



## Standard operating procedure

Title: Preparation of ESUAvet annual reports		
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### 1. Purpose

This SOP covers the preparation of the ESUAvet annual report based on antimicrobial veterinary medicinal product (VMP) sales and antimicrobial use data for the preceding calendar year, reported by Member States to the Agency under the framework of Article 57 of Regulation (EU) 2019/6, describing the end-to-end process for the preparation and publication of the annual ESUAvet reporting cycle, from governance and planning through data submission by Member States (MSs), validation, analysis, report drafting and production, review and consultation, endorsement, adoption, publication, and post-publication follow-up.

It provides a structured and consistent framework to ensure that the report is produced in line with the legal mandate, scientific standards, and EMA quality and editorial requirements.

### 2. Scope

This SOP applies to staff in the Veterinary Antimicrobial Monitoring and Resistance Service (V-SR-AMR) of the Surveillance and Regulatory Support (V-SR) department.

### 3. Responsibilities

It is the responsibility of the Head of V-SR-AMR to ensure that this procedure is adhered to. The roles responsible for each step are further detailed under section 9.

### 4. Changes since last revision

New SOP.



## 5. Documents needed for this SOP

- EMA editorial and publication guidance (EMA/39139/2026)
- Antimicrobial Sales and Use Platform | European Medicines Agency (EMA)
- Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022)

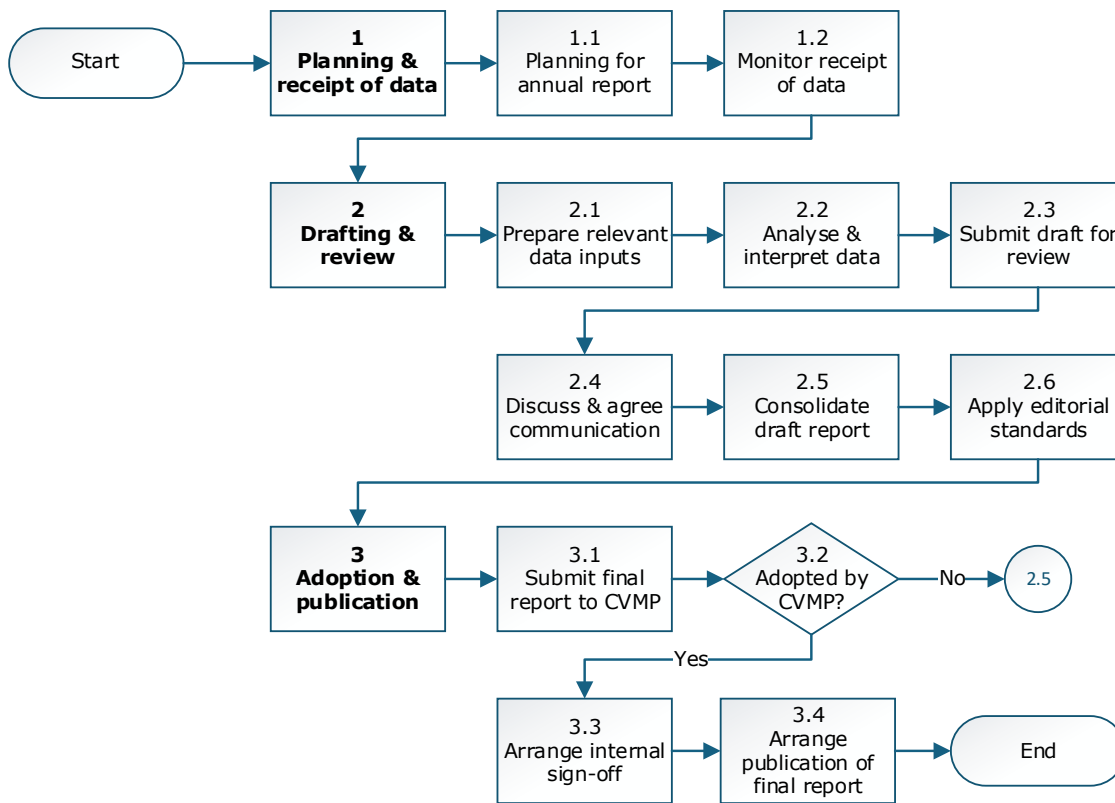
## 6. Related documents

- 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
- 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
- Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

