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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	29 January 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2021) 435 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 29.1.2021 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

Delegations will find attached document C(2021) 435 final.

Encl.: C(2021) 435 final

EUROPEAN
COMMISSION

Brussels, 29.1.2021
C(2021) 435 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 29.1.2021

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2019/6 of the European Parliament and of the Council lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products.

Antimicrobial resistance to medicinal products for human use and to veterinary medicinal products is a major health threat that is growing both at Union and global levels. In order to develop targeted measures to fight antimicrobial resistance it is essential to identify possible risk factors. The identification of relevant trends in the volume of sales and use of antimicrobials in animals at national and Union level should allow to determine such risk factors, establish appropriate risk management priorities, define targeted measures and monitor their effect. This should facilitate an integrated analysis of these trends with trends on the consumption of antimicrobials in humans and with data on antimicrobial resistant organisms found in animals, food, humans and the environment, in line with the 'One Health' approach to fight antimicrobial resistance.

Collecting data on the volume of sales and use of antimicrobials in animals is therefore instrumental to achieve the objectives mentioned hereinabove and these data need to be sufficiently detailed and comparable at Union level. To ensure that the data collected can be used effectively, appropriate technical rules should be laid down concerning the collection and the transfer of data. The Member States should be responsible for collecting data on the sales and use of antimicrobials used in animals under the coordination of the Agency.

To this aim, according to Article 57(3) of Regulation (EU) 2019/6, the Commission should adopt delegated acts, in accordance with Article 147, and establish the specific necessary requirements for this data collection.

In accordance with Article 153(3), that delegated act shall be adopted at the latest by 27 January 2021, i.e. 12 months before the date of application of Regulation (EU) 2019/6.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 147(5) of Regulation (EU) 2019/6, the Commission has carried out substantial consultation with Member States' experts on veterinary medicines, who generally supported the content of the act.

In addition, the Commission has carried out targeted stakeholder consultations as well as consulted the European Medicines Agency.

This draft Delegated Regulation was also made available to the European Parliament and the Council.

There were no comments received from the Council.

There were no comments received from the European Parliament.

In addition, stakeholders' comments on the draft Delegated Regulation were collected in the context of the Better Regulation feedback mechanism during the period between 20 November 2020 and 18 December 2020. Comments from 2 non-governmental organisations, 3 business associations, 2 public authorities, 2 company/business organisations, one consumer

organisation and one citizen were received via the online platform 'Have your Say'[1]. Comments from 2 public authorities were received via email, sent to the relevant Commission service.

A vast proportion of the comments included requests to add new provisions, which were not relevant to the scope of the present draft delegated act, but rather related to the scope of Regulation (EU) 2019/6. Such comments were therefore not taken into account in the context of the present delegated act.

Other comments were also not pertinent to the scope of the present delegated act, but rather to the scope of another delegated act, which is to be adopted at a later stage by the Commission in relation to Article 118 of Regulation (EU) 2019/6.

Some comments, on the other hand, were of pertinence to the scope of the present draft delegated act and were therefore examined carefully by the Commission; the most important ones are listed thereafter.

One of the comments mentioned that the present draft delegated act did not foresee to collect data on: 1) antimicrobials that will be reserved for the treatment of certain infections in humans, 2) antimicrobials that will not be allowed to be used outside the terms of their marketing authorisation and 3) antimicrobials that will be allowed to be used outside the terms of their marketing authorisation subject to certain conditions. Given the importance these antimicrobials may play in the development of antimicrobial resistance, the stakeholder suggested to collect data on these three categories of antimicrobials in order to make visible and punishable any infringement to the ban on their use. The detailed list of antimicrobials falling in these three categories will be laid down in forthcoming implementing acts (as provided for in Articles 37(5) and 107(6) of Regulation (EU) 2019/6). Regulation (EU) 2019/6 provides for controls to be led by the national competent authorities in order to ensure compliance with its provisions.

It was mentioned that the information required for the collection of data on sales and use of antimicrobials in the present draft delegated act was too superficial and would not allow for an appropriate identification of risk factors that could lead to antimicrobial resistance. The Commission wishes to emphasise that the detailed format of the data to be collected will be provided for in a forthcoming implementing act (provided for in Article 57(4) of Regulation (EU) 2019/6). It will include more specifics as to the type of information required in the context of the collection of data on the volume of sales and the use of antimicrobials in animals.

