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Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations

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Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations

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1. Introduction

This document provides guidance on the development and implementation of a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 foreseen in Article 7(1) of Commission Delegated Regulation (EU) 2021/578.

The data quality management plan is to ensure that the data quality requirements outlined in Article 6 of Commission Delegated Regulation (EU) 2021/578 are fulfilled at all stages of the data management workflow. The data quality management plan should be developed based on the data type collected and in collaboration between the agencies/bodies, as applicable.

The procedures for data quality management along the different steps of the workflow, as well as risk mitigation strategies, aim to ensure preparedness to address data quality gaps and errors, foster a data-driven culture that prioritizes accuracy, integrity, and compliance. Regular monitoring and review, coupled with continuous improvement and training initiatives, will ensure that the data quality management plans or systems remain effective and meet the regulatory requirements consistently. The implementation of a robust and well-designed quality management plan will enable the provision of high-quality data to support evidence-based decision-making and safeguard public health and animal health and welfare.

As per Article 7(2)(c) of Commission Delegated Regulation (EU) 2021/578, the national contact points and data managers are to take account of the 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. The purpose of this Manual is therefore to provide high level guidance and support on the requirements of a data quality management plan for the collection of antimicrobial sales and use data. This Manual also aims to create a common understanding and harmonisation between Member States on such plan, promoting and facilitating best-practice and knowledge-sharing activities between Member States. It includes recommendations for Member States to adapt according to their national context, background and needs. It should be understood as a guidance document only to support Member States in fulfilling their legal obligations. Furthermore, for national agencies/bodies that already have a quality system implemented, the data management workflow process presented here can be integrated in that system, together with the relevant quality control and assurance requirements. For agencies that do not have a quality system already implemented, the data quality management plan can be used or transformed in a quality system.

During the development of this document, it was agreed to align the terminology used with the one on Regulation (EU) 2019/6 and Commission Delegated Regulation (EU) 2021/578 and to refer to ISO 9000:2015 for specific terminology linked with quality management, in order to have a common understanding and harmonisation across Member States. With the same purpose, ISO 9001:2015, ISO 10005:2018 and ISO 9004:2018 were also used as supporting and reference documents during the development and drafting process.

Member States should update their data quality management plan regularly or as appropriate, in order to take account of scientific and technical developments in the area, as required in Article 7(3) of Commission Delegated Regulation (EU) 2021/578. The data quality management plan does not need to be sent to the Agency. Should the legislative acts be updated in the future, or the need to update the content of this Manual is identified, this document will also be updated accordingly.

This Manual was developed by the Agency in collaboration with the European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) data quality management subgroup. Representatives from the whole ESUAvet WG were consulted, and representatives from the European Commission were invited as observers. The Manual was discussed and adopted during the CVMP April 2024 meeting.

2. Suggested structure of the data quality management plan

1 Introduction

1.1 Background

In this section, provide an overview of the data collection and reporting project and its importance in monitoring data on the volume of sales and on the use of antimicrobial medicinal products in animals in your country, as well as animal population data, when applicable. If appropriate, refer to the legal basis mentioned in section 2.

Indicate, if applicable:

- The alignment of the plan with ISO 9000:2015, ISO 9001:2015, ISO 10005:2018 and ISO 9004:2018 standards, demonstrating the national agency/body's commitment to a robust data quality management system.

- The role of the standard operating procedures (SOPs) in guiding the data quality management process, allowing for a harmonised procedure and addressing main data gaps and errors through the defined data management workflow and steps.

- The focus on continuous improvement, risk management, and regular monitoring and reviewing to maintain and enhance data quality over time.

- The commitment to training and information campaigns to ensure that national contact points, data managers and national data providers are competent and informed about the data quality requirements and data management best practices.

1.2 Purpose, Scope and Customers

Clearly state the purpose of the data quality management plan, which is to establish a systematic approach for ensuring the collection and reporting of data on the volume of sales and on the use of antimicrobials in animals which meet the requirements laid down in Article 6 of Commission Delegated Regulation (EU) 2021/578. Define the scope of the plan, including geographic area covered, if applicable (e.g., when there are autonomous regions) and the types of data being collected.