## 7. Definitions

Adoption	Formal acceptance of the annual ESUAvet report by the CVMP in accordance with its procedures
CVMP	Committee for Veterinary Medicinal Products
EMA	European Medicines Agency
ESUAvet	European Sales and Use of Antimicrobials for Veterinary Medicine
ESUAvet Working Group (WG)	CVMP Working Group supporting the Agency in the scientific preparation and review of ESUAvet outputs. All Member States that collect and report to EMA data under Article 57 of Regulation (EU) 2019/6 have nominated members in the WG.
HDep	Head of Department (in Veterinary Surveillance and Regulatory Support)
HDiv	Head of (Veterinary Medicines) Division
HSer	Head of Service (in V-SR-AMR)
MS	Member State of the European Union and European Economic Area, plus Northern Ireland
SL	EMA Scientific Lead in V-SR-AMR
V-SR	Surveillance and Regulatory Support department in Veterinary Medicines Division
V-SR-AMR	Veterinary Antimicrobial Monitoring and Resistance Service in V-SR

## 8. Process map(s)/ flow chart(s)



## 9. Procedure

Step	Action	Responsibility
<b>1</b>	<b>Planning &amp; receipt of data submissions</b>	
1.1	<p><i>In Q1 of each year:</i></p> <p>Establish the framework for the reporting cycle, including how the legally defined scope is implemented for the year, timeline and key milestones, in agreement with HSer. Identify risks, constraints and discuss mitigation approaches. Consider lessons learnt and continuous improvement opportunities based on gained experience from previous reporting cycle and on the feedback received from internal and external stakeholders, as applicable.</p>	SL
1.2	<p><i>In Q2 of each year:</i></p> <p>Monitor the receipt of validated quantitative data and qualitative information submitted by MSs.</p>	SL
<b>2</b>	<b>Annual report drafting &amp; review</b>	
2.1	<p><i>Approximately in July/August each year:</i></p> <p>Select and prepare relevant quantitative and qualitative data required for ESUAvet annual report. Compile contextual information supporting interpretation of trends. Generate structured outputs (e.g. tables, indicators, summary analyses).</p>	SL
2.2	<p>Analyse the report-level inputs to identify trends, patterns and key features in the data relevant to antimicrobial sales and use in animals at the Union and country level. Interpret analytical results in the context of data coverage, methodological considerations, known limitations and information from previous reporting cycles, and integrate structured analytical outputs into narrative text.</p>	SL
2.3	<p><i>Approximately in September/October of each year:</i></p> <p>Submit draft to ESUAvet WG for comments, to refine analyses and avoid over-interpretation, overstating conclusions or implying causality beyond what the data can support.</p> <p>Submit draft for internal review (HSer, HDep and relevant staff in V-SR-AMR) to ensure clarity, accuracy and coherence, as well as alignment with the regulatory framework.</p>	SL
2.4	<p><i>Approximately 3 months before publication:</i></p> <p>Discuss and agree development of any additional communication materials via the Communication Focal Points.</p>	SL

<b>Step</b>	<b>Action</b>	<b>Responsibility</b>
2.5	<i>Approximately in October/November of each year:</i>  Consolidate draft report, ensuring all comments are documented, addressed and considered. Where relevant, ad hoc scientific exchanges with the WG may be undertaken.	SL
2.6	<i>Approximately 1 month before publication:</i>  Apply EMA editorial and publication standards to support a coherent report.	SL
<b>3</b>	<b>Adoption &amp; publication</b>	
3.1	The final version of the ESUAvet report is submitted to CVMP for adoption no later than the December meeting of CVMP.  Note: results and findings from the annual ESUAvet report may be presented to CVMP prior to formal adoption. Ensure adherence to EMA editorial and publication standards.	SL
3.2	Was the ESUAvet report adopted by CVMP?  <i>If yes, go to 3.3</i> <i>If no, go to 2.5</i>	
3.3	<i>Approximately 1-2 weeks before publication:</i>  Arrange internal sign-off by HSer, HDep and HDiv.	SL
3.4	Arrange publication of the final ESUAvet annual report on the EMA corporate website by 20th December at the latest, in parallel with any agreed additional communication materials (e.g. news announcement, Q&A, infographics).	SL
<b>4</b>	<b>End of process</b>	

## 10. Records

Documentation and records generated during the preparation and publication of the annual ESUAvet report are maintained in accordance with applicable EMA record management requirements.

Records generated during the reporting cycle process may include:

- Planning and governance documentation.
- Analytical and preparatory materials supporting the report, structured outputs and intermediate materials.
- Draft and final versions of the report, records of scientific and internal review, adoption and sign-off.
- Materials documenting lessons learned and improvement actions.

These are saved in the appropriately labelled folder in DREAM: EDMS \ 14. Working areas \ 14.06 V-Division \ 01. V-Division Administration \ 07. V - Other activities \ Knowledge bases \ Antimicrobial resistance \ ESUAvet