Some stakeholders enquired whether the present draft delegated act would enable Member States to have some room for manoeuvre in terms of implementation modalities for the collection of data on the volume of sales and the use of antimicrobials. The text proposed by the Commission gives a clear framework describing the main requirements for the implementation of the collection of data (including the use of semi- or fully-automated continuous data collection systems), while leaving sufficient flexibility to Member States on certain implementation modalities, bearing in mind that administrative burden for national competent authorities, as well as for stakeholders involved in the process of the collection of data, should be avoided as far as possible. The Commission wishes to underline that the development of semi- or fully-automated continuous systems will allow to collect data on antimicrobial use in a systematic, consistent and comparable way over time at national level and thereby facilitate the analysis of trends in antimicrobial consumption.

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11572-Method-for-the-Collection-of-data-on-antimicrobial-medicinal-products-used-in-animals

Comments were also received as regards the link between the collection of data on the volume of sales of antimicrobials which is the object of the present draft delegated act and the collection of data through the Union Product Database on veterinary medicinal products, which is to be created in line with Article 55 of Regulation (EU) 2019/6. More specifically, there were concerns from stakeholders about the administrative burden which could be generated in case the same information would be asked twice from marketing authorisation holders in the context of the two types of collection of data. In order to address this concern, the Commission improved the wording of the present draft delegated act accordingly in order to further incentivise the use by Member States of the newly-created Union Product Database as a primary source of data for the collection of data on the sales of veterinary antimicrobial medicinal products registered by marketing authorisations holders.

It was pointed out by a stakeholder that it would be useful to clarify in the present draft delegated act that if using data from the Union product database as a source for reporting on the volume of sales of antimicrobials, then such reporting should be based on an identification in the Union product database at the level of medicinal product presentations, not only at the level of medicinal products. Otherwise, it would then become difficult to compare the volumes reported for sales with those reported for use, as these would be based on different units. The Commission therefore adapted the wording accordingly to take this comment into account.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act is to establish requirements for the collection of data on antimicrobial medicinal products used in animals and should provide for:

– the types of antimicrobial medicinal products used in animals for which data shall be collected;

– the quality assurance that Member States and the Agency shall put in place to ensure quality and comparability of data; and

– the rules on the methods of gathering data on the use of the antimicrobial medicinal products used in animals and on the method of transfer of those data to the Agency.

COMMISSION DELEGATED REGULATION (EU) …/...

of 29.1.2021

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

(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[2], and in particular Article 57(3) thereof,

Whereas:

(1) In order to develop targeted measures to fight antimicrobial resistance, it is paramount to determine possible risk factors to public and animal health. The identification of relevant trends in the volume of sales and use of antimicrobials in animals at national and Union level should in turn allow to identify such risk factors following the use of antimicrobials in animals. This should set the basis for establishing appropriate risk management priorities, defining targeted measures to fight antimicrobial resistance and monitoring their effect. In line with the approach of the European One Health Action Plan against Antimicrobial Resistance[3], those priorities and measures should facilitate an integrated analysis of the relevant trends in the volume of sales and use of antimicrobials in animals with trends regarding the consumption of antimicrobials in humans and with relevant data on antimicrobial resistant organisms found in animals, food, humans and the environment, when available.

(2) Since the establishment of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project[4] in 2010 by the European Medicines Agency ('the Agency') at the request of the Commission, data on the volume of sales of veterinary antimicrobial agents for use in animals have been collected and reported following a harmonised approach at European level. All Member States, as well as Norway, Iceland and Switzerland participated in that project. Participating countries have reported on a voluntary basis the national sales figures of veterinary medicinal products classified as antibiotics and antiprotozoals with antibiotic effect. The data collected and the analyses carried out constituted a solid reference for the adoption of national action plans against antimicrobial resistance or other measures to promote prudent and responsible use of antimicrobials.

(3) Although existing systems for the collection of data on the volume of sales have already made an important contribution to the significant decrease of sales of

[2] OJ L 4, 7.1.2019, p. 43.
[3] COM (2017)339
[4] https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac

antimicrobials for animal use across Europe from 2011 to 2018, as shown by the ESVAC project, additional data are necessary to better target risk management measures and to further increase their efficiency. Therefore, it is relevant to broaden the types of antimicrobial medicinal products for which data on the volume of sales are collected, develop data collection on the use of antimicrobial medicinal products per animal species and categories as well as set up appropriate national data collection systems on use.

