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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 57(4) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2021/578 ([2]) sets out the requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals.

(2) In order for Member States to be able to collect and report such data to the European Medicines Agency ('the Agency'), the format of such data should be clearly defined.

(3) The required format of the data should apply to the data collected for the antimicrobials referred to in Articles 1 to 4 of Delegated Regulation (EU) 2021/578 in order to have harmonised and comparable data. The required format of the data should equally apply to data collected on antimicrobials contained in medicated feed and intermediate products, in line with Article 4(4) of Regulation (EU) 2019/4 of the European Parliament and of the Council ([3]).

(4) The format, which Member States are to use for reporting antimicrobial sales and use data to the Agency, should take into account specific data variables that need to be provided per product presentation in order to enable the Agency to calculate the quantity of antimicrobial active substances from veterinary medicinal products sold per Member State for use on its territory during the year of data collection. Those data variables should also enable the Agency to calculate the quantity of antimicrobial active substances from medicinal products used in designated animal species or categories per Member State on its territory during the year of data collection. Additional data variables should be provided by Member States to the Agency, per reporting year, in order to allow for an accurate analysis and interpretation of the data.

(5) The Agency should provide the necessary supporting information to Member States in order to facilitate the harmonised calculation of the volume of sales and of the use of antimicrobials and to facilitate subsequent data validation by Member States before reporting to the Agency. Such supporting information is to be provided to Member States by the Agency through the web interface for collated data reporting referred to in Article 10 of Delegated Regulation (EU) 2021/578.

([1]) OJ L 4, 7.1.2019, p. 43.

([2]) 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).

([3]) Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).

(6) In addition, the Agency should minimise the efforts required by Member States to enter data in the web interface, by pre-filling data entry fields whenever data is already available from existing databases under the remit of the Agency. At the same time, in line with Article 6 of Delegated Regulation (EU) 2021/578, Member States remain responsible for the fulfilment of the data quality requirements with respect to the information provided on the antimicrobial medicinal products authorised at national level, including the accuracy of the information provided by the Agency in those pre-filled data entry fields.

(7) To ensure that the data collected on the sales and the use of antimicrobials is comparable year-over-year within Member States and within the Union and that those data are adequately analysed, the format for reporting of the data should take into account the size of the animal population that is likely to be treated with antimicrobials. This should also facilitate the comparison of data reported at national level and at Union level with data available from non-Union countries and at global level. It is therefore important to define the format according to which the animal population data should be referred to. Any comparison of data across Member States should take into account the diversity of practices within the Union and the differences in national legal contexts.

(8) The most appropriate format for the animal population data as regards terrestrial animals should be the number of living animals or the number of slaughtered animals, depending on the animals species or categories concerned, while the most appropriate format for the animal population data as regards farmed fish should be the produced biomass. However, in order to appropriately reflect each Member State's animal population data in the context of the collection of data on the volume of sales and on the use of antimicrobials in animals, so that it can be effectively used by the Agency, the animal population data should be adjusted according to so-called denominators, such as the population correction unit or other denominators, as appropriate. Such adjustments are necessary for the Agency to identify trends in the volume of sales and the use of antimicrobials in animals and make relevant analyses.

(9) This Regulation is necessary for the application of Regulation (EU) 2019/6, which applies from 28 January 2022. Therefore, and in accordance with Article 153(1) of Regulation (EU) 2019/6, this Regulation should apply from that same date.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products referred to in Article 145 of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

Article 1

Data to be reported to the Agency on the volume of sales of veterinary antimicrobial medicinal products

1. Data on the volume of sales of veterinary antimicrobial medicinal products shall be reported by the Member States to the Agency using the format specified in Annex I.

2. The Agency shall include the format of the data referred to in paragraph 1 in the protocols and templates it makes available to the Member States, as provided for in Article 8 of Delegated Regulation (EU) 2021/578. The terminology used in the Agency's protocols and templates for reporting shall be based on controlled terms defined in existing catalogues of terms maintained by the Agency, as much as possible.

Article 2

Data to be reported to the Agency on the use of antimicrobial medicinal products in animals

1. Data on the use of veterinary antimicrobial medicinal products shall be reported by the Member States to the Agency through the web interface referred to in Article 10 of Delegated Regulation (EU) 2021/578, using the format specified in Annex II.

