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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/576

of 30 November 2020

amending Annex III to Regulation (EU) No 978/2012 to include the Republic of Uzbekistan among the countries benefiting from tariff preferences under the GSP+

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 978/2012 of the European Parliament and of the Council of 25 October 2012 applying a scheme of generalised tariff preferences and repealing Council Regulation (EC) No 732/2008 ([1]), and in particular Article 10(4) thereof,

Whereas:

(1) Article 9(1) of Regulation (EU) No 978/2012 establishes specific eligibility criteria for the granting of tariff preferences under the special incentive arrangement for sustainable development and good governance ('GSP+') to a requesting country. For that purpose, the country should be considered vulnerable. It should have ratified all the conventions listed in Annex VIII to Regulation (EU) No 978/2012 and the most recent available conclusions of the relevant monitoring bodies should not identify a serious failure to effectively implement any of those conventions. In relation to any of the relevant conventions, the country should not have formulated a reservation which is prohibited by the convention or which, for the exclusive purposes of Article 9 of Regulation (EU) No 978/2012, is considered to be incompatible with the object and purpose of that convention. It should accept without reservation the reporting requirements imposed by each convention and give the binding undertakings referred to in points (d), (e) and (f) of Article 9(1) of Regulation (EU) No 978/2012.

(2) A GSP beneficiary country wishing to benefit from GSP+ has to submit a request accompanied by comprehensive information concerning ratification of the relevant conventions, its reservations and the objections to those reservations made by other parties to the convention, and its binding undertakings.

(3) On 9 June 2020, the Commission received a GSP+ request from the Republic of Uzbekistan.

(4) The Commission has examined the request and has established that the Republic of Uzbekistan meets the eligibility criteria laid down in Article 9(1) of Regulation (EU) No 978/2012. The Republic of Uzbekistan should therefore be granted GSP+ and Annex III to Regulation (EU) No 978/2012 should be amended accordingly.

(5) The Commission will keep under review the status of ratification of the relevant conventions and their effective implementation by the Republic of Uzbekistan, as well as the Republic of Uzbekistan's cooperation with the relevant monitoring bodies, in accordance with Article 13 of Regulation (EU) No 978/2012,

([1]) OJ L 303, 31.10.2012, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

In Annex III to Regulation (EU) No 978/2012, the following country and the corresponding alphabetical code are added in columns A and B, respectively:

'UZ	Republic of Uzbekistan'

Article 2

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

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

Done at Brussels, 30 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2021/577

of 29 January 2021

supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the content and format of the information necessary to apply Articles 112(4) and 115(5) and to be contained in the single lifetime identification document referred to in Article 8(4) of that Regulation

(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 109(1) thereof,

Whereas:

(1) In accordance with Article 8(4) of Regulation (EU) 2019/6, certain data, normally required for the marketing authorisation of a veterinary medicinal product, do not need to be submitted for products intended for animals of the equine species that have been declared as not being intended for slaughter for human consumption in the 'single lifetime identification document' referred to in point (c) of Article 114(1) of Regulation (EU) 2016/429 of the European Parliament and of the Council ([2]).

(2) Article 112 of Regulation (EU) 2019/6 provides for a derogation in respect of non-food-producing animal species from the rule that a veterinary medicinal product must be used in accordance with the terms of the marketing authorisation. In accordance with Article 112(4), that derogation also applies to the treatment by a veterinarian of an animal of the equine species provided that it is declared as not being intended for slaughter for human consumption in the single lifetime identification document.

(3) Article 115(5) of Regulation (EU) 2019/6 empowers the Commission to establish, by means of implementing acts, a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species is six months. In order to ensure consumer protection, details of a treatment applied in accordance with Article 115(5) should be documented in the single lifetime identification document.

(4) Taking into account the longevity of equids and the singularity of their accompanying identification document, valid identification documents issued in accordance with Commission Decisions 93/623/EEC ([3]) and 2000/68/EC ([4]), Commission Regulation (EC) No 504/2008 ([5]) and Commission Implementing Regulation (EU) 2015/262 ([6]) should be deemed to meet the content and format requirements as regards the information necessary to apply a treatment with a veterinary medicinal product applied in accordance with Article 112(4) or containing a substance listed in accordance with Article 115(5) of Regulation (EU) 2019/6 in the format laid down in this Regulation.

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

([2]) 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 84, 31.3.2016, p. 1).

([3]) Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae (OJ L 298, 3.12.1993, p. 45).

([4]) Commission Decision 2000/68/EC of 22 December 1999 amending Commission Decision 93/623/EEC and establishing the identification of equidae for breeding and production (OJ L 23, 28.1.2000, p. 72).

([5]) Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae (OJ L 149, 7.6.2008, p. 3).

([6]) Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of equidae (Equine Passport Regulation) (OJ L 59, 3.3.2015, p. 1).

(5) This Regulation should be applicable from 28 January 2022 in accordance with the date of application provided for in Regulation (EU) 2019/6.

