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## European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Sales Data and Animal Population Data Collection Protocol (version 3)

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# 1. Introduction

## 1.1. Terms of reference

The European Commission has requested the European Medicines Agency to take the lead in collating data on the use of antimicrobial agents in animals in the European Union and to manage the database. The European Medicines Agency was asked to develop a harmonised approach for the collection and reporting of data based on national sales figures as well as data on usage in at least major groups of animal species and to ensure comparability with the sale/use of antimicrobial agents in human medicine. The intended use of the surveillance data, both at national and community level would be:

- To aid interpretation of patterns and trends regarding antimicrobial resistance (AMR);
- As input to risk profiling and risk assessment regarding AMR;
- For setting risk management priorities;
- For evaluation of the effectiveness of control measures being implemented;
- To identify emerging use of veterinary antimicrobial agents, e.g. of specific classes of antimicrobial agents such as those identified by World Health Organisation (WHO) as critically important for human medicine;
- To aid comparison of usage of veterinary antimicrobial agents between human and veterinary medicine, time periods and countries;
- As a basis for focused and targeted research and development.

This protocol addresses collection of sales data and data on animal population.

The revision of the Web Based Sales Data and Animal Population Data Collection Protocol includes update on sales data quality check, confidentiality and security matters and some minor editorial amendments.

Details on data collection for the stratification of sales of antimicrobials by species are clarified in a separate protocol.

## 1.2. Approach

To enable harmonised reporting of the data as well as comparison with data between time periods within and between different European countries standardisation and harmonisation of the data collected is of vital importance. This applies also for the animal demographic data that is used to normalise the sales data for reporting of the sales. In ESVAC, a population correction unit (PCU) is used as the denominator and this represents purely a technical unit of measurement. The data sources used and the methodology for the calculation of PCU are comprehensively described in Appendix 2 of the Agency's report 'Trends in the sales of veterinary antimicrobial agents in nine European countries: 2005-2009' (EMA/238630/2011)<sup>1</sup>.

The data collection package consists of the following items:

- ESVAC sales and animal population data collection protocol (ESVAC Sales Protocol);
- ESVAC Sales Template;

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<sup>1</sup> Available from the Agency's website via: [Home > Regulatory > Veterinary medicines > Overview > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption](#)

- ESVAC population correction unit template (ESVAC PCU Template).

In order to obtain reliable and harmonised data in the ESVAC database the ESVAC Sales Protocol, the ESVAC Sales Template and the PCU Template have to be adhered to.

### 1.3. Target groups of the protocol and templates

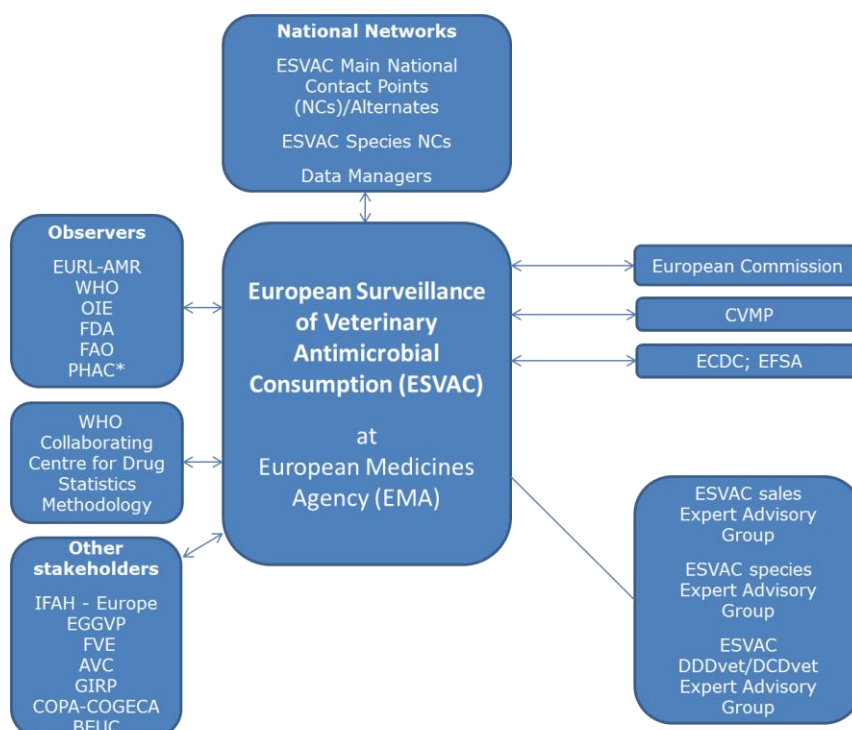
This version of the ESVAC Sales Protocol is primarily developed for web based submission of sales data and animal population data for countries participating in ESVAC but is thought to be applicable also for countries outside the EU/EEA area that want to collect such data.

