costs of EUR 11,500 are incurred for the SAS licences required for data evaluation (= EUR 1,500) and public relations work (= EUR 10,000, e.g. for organising training courses, for training materials, instructions, publications, etc.).[10)] This results in an annual EU-related compliance expenditure of around EUR 238,000.

§ 61 Paragraph 1, point 3 (fur animals; Stage 3)

There will be no antibiotic applications expected for as fur animals kept foxes and minks (§ 61a(1)(3) TAMG, as amended), as the closure of the last fur farm in Germany in 2019 means that there is no longer any economic fur farming in Germany.[11)] The BVL has therefore only calculated the time expenditures required to check whether the situation remains unchanged and to set up a reporting option. In addition, a hypothetical effort for data collection, processing and transmission to the EMA is taken into account if foxes and/or minks were to be kept for the purpose of fur production again in the future.

The BVL estimates an additional time expenditure of 1,140 minutes to set up the basic reporting option. With a federal wage cost rate of EUR 70.50 (higher civil service), this gives rise to a one-off EU-related compliance expenditure of around EUR 1,000. In the event that individual reports are required, the additional time expenditure required was estimated at an average of 630 minutes per year).[12)] With a wage cost rate of EUR 70.50, the EU-related annual compliance expenditure amount to around EUR 740.

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9) According to the BVL, the material costs for the nationally advanced stage 3 (dog/cat) are taken into account at a rate of EUR 11,500 per year. In total, the BVL incurs material costs of EUR 23,000 per year for stages 2 and 3.

10) According to the BVL, the material costs for the stage 3 (dog/cat) are taken into account at a rate of EUR 11,500 per year. In total, the BVL incurs material costs of EUR 23,000 per year for stages 2 and 3.

11) See Animal Welfare Report (2023), p. 40; cf. URL: https://www.tierschutzbund.de/tiere-themen/tierschutz-im-alltag/pelz [accessed on 19.3.2024].

12) A time expenditure of 180 minutes per year was assumed for the routine check to ensure that no fur farms in Germany are affected by the antibiotic consumption quantity recording. In the event that notifications are nevertheless required, the time required was estimated at 1,080 minutes per year, resulting in an average time expenditure of 630 minutes per year.

Requirement 2: Training expenditure for the monitoring authorities due to the inclusion of new animal species (§ 61a TAMG, as amended)

In the Länder's view, the inclusion of the new animal species will create an additional training burden for the monitoring authorities, in particular as a result of the need for further specialisation of employees in this area of legislation. Due to the lack of data from the Länder, the one-off time expenditure required for training was estimated at around eight hours[13)] per Land for one employee. By analogy with the estimation of additional training needs under the 2021 Veterinary Medicinal Products Act, it can be assumed that, on average, at least ten people per Land need to be trained accordingly. It is calculated at an average wage cost rate – Land hierarchy of EUR 43.80. This gives rise to one-off compliance expenditure of around EUR 56,000 (= 16 Länder x 10 employees x 8 hours x EUR 43.80).

Requirement 3: Monitoring by the competent authorities of the Länder (including municipalities) (§ 61a TAMG, as amended)

Although the responsibility for data collection lies with the BVL and the new animal species will not be included in the antibiotic minimisation plan, the implementation of the consumption quantity recording and the examination of veterinary notifications under Section 61a(1) TAMG, as amended will nevertheless involve an additional monitoring effort for the Länder. The Länder estimate the additional time expenditure to be around 30 to 60 minutes (45 minutes on average). With a case number of approximately 6,000 inspections of veterinary dispensing stations per year, an average wage cost rate – Land level of EUR 43.80 – gives an annual compliance expenditure of around EUR 197,000. It was also argued by Länder and associations that the new data reporters are likely to require more counselling. However, these consultancy costs have been taken into account in the compliance expenditure of the BVL, which is responsible for data collection (see requirement 1).

Requirement 4: Performance of risk assessment by BfR and publication of the report (§ 61b(2), as amended)

The regulation corresponds to § 59(1) in conjunction with § 57(4) of the old version of the TAMG for stages 2 and 3 data collected in accordance with § 61a. The new data included in Annex 2 are communicated by the BVL to the BfR in pseudonymised form for the purpose of risk assessment in the field of antimicrobial resistance. On the basis of the data submitted, the BfR carries out an annual risk assessment on the basis of the data submitted, merely supplemented by the above-mentioned data for stages 2 and 3. A report is drawn up, which is to be published annually on the BfR's website.