2. The Agency shall include the format of the data referred to in paragraph 1 in the protocols and templates it makes available to the Member States, as provided for in Article 8 of Delegated Regulation (EU) 2021/578. The terminology used in the Agency's protocols and templates for reporting shall be based on controlled terms defined in existing catalogues of terms maintained by the Agency, as much as possible.

Article 3

Information to be provided by the Agency for calculation and validation purposes

When providing the information necessary for the purposes of calculating the volume of sales and of the use of antimicrobials and validating data, the Agency shall use the variables specified in Annex III.

Article 4

Animal population data

1. Data identified by the Agency or reported by the Member States on the relevant animal populations, as specified in Article 16(5) of Delegated Regulation (EU) 2021/578, shall take into account animal species, categories and stages thereof as listed in Article 15 of Delegated Regulation (EU) 2021/578 according to the following format:

(a) for terrestrial animals: the number of animals per year (living animals or slaughtered animals, depending on the animal species or categories concerned, as specified in the Agency's protocols and templates for the reporting of data);

(b) for farmed fish: the biomass produced per year (live weight at slaughter).

2. While identifying or reporting the data on the relevant animal populations, the Agency or the Member States, as specified in Article 16(5) of Delegated Regulation (EU) 2021/578, shall take into account the number of animals brought in from other Member States and sent to other Member States for fattening or slaughter, for the relevant animals species, categories and stages thereof, when appropriate, in accordance with the Agency's protocols and templates referred to in Article 8 of Delegated Regulation (EU) 2021/578.

3. When Member States report the data on the relevant animal populations in their territories, they shall submit to the Agency a detailed description of the methodologies they used to generate the relevant animal population data.

Article 5

Adjustments to the animal population data for analysis purposes

1. The Agency shall adjust the data for the relevant animal populations referred to in Article 4 according to so-called denominators, which are calculated on the basis of a combination of the number of animals slaughtered and of the number of live animals present in a Member State during the data collection period, multiplied by standardised animal weights.

2. Depending on the data concerned, the most appropriate denominator to be used shall be indicated in the Agency's protocols and templates referred to in Article 8 of Delegated Regulation (EU) 2021/578.

3. The data sources and the methodology for the calculation by the Agency of the different denominators shall be specified in the Agency's protocols and templates referred to in Article 8 of Delegated Regulation (EU) 2021/578.

Article 6

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 28 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Format for the reporting of data to the Agency on the volume of sales of veterinary antimicrobial medicinal products

Number	Name of the data variable	Description
1. **Data to be reported per product presentation**		
1	ISO Country Code	Two-letter code (alpha-2 code), according to the International Standard for country codes (ISO, 2013); XI for Northern Ireland.
2	Year	Four-digit number.
3	Allowed for use under Article 116 of Regulation (EU) 2019/6	A choice of yes/no to be selected to indicate whether the product is allowed for use under Article 116 of Regulation (EU) 2019/6.
4	Identification from the Union product database of the veterinary medicinal product presentation	Structured data field to indicate the permanent and unique identification from the Union product database of the veterinary antimicrobial medicinal product presentation, in line with Article 12(1) of Delegated Regulation (EU) 2021/578.
5	Reference number from other relevant database(s) of the veterinary medicinal product presentation	Open-text field to indicate the reference number from other relevant database(s), such as national database(s), of the veterinary antimicrobial medicinal product presentation. Optional for Member States.
6	Name of the medicinal product	Open-text field to include the name of the veterinary antimicrobial medicinal product as per product information.
7	Product form	Product form, to be selected from a pre-defined list, in line with the Agency's latest protocols and templates.
8	Pack size	Numerical value only, to indicate the content quantity in the pack size.
9	Pack size unit	Unit of measurement of the pack size content, to be selected from a pre-defined list, in line with the Agency's latest protocols and templates. The unit of measurement of the pack size content shall correspond to the unit of measurement of strength of the antimicrobial active substance.
10	ATCvet code: Anatomical Therapeutic Chemical classification code for veterinary medicinal products	Code to be selected as per the latest version of the ATCvet index.
11	Authorised for companion animals only	A choice of yes/no, to be selected to indicate if the veterinary antimicrobial medicinal product is authorised for use in companion animals only.
12	Number of packages sold	Numerical value to indicate the number of packages of product presentation sold within the reporting year in the reporting Member State.