The web delivery of data allows for the submission of data without using the ESVAC Sales Template; however the requirements of the Data Collection Protocol should be fulfilled. If uploading data directly as comma-separated values (CSV) files without the use of the Excel template as the basis, please disregard the parts of this protocol that are not applicable.

### 1.4. Organization of the ESVAC project

The ESVAC project is organised into three main work streams: collection of sales data, collection of data on consumption by species and establishing and maintaining lists of defined daily doses animals (DDDvet) and defined course doses animals (DCDvet). Separate expert groups are established for these three work streams. The organisation of the ESVAC project is illustrated in Figure 1. The ESVAC main National Contact Point/Alternates and/or Data Managers are responsible for collecting, validating and submitting sales data and validating the PCU data uploaded by the ESVAC sales team. The ESVAC strategy 2016 – 2020 has been published on the ESVAC web page<sup>2</sup>.

**Figure 1.** Organisation of the ESVAC project



<sup>2</sup> Available from the Agency's website via: [Home > Regulatory > Veterinary medicines > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption](#)

## 1.5. Web based delivery of data

The detailed user guide for web based delivery of sales data is described in document ESVAC web data collection – user guide. The user guidance describes the process of uploading the sales data via the web application, how to correct data sets with errors before submission and finally submission of the sales data via the web application. No information is provided in this protocol about the questionnaire as the questionnaire varies from year to year. This user guide also includes the collection of data on animal population by the ESVAC sales team and the validation of these data by the participating countries.

## 2. ESVAC sales data

### 2.1. Selection of data source

The infrastructure of the distribution of veterinary antimicrobial agents may vary considerably from country to country; such medicinal products are dispensed to the end-users by wholesalers, pharmaceutical industry, pharmacies, veterinarians or a mixture of these. Wholesalers and pharmaceutical industries may also trade between each other and export veterinary antimicrobial agents to other Member States (MS). The first step in setting up surveillance of veterinary antimicrobial agents is therefore to identify and describe of the distribution system for veterinary antimicrobial agents. The data source selected should if possible **provide data on sales to end-users within the country** such as veterinarians, farmers and wholesalers.

### 2.2. Veterinary antimicrobial agents to be included in ESVAC sales data

To harmonise the veterinary antimicrobial agents to be included in the data sets, the Anatomical Therapeutic Chemical classification system for veterinary medicinal products (ATCvet) is applied (Table 1) ([http://www.whooc.no/atcvet/atcvet\\_index/](http://www.whooc.no/atcvet/atcvet_index/)). This includes all pharmaceutical forms and medicated feed except dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS). The contribution from these groups of antimicrobial agents, in tonnes of active ingredient, to the total amounts is minimal, and therefore the effect of the deviation is negligible.

The veterinary antimicrobial agents (ATCvet groups) to be reported to the ESVAC database are shown in Table 1.

**Table 1.** Categories of veterinary antimicrobial agents to be included in ESVAC ([http://www.whooc.no/atcvet/atcvet\\_index/](http://www.whooc.no/atcvet/atcvet_index/))

Groups of antimicrobial agents	ATCvet codes
Antimicrobial agents for intestinal use	QA07AA; QA07AB
Antimicrobial agents for intrauterine use	QG01AA; QG01AE; QG01BA; QG01BE QG51AA; QG51AG
Antimicrobial agents for systemic use	QJ01
Antimicrobial agents for intramammary use	QJ51
Antimicrobial agents used as antiparasitic agents	QP51AG

### 2.3. Variables to be collected for each veterinary medicinal product (VMP) presentation

**Table 2.** Variables to be collected for each VMP presentation

		Variable	Description of variable	Comments
PRODUCT INFORMATION		<b>COUNTRY</b>	ISO Code ( <a href="http://www.iso.org/iso/country_codes">http://www.iso.org/iso/country_codes</a> )	To identify place of collected sales data
		<b>YEAR</b>		To identify time period for collected sales data
		<b>MA</b>	<b>Marketing Authorisation Number</b>	To enable link with other databases
		<b>PRESENTATION ID</b>	<b>Medicinal Product Package Code Value</b> Digit code being a unique identifier for each package size, strength and formulation of the VMP presentation. Because it is a key variable in many databases it has to be stable over time i.e. so that VMP presentations no longer available on the market or that are no longer registered still can be identified to allow for analysis of historical data	To allow a unique identification of the Veterinary Medicinal Product (VMP) presentation.  To identify and correct duplicates when uploading data on the web application
		<b>NAME</b>	<b>Medicinal Product Name (in national language)</b> E.g.: Harmony vet 50 mg tablets 2 x 30; Harmony vet long acting 10 mg/ml injection 10 ml	For validation purposes <ul style="list-style-type: none"> <li>• At country level prior to submission via web application;</li> <li>• By ESVAC after data submission.</li> </ul>
		<b>FORM</b>	<b>Pharmaceutical Form</b> Bolus (BOLUS), Injection (INJ), Intramammary (INTRAMAM), Intramammary dry cow treatment (INTRAMAM-DC), Oral solution and oral powder for water administration (ORAL SOLU), Oral paste (ORAL PASTE), Oral powder (ORAL POWD), Premix (PREMIX), Capsules and Tablets etc. (TABL), Intrauterine preparation (INTRAUT)	
	<b>LONG ACTING</b>	<b>Long-acting injectable preparations</b>  It refers to injectable preparations that maintain its antimicrobial activity over a long period of time once injected.	Optional	

