



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stratification of sales data of antimicrobials by species

Data collection protocol 2017

1. Introduction

1.1. Concept

Stratification of sales data of antimicrobials is an estimate of the antimicrobial consumption per species based on an approximate allocation of the proportion of total sales to each of the species for which a veterinary medicinal product (VMP) containing antimicrobials is used.

The stratification of sales data is an interim approach that allows to estimate the use of antimicrobials by species, until for example a collection system of detailed data on the use or consumption per each animal category is available. The stratification of sales is also a complementary system that could provide additional information in EU/EEA countries that have already systems in place to collect data on use and on sales, for example allowing the estimation of use in additional animal species for which the use data are not collected or facilitating the follow up on trends.

1.2. Approach

The estimation of the antimicrobial consumption per species is based on an approximate allocation of the proportion of total sales that are used in each species for which a VMP is indicated (stratification of sales data). As a general principle, direct attribution of sales for use to one animal species could be done for those products that are authorised for only one animal species, except when information is available that the VMP is also used or sold for other species (e.g. off-label). For VMP that are authorised for multiple species, attribution of proportions of sales should be made to each of the animal species for which the VMP is indicated or used, including off-label use in case the VMP has been presumably prescribed for species other than those approved.

To harmonise the reporting of data and in order to reduce as much as possible the administrative burden for the ESVAC participating countries, the collection of stratification of sales data by species has been incorporated into the template of ESVAC sales data collection. This protocol is therefore an extension of, and should be read in conjunction with the ESVAC Sales Data and Animal Population Data Collection Protocol 2017.

The source for the collection of data may vary per MS, whilst most will be collecting the data from MAH, some might collect it from other sources (e.g. wholesalers, prescription data). A pilot project with



6 volunteering countries is testing the methodology and providing an overview of possible approaches for the collection and analysis of sales data for stratification for EU/EEA countries. This protocol is based on the ongoing experience of the pilot project.

Concerning the confidentiality and security of submitted data for the stratification exercise, please see Section 8 of the ESVAC sales and animal data collection protocol. As usual, no data will be published with specific reference to a country unless this has been authorised by the country.

2. Terms of Reference for the collection of data by species for the stratification project 2017

In 2009 the European Commission requested the European Medicines Agency (EMA) "to develop a harmonised approach for the collection and reporting of data based on national sales figures combined with estimations of usage in at least major groups of species". Since 2009 the EMA has been collecting overall sales data of antimicrobial agents in the Member States through the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project. Estimated antimicrobial use by animal species will be based on the data submitted by Member States.

2.1. Scope of the data collection for the stratification project

The stratification project covers the estimation per animal species of all product presentations submitted for the ESVAC sales exercise.

The allocation of percentage of use of each product presentation will be an estimate of the use made by the Marketing Authorisation Holders (MAH) or by other sources in case the MAHs cannot provide these data.

The project covers the estimation of the percentage of use in the 3 major animal species (cattle, pigs and poultry). Whenever possible, Member States can also provide the estimates of the use in other species (e.g. sheep and goats, fish, horses, rabbits, cats and dogs). Member States may also provide the estimates for poultry specified separately for turkeys and chickens.

The project covers the possible off-label use of product presentations. The project does not cover the use of non-authorized product presentations in veterinary medicine, e.g. human medicinal products that are used in veterinary medicine through the cascade. Nevertheless, if a Member States wish to provide these additional data, this can be done as indicated in Annex I.

3. Stratified sales data by animal species

3.1. Selection of data source

The infrastructure of the distribution of veterinary antimicrobial agents may vary considerably from country to country. After veterinary prescription, medicinal products may be dispensed to the end-users by wholesalers, pharmaceutical industry, feed mills, pharmacies, veterinarians or in a combination of these sources.

It is assumed that MAHs have knowledge of proportion of products sales per animal species for which the product is indicated and presumably used.

MAHs will be asked by the National Competent Authorities (NCAs) to provide a distribution (as percentage %) of antimicrobial use according to the categories of species for which each individual VMP presentation has presumably been used.

In the countries where the sources of the data for the ESVAC project are wholesalers or other providers, the default proposal is that the MAHs provide such data, but any other approach to assign percentages of sales of individual VMPs per animal species might be considered.