Describe who are your customers and any other interested parties, i.e., who will receive/use the data collected or to whom you will report the data (e.g. the European Medicines Agency, Public Health bodies, Ministry of Health, WOAH, etc.). Include, if relevant, a description of the impact of such data and any other relevant information.

1.3 Quality objectives

Explain the main objectives of the data quality management plan, i.e. to ensure compliance with the data quality requirements listed in Article 6, which includes data accuracy, coverage, completeness, timeliness and consistency.

1.4 National agencies/bodies involved

Identify the national agencies/bodies involved in the collection and reporting of data, specifying the type of data handled by that agency/body [numerator (sales and/or use), denominator (animal population data) or both] and if they are responsible only for collecting the data from the national data

providers, only for reporting the data to the EMA, or both. Furthermore, the national competent authority responsible for the information on veterinary medicinal products in the Union Product Database (UPD) should be identified.

The data quality management plan should be developed based on the data type collected and in collaboration between the agencies/bodies, as applicable. When several national agencies/bodies are involved in the data collection and reporting, a single or several data quality management plan(s) could be implemented and this decision should be taken at national level, after careful consideration about the national system, context and applicable laws. For agencies that already have a quality system implemented, the data management workflow process can be integrated in that system, together with the relevant quality control and assurance requirements. For agencies that do not have a quality system already implemented, the quality plan can be used or transformed in a quality system.

The animal population data used as denominator for the analysis of data, which are already sourced in European databases, such as EUROSTAT and TRACES, will be made available to Member States by the Agency. These data should be complemented by national data, when needed, thus the involvement of the relevant national agencies/bodies should be considered on a case-by-case basis and taking into consideration the national context.

Templates for reporting the data on the volume of sales and on the use of antimicrobials, containing information on the relevant veterinary medicinal products retrieved from UPD, are also made available by the Agency to the Member States, via the ASU platform. Details on the veterinary medicinal products have to be validated against the product information and national databases, and when errors are detected, the information needs to be corrected in UPD by the relevant National Competent Authority (Reference Member State).

ISO 10005:2018 provides examples of data quality plans as summarised tables. The content of the data quality management plan could be presented as a summarised table, following the examples provided in this norm and using this Manual as guidance, if feasible and appropriate.

In order to identify the different national agencies/bodies involved in the collection and reporting of data, as example, the following table could be used. Please note that this table is only an example and should not be interpreted as a suggestion for Member States to consider at national level, as the chosen organisation depends on the number of agencies/bodies involved, national context and background.

Name of the national agency/body	Type of data handled [numerator (sales and/or use) and/or animal population]	Actions (collecting, reporting to the EMA or both)	Data quality management plan (e.g. identification of the plan, parts of the DQMP that apply, comments regarding the DQMP, etc)
National agency 1	Sales	Collecting and reporting to the Agency, including validation of templates	Plan 1
National agency 2	Use	Collecting and reporting to the Agency, including validation of templates	Plan 2

National agency 3	Animal population	Collecting and reporting to the Agency, including validation of templates	Plan 3
National agency 4	UPD-information	Ensuring UPD information is correct and support ASU needs (i.e., non-editable fields in templates)	Plan 4

2. Regulatory Framework

2.1 European legislation

The following text is proposed as a harmonised description of the European legislation applicable to the collection of data on antimicrobials in animals.

The requirements for the collection and reporting of data in relation to the volume of sales and use of antimicrobial medicinal products in animals are set out in various legal acts.

Regulation (EU) 2019/6 lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products. Article 57 requires Member States to collect and report to the Agency relevant and comparable data on the volume of sales and on the use of antimicrobial medicinal products in animals by Member States. The purpose is to have sufficiently detailed and comparable data, to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced.

Commission Delegated Regulation (EU) 2021/578 supplements Regulation (EU) 2019/6, with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals. It includes requirements regarding the types, scope and quality of data to collect, data providers and timelines for reporting the data to the Agency and for the publication of the report by the Agency. It also establishes the methods and systems for collecting data. Additionally, Article 7 requires Member States to set out a data quality management plan that comprises appropriate data quality management procedures, including procedures for data quality assurance, validation and quality control.

Commission Implementing Regulation (EU) 2022/209 establishes the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals. It includes information on the format of the different variables to be reported to the Agency and requirements linked to the animal population data. This regulation should be taken into account together with the Agency's protocols and templates to ensure standardization of reporting practices.