Variable	Description of variable	Comments
<b>PACKSIZE</b>	<b>Content Quantity in Package: Pack size (numerical only)</b> E.g.: 100 for 100 tablets or 100 intramammaries; 10 for 10 ml injection; Package of 2 kg premix: 2; Box of 10 blisters of 30 tablets: 300; Box of 12 injectors: 12	To allow for calculation of the amount of active ingredient in each VMP presentation <ul style="list-style-type: none"> <li>For validation at country level prior to submission via web application;</li> <li>By BI (Business Intelligence) after submission of data.</li> </ul>
<b>PACKSIZEU</b>	<b>Content Unit of Measurement</b> E.g.: ML, L, G, KG, PIECE (for e.g. tablets, capsules, bolus and intramammary preparations) To be harmonised with strength unit – e.g. if pack size is 1 KG strength unit should be per KG	To enable calculation of amount active ingredient in each VMP presentation <ul style="list-style-type: none"> <li>For validation at country level prior to submission via web application;</li> <li>By BI after submission of data.</li> </ul>
<b>ATCVET</b>	<b>ATCvet- 5th level: Anatomic Therapeutic Chemical (Classification) Veterinary</b>	Only last version of ATCvet codes will be accepted by the system.  If an ATCvet code has not been assigned for an ingredient the ESVAC sales team has to be contacted.
<b>SPECIES</b>	<b>Animal Species</b> <u>All</u> the animal species for which the VMP is approved. E.g. cattle (CA), poultry (POU)	Optional
<b>NO PACKS</b>	<b>Number of Packages Sold/Year/Country</b>	To calculate weight of active ingredient sold for each VMP presentation <ul style="list-style-type: none"> <li>For validation at country level prior to submission via web application;</li> <li>By BI after submission of data;</li> <li>For validation by ESVAC after data submission.</li> </ul>
<b>INGR_ID</b>	<b>Ingredient Code Value</b>	Serve as a unique identifier for each ingredient for each product.  Needed for data management purposes.

Variable		Description of variable	Comments
INGREDIENT	<b>INGR</b>	<b>Active Ingredient Name (ATCvet name)</b>	<p>Only last version of ATCvet names will be accepted by the system.</p> <p>If an ATCvet name has not been assigned for an ingredient, the ESVAC sales team has to be contacted.</p> <p>For combination VMPs the ATCvet name of all the ingredients has to be given in separate columns.</p>
	<b>SALT</b>	<b>Salt of Active Ingredient</b>	<p><b>Only</b> in cases when the strength is given in international units (IU), IU/ML or IU/UNIT <b>and when</b> different salts exists.</p> <p>Currently only applicable for colistin sulphate and colistin methane sulphonate.</p> <p>To enable conversion to weight of active ingredient</p> <ul style="list-style-type: none"> <li>For validation at country level prior to submission via web application;</li> <li>By BI after submission of data.</li> </ul>
	<b>PRODRUG</b>	<b>Prodrug name (ATCvet name)</b> E.g.: Procaine penicillin that is the prodrug for benzylpenicillin	<p>Names of prodrugs are listed in Table 3.</p> <p>To allow for calculating the weight of the active ingredient</p> <ul style="list-style-type: none"> <li>For validation at country level prior to submission via web application;</li> <li>By BI after submission of data.</li> </ul>
	<b>STRENGTH</b>	<b>Quantity of the Active Ingredient in Each Unit as declared in name (if not in name as in Summary Product Characteristics (SPCs)): Strength (numerical only)</b> E.g. 10 for 10 MG/TABLET, 10 IU/TABLET, 10 MG/ML, 10 IU/ML, 10 MG/PIECE or 10 IU/PIECE  In case of a combination VMP strengths has to be given for each ingredient in separate lines	<p>For validation purposes To enable calculation of the amount of active ingredient in each package/product</p> <ul style="list-style-type: none"> <li>For validation at country level prior to submission via web application;</li> <li>By BI after submission of data.</li> </ul>