(6) In accordance with Article 147(5) of Regulation (EU) 2019/6, the Commission has consulted experts designated by each Member State,

HAS ADOPTED THIS REGULATION:

Article 1

Content and format of the information necessary to apply Articles 112(4) and 115(5) of Regulation (EU) 2019/6

The content and format of the information necessary to apply Articles 112(4) and 115(5) of Regulation (EU) 2019/6 and to be contained in the single lifetime identification document shall comply with the requirements set out in Annexes I and II to this Regulation.

Article 2

Transitional measures

By way of derogation from Article 1, the following shall be deemed to meet the content and format requirements of information referred to in Article 1:

(a) the content and format of the information in 'Section IX Medicinal Treatment' of the identification document set out in the Annex to Decision 93/623/EEC and issued in accordance with Article 43(1)(a) of Implementing Regulation (EU) 2015/262;

(b) the content and format of the information in 'Section IX Administration of veterinary medicinal products' of the identification document as set out in Annex I to Implementing Regulation (EC) No 504/2008 and issued in accordance with Article 43(1)(b) and (c) of Implementing Regulation (EU) 2015/262;

(c) the content and format of the information in 'Section II Administration of veterinary medicinal products' of the identification document set out in Part 1 of Annex I to Implementing Regulation (EU) 2015/262 issued in accordance with Article 9 or 14 of that Regulation.

Article 3

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 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

1. The content of the information necessary to apply Article 112(4) of Regulation (EU) 2019/6 shall be the following:

   (a) contact details of the signing veterinarian responsible who treated the equine animal concerned with a veterinary medicinal product authorised under the exemption provided for in Article 8(4) or administered in accordance with Article 112(4) of Regulation (EU) 2019/6;

   (b) the declaration for the equine animal concerned that it is not intended for slaughter for human consumption to be done by the veterinarian responsible in consent with the owner or operator of the equine animal.

2. The content of the information necessary to apply Article 115(5) of Regulation (EU) 2019/6 shall be the following:

   (a) contact details of the signing veterinarian responsible who administered a veterinary medicinal product containing a substance included in the list established in accordance with Article 115(5) of Regulation (EU) 2019/6;

   (b) date and place of the last administration of the veterinary medicinal product referred to in point (a) to the equine animal concerned;

   (c) details of the substance referred to in point (a).

ANNEX II

1. The information necessary to apply Articles 112(4) and 115(5) of Regulation (EU) 2019/6 shall be included in a dedicated section that:

   (a) shall be indivisibly integrated in the single lifetime identification document;

   (b) shall contain titled form fields to be completed in accordance with detailed instructions; those titled form fields and the instructions for their completion shall be displayed in French, English and the official language of the Member State in which the single lifetime identification document is issued;

   (c) shall consist of at least two parts providing form fields for the entry of information necessary:

      (i) to declare the equine animal as not intended for slaughter for human consumption in order to apply Article 112(4);

      (ii) to document the date of last administration of a veterinary medicinal product containing a substance included in the list established in accordance with Article 115(5) of Regulation (EU) 2019/6, and details of that substance.

2. The format of the information necessary to apply Article 112(4) of Regulation (EU) 2019/6 shall meet the following additional criteria:

   (a) the format of the dedicated section referred to in paragraph 1 shall ensure that at least the declaration on the exclusion from slaughter for human consumption can be protected from fraudulent alterations;

   (b) the format of the declaration referred to in point (a) shall be compatible with a corresponding entry in the database referred to in Article 109(1)(d) of Regulation (EU) 2016/429.

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

(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(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 ([2]), 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 ([3]) 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 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.

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

(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) ([4]) and the Anatomical Therapeutic Chemical veterinary (ATCvet) ([5]) 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 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.

([4]) 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.

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

(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 ([6]).

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.

([6]) 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) (OJ L 7, 11.1.2021, p. 1).

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).

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.

([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 84,31.3.2016, p. 1).

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 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

1. **VETERINARY ANTIMICROBIAL MEDICINAL PRODUCTS FOR WHICH DATA ON THE VOLUME OF SALES SHALL BE COLLECTED AND REPORTED TO THE AGENCY AS REFERRED TO IN ARTICLE 1**

(1) Antidiarrheals, intestinal anti-inflammatory and anti-infective agents:

(a) QA07AA; QA07AB;

(b) QA07AX03;

(c) QA07AX04.

(2) Gynaecological antiinfectives and antiseptics:

(a) QG01AA;

(b) QG01AE;

(c) QG01BA;

(d) QG01BE.

(3) Antiinfectives and antiseptics for intrauterine use:

(a) QG51AA;

(b) QG51AG.

(4) Antibacterials for systemic use: QJ01.

(5) Antibacterials for intramammary use: QJ51.

(6) Antiprotozoals (with antibacterial effect): QP51AG.

(7) Antimycobacterials for intramammary use: QJ54.

2. **VETERINARY ANTIMICROBIAL MEDICINAL PRODUCTS FOR WHICH DATA ON THE VOLUME OF SALES MAY BE COLLECTED AND REPORTED TO THE AGENCY AS REFERRED TO IN ARTICLE 2**

(1) Antiprotozoals (other than QP51AG): QP51.