Taken together, those regulations intend to harmonise at EU level the collection and reporting of high quality data on the volume of sales and on the use of antimicrobial medicinal products in animals and to improve surveillance and monitoring of antimicrobial use.

2.2 National legislation and policy framework

If applicable, please include references to the national legislation applicable to the collection and reporting of sales and use data by national data providers to the national agencies/bodies.

For animal population data, if applicable, please include here references to the national legislation and/or other applicable national rules or procedures, specifying the animal species for which it refers to.

On this point, a brief description of the 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, could also included, as outlined in Articles 12(3)(d) and 13(4)(d) of Commission Delegated Regulation (EU) 2021/578.

2.3 Applicable guidance

Any applicable guidance available nationally or internationally should be described in this section. EMA guidance made available to Member States should also be described.

EMA guidance includes several guidelines, manuals and protocols to assist and support with the data collection and reporting. They are reviewed and updated periodically, according to the needs identified, thus Member States should ensure that they are using the correct and updated versions published on the EMA webpage: https://www.ema.europa.eu/en/veterinary-regulatory-overview/antimicrobial-resistance-veterinary-medicine/antimicrobial-sales-and-use-platform

Manuals and guidelines:

- EMA, Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022). 2023: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-reporting-antimicrobial-sales-and-use-animals-eu-level-denominators-and-indicators_en.pdf.
- EMA, Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency (EMA/757638/2021). 2022: https://www.ema.europa.eu/en/documents/other/antimicrobial-use-data-reporting-animal-categories-numerator-manual-reporting-data-ema_en.pdf.
- EMA, Concept paper on the reporting of antimicrobial sales and use in animals at the EU level Draft (EMA/222040/2020). 2020: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/draft-concept-paper-reporting-antimicrobial-sales-use-animals-eu-level_en.pdf.

Reporting protocols and templates:

- EMA, Antimicrobial Sales and Use (ASU) technical implementation protocol - Implementation of the requirements of Regulation (EU) 2019/6 for the collection of data on volume of sales of veterinary antimicrobials and use of antimicrobial medicinal products animals (EMA/27838/2024). 2024: https://www.ema.europa.eu/en/documents/other/antimicrobial-sales-and-use-asu-technical-implementation-protocol_en.pdf.
- EMA, Antimicrobial Sales and Use (ASU) Power BI Application User guide for National Competent Authorities users (EMA/27837/2024). 2024: https://www.ema.europa.eu/en/documents/other/antimicrobial-sales-and-use-asu-power-bi-application_en.pdf.
- EMA, Antimicrobial Sales and Use (ASU) Platform User Guide User guide for National Competent Authority users (EMA/27839/2024). 2024: https://www.ema.europa.eu/en/documents/other/antimicrobial-sales-and-use-asu-platform-user-guide_en.pdf.

- EMA, Antimicrobial Sales and Use (ASU) - Sales data template. 2024: https://www.ema.europa.eu/en/documents/template-form/antimicrobial-sales-and-use-asu-sales-data-template_en.xlsx-0.
- EMA, Antimicrobial Sales and Use (ASU) - Use data template. 2024: https://www.ema.europa.eu/en/documents/template-form/antimicrobial-sales-and-use-asu-use-data-template_en.xlsx-0.
- EMA, Antimicrobial Sales and Use (ASU) - Animal population data template. 2024: https://www.ema.europa.eu/en/documents/template-form/antimicrobial-sales-and-use-asu-animal-population-data-template_en.xlsx.

3. Data Quality Management System

3.1 Data Quality Policy

Present the national agency/body's data quality policy, including a reference to its vision and mission, which outlines the commitment to data quality objectives and data quality requirements, in compliance with Article 6 of Commission Delegated Regulation (EU) 2021/578. Include key principles and values related to data quality.

3.2 Roles and Responsibilities

Include the relevant references to the job descriptions, and described, if appropriate, the required expertise and responsibilities of the roles involved in the data workflow process, including top management/leadership, and national contact points and data managers, as indicated in Article 7(2) of Commission Delegated Regulation (EU) 2021/578. Other possible roles and responsibilities that could be described are data collectors, data entry personnel, data validators, data analysts, and management. Explain how communication and collaboration will be facilitated among the team.