Variable	Description of variable	Comments
<b>STRENGTHU</b>	<p><b>Unit of Measurement for Strength</b> E.g.: IU, IU/G, IU/ML, IU/PIECE, G, G/KG, G/L, MG, MG/ML, MG/PIECE</p> <p>In case of a combination VMP unit of measurement strength has to be given for each ingredient in separate lines</p>	<p>To enable calculation of the amount of active ingredient in each package/product</p> <ul style="list-style-type: none"> <li>For validation at country level prior to submission via web application;</li> <li>By BI after submission of data.</li> </ul>
<b>CONV FACT IU</b>	<p><b>Conversion Factor IU</b> When strength is given as IU, IU/ML or IU/PIECE</p>	<p><b>In ESVAC template conversion factor IU will be recorded by use of a macro.</b></p> <p>Conversion factors are listed in Table 4.</p> <p>To allow for calculation of the weight of active ingredient in each package by MS for validation of data prior to upload via web application.</p> <p>If an ingredient with strength given in IU is not listed, ESVAC sales team should be contacted.</p>
<b>CONV FACT PRODR</b>	<p><b>Conversion Factor Prodrug</b> Only when strength is given for the prodrug and not for the active ingredient (e.g. procaine penicillin that is a prodrug for benzylpenicillin)</p>	<p><b>In ESVAC template it will be recorded by use of a macro.</b></p> <p>Conversion factors listed in Table 3.</p> <p>To enable for the calculation of the weight of the active ingredient in package</p> <ul style="list-style-type: none"> <li>For validation at country level prior to submission via web application;</li> <li>By BI after submission of data.</li> </ul> <p>If a prodrug is not listed, ESVAC sales team should be contacted.</p>

Variable	Description of variable	Comments
<b>CONTENT</b>	<b>Content of Active Ingredient in Package</b> In case of combination VMP the content in the package has to be given separately for each ingredient in separate lines	For validation of data by MS prior to upload via web application <ul style="list-style-type: none"> <li>For validation at country level prior to upload and submission via web application;</li> <li>By BI after submission of data.</li> </ul>
<b>CONTENTU</b>	<b>Unit of Active Ingredient in Package</b> To be given in gram (G) for all ingredients In case of combination VMP the content unit has to be given separately for each ingredient in separate lines	For validation at country level prior to upload and submission via web application.
<b>TONS SOLD</b>	<b>Tons Sold of Active Ingredient</b>	<ul style="list-style-type: none"> <li>For validation at country level prior to upload and submission via web application;</li> <li>For validation by ESVAC after data submission.</li> </ul>

### 2.3.1. Conversion factors of prodrugs

In order to obtain harmonised data, the conversion factors shown in Table 3 are applied to calculate amount of active ingredient sold of a prodrug.

**Table 3.** Name of prodrugs and prodrug conversion factors

Prodrug	Conversion factor
Benethamine benzylpenicillin	0.65
Benzathine benzylpenicillin <sup>3</sup>	0.74
Cefapirin benzathine	0.41
Cefalexin benzathine	0.36
Cloxacillin benzathine	0.43
Oxacillin benzathine	0.69
Penethamate hydriodide	0.63
Procaine penicillin	0.61

### 2.3.2. Conversion factors when strength is given in IU

When strength is given in international units (e.g. IU/ML) the amount sold has to be calculated to present data in weight of active ingredient. In order to obtain harmonised data, the conversion factors shown in Table 4 are applied by ESVAC to calculate amount of active ingredient sold. Note that if the strength of an ingredient is reported in IU, the conversion factor from IU to mg as shown in Table 4 is applied to calculate amount of active ingredient sold.

<sup>3</sup> The correction factor was revised at the beginning of 2016

**Table 4.** Conversion factors for calculation from IU to mg of active ingredient

<b>Ingredient</b>	<b>IU/MG</b>	<b>Conversion factor (MG/IU)</b>
Bacitracin	74	0.01351
Benzylpenicillin <sup>4</sup>	1667	0.00060
Chlortetracycline	900	0.00111
Colistin sulphate	20500	0.00005
Colistin methane sulphonate	12700	0.00008
Dihydrostreptomycin	820	0.00122
Erythromycin	920	0.00109
Gentamicin	620	0.00161
Kanamycin	796	0.00126
Neomycin	755	0.00133
Framycetin	670	0.00149
Oxytetracycline	870	0.00115
Paromomycin	675	0.00148
Polymyxin B	8403	0.00012
Spiramycin	3200	0.00031
Streptomycin	785	0.00127
Tetracycline	982	0.00102
Tobramycin	875	0.00114
Tylosin	1000	0.00100

### 3. Call for data

Prior to the annual call for data the ESVAC team updates the lists of ATCvet codes and names for each country specific ESVAC sales register (ESVAC Sales Template). A list of new ATCvet codes and names will be provided together with the call.