As part of the ex-ante estimation of the Act amending the Veterinary Medicinal Products Act to collect data on antibiotic medicinal products and to amend further regulations from 2022, the BfR had estimated a period of twelve weeks to prepare the report. The BfR estimates the expected time expenditure resulting from the expansion of the animal/use types at twelve weeks (60 working days for creating the routines for data preparation and analysis) and an additional nine weeks on balance in the first reporting year[14)] (45 days for evaluating the data), i.e. a total of 21 weeks, as well as a permanent balance of ten weeks (twelve weeks for data preparation and six weeks for evaluating the data minus the previous time expenditure of eight weeks). Converted into hours, this results in a time expendi-

13) This corresponds to an average training period of one working day of 8 hours each.

14) The BfR estimates the time needed to assess the data for the 15 types of use in the first reporting year at four to five days per type of use per year, i.e. 15 weeks (75 working days), and in subsequent years at two days per type of use per year, i.e. six weeks (30 working days). The balance results in a one-off time expenditure of nine weeks (45 working days) as a result of the need to build up expertise in the first reporting year and the analysis of comparative data and analyses, which will be significantly reduced to an annual time of six weeks in the following years.

ture (assuming that a working week comprises five working days of eight hours each) of 840 hours once and 400 hours per year.

The BfR indicates that a senior scientist will be employed for reporting purposes. According to the StBA's wage cost table, the wage rate in this case is EUR 70.50 per hour. The publication of the report on the BfR website is negligible in terms of expenditure, which is why no material costs are incurred.

This results in a one-off compliance expenditure of EUR 59,000 (= 1 x 840 hours x EUR 70.50/hour) and annual compliance expenditure of EUR 28,000 (= 1 x 400 hours x EUR 70.50/hour).

Requirement 5: Handling of administrative offences (§ 89(2)(8) and (12) as amended)

Two additional administrative offences have been included in Section 89(2), whereby in Section 89(2)(8) a breach of the general prohibition on the dispatch of veterinary medicinal products subject to veterinary prescription and in Section 89(12) a failure to provide a notification in accordance with Section 61a(1), or to provide it correctly, completely or in the prescribed manner, may be punished as an administrative offence. It is assumed that the additional administrative offences will mean that a total of around 80 additional administrative offence proceedings per year will have to be processed by the enforcement authorities.[15]) The additional time spent is on average two hours per procedure, or 160 hours per year. A wage cost rate of EUR 65.20 per Land is assumed for processing. This results in an additional enforcement effort of around EUR 10,000 per year (= 80 proceedings x 2 hours x EUR 65.20).

5. Further costs

The industry (animal keepers and veterinarians) does not incur any additional costs in complying with the requirements laid down in the Act, in addition to the above-mentioned compliance costs.

The effects of the Act on individual prices and price levels, in particular on consumer price levels, are not expected as a result of the changes.

The impact on public budgets is so low that it has no direct price effects.

However, the costs of the judiciary are also recognised as 'other costs'. This is understood to mean the personnel and material costs of judges in clarifying the legal situation or those of the public prosecutor's office/police in criminal investigations and prosecutions. The inclusion of an additional offence in Section 88(4) (as amended) now also criminalises the unlawful manufacture of a veterinary medicinal product, an active substance or a veterinary medicinal technology product (§ 38(3)). A small number of additional criminal proceedings (approx. two proceedings per Land per year) and an average time expenditure of eight hours per proceeding are expected, so that the judicial administration of the Länder will probably incur additional costs of around EUR 17,000 (= 16 additional criminal proceedings x 8 hours x EUR 65.20).

No costs arising from mail order sales of veterinary medicinal products by pharmacies (Section 44a(2) and Article 2) are incurred by the competent authorities, as no separate applications for authorisation of such mail order and no increased testing effort are required. A mail order authorisation issued by a pharmacy applies equally to medicinal products for human use and veterinary medicinal products on the basis of identical requirements.

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[15]) The Länder estimate the annual additional administrative offence proceedings at five per Land.

6. Other legal consequences

The exceptions to the respective laws provided for in the draft Act have been reviewed for their gender relevance. There were no indications that genders were affected differently. The provisions apply equally to women and men. There is no indirect or direct gender-related disadvantage. The equality of men and women in language is preserved.

The Act does not have a negative impact on consumers.

From a demographic point of view, the draft is also not expected to have any impact. The same applies to effects on the requirement of equivalent living conditions.

In accordance with the Guidance paper on implementing the ‘equivalence check’ (GL-Check) for draft federal legislation of 20 April 2020, it has been examined whether and what impact the draft federal legislation would have on the equivalence of people’s living conditions in Germany. With regard to the ‘Municipal financial situation factor’ mentioned in the Guidance paper, no impact on the disparities between financially strong and financially weak municipalities is expected. With regard to the ‘natural livelihoods’ factor, a further contribution to curbing the spread of antimicrobial resistance can be assumed.

VII. Time limit; evaluation

A limitation of the Act shall not apply as the proposed regulations are intended to be permanent. The objective of data collection in accordance with Article 57 of Regulation (EU) 2019/6 (second and third stages of data collection) cannot be achieved otherwise.