3.3 Training and Competence

Detail the education level and the training programs implemented to ensure the competence of personnel involved in data collection, validation, and analysis. Emphasise the importance of skilled and knowledgeable staff for ensuring data quality.

Examples of specific trainings and/or knowledge that national contact points and/or data managers should have:

- EMA trainings on ASU and ASU/UPD available in EU Network Training Centre;
- data management/analytics trainings;
- knowledge of quality assurance best-practices;
- knowledge of the medicine chain/lifecycle of the medicine;
- knowledge of relevant animal production and its structure;
- knowledge of the relevant ISO norms.

3.4 Data collection system and other software solutions

Describe the systems used for the collection of data on the volume of sales and on the use of antimicrobial medicinal products, including if they are semi- or fully-automated continuous, as required for use data collection in Article 14(1) of Commission Delegated Regulation (EU) 2021/578. Describe any other relevant software solution(s), required in Article 14(2) of Commission Delegated Regulation (EU) 2021/578, which are used to facilitate the data collection and/or to support quality assurance, control and validation (e.g. national Power BI reports or other data visualization/analytics tools used for validating, analysing or monitor the quality of the data).

3.5 Quality assurance

Describe the steps and procedures implemented to assure the quality of the data, as required in Article 7(2)(b) of Commission Delegated Regulation (EU) 2021/578, linking them to the respective chapters in the DQMP or including a reference to the relevant document, as appropriate.

The quality assurance should include at least:

- Hierarchy and organisation structure – tasks and responsibilities;
- The description of national contact points and data managers training and competences;
- The description of the training programmes and/or other information campaigns delivered to the national data providers;
- The Correction Actions and Preventive Actions (CAPA) plans implemented;
- Internal and external audit plans;
- Control of documentation and versions;
- Data protection and safeguard;
- Risk management and mitigation.

4. Data Management Workflow and Standing Operating Procedures

The complete data management workflow can be consulted in Annex I of this Manual. Each step of the workflow should be linked to the respective procedure, when needed and appropriate.

Commission Delegated Regulation (EU) 2021/578 sets out in Article 7(1) several data quality management procedures that should be implemented nationally. These includes the following procedures:

- Procedures for data quality management (general procedures, if applicable, such as the ones referred to in sections 3.1 to 3.4)
- Procedures for data quality assurance (please refer to section 3.5 for further information on what should be considered for quality assurance)
- Procedures for data quality validation
- Procedures for data quality control

In addition to these procedures, other procedures can also be used, according to the national context, with the data collection system that is used and with the quality management systems already implemented in the national agency/body, if applicable. Some examples are:

- Procedures for Data Call
- Procedures for Data Collection
- Procedures for Data Entry
- Procedures for Data Storage and Access
- Procedures for Data Handling for animal species categories – use data numerator
- Procedures for Data Analysis (national step)
- Procedures for Data Reporting to the Agency
- Procedures for Data Submission
- Procedures for Communication with the Agency

The next subchapters provide further detail on each step of the data management workflow, which could be used to develop these procedures at national level.

4.1 National Process only

4.1.1 Data Call

The data workflow starts with the national data call sent to the data providers. For continuous automatic collection systems, all steps may not apply or apply only at its launching.

For systems with annual call for data, indicate here:

- When should the data call start;
- The data providers (for sales and use data) selected (with a brief explanation of why they were selected);
- The data sources (for use data) (with a brief explanation of why they were selected);
- The communication tools used (via the national web application, by email, letters or other);

For all systems, indicate here:

- The national data lock point (deadline to report the requested data) to receive the data from the data providers;
- Methods or procedures implemented to ensure that there is an alignment between the specifications for data reporting by the national data providers and the specifications for data reporting to the Agency, as foreseen in Article 7(2)(a) of Commission Delegated Regulation (EU) 2021/578;
- Any data privacy and ethical considerations.

The data providers and data sources should be selected taken into consideration the national context and framework, the relevant medicine chain and the provisions included in Article 11 and 13 of Commission Delegated Regulation (EU) 2021/578.