(4) The prioritisation of the types of antimicrobial medicinal products for which data on the volume of sales and on use is to be collected by Member States should be carried out taking into account the best available scientific evidence. Furthermore, in order to allow integrated analysis of data on antimicrobial use and resistance across public health and animal health sectors, another criterion to be taken into account is the availability of resistance data in animals and humans.

(5) The criteria referred to in recital (4) should determine whether data on the volume of sales and on the use of antimicrobials should be collected on a mandatory or a voluntary basis. For example, as regards those antimicrobials used in major food-producing animal species at Union level, the data collection should be mandatory. On the other hand, as regards those antimicrobials for which no resistance data are available at Union level, data may be collected on a voluntary basis. Member States may therefore collect data on types of antimicrobials other than those designated for mandatory data collection in this Regulation. In such cases, only the data originating from antimicrobials designated in this Regulation as relevant for a voluntary data collection may be submitted to the Agency for analysis.

(6) A valid and recognised classification system should be used to identify antimicrobials for which data should or may be collected. Such a system should allow for a general comparison of the use of medicines between the public health and animal health sectors. The World Health Organisation (WHO) Anatomical Therapeutic Chemical (ATC)[5] and the Anatomical Therapeutic Chemical veterinary (ATCvet)[6] classification systems fulfil this objective. The codes of those WHO classification systems should be used with a view to identifying the antimicrobial medicinal products for data collection, regardless of the therapeutic indications associated to the codes.

(7) In accordance with Article 57(3) of Regulation (EU) 2019/6, Member States and the Agency should put in place quality assurance measures to ensure the quality and comparability of the data collected and reported. In order to ensure that the appropriate data quality requirements are fulfilled at all stages of the data management workflow, Member States should set out a data quality management plan describing the main procedures for data quality management along the different steps of the workflow. The Agency should also develop a protocol and a template for data reporting, as well as develop a web interface that facilitates the timely electronic reporting by Member States of collated data on the volume of sales and on the use of the antimicrobials referred to in this Regulation. Where necessary, the Agency should provide assistance on data quality management to the Member States.

(8) Since data sources and data providers for the collection of data on sales and on use per species may vary considerably between Member States, they should select sources and

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5 WHO Collaborating Centre for Drug Statistics Methodology, Guidelines for ATC classification and DDD assignment 2020. Oslo, Norway, 2019; ISSN 1726-4898, ISBN 978-82-8406-046-0.

6 WHO Collaborating Centre for Drug Statistics Methodology, Guidelines for ATCvet classification 2020. Oslo, 2020; ISSN 1020-9891, ISBN 978-82-8406-047-7.

providers for that data, as appropriate, to ensure that they obtain full coverage data in the process. Furthermore, Member States should introduce necessary control measures to avoid double reporting.

(9) Requirements for the collection of data on the volume of sales should take account of the fact that many veterinary antimicrobial medicinal products marketed are authorised for use in two or more animal species. Therefore, it is not possible to identify the amounts sold for each animal species for such antimicrobial medicinal products. In such cases, data on overall sales of veterinary antimicrobial medicinal products should represent sales for the corresponding animal population in the reporting Member State.

(10) When reporting to the Agency on the data they have collected, Member States should also provide a brief description of their national policy framework to fight antimicrobial resistance, as well as an indication of initiatives led within the Member State and relevant specific factors which may explain the results observed at national level, including possible pattern changes and trends. This would support an adequate interpretation and comparison of data, by allowing a better understanding of the national context in which those data have been produced.

(11) Member States should develop suitable national data collection systems to ensure full coverage and high quality data on use per animal species. Such systems should consist in semi- or fully-automated continuous data collection systems, which enable direct evaluation of use and which allow to review the consistency of the data and to ensure the validity of the data per animal species.

(12) In order to ensure an appropriate understanding and interpretation of the data on the volume of sales and on use collected by the Member States, it is essential that the analyses of the data by the Agency consider the relevant animal populations per Member State.