The ESVAC Data Collection Form contains lists to facilitate that the data are standardised and harmonised prior to the submission.

#### 3.1. Data submission

Data have to be submitted using the ESVAC web application. For countries using the Microsoft Excel template it is recommended to send the final filled-in Microsoft Excel template to ESVAC sales team.

### 4. Filling in the ESVAC Sales Template

#### 4.1. General considerations

The sales data should always be recorded in the country specific ESVAC register (template) provided together with the call for data. For new countries the general ESVAC template should be applied.

<sup>4</sup> Applies to all prodrugs of benzylpenicillin

In case of combination VMPs, the columns for the INGREDIENT variables have to be filled in for each ingredient in separate columns in the same row.

Enzyme inhibitors such as clavulanic acid are not active ingredients and are not included in the list of ATCvet names of ESVAC and therefore are not accepted by the ESVAC web system. As it is important to quantify use of e.g. amoxicillin+ clavulanic acid the ATCvet code for the combination with active ingredients should be given (e.g. QJ01CR02 for amoxicillin+ clavulanic acid).

The species column is optional; the purpose is to provide the ESVAC sales team with information for better understanding of the data.

## **4.2. Comments on the various fields components**

### **Presentation identifier (ID) (Medicinal Product Package Code Value)**

When this information is not available, it is necessary to assign individual value for each package.

The use of a standard and stable Presentation ID, e.g. International Article Number (EAN) (originally European Article Number), might facilitate the traceability of products as well as interaction with other databases (e.g. the EU Veterinary Medicinal Product Database). Furthermore, it enables identification of duplicates.

In case Presentation IDs are not available, these IDs can be derived from other variables. It is recommended to combine the marketing authorisation number (MA), name with the FORM, the PACKSIZE and PACKSIZEU variables. This combination of MA+NAME+FORM+PACKSIZE+PACKSIZEU should be unique per medicinal product package.

Finally, in case marketing authorisation numbers are not available, it is recommended to use the line number as Presentation ID. All missing Presentation IDs must be entered without sorting in between to avoid assigning the same ID to two different products.

### **ATCVET [ATCvet code- 5th LEVEL]**

If an ingredient ATCvet code has not been assigned for the VMP/ingredient/combination VMP in question please contact the ESVAC sales team that will ask the WHO Collaborating Centre for Drug Statistics Methodology Norwegian Institute of Public Health (WHO Centre) to provide a code for such products and the dataset will be updated by ESVAC sales team when the codes have been assigned.

The ESVAC web system would not allow the upload of a product unless a valid ATCvet code has been assigned (see the user's guide for further information).

### **INGR\_ID [Ingredient Code Value]**

If using the macro of the excel template, the INGR\_IDs is assigned automatically by the macro.

If the template is not used or the macro is not used, it is recommended to assign the INGR\_ID by concatenating the Presentation ID with the sequence of the ingredient in the medicinal product package separating by a '#', e.g. for a medicinal product package with a presentation ID of "AZE10" containing two ingredients the first ingredient will be coded "AZE10#1" and the second one "AZE10#2".

### **INGR [Active Ingredient Name (ATCvet name)]**

If an ATCvet name has not been assigned for the VMP, it is necessary to inform the ESVAC project team as soon as possible. When receiving your email the ESVAC project team will ask the WHO Centre to provide the ATCvet name for such ingredients and the ESVAC project team will provide you temporary solution or the correct name when the ATCvet names have been assigned.

## **CONV FACT IU (Conversion Factor IU) and CONV FACT PRODR (Conversion Factor Prodrug)**

These will be recorded automatically by use of a macro designed for the ESVAC Sales Template.

If a Conversion Factor IU or Conversion Factor Prodrug for the ingredient/prodrug in question is not included in the ESVAC Data Collection Form, the ESVAC Sales Team ([ESVAC@eu.europa.eu](mailto:ESVAC@eu.europa.eu)) has to be contacted and will provide the (standardised) value.

## **5. ESVAC data quality check**

The ESVAC sales and animal data quality requirements are confirmed by representatives of the ESVAC participating countries and by the ESVAC secretariat at the data entry and data checking phase., Responsibility to ensure that sales data submitted to EMA fulfils business information demand largely lies on the ESVAC NCs (National Contact Points) and/or DMs (Data Managers). Suitable quality control procedures are defined by each country taking into account their individual data collection process. It is strongly advised to establish a procedure for checking the data quality, including data coverage, prior to data collection and reporting; this includes steps to be taken before, during and after data collection, in order to obtain high quality of data available in the ESVAC database.

Although ESVAC NCs/DMs validate their data prior to submission via ESVAC web based application, the ESVAC project team in addition gathers essential details via the annual questionnaire. In line with the EMA proposed framework intended to serve as quality indication for data completeness and logical consistency of every approved dataset, the ESVAC secretariat follows up with the responsible NCs/DMs on any potential outlier identified.