When the data collected from the data providers are not anonymised and include collection of personal data, Regulation (EU) 2016/679, the General Data Protection Regulation (hereafter, GDPR), applies with regards to the processing of such data. In these cases, personal data should be safeguarded, as outlined in Articles 12 and 13 (or 14) of GDPR. The national agency/body's Data Protection Officer

(DPO) should be contacted to develop the appropriate Data Protection Notice to be sent with the data call.

4.1.2 Data Collection

Describe the national data collection process, referring to the system used, relevant timelines and how the overall process of collecting the data is monitored by the national contact points and/or data managers. Include tools for communicating with the national data providers when errors are identified or when there are questions regarding the data reported and alternative procedures in case there is a failure in the system.

4.1.3 Data Entry (optional)

Describe the process used for data entry, when data from national providers are received in Excel/CSV files and need to be uploaded in the data collection system or national database. Any preventive measures implementation to avoid errors, duplicates, unauthorised access or changes to the data during this step should also be described here.

4.1.4 Data Storage and Access

Describe the national database and the data storage infrastructure, including backup systems and security measures. Indicate the time retention for raw data and personal data collected and link it with national legislation and GDPR, as appropriate and if applicable. Describe access controls to ensure data confidentiality, integrity and protection from unauthorised access or changes. If applicable, describe also the measures implemented to ensure the safeguarding and protection of personal data.

The time for retention of raw and/or personal data should be defined taking into consideration:

1) timelines for storing raw data for (public) health purposes defined in the national legislation;

2) application of the General Data Protection Regulation (GDPR) with regards to processing personal data, when the data collected from the national sources are not anonymised and can be linked to a specific person/organisation/company;

3) historical corrections at the EMA ASU database (in ASU currently there are no limits to the historical corrections).

Depending on the type of data collection system used nationally, this point could also be included as a sub-section of 4.1.2.

4.1.5 Data Quality Control (national step)

The data control includes the steps taken to ensure that the data collected and reported to the Agency fulfils data quality requirements provided for in Article 6 of Commission Delegated Regulation (EU) 2021/578.

At this point, describe how the data are cleaned from duplicates or veterinary medicinal products with ATCvet codes not indicated in the Annex to Commission Delegated Regulation (EU) 2021/578, how data are amended in case gaps, errors or inconsistencies are identified and how it is confirmed that the data reported by the national data providers conform to the standardised specifications of the latest Agency's ASU reporting protocols and templates.

Describe the process of reporting data errors or gaps identified back to the national providers, including the channels for reporting and the responsibilities for handling corrections. Explain how timely corrections are made to maintain data accuracy.

Describe how the data are checked to confirm their coverage and accuracy, as well as any measure implemented to avoid double reporting, as described in Article 12(3)(b) and Article 13(4)(b) of Commission Delegated Regulation (EU) 2021/578. For sales, describe also the measures implemented to confirm that the data include sales of those antimicrobials brought in from other Member States to be used nationally and excludes sales of those antimicrobials sent to other Member States to be used outside of the national territory; and if and how data are corrected in relation to movements of veterinary medicinal products for parallel trade, as indicated in point 21 of Annex I of Commission Implementing Regulation (EU) 2022/209. For use, describe the quality checks needed to confirm national data granularity of the use data numerator in line with 'Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency'.

In this step the following data quality requirements can be verified:

a) Data reported conform to the standardised specifications of the latest Agency's ASU reporting protocols;

b) Data included in non-editable fields of templates for report sales and use data conform with the respective product information. The relevant National Competent Authority (Reference Member State) should be contacted to solve any discrepancies or errors found, when appropriate;

c) Data are amended in case gaps, errors or inconsistencies are identified;

d) Data on the volume of sales covers at least all sales of the antimicrobials listed by ATCvet code in point 1 of the Annex of Commission Delegated Regulation (EU) 2021/578;

e) Data includes sales of those antimicrobials brought in from other Member States to be used nationally and excludes sales of those antimicrobials sent to other Member States to be used outside of the national territory;

f) Data on use covers all national use of at least the antimicrobials listed by ATCvet code in point 3 of the Annex for all animal species and categories or stages listed in Article 15 of Commission Delegated Regulation (EU) 2021/578.