(13) Article 8(4) of Regulation (EU) 2019/6 provides for a derogation for marketing authorisations of veterinary medicinal products intended for equine animals declared as not being intended for slaughter for human consumption. However, available statistics on the living horse animal population cover all horses, whether being intended or not for slaughter for human consumption. Use of antimicrobial medicinal products authorised for horses declared as not being intended for slaughter for human consumption should therefore also be included in the collection of data on the use of antimicrobial medicinal products in horses.

(14) This Regulation should apply from 28 January 2022 in accordance with Article 153(3) of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

CHAPTER I
TYPES OF ANTIMICROBIAL MEDICINAL PRODUCTS FOR WHICH DATA ON THE VOLUME OF SALES AND ON USE SHALL BE COLLECTED AND REPORTED TO THE AGENCY

Article 1

Veterinary antimicrobial medicinal products for which data on the volume of sales shall be collected and reported to the Agency

Member States shall collect data on the volume of sales of the veterinary antimicrobial medicinal products listed in point 1 of the Annex and shall report those data to the Agency.

Article 2

Veterinary antimicrobial medicinal products for which data on the volume of sales may be collected and reported to the Agency

Member States may collect data on the volume of sales of the veterinary antimicrobial medicinal products listed in point 2 of the Annex and report those data to the Agency.

Article 3

Antimicrobial medicinal products for which data on use shall be collected and reported to the Agency

Member States shall collect data on the use in animals of the antimicrobial medicinal products listed in point 3 of the Annex and shall report those data to the Agency.

Article 4

Antimicrobial medicinal products for which data on use may be collected and reported to the Agency

Member States may collect data on the use in animals of the antimicrobial medicinal products listed in point 4 of the Annex and report those data to the Agency.

Article 5

Classification Systems for the identification of antimicrobial medicinal products for which data shall be collected and reported to the Agency

Member States and the Agency shall use the Anatomical Therapeutic Chemical veterinary (ATCvet) classification system and the Anatomical Therapeutic Chemical (ATC) classification system, as applicable, to identify substances with antibiotic effect, antifungals, antivirals and antiprotozoals of relevance for the collection of data.

CHAPTER II

QUALITY ASSURANCE

SECTION 1

OBLIGATIONS OF MEMBER STATES

Article 6

Data Quality Requirements

Data collected and reported by Member States to the Agency shall be accurate, complete and consistent. They shall at a minimum fulfil the following quality requirements:

(a) data shall be validated and reported according to the standardised specifications of the latest reporting protocols and templates made available by the Agency, in accordance with Article 8;

(b) upon reporting, data shall be processed through the automated data entry checks as performed by the Agency's web interface, as referred to in Article 10;

(c) data shall be amended in case gaps, errors or inconsistencies are identified;

(d) data on the volume of sales shall cover all sales per Member State of at least the antimicrobials listed in point 1 of the Annex to be used on a Member State territory, including sales of those antimicrobials brought in from other Member States to be used on a Member State territory and excluding sales of those antimicrobials sent to other Member States to be used outside of a Member State territory;

(e) data on use shall cover all use per Member State territory of at least the antimicrobials listed in point 3 of the Annex for all animal species and categories or stages listed in Article 15;

Article 7

Data quality management plan, national contact point and data managers

1. For the purpose of ensuring compliance with the data quality requirements listed in Article 6, Member States shall set out a data quality management plan that comprises appropriate data quality management procedures, including procedures for data quality assurance, validation and quality control.

2. Member States shall nominate a national contact point and data managers in accordance with the data quality management procedures defined in the data quality management plan. The national contact point and data managers shall:

   (a) ensure that there is an alignment between the specifications for data reporting by the data providers to them and the specifications for data reporting by them to the Agency;

   (b) ensure that quality assurance and quality control measures are adopted and that the data to be collated and reported to the Agency are validated and approved;

(c) use the latest reporting protocols and templates made available by the Agency, as referred to in Article 8, and take account of other relevant guidance documents produced by the Agency, such as manuals or guidelines, to allow for the collection and reporting of standardised and harmonised data to the Agency;

(d) provide the Agency, without delay, with appropriate amendments to any reported data which the Agency would have qualified as not fulfilling the necessary data quality requirements. Such amended data may be obtained with the support of data providers where necessary;

(e) verify and validate relevant animal population data gathered by the Agency and where necessary amend these data, as referred to in Article 16(5);