A brief overview of the outlier-detection measures taken by the ESVAC secretariat to assist in the identification of possible errors in data submitted to the ESVAC database are included in Annex 1 of this protocol.

For the EU Member States, the ESVAC reference animal data are downloaded from the Eurostat database and provided to the NCs and/or DMs for their approval; EEA countries have to fill in these data themselves. Typically, ESVAC representatives approach suitable institutions in their country to confirm statistics and where it's necessary replace reference values with the data provided from their national statistical offices.

### **5.1. Checking the completeness of the sales data**

A verification that the sales data submitted to the ESVAC web system are as complete as possible is expected from every ESVAC NC and/or DM; therefore representatives are highly recommended to follow processes listed below:

**Table 5.** Processes for ensuring the completeness of the sales data

Item	Steps	Comments
<b>Stage 1.</b> Establishing a procedure for checking the data quality, including data coverage, prior to the data collection	1.1. Identify ALL the actual data providers through the national register of VMP suppliers – e.g. wholesalers, MAHs, pharmacies, feed mills etc.	<ul style="list-style-type: none"> <li>The National Medicines Authority is usually responsible for keeping registers of authorised VMPs and VMP suppliers; exceptionally no such information may be available of feed mills.</li> <li>Identify if there are any other data sources of sales data that can be used for comparison or for cross-checking of data</li> </ul>
	1.2. In case sales data are obtained from prescriptions (e.g. from pharmacies, veterinarians), identify all antimicrobial agents for which data are to be collected	
	1.3. Specify the veterinary antimicrobial agents to be included in the data call/selection <sup>5</sup> – i.e. the ATCvet codes to be covered (see Table 1.)	
<b>Stage 2.</b> Sending a call for data or download data from the system		
<b>Stage 3.</b> Data collection – after a deadline has passed for data to be delivered by the national data providers	3.1. Check that all data providers have delivered the data	<ul style="list-style-type: none"> <li>In case not all data providers have delivered the data, submit a reminder; ask for a written confirmation in case of no sales of specific VMP</li> <li>Alternatively, after entering data into the ESVAC template compare the output with the filled-in national data</li> <li>As an additional verification step, data can be cross-checked with other sales sources, if available</li> </ul>
	3.2. Identify/review that all VMPs presentations are included in the dataset for the corresponding year	
<b>Stage 4.</b> When responses received from all identified data providers	4.1. After entering data in ESVAC template, compare NO PACKS, e.g. number of packages, and TONS SOLD, e.g. calculated tonnes sold, by ID number with data in template for previous year(s) to identify potential outliers (if applicable)	
	4.2. For the assumed outliers contact corresponding data provider(s) and ask for verification	

<sup>5</sup> It is a responsibility of the National Authority to ensure the collection of other antimicrobial agents, if required for national reporting.

Item	Steps	Comments
	4.3. Run a validation by using the macro included in the template to identify any inconsistencies in the data and correct any identified mistakes	
	4.4. Additionally, cross-check ATCvet entries and corresponding ingredients per presentation	
<b>Stage 5.</b> Submitting sales data after the initial validation via the ESVAC web system for corresponding year	5.1. Run validation reports from the ESVAC BI application to identify any outliers (see Annex 1)	<ul style="list-style-type: none"> <li>For potential outliers compare latest submitted dataset with dataset approved for previous year by classes of antimicrobials and by pharmaceutical forms</li> </ul>
	5.2. After receiving validation report, clarify the major differences in sales, if possible	
<b>Stage 6.</b> After sales data are finalised and corrected, sending approval to the ESVAC team to confirm that corresponding dataset can be used for further analysis and for preparation of the next report	6.1. Upload the final sales dataset into the ESVAC web application, if necessary, and send a final excel file to the ESVAC secretariat	
	6.2. Review suggestions sent by the ESVAC secretariat, when applicable, and send your approval to use the finalised dataset for further analysis	

## 6. ESVAC PCU data

### 6.1. Animal categories included in PCU

Eurostat, the Statistical Office of the European Union, covers data on numbers and biomass of food-producing animals slaughtered, as well as data on livestock food-producing animals per EU MS. Therefore, Eurostat<sup>6</sup> is selected as the source for data on this animal category. In cases where data are not available in Eurostat (e.g. for rabbits), national statistics is applied. For horses (food-producing species according to the EU legislation), national statistics provided by the ESVAC national representatives are used. As data on population of dogs and cats are not available in all participating countries, these species are not included in the PCU, in order to have comparable data. Therefore, antimicrobial VMPs approved for use in companion animals only, i.e. tablets, are excluded from the datasets prior to the normalisation of the sales by the PCU.