4.1.6 Data handling for animal species category – use data numerator (optional)

For use data, describe if further increase or decrease of the granularity at national level of the collected data applies and for which animal species category. Describe also how the data are aggregated or disaggregated in line with 'Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency'.

4.1.7 Data Validation (national step)

Outline the methods and procedures used for data validation, including validation rules, acceptance criteria, and methods for resolving discrepancies. Explain how data quality issues are identified and addressed. Explain how outliers, odd trends and any remaining data errors are identified and resolved and how the data are compared with previous year(s) data, if applicable.

When this step is taken, the data workflow can re-start in 4.1.2 or 4.1.5, as appropriate.

4.1.8 Data Analysis (national step)

Present the methods and tools used for data analysis at national level (e.g. for the national report publication, any specific queries) to derive meaningful insights and trends. Mention any statistical techniques applied during the analysis.

4.2 Interaction between the Member State and the Agency

4.2.1 Data Reporting to the Agency

Outline how sales and use data are reported to the ASU database and via the web interface, within the legal deadlines and using the Agency's protocols and templates, as required in Commission Delegated Regulation (EU) 2021/578. Describe the different steps, timelines, internal and external communication steps and definition of responsibilities, including validation of information in the templates made available by the Agency for reporting sales, use and animal population data.

4.2.2 Data Quality Control (ASU step)

Upon reporting, the data are to be processed through the automated data entry checks as performed by the Agency's ASU web interface, as provided for in Article 6(b) and Article 10(1)(b).

Describe the procedures in place to amend the data reported and eliminate data gaps, errors and inconsistencies, as required in Article 7(2)(d) and Article 10(1)(c) of Commission Delegated Regulation (EU) 2021/578.

Describe any procedures, tools for communication with national bodies, timelines and responsibilities, which are implemented to verify, validate and, if necessary, amend the animal population data gathered by the Agency, as indicated in Article 7(2)(e), Article 10(1)(d) and Article 16(5) of Commission Delegated Regulation (EU) 2021/578.

4.2.3 Data Validation (ASU step)

Describe how the Agency's ASU Power BI reports are used for data validation, before the final submission to the Agency. Explain how the numerator and denominator are validated and how data quality issues are identified and addressed. Explain how outliers, odd trends and any remaining data errors are identified and resolved and how the data are compared with previous year(s) data, if applicable.

When this step is taken, the data workflow can re-start in 4.2.1 or 4.2.2, as appropriate.

4.2.4 Data Submission

Describe any procedures, internal or external communication steps, timelines and responsibilities to make the final submission of the data to the Agency, via the ASU web interface, and confirming that the data submitted comply with the data quality requirements laid down in Article 6 of Commission Delegated Regulation (EU) 2021/578.

4.2.5 Communication with the Agency

Describe any procedures, internal or external communication steps, timelines and responsibilities to answer the Agency's requests and to take any necessary actions to ensure compliance with data quality requirements and/or to amend the data reported to the Agency, if requested by the Agency, in

order to eliminate data gaps, errors and inconsistencies, as required in Article 9(2) of Commission Delegated Regulation (EU) 2021/578.

When this step is taken, the data workflow can re-start in 4.2.1 or 4.2.2, as appropriate.

Following this step, the national workflow stops and the data are processed by the Agency in collaboration with Member States. The data are analysed at EU level and are published in the ASU database and annual report, as required in Articles 16 and 17 of Commission Delegated Regulation (EU) 2021/578.

5. Data Quality Metrics

5.1 Key Performance Indicators (KPIs)

Identify the key data quality metrics to measure the success of the data quality management process. Explain how each KPIs will be monitored, reported, and assessed against established targets.

The accuracy and coverage of data on the volume of sales and on the use need to be reported to the Agency, as foreseen in Articles 12(3)(b) and 13(4)(b) of Commission Delegated Regulation (EU) 2021/578:

- **Accuracy** rate: measures the correctness of values within a dataset as a percentage of the total data entries (e.g., known and identifiable errors linked to the reporting of veterinary medicinal product per package by the national data provider on the data fields that are to be reported to the Agency).
- **Coverage** rate: measures the volume of sales and/or use data captured by the data call as a percentage of the total quantity of antimicrobial active substance sold and/or used.