(f) provide at the time of their first reporting, and update for the following reporting periods when necessary, a brief description of their national policy framework or main initiatives in place to fight antimicrobial resistance and reduce any use of antimicrobials in animals that is neither prudent nor responsible, in accordance with point (d) of Articles 12(3) and 13(4);

(g) support prompt resolution of technical questions arising in relation to the data on the volume of sales and on the use of antimicrobial medicinal products reported to the Agency via the web interface;

(h) cooperate with the Agency and with other Union agencies, where applicable, to ensure the quality of the data analyses necessary for the preparation and publication of the Agency's reporting on the volume of sales and on the use of antimicrobial medicinal products in animals.

3. Member States shall update their data quality management plan referred to in paragraph 1, as appropriate, in order to take account of scientific and technical developments in the area.

SECTION 2

OBLIGATIONS OF THE AGENCY

Article 8

Protocols and templates for data reporting by Member States

The Agency shall make available protocols and templates for data reporting, in order to assist the Member States when applying the format of the data to be submitted by Member States to the Agency.

Article 9

Assistance to Member States on data quality management

1. The Agency shall validate the data collated and reported by Member States, once it has assessed that the data fulfil the quality requirements laid in Article 6.

2. In the event that the Agency assesses that part or the totality of the reported data does not fulfil the quality requirements laid in Article 6 the Agency shall:

(a) inform the relevant Member States of the necessary actions they shall take in order to ensure compliance with those requirements;

(b) request the relevant Member States to amend the reported data accordingly, so that data gaps, errors and inconsistencies are eliminated.

3. The Agency shall organise trainings on data quality requirements and data quality management. The Agency shall provide targeted assistance, as appropriate, to those Member States setting up new antimicrobial data collection systems upon their request.

Article 10

Web interface for collated data reporting by Member Sates

1. The Agency shall develop and maintain a web interface allowing Member States, by electronic means and in a timely manner, to:

(a) report to the Agency their collated data on the volume of sales of veterinary antimicrobial medicinal products and their data on the use of antimicrobial medicinal products in animals per animal species;

(b) receive instant data quality preliminary assessments, based on automated data entry checks upon reporting their data;

(c) provide any amendments to the data reported that are necessary to eliminate data gaps, errors and inconsistencies;

(d) verify and validate relevant animal population data gathered by the Agency and where necessary amend these data, as referred to in Article 16(5).

2. The web interface shall be available at least in the English language.

3. The Agency shall conduct validation activities to ensure that the web interface meets the minimum requirements for its specified application and intended use.

4. The Agency shall organise regular trainings, and, as appropriate, provide additional specific assistance to Member States on the use of the web interface and the completion of the relevant reporting templates.

CHAPTER III

METHODS FOR THE COLLECTION OF DATA AND THEIR REPORTING TO THE AGENCY

SECTION 1

DATA ON THE VOLUME OF SALES

Article 11

Methods for collecting data on the volume of sales of veterinary antimicrobial medicinal products

1. For the purpose of collecting national data on the volume of sales of the veterinary antimicrobial medicinal products, as referred to in Articles 1 and 2, Member States shall consider the following data providers, as appropriate: marketing authorisation holders, wholesalers, retailers, feed mills, pharmacies or veterinarians.

2. Member States shall, as far as possible, use the data on the volume of sales provided by marketing authorisation holders to the Union product database as the primary data source for the volume of sales of the veterinary antimicrobial medicinal products registered by marketing authorisation holders. They shall correct these data in terms of movements of products across their borders as part of parallel trade and complete them with that of other data providers when appropriate. They shall ensure that the format of those data is in line with the requirements included in the protocols and templates made available by the Agency for data reporting.

Article 12

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

1. Member States shall report their data to the Agency on the volume of sales of the relevant antimicrobials via the web interface, using the protocols and templates made available to this end by the Agency and taking account of other relevant guidance documents produced by the Agency. When reporting their data to the Agency, Members States shall use the permanent and unique identification from the Union product database for the relevant veterinary antimicrobial medicinal product presentations, as referred to in Article 15(2) of Commission Implementing Regulation (EU) 2021/16.

2. Member States shall report, by 30 June of each year, their data on the volume of sales for the relevant veterinary antimicrobial medicinal products that were sold during the preceding calendar year for use within their respective national territories, in line with Article 6(d). They shall send their first report to the Agency by 30 June 2024.