Animals exported for fattening or for slaughter in another Member State are likely to be treated with antimicrobial agents in the country of origin, and therefore it is important to correct this for the major species (cattle, pigs, poultry and sheep). However, the Eurostat data on numbers of animals exported or imported for fattening or slaughter are not valid, as these are reported only when above a certain limit, which implies that the Eurostat data represent an underestimate of these for most species and

<sup>6</sup> <http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/themes>

countries. Such data are therefore obtained from TRACES (DG SANCO, European Commission), as these are based on health certificates, which are obligatory for all animals crossing any border.

Typically, at the start of September of each year the ESVAC sales team provides the reference data for the animal categories shown in Table 6 available in Eurostat and TRACES for the categories available from these data bases. These are the only animal categories that are accepted by the ESVAC web application. For categories for which data are not available in Eurostat or TRACES, countries may submit missing values in addition for the PCU calculations.

EEA countries are requested to upload all animal population data per specified categories as no values are available through Eurostat and TRACES.

**Table 6.** Animal categories included in the calculation of the population correction unit (PCU) and data types to be reported

<b>Animal category</b>	<b>Numbers/tonnes</b>
<b>Cattle (heads/number of animals)</b>	
Slaughtered cows	
Slaughtered heifers	
Slaughtered bullocks and bulls	
Slaughtered calves and young cattle	
Slaughtered bovine - Import	
Slaughtered bovine - Export	
Fattening bovine - Import	
Fattening bovine - Export	
Living dairy cows	
<b>Pigs (heads/number of animals)</b>	
Slaughtered pigs	
Slaughtered pigs - Import	
Slaughtered pigs - Export	
Fattening pigs - Import	
Fattening pigs - Export	
Living sows	
<b>Poultry (heads/number of animals)</b>	
Slaughtered broilers	
Slaughtered turkeys	
Slaughtered poultry - Import	
Slaughtered poultry - Export	
<b>Caprinae (heads/number of animals)</b>	
Slaughtered sheep and goats	
Slaughtered sheep - Import	
Slaughtered sheep - Export	
Fattening sheep - Import	
Fattening sheep - Export	
Living sheep	
Slaughtered goat - Import	
Slaughtered goat - Export	
Fattening goat - Import	
Fattening goat - Export	
<b>Equidae (heads/number of animals)</b>	



Animal category	Numbers/tonnes
Living horses	
<b>Rabbits (heads/number of animals)</b>	
Slaughtered rabbits	
<b>Farmed fish (tonnes)</b>	
Biomass live weight	

## 6.2. Calculation of PCU

Essentially, the PCU for each animal category is calculated by multiplying numbers of livestock animals (dairy cows, sheep, sows and horses) and slaughtered animals (cattle, pigs, lambs, poultry and turkeys) by the theoretical weight at the time most likely for treatment. In case of animals exported or imported for fattening or slaughter (cattle, pigs and poultry), the PCU is calculated by multiplying the number of animals with a standardised weight (Table 7).

For farmed fish, Eurostat data is given only as live-weight slaughtered, as information on weight at treatment has not been identified; therefor in case of farmed fish, the PCU is taken as a biomass live-weight slaughtered in each country. The PCU of the animals exported for fattening or for slaughter in another Member State is added to the PCU of livestock and to the PCU of slaughtered animals in the country of origin, because young animals are typically treated more frequently than at other age classes. The PCU for animals imported for fattening or for slaughter in another Member State is subtracted from the total PCU of livestock and slaughtered animals, since it is included in the data of slaughtered animals (Eurostat data) and in order to avoid double counting (both in exporting and importing country).

**Table 7.** Weights used to calculate the population correction unit

Animal category	Weight in kg
<b>Slaughtered or livestock (Eurostat)</b>	
Slaughtered cow	425
Slaughtered heifer	200
Slaughtered bullocks and bulls	425
Slaughtered calves and young cattle	140
Living dairy cow	425
Slaughtered pig	65
Living sow	240
Slaughtered broiler	1
Slaughtered turkey	6.5
Slaughtered sheep and goats	20
Living sheep	75
Living horse	400
Slaughtered rabbit	1.4
<b>Imported/exported for fattening or slaughter (TRACES data)</b>	
Slaughtered bovine	425
Fattening bovine	140
Slaughtered pig	65
Fattening pig	25
Slaughtered poultry	1
Slaughtered sheep	20

Animal category	Weight in kg
Fattening sheep	20
Slaughtered goat	20
Fattening goat	20

#### PCU calculation by species, age class and production type

1. Number of animals slaughtered × estimated weight at treatment.
2. Number of livestock × estimated weight at treatment.
3. Number of animals transported (net export) to another country × estimated weight at treatment.