13	Name of the antimicrobial active substance	Name to be selected from a pre-defined list of antimicrobial active substances, in line with the Agency's latest protocols and templates, which includes International Non-proprietary Name (INN) of antimicrobial substances, as presented according to the latest version of the ATCvet Index. In case of fixed combination products, all the antimicrobial active substances shall be reported individually.
14	Name of the salt of the antimicrobial active substance when strength expressed in international unit (IU)	Name of the salt to be selected from a pre-defined list, in line with the Agency's latest protocols and templates, when applicable, in order to enable the conversion to mass of active substance in a standardised manner.
15	Name of the derivative or compound of the antimicrobial active substance	Name of the derivative or compound to be selected from a pre-defined list, in line with the Agency's latest protocols and templates, when applicable, to enable the calculation of the mass of the antimicrobial active moiety in a standardised manner.
16	Strength	Numerical value of the strength or the quantity of the antimicrobial active substance(s), as declared in the product information, in order to enable the calculation of the quantity of antimicrobial active substance(s) in each product presentation.
17	Unit of measurement of strength	Unit of measurement of strength to be selected from a pre-defined list, in line with the Agency's latest protocols and templates. The unit of measurement of strength shall correspond to the unit of measurement of the pack size.
2. **Data to be provided per reporting year**		
18	Data provider(s)	Data provider(s) to be selected from a pre-defined list including: — Marketing Authorisation Holders; — Wholesalers; — Retailers; — Feed mills; — Pharmacies; — Veterinarians.
19	Contact details of the national contact point and data managers	Open-text field to identify and provide the contact details of the national contact point and of the data managers of the Member State for liaison with the Agency with regards to the reporting of data on the sales of veterinary antimicrobial medicinal products.
20	Actions taken to avoid double reporting of sales	A choice of yes/no to be selected to indicate if necessary actions have been taken or not to avoid double reporting of sales.
21	Correction of the data reported on the sales of veterinary antimicrobial medicinal products, in relation to movements of veterinary medicinal products approved for parallel trade	A choice of yes/not applicable to be selected to confirm whether the data reported on the sales of veterinary antimicrobial medicinal products in the territory of the Member State has been corrected for movements of such products across the Member State's borders as part of parallel trade, in accordance with Article 102 of Regulation (EU) 2019/6.

ANNEX II

Format for the reporting of data to the Agency on the use of antimicrobial medicinal products in animals

Number	Name of the data variable	Description
1. **Data to be reported per product presentation**		
1	Animal species	Animal species, categories and stages thereof, for which data on the use of antimicrobial medicinal products shall be collected and reported, to be selected from a pre-defined list, in line with the requirements set in Article 15 of Delegated Regulation (EU) 2021/578.
2	ISO Country code	Two-letter code (alpha-2 code), according to the International Standard for country codes (ISO, 2013); XI for Northern Ireland.
3	Year	Four-digit number.
4	Identification from the relevant Union database of the medicinal product presentation	Structured data field to indicate: — the permanent and unique identification from the Union product database of the veterinary antimicrobial medicinal product presentation; or — the Packaged Medicinal Product Identifier (PCID) from the Product Management Services (PMS) of the human antimicrobial medicinal product presentation.
5	Reference number from other relevant database(s) of the medicinal product presentation	Open-text field to indicate the reference number from other relevant database(s), such as national database(s), of the antimicrobial medicinal product presentation. Optional for Member States.
6	Name of the medicinal product	Open-text field to include the name of the medicinal product as per product information
7	Product form	Product form to be selected from a pre-defined list, in line with the Agency's latest protocols and templates.
8	Identification of long-acting parenteral products	Two-letter code (LA) for injectable products only, when applicable, in order to identify parenteral products with long acting/prolonged release dosage forms, whose modified release dosage forms are showing slower release than that of the conventional release dosage form administered by the same route. Prolonged release is achieved through special formulation design and/or manufacturing method.
9	Pack size	Numerical value only, to indicate the content quantity in the pack size.
10	Pack size unit	Unit of measurement of the pack size content to be selected from a pre-defined list, in line with the Agency's latest protocols and templates. The unit of measurement of the pack size content shall correspond to the unit of measurement of strength of the antimicrobial active substance.
11	ATC or ATCvet code: Anatomical Therapeutic Chemical classification code for human and veterinary medicinal products	Code to be selected as per the latest version of the ATC or ATCvet indexes.