3. Member States shall also report the following information to the Agency, via their national contact points and data managers and using the web interface:

(a) the type of data providers from which they collected their data on the volume of sales, along with a short description of their national distribution systems for veterinary medicinal products;

(b) the coverage and accuracy of their data on the volume of sales, together with measures taken to avoid double reporting;

(c) any initiatives led within the country or any relevant specific factors which may explain the results observed at national level, including possible pattern changes and trends;

(d) a brief description of their national policy framework or main initiatives in place to fight antimicrobial resistance and reduce any use of antimicrobials in animals that is neither prudent nor responsible.

4. Member States shall provide the information listed in paragraph 3 for the first data report by 30 June 2024 and update it subsequently in the following reporting periods, as applicable.

SECTION 2

DATA ON THE USE

Article 13

Methods for collecting and reporting to the Agency data on the use of antimicrobial medicinal products

1. In order to facilitate the collection of standardised and harmonised data on the use of the antimicrobial medicinal products referred to in Articles 3 and 4, Member States shall collect those data:

(a) from the following data providers, as appropriate: veterinarians, retailers, pharmacies, feed mills and end-users, including farmers or breeders;

(b) based on the following data sources, as appropriate: health records, treatment logbooks, delivery notes, invoices from farms, prescriptions, pharmacy records or veterinary practice records;

(c) using the systems for the collection of data on use referred to in Article 14.

2. Member States shall report their data on the use of the relevant veterinary antimicrobial medicinal products and antimicrobial medicinal products for human use, which may exceptionally be used in animals, for each product presentation, and for relevant animal species, categories or stages described in Article 15. They shall ensure that the data cover all uses of the relevant antimicrobial medicinal products during the preceding calendar year within their respective Member State territories, in line with Article 6(e).

The first report shall be sent to the Agency by 30 September 2024 and shall cover the data of antimicrobial medicinal products used during the preceding calendar year for relevant animal species, categories or stages.

The following reports after the first report shall be sent to the Agency by 30 June of each year and shall cover the data of antimicrobial medicinal products used during the preceding calendar year for relevant animal species, categories or stages.

3. Member States shall report their data on the use of the relevant antimicrobials via the web interface, using the protocols and templates made available to this end by the Agency and taking account of other relevant guidance documents produced by the Agency.

4. Member States shall also report the following information to the Agency, via their national contact points and data managers and using the web interface:

   (a) the type of data providers and data sources from which they collected their data on use, along with a short description of the main characteristics of their national systems for collection of data on use of antimicrobial medicinal products in animals;

   (b) the coverage and accuracy of their data on use, together with measures taken to avoid double reporting;

   (c) any initiatives led within the country or any relevant specific factors which may explain the results observed at national level, including possible pattern changes and trends;

   (d) a brief description of their national policy framework or main initiatives in place to fight antimicrobial resistance and reduce any use of antimicrobials in animals that is neither prudent nor responsible.

5. Member States shall provide the information described in paragraph 4 for the first data report by 30 September 2024 and update it subsequently in the following reporting periods, as applicable.

Article 14

Systems for the collection of data on the use of antimicrobial medicinal products

1. Member Sates shall develop semi- or fully-automated continuous data collection systems in order to gather data on the use of antimicrobial medicinal products in animals.

2. Member States shall develop software solutions to facilitate such data collection and support quality assurance, validation and quality control.

3. Taking into account the diversity of practices across the Union and the differences in national legal contexts, the Agency together with Member States shall organise, as appropriate, best practice sharing activities to support Member States in the development of their systems for collection of data on use.

4. Member States shall organise regular training sessions, or other information campaigns, for data providers on how to report data on the use of antimicrobials in animals via their respective national data collection systems.

Article 15

Animal species, categories and stages thereof, for which data on the use of antimicrobial medicinal products shall be collected and reported

1. Member States shall collect data on use for the following food-producing animal species, including all categories and stages, and report the data yearly to the Agency starting from 30 September 2024:

(a) cattle, while distinguishing beef cattle from dairy cattle and specifying use in bovines under one year of age separately when the production of meat from slaughtered bovines under one year of age exceeds 10 000 tonnes per year;

(b) pigs, while specifying use in fattening pigs;

(c) chicken, while specifying use in broilers and in laying hens;

(d) turkeys, while specifying use in fattening turkeys.