For national purposes, other rates related with the collected data from national data providers can also be considered, for example:

- Completeness rate: measures the completed data fields as a percentage of the total required fields.
- Response rate: measures the number of responders as a percentage of the total number of national data providers to whom the call was sent.
- Timeliness rate: measures the percentage of national data providers who reported the data within the national data lock point.

The calculation of the rates can be calculated at different levels and several times during the data management workflow, depending on the national context and national providers (e.g. individually per data provider, if applicable, globally including all data providers, during the quality control or data validation, etc.).

5.2 Data Quality Targets

Set specific data quality targets for each KPI included in the plan, taking into account the requirements of Commission Delegated Regulation (EU) 2021/578.

Explain the approach to conducting data quality assessments regularly to measure the achievement of data quality targets. Describe the assessment criteria and methods used.

6. Data Quality Improvement

6.1 Deviations, gaps and nonconforming outputs

Present the procedures implemented to detect, assess and record deviations, gaps and nonconforming outputs, in order to identify areas for improvement or that are missing in the current data quality management process and implement appropriate corrective and/or preventive actions.

6.2 Corrective Actions and Preventive Actions plans

Describe how corrective actions and preventive actions (CAPA) plans are developed, implemented and monitored to address the identified deviations, gaps and/or non-conformities.

6.3 Continuous Improvement and change management

Outline the approach to continuous improvement in data quality management. Describe how feedback from stakeholders, data quality assessments, and internal reviews, as well as the detection of deviations, gaps and/or non-conformities will be used to drive improvements.

Describe the procedures and assignment of tasks and responsibilities, when a risk-based approach assessment is needed to manage and implement upcoming changes (e.g. new IT system, new animal species for which use data needs to be reported).

8. Risk Management

8.1 Data Security Risks

Identify potential data security risks, including data breaches and unauthorised access or updates to data. Propose risk mitigation strategies and controls to protect data. If personal data are collected, describe how data are safeguarded from unauthorised access and how such data are eliminated after the defined retention period.

Describe back-ups in place to safeguard the data and procedures in place to deal with possible problems that put at risk the safety of the data (e.g., power losses, cybersecurity incidents, etc.).

8.2 Mitigation Strategies

Present an overview of the strategies and controls in place to mitigate data quality risks, which might prevent the fulfilment of the data quality requirements set out in Article 6 of Commission Delegated Regulation (EU) 2021/578. Describe different levels of supervision/monitoring of the quality of the data reported by national data providers (e.g., new data providers vs experienced data providers), following a risk-based approach, if applicable. Mention how these strategies align with ISO 9001:2015 and ISO 31000 risk management principles.

9. Monitoring and Review

9.1 Audits

Describe what type of audits will be conducted (internal and/or external) to assess the effectiveness of the data quality management system, to verify and monitor conformity with the data quality

requirements, and compliance with the SOPs. Describe the audit process and frequency and identify the key people (e.g., people responsible for the quality system, top management).

9.2 Management Review

Describe the process of management/top leadership review to evaluate the overall performance of the data quality management system and identify areas for improvement. Mention how feedback from management is used for decision and change-making.

10. Training programs and other information campaigns

As outlined in Article 14(4) of Commission Delegated Regulation (EU) 2021/578, describe the (specific) training programs and/or other information campaigns conducted to educate key people and stakeholders involved in the national data collection and reporting (e.g., data providers, veterinarians, etc.) on data collecting, data reporting via the national data collection system, communication procedures and on the data quality requirements. Indicate how records of the training programs are kept and, optionally, describe how training effectiveness is evaluated (e.g., surveys, tests, etc.).

11. Control of documented information

Describe how the relevant documentation is identified, when and by whom it is reviewed and approved, how its distribution and access is controlled, and how it is maintained (control of versions) and protected from unintended alteration and made available when required.

Identify which documentation should be retained to provide evidence of conformity with the data quality requirements, in which language format and media and for which period of time. Identify any documentation to be supplied to the relevant customers, when and by what means.

12. External providers

If the services of external providers are used or parts of the process are outsourced, identify the external providers, specify the critical characteristics of externally provided processes, products and services that can affect the data quality requirements and describe the process for outsourcing and the contract in place. Describe the methods used for the evaluation, control and monitoring of the services contracted, in order to ensure compliance with the statutory and regulatory requirements. This point is not applicable to national data providers reporting the data, it refers specifically to the outsourcing of a specific task(s) or step(s) of the data management workflow, considering that specific tasks can be delegated to external contractors, but the responsibility remains with the national agency/body.