(2) Antifungals for topical use: QD01A.

(3) Antifungals for systemic use: QD01B.

(4) Antimycotics for systemic use: QJ02.

(5) Antimycobacterials: QJ04.

(6) Antivirals for systemic use: QJ05.

(7) Antibiotics and chemotherapeutics for dermatological use: QD06.

(8) Other nasal preparations:

(a) QR01AX06;

(b) QR01AX08.

(9) Ophthalmological antiinfectives:

(a) QS01AA;

(b) QS01AB;

(c) QS01AD;

(d) QS01AE;

(e) QS01CA;

(f) QS01CC.

(10) Otological antiinfectives:

(a) QS02AA;

(b) QS02CA;

(c) QS03AA;

(d) QS03CA.

3. **ANTIMICROBIAL MEDICINAL PRODUCTS FOR WHICH DATA ON USE IN ANIMALS SHALL BE COLLECTED AND REPORTED TO THE AGENCY AS REFERRED TO IN ARTICLE 3**

(1) Antidiarrheals, intestinal anti-inflammatory and anti-infective agents:

(a) QA07AA, A07AA;

(b) QA07AB, A07AB;

(c) QA07AX03, A07AX03;

(d) QA07AX04, A07AX04.

(2) Gynaecological antiinfectives and antiseptics:

(a) QG01AA, G01AA;

(b) QG01AE, G01AE;

(c) QG01BA, G01BA;

(d) QG01BE, G01BE.

(3) Antiinfectives and antiseptics for intrauterine use: QG51AA.

(4) Antibacterials for systemic use: QJ01, J01.

(5) Antibacterials for intramammary use: QJ51.

(6) Antiprotozoals (with antibacterial effect): QP51AG.

4. **ANTIMICROBIAL MEDICINAL PRODUCTS FOR WHICH DATA ON USE IN ANIMALS MAY BE COLLECTED AND REPORTED TO THE AGENCY AS REFERRED TO IN ARTICLE 4**

(1) Antibiotics and chemotherapeutics for dermatological use: QD06, D06.

(2) Other nasal preparations:

(a) QR01AX06, R01AX06;

(b) QR01AX08, R01AX08.

(3) Antimycobacterials for intramammary use: QJ54.

(4) Ophthalmological antiinfectives:

(a) QS01AA, S01AA;

(b) QS01AB, S01AB;

(c) QS01AD, S01AD;

(d) QS01AE, S01AE;

(e) QS01CA, S01CA;

(f) QS01CC, S01CC.

(5) Otological antiinfectives:

(a) QS02AA, S02AA;

(b) QS02CA, S02CA;

(c) QS03AA, S03AA;

(d) QS03CA, S03CA.

(6) Antiprotozoals (other than QP51AG): QP51, P01.

(7) Antifungals for topical use: QD01A, D01A.

(8) Antifungals for systemic use: QD01B, D01B.

(9) Antimycotics for systemic use: QJ02, J02.

(10) Antimycobacterials: QJ04, J04.

(11) Antivirals for systemic use: QJ05, J05.

DECISIONS

COUNCIL DECISION (CFSP) 2021/579

of 8 April 2021

amending Decision (CFSP) 2019/615 on Union support for activities leading up to the 2020 Review Conference of the Parties to the Treaty on the Non-Proliferation of Nuclear Weapons (NPT)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 31(1) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 15 April 2019 the Council adopted Decision (CFSP) 2019/615 ([1]).

(2) On 29 June 2020 the Council adopted Decision (CFSP) 2020/906 ([2]), which amended Decision (CFSP) 2019/615.

(3) Decision (CFSP) 2019/615 provides for a 24-month implementation period, beginning on the date of conclusion of the financing agreement referred to in Article 3(3) thereof, for the activities referred to in Article 1 thereof ('the implementation period').

(4) The United Nations Office for Disarmament Affairs (UNODA) has requested an additional extension of the implementation period until 15 October 2021 because of the worldwide COVID-19 crisis and the temporary suspension of the activities referred to in Article 1 of Decision (CFSP) 2019/615.

(5) The activities referred to in Article 1 of Decision (CFSP) 2019/615 can be continued until 15 October 2021 without any consequences as regards financial resources.

(6) Decision (CFSP) 2019/615 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 5 of Decision (CFSP) 2019/615, paragraph 2 is replaced by the following:

'2. This Decision shall expire on 15 October 2021.'.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 8 April 2021.

For the Council
The President
A. P. ZACARIAS

([1]) Council Decision (CFSP) 2019/615 of 15 April 2019 on Union support for activities leading up to the 2020 Review Conference of the Parties to the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) (OJ L 105, 16.4.2019, p. 25).

([2]) Council Decision (CFSP) 2020/906 of 29 June 2020 amending Decision (CFSP) 2019/615 on Union support for activities leading up to the 2020 Review Conference of the Parties to the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) (OJ L 207, 30.6.2020, p. 36).

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