2. Member States shall collect data on use for the following food-producing animal species, including all categories and stages, and report the data yearly to the Agency starting from 30 June 2027:

(a) other poultry (ducks, geese);

(b) sheep;

(c) goats;

(d) finfish (Atlantic salmon, Rainbow trout, Gilthead seabream, European seabass, Common carp);

(e) horses (including ones declared as not being intended for slaughter for human consumption in the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429 of the European Parliament and of the Council[7]);

(f) rabbits (food-producing);

(g) any other food-producing animals of relevance to them.

3. Member States shall collect data on use for the following non-food-producing animal species, and report the data yearly to the Agency starting from 30 June 2030:

(a) dogs;

(b) cats;

(c) fur animals (minks and foxes).

SECTION 3

REPORT BY THE AGENCY ON THE VOLUME OF SALES AND ON THE USE

Article 16

Data and analyses to be included in the report by the Agency on the volume of sales of veterinary antimicrobial medicinal products and on the use of antimicrobial medicinal products

1. The Agency shall include in its report the data on the volume of sales of veterinary antimicrobial medicinal products and on the use of antimicrobial medicinal products per animal species, as referred to in Articles 12(2) and 13(2).

[7] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (Animal Health Law) (OJ L 084 31.3.2016, p. 1).

2. The data included in the Agency's report on the volume of sales of veterinary antimicrobial medicinal products shall be compared to the data of the preceding reporting periods, including data on the volume of sales reported under the ESVAC project, as appropriate and as far as the quality and the format of the data allows it.

3. The data included in the Agency's report on the use of antimicrobial medicinal products, starting from the second report to be published by 31 December 2025, shall be compared with the data of the preceding reporting periods.

4. The Agency shall analyse the data on the volume of sales of veterinary antimicrobial medicinal products and on the use of antimicrobial medicinal products and identify trends and pattern changes over time, both at national and Union levels. Those analyses shall be carried out in cooperation with Member States and other Union agencies, as appropriate, and included with the identified trends and pattern changes in the Agency's reports, together with the information provided by Member States as referred to in Article 12(3) and Article 13(4).

5. The Agency shall consider relevant animal populations per Member State in its analyses of the national data on the volume of sales of veterinary antimicrobial medicinal products and on the use of antimicrobial medicinal products. To this end, the Agency shall identify the necessary data on relevant animal populations per Member State via publicly accessible existing Union databases and ask Member States to verify and validate them. In the event that the necessary data on relevant animal populations is not available in such Union databases, or that those data would not comply with the data quality requirements laid down in Article 6, the Agency shall require Member States to provide or amend such data via the web interface.

6. For the reporting on the volume of sales of veterinary antimicrobial medicinal products, the Agency shall report the data for the corresponding animal populations likely to be treated with these products in the reporting Member States. The data shall be reported for food-producing animals and for other animals kept or bred, separately.

7. For the reporting on the use of antimicrobial medicinal products, as regards food-producing species, if data on certain animal populations are not available at national level because of very low production levels, then data on use for those animal populations may be reported under the animal group referred to in Article 15(2)(g).

Article 17

Publication by the Agency of its report on the volume of sales of veterinary antimicrobial medicinal products and on the use of antimicrobial medicinal products

1. The first report on the volume of sales of veterinary antimicrobial medicinal products and on the use of antimicrobial medicinal products per animal species shall be published by the Agency by 31 March 2025 and shall include the following:

   (a) the volume of sales of veterinary antimicrobial medicinal products, covering data from 2023 and submitted by Member States by 30 June 2024;

   (b) the use of antimicrobial medicinal products for relevant animal species, categories or stages covering data from 2023 and submitted by Member States by 30 September 2024.

2. As from 2025, the following reports after the first report shall be published by the Agency by 31 December and shall include the following:

(a) the volume of sales of veterinary antimicrobial medicinal products submitted by Member States by 30 June of each year, covering data from the preceding calendar year;

(b) the use of antimicrobial medicinal products for relevant animal species, categories or stages submitted by Member States by 30 June of each year, covering data from the preceding calendar year.

Article 18

Entry into force and application

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, 29.1.2021

For the Commission
The President
Ursula VON DER LEYEN