## 7. Indicator for reporting of the sales data

The main indicator to be applied expressing the sales of veterinary antimicrobials is mg of active ingredient normalised by the population correction unit (mg/PCU):

$$\frac{\text{Amount sold in metric tonnes} \times 10^9}{\text{PCU in kg}}$$

The data are presented according to the ATCvet hierarchical system, and for combination preparations - each active ingredient is allocated to the relevant ATCvet code for single substances (e.g. spectinomycin is included in 'Other antibacterials').

## 8. Confidentiality and security of submitted sales data

Prior to the publication of the submitted data, NCs and/or DMs are requested to inform the ESVAC secretariat on any data which for reasons of commercial confidentiality (or any other grounds) cannot be disclosed either on the ESVAC annual report and/or on the ESVAC Interactive Database.

Data published by the Agency, either on the public web page or as part of scientific or other publication, do not contain, or in any other way disclose, any commercially confidential information on specific veterinary products. Principles for ensuring the confidentiality of data supplied to the ESVAC project ([EMA/327935/2010](#)) are published on the EMA web page.

EMA has dedicated controls that adhere to the three main requirements related to the security of information: availability, confidentiality and integrity.

- Data is stored in a secure location on EMA premises and backed-up regularly. The EMA IT infrastructure provides high availability of services.
- Data is made publicly available by the ESVAC secretariat at the agreed date of publication (typically the same day when the ESVAC annual report is published). Until this time, only users can see their own datasets (to which they have full access). As no personal data are held in the ESVAC databases, no specific controls are required.
- Networks are segregated so that stored data is filtered with only relevant data being exposed, in a consolidated format, to the public via the BI platform. Data is not otherwise classified.

## **ANNEX 1**

### **1. Additional information for review of ESVAC data quality**

The ESVAC web based application runs data accuracy check ensuring that information provided is in compliance with the requirements, as noted in sections 2.2 of this protocol, and as per predefined lists, as available in the sales data template, e.g., confirmed ATCvet codes and substance names. In case of any inconsistencies identified, the system does not allow to proceed with the submitted dataset, instead a list with errors identified is provided for a follow up actions.

#### **1.1. Validation of sales data**

To facilitate quality and validity checks of the submitted data, validation reports are provided via the Oracle Business Intelligence Enterprise Edition (BI) tool, known as ESVAC BI application.

A set of ESVAC BI validation templates are available to each ESVAC representative to run analysis for any uploaded datasets of their own country. Validation reports include:

- 1.1 Substance Sales Report;
- 1.2 Register Report;
- 1.3 Product Sales Report;
- 1.4 PCU Category Report;
- 1.5 PCU Report;
- 1.6 Sales Data Compare Report.

Validation reports support comparison of sales and animal population data with previously uploaded values. The comparison between two datasets is provided by antimicrobial classes and/or pharmaceutical forms, and also by presentations.

#### **1.2. Accuracy check of sales data (supplementary information to section 5)**

For supporting accuracy check of sales data, the NCs/DMs are requested to send to the ESVAC secretariat also the excel template (previously named INPUT file) to the ESVAC project team - i.e. the complete sales file used to create 3 CSV files for uploading on the ESVAC web application. To identify any possible errors, e.g. missing ingredients, inaccurate strength value, imprecise ATCvet codes, data recorded per each product in the excel file are compared with the details from the publically available SPCs by the ESVAC team. All identified potential discrepancies are reported to the NCs/DMs for their attention and confirmation.

Manual checking, run by the ESVAC team, for standardization and harmonization concern following fields of the excel template:

- 1. COUNTRY – to confirm if all lines are completed;
- 2. YEAR – to confirm if all lines include reference to corresponding year;
- 3. PRESENTATION ID – to confirm if ID is provided in all lines and if there are any possible duplicates;
- 4. FORM – to filter by form and gradually cross-check with product names and ATCvet codes;

5. LONG ACTING – to confirm if all injectable preparations with indication to long acting duration (e.g. LA or L.A) or any previously identified VMPs and/or ingredients are marked as long acting;
6. ATCvet – to confirm codes with a special attention to intramammary, intrauterine preparations and penicillins; to confirm if all ingredients are reported in the line with ATCvet index indicating combination products;
7. SPECIES – to confirm if species information is provided in the template; to search for corresponding SPCs to add missing details for NCs and/or DMs consideration;
8. INGR – to cross-check if all ingredients are provided as per corresponding SPCs;
9. SALT – to filter any lines where strength is given in IU and to confirm details as per available SPCs; to confirm that salts are only provided for colistin;
10. STRENGTH – to confirm if strength is in line with the name of VMP or as per available SPC, when applicable; and to confirm any peculiar strength values reported;
11. STRENGTHU – filtering by PACK SIZEU, to confirm if strength unit is given accurately (e.g. if packsize unit is provided in ML, then strength unit should be given as IU/ML or MG/ML); all strength units should be checked by line for all ingredients.