3. References

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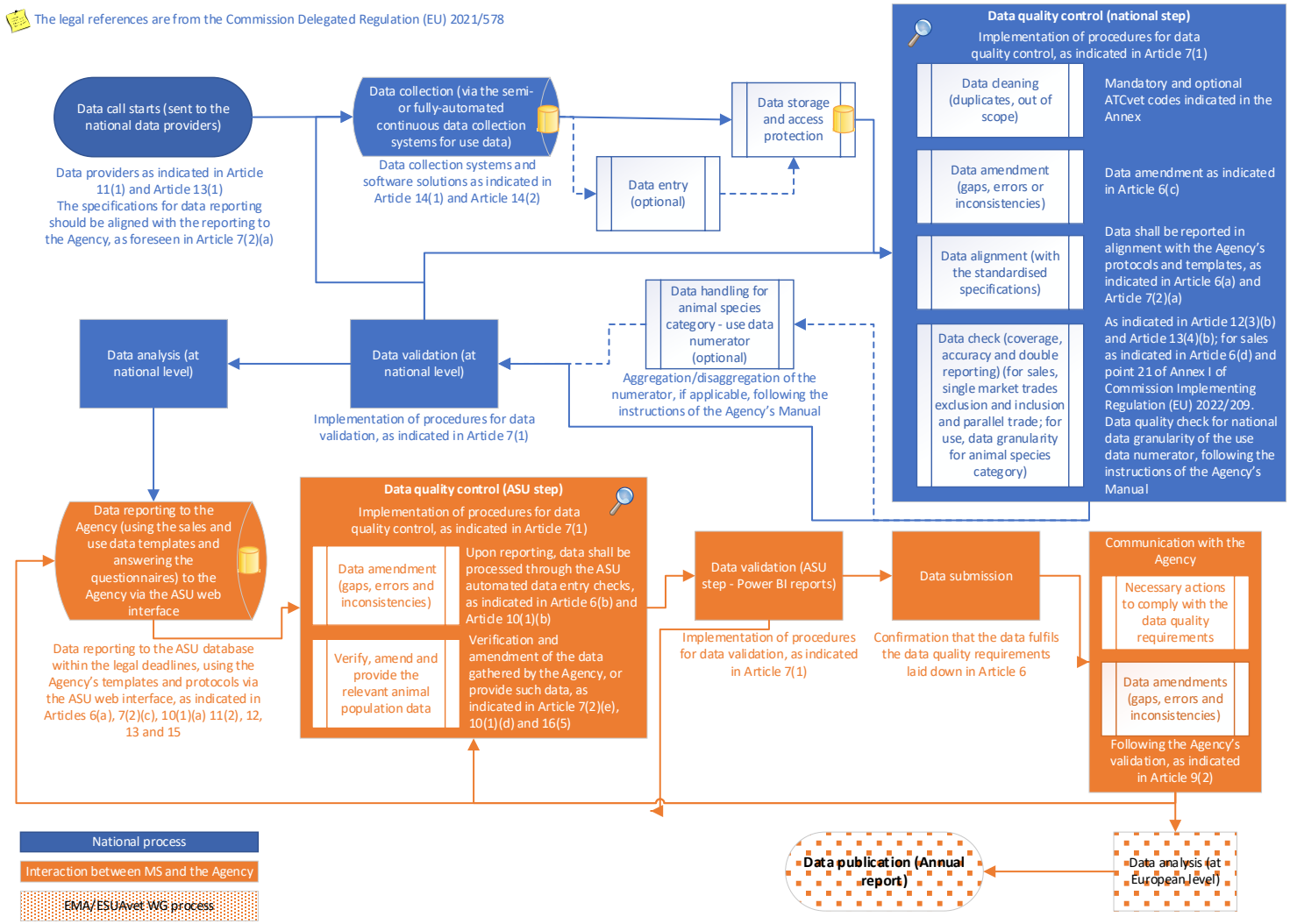
Annex I – Data management workflow



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