12	Number of packages used	Numerical value to indicate the number of packages of product presentation used within the reporting year per Member State and per animal species, animal species category or animal species stage, as specified in Article 15 of Commission Delegated Regulation (EU) 2021/578. In case any data at national level are collected in other units than packages used for each antimicrobial product by the animal species in question, the number of packages used may be calculated by the Member State from the amounts used (expressed in weight or in volume) before reporting to the Agency.
13	Name of the antimicrobial active substance	Name to be selected from a pre-defined list of antimicrobial active substances, in line with the Agency's latest protocols and templates, which includes International Non-proprietary Name (INN) of antimicrobial substances, as presented according to the latest versions of the ATC or ATCvet Indexes, to report antimicrobial use in a standardised manner per antimicrobial classes and active substances. In case of fixed combination products, all the antimicrobial active substances shall be reported individually.
14	Name of the salt of the antimicrobial active substance, when strength is expressed in international unit (IU)	Name of the salt to be selected from a pre-defined list, in line with the Agency's latest protocols and templates, when applicable, in order to enable the conversion to mass of active substance in a standardised manner.
15	Name of the derivative or compound of the antimicrobial active substance	Name of the derivative or compound to be selected from a pre-defined list, in line with the Agency's latest protocols and templates, when applicable, in order to enable the calculation of the mass of the antimicrobial active moiety in a standardised manner.
16	Strength	Numerical value of the strength or of the quantity of the antimicrobial active substance(s), as declared in the product information, to enable the calculation of the quantity of antimicrobial active substance in each product presentation.
17	Unit of measurement of strength	Unit of measurement of strength to be selected from a pre-defined list, in line with the Agency's latest protocols and templates. The unit of measurement of strength shall correspond to the unit of measurement of the pack size.
2. **Data to be provided per reporting year**		
18	Data source(s)	Data source(s) to select from a pre-defined list including: — Health records; — Treatment logbooks; — Delivery notes; — Invoices from farms; — Prescriptions; — Pharmacy records; — Veterinary practice records.

19	Data provider(s)	Data provider(s) to select from a pre-defined list including: — Veterinarians; — Retailers; — Pharmacies; — Feed mills; — End-users (including farmers or breeders).
20	Contact details of the national contact point and data managers	Open-text field to identify and provide the contact details of the national contact point and of the data managers of the Member State for liaison with the Agency with regards to the reporting of data on the use of antimicrobial medicinal products in animals.

ANNEX III

Information to be provided by the Agency for calculation and validation purposes

Number	Name of the variable to be provided	Description
1	Conversion factor for the antimicrobial active substance, when strength is expressed in international units (IU)	Conversion factor assigned automatically by the Agency in the web interface, when the strength of the antimicrobial active substance is reported in IU and the substance is included in the pre-defined list, in line with the Agency's latest protocols and templates. This information variable shall enable the conversion from IU to mass of the antimicrobial substance sold or used, per each product presentation.
2	Conversion factor for the derivative or compound of the antimicrobial active substance	Conversion factor assigned automatically by the Agency in the web interface, when the strength is reported for the derivative or compound and not for the antimicrobial active moiety, and the derivative or compound is included in the pre-defined list, in line with the Agency's latest protocols and templates. This information variable shall enable the calculation of the mass of the antimicrobial active moiety sold or used, per each product presentation.
3	Content of antimicrobial active substance per presentation	Content of antimicrobial active substance per gram of product presentation. This information variable shall enable the calculation of the volume of sales and of the use.
4	Unit of antimicrobial active substance per product presentation	Unit of measurement of the content of antimicrobial active substance per presentation in grams. This information variable shall enable the calculation of the volume of sales and of the use.
5	Tonnes of antimicrobial active substance sold or used	Volume of sales and use (in tonnes) of antimicrobial active substance per product presentation. This information variable shall enable further analysis and interpretation of data.