This scheme will be evaluated no later than five years after the entry into force, among other things, on the basis of data from the Federal Institute for Risk Assessment (BfR) and the Federal Office for Consumer Protection and Food Safety (BVL). In doing so, the Federal Government will assess, in a technically appropriate manner, on the basis of developments in antimicrobial resistance in bacteria in the livestock sector and the annual consumption quantities for veterinary medicinal products containing antibacterial active substances, whether and to what extent the intended effects on resistance and the collection of data on the use of antimicrobial medicinal products in animals, as required by EU law, have been achieved. The Federal Government will also examine how the compliance costs to the parties addressed have developed and whether this development is in reasonable proportion to the regulatory effects identified. The evaluation will include investigating any unintentional secondary effects and the acceptance and practicability of the regulations.

B. Specific part

Re Article 1 (Amendment of the Veterinary Medicinal Products Act)

Re Point 1

The table of contents is amended and supplemented as a consequential amendment to points 3, 7, 8 and 15.

Re Point 2

The amendment serves as an editorial correction.

Re Point 3

The provision makes it clear in § 44a(1) that the dispatch of veterinary medicinal products subject to medical prescription is in principle prohibited unless the legislature has adopted rules derogating from that prohibition. Such a rule is set out in the following paragraphs 2 to 5, which set out the conditions under which veterinary medicinal products subject to veterinary prescription may be dispatched by pharmacies and veterinarians in the context of the operation of a veterinary dispensing station.

The regulation does not constitute recourse to paragraph 2 of Article 104 of Regulation (EU) 2019/6, as it does not concern rules on the distance marketing of veterinary medicinal products offered by information society services.

Re Point 4

Re letter (a)

The amendment aims to clarify the situation and reflects the current legal situation.

Re letter (b)

The previous reporting obligations in § 45(10) and the previous rule-making powers in § 45(11) can be repealed, as the regulations themselves are directly incorporated into the law in point 7.

Re Point 5

The editorial amendment aims to clarify the intention.

Re Point 6

The Federal Government agrees that the authorisation to regulate the prices of veterinary medicinal products should be transferred to the competent Federal Ministry of Food and Agriculture.

Re Point 7

Need to insert a specific sub-section for rules on veterinary notifications on the use of antimicrobial medicinal products in accordance with Delegated Regulation (EU) 2021/578 for

- food-producing animals not yet covered;
- non-food-producing horses;
- dogs, cats and
- as fur animals kept foxes and minks.

The obligation under the 2nd and 3rd stages for reporting the quantities of medicinal products containing substances with antibiotic effect is based on the relevant provisions of Delegated Regulation (EU) 2021/578. That list, in point 3 of the Annex, those antibiotic medicinal products the levels of which are mandatory for Member States to collect and report to the European Medicines Agency and, in point 4 of the Annex, those antimicrobial medicinal products whose use levels may be additionally collected and reported by Member States.

1. Re § 61a

The aim of the regulation is to ensure full data collection for the purposes of Article 57 of Regulation (EU) 2019/6 on veterinary medicinal products. It is based on the provisions of § 56 TAMG, but does not cover the species of 2nd and 3. stages to the antibiotic minimisation concept.

Paragraph 1 sets out the types of use for which veterinary notifications on the use of medicinal products are required.

Paragraph 2

The medicinal products covered by the veterinary notification obligation are those containing substances with antibiotic effect described by the codes listed in points 3, 4(1) to (5) and (10) of the Annex to Delegated Regulation (EU) 2021/578 in accordance with the Anatomical Therapeutic Chemical (ATC) classification system or the Anatomical Therapeutic Chemical veterinary (ATCvet) classification system of the World Health Organisation. A definition of the term ‘antibiotic’ can be found in Article 4(14) of Regulation (EU) 2019/6.

The information referred to in paragraph 2, first sentence, point 1 in accordance with points 4, 5, 6 and 9 of Annex II to Implementing Regulation (EU) 2022/209 shall be the following:

- The information referred to in point 4 of Implementing Regulation (EU) 2022/209 – ‘identification from the relevant Union database of the medicinal product presentation’ – corresponds to the indication ‘Permanent Identifier of a veterinary medicinal product’ in accordance with point 3.1 of Annex III to Commission Implementing Regulation (EU) 2021/16 of 8 January 2021 laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products (Union product database).

- The information referred to in point 5 of the above-mentioned Implementing Regulation (EU) 2022/209 – ‘Reference number from other relevant database(s) of the medicinal product presentation’ – is the approval number issued in Germany by the Federal Office of Consumer Protection and Food Safety.

- The information referred to in point 6 of Implementing Regulation (EU) 2022/209 – ‘Name of the medicinal product’ – refers to the name of the medicinal product according to the accompanying texts (package leaflet, summary of product characteristics).

- The information referred to in point 9 of Annex II to the aforementioned Implementing Regulation – ‘Pack size’ – is the numerical value used to indicate the quantity of the pack size.

This information, together with the information pursuant to paragraph 2, first sentence, points 2 to 4, is necessary for compliance with the obligation under EU law pursuant to Article 57 paragraph 2 and paragraph 5 of Regulation (EU) 2019/6 and to Article 2 of Commission Implementing Regulation (EU) 2022/209 of 16 February 2022.

The information referred to in paragraph 2, first sentence, point 2 is necessary for the quality assurance of the data to be transmitted to the EU to be carried out by Member States in accordance with Article 6 (Data quality requirements) of Delegated Regulation (EU) 2021/578. The second sentence makes it clear that indicating the name of the practice is also permitted.

Paragraph 3 lays down the requirement for the Federal Republic of Germany to submit this information to the competent authority as a condition for compliance

with the obligations under European law of Article 57, paragraph 2, first sentence in conjunction with paragraph 5 of Regulation (EU) 2019/6 and Article 2 of Commission Implementing Regulation (EU) 2022/209 of 16 February 2022.

Paragraph 4 clarifies the powers under data protection law.

2. Re § 61b:

The provision is based on § 59(1) TAMG for the new stages 2 and 3 data collected in accordance with § 61a. The new data included in Annex 2 (see point 17) are communicated by the Federal Office for Consumer Protection and Food Safety to the Federal Institute for Risk Assessment in pseudonymised form for the purpose of risk assessment in the field of antimicrobial resistance. For scientific purposes, the relevant data may be used in pseudonymised form.

Re Point 8

This is a consequential amendment due to the insertion of the new subsection 6.

Re Point 9

The amendment specifies the previous regulation to the effect that it is now the duty of the Federal Office of Consumer Protection and Food Safety to provide information on the retail sale of veterinary medicinal products at a distance in accordance with Article 104 of Regulation (EU) 2019/6 via a generally accessible internet portal and to link this internet portal to the internet portal operated by the European Medicines Agency, which contains information on the retail sale of veterinary medicinal products at a distance and the common logo in accordance with Article 104(9) of Regulation (EU) 2019/6.

Re Point 10

These are consequential changes resulting from points 4b and 7. The obligation to transmit data in § 69(3) TAMG is repealed and can now be found in § 61a. This leads to a renumbering of the previous paragraphs.

Re Point 11

Correction of an editorial error. The measures referred to in Regulation (EU) 2019/6 can be found in Articles 129 to 134, not 131.

Re Point 12

The penalisation of the prohibitions in § 38(1) to (3) TAMG has so far been incomplete. Strengthening only the prohibition of unlawful making available on the market is inappropriate. On the contrary, illegal production should also be punishable.

Re Point 13

Re letter (a)

An infringement of the general prohibition on the dispatch of veterinary medicinal products subject to prescription should be punishable as an administrative offence. A new point 8 is added to § 89(2).

Re letter (b)

Consequential amendment to point 13a.

Re letter (c)

By analogy with the offence of failing to report, incorrectly reporting or incompletely reporting animal species in Section 56, this offence is now also punishable as an administrative offence when reporting the animal species listed in Section 61a.

Re letter (d)

Consequential amendment to point 13c.

Re Point 14

Editorial amendment of the previous transitional provision, as a result of the creation of a further transitional provision in point 15.

Re Point 15

The amendment includes a transitional provision in the form of a new § 95 for 2nd and 3rd animal species, specifying the dates of the first transmissions.

Re Point 16

Consequential amendment to point 15.

Re Point 17

The existing Annex entitled ‘Data to be provided to the Federal Institute for Risk Assessment for the purpose of carrying out a risk assessment’ is extended to include the information under § 61a for 2nd and 3rd animal species.

Re Article 2 (Amendment of the Pharmacies Act)

Re Point 1

This is a consequential amendment to § 44a(2) TAMG. The dispatch licence is formally extended to human and veterinary medicinal products under the new rules on the dispatch of veterinary medicinal products in the Veterinary Medicinal Products Act. Facilities and equipment for e-commerce of non-prescription veterinary medicinal products must be in place. E-commerce of veterinary medicinal products subject to prescription remains prohibited.

Re Point 2

Section 28a clarifies that authorisations already granted relate to the dispatch of both medicinal products for human and veterinary use, which was previously governed exclusively by Section 43 of the Medicinal Products Act. This also applies to authorisations granted after the entry into force of the TAMG. Accordingly, there is no obligation to apply for new separate authorisation. The competent authorities may continue to examine whether the conditions for issuing a mail order authorisation are met in the context of a common procedure and an authorisation covering both situations may be issued.

Re Article 3 (Entry into force)

This Article provides for the entry into force.