For example, in case the MAHs are not able to provide the estimates for the stratification data, the Member State may consider obtaining the estimates from other sources like for example wholesalers, feed mills, pharmacies, veterinary prescriptions or farm level data.

Each MS will have to define the source for the collection of stratification data based on the national situation. The ESVAC secretariat is willing to assist MS on this process.

3.2. Variables to be collected for each VMP presentation

The following columns are added to the current ESVAC sales data collection template in order to collect the estimates of the proportion of total sales that are used in each species.

Table 1. Variables to be collected for each veterinary medicinal product presentation for stratification of sales data by species

	Variable	Description of variables	Comments
MAIN SPECIES ("MANDATORY" SPECIES)	CATTLE	The proportion of the VMP presentation sold for cattle	Introduce 0 if not applicable
	PIGS	The proportion of the VMP presentation sold for pigs	Introduce 0 if not applicable
	POULTRY	The proportion of the VMP presentation sold for poultry	Introduce 0 if not applicable or you know the separated proportion of VMP presentation sold for chickens and turkeys (see additional column chicken/turkeys)
OTHER ANIMAL SPECIES	SHEEP AND GOATS	The proportion of the VMP presentation sold for sheep and goats	Introduce 0 if not applicable
	FISH	The proportion of the VMP presentation sold for fish	Introduce 0 if not applicable
	HORSES	The proportion of the VMP presentation sold for horses	Introduce 0 if not applicable
	RABBITS	The proportion of the VMP presentation sold for rabbits	Introduce 0 if not applicable
	CATS AND DOGS	The proportion of the VMP presentation sold for cats and dogs	Introduce 0 if not applicable
	OTHER ANIMAL SPECIES OR UNKNOWN	The proportion of the VMP presentation sold for other species (e.g.	Introduce 0 if not applicable

	Variable	Description of variables	Comments
		off-label use)	
ADDITIONAL INFORMATION	CHICKEN	The proportion of the VMP presentation sold for chickens	Optional: Leave empty if not applicable or if you can only estimate the joint proportion sold of poultry
	TURKEYS	The proportion of the VMP presentation sold for turkeys	Optional: Leave empty if not applicable or if you can only estimate the joint proportion sold for poultry
ADDITIONAL INFORMATION	ADDITIONAL INFORMATION	Please provide all other species for which VMP was used including species for which the product is not authorised for (off-label) Provide information how estimates are generated for this presentation Provide any other information	Optional: Provide any other additional information

Additional explanation and examples:

See ANNEX 1 for additional explanation and examples.

4. Quality assurance

To ensure and harmonise the quality level of the data reported, MS are requested to check the % provided by the MAH or collected from other sources, especially the completeness and logical consistency of the submitted data set. The ESVAC secretariat may assist MSs in this task, for example in the detection of possible errors, to facilitate the quality check to be done by the MS.

When possible, the MSs are requested to validate the data received from MAH or collected from other sources. For example, using other available information (prescription data, farm data, etc.) or following trends from previous year. The ESVAC team may assist MS on this process.

5. Reporting process

Reporting of stratified data by species should be done in % of the estimated use. If this is not possible, the MS should specify the units used for the attribution for each of the VMPs.

The reporting should be complemented by providing details about the data collection process and the evaluation of the results. For this purpose, Member States are requested to fill in the template in Annex 2 including information about the source of data, the data coverage, validation of the data and other additional information.

6. Call for data and timetable

The call for stratified data 2017 is done as part of the annual call for ESVAC sales data and therefore will be running in parallel, in the same way and under the same conditions as the ESVAC sales data project. Some MS may not be able to submit the stratification data for 2017 together with the ESVAC

sales data 2017, for example because the first year the MS has not yet a system in place to collect the stratified data and need additional time to define and develop the system. MSs may contact the ESVAC secretariat to discuss alternatives.

The results of the stratification data 2017 will be analysed and published separately from the ESVAC report 2017. As usual, no data will be published with specific reference to a country unless this has been authorised by the country.

ANNEX 1: Additional explanation and examples

- a) Estimates of the proportion (%) of all VMP presentations submitted for the ESVAC project should be provided for the stratification project
- b) Stratification data for the 3 main species, cattle, pigs and poultry, should be completed in all cases. Also in the case that the VMP is not used for the species. In this case, a 0% should be filled in
- c) If information is available only for the 3 main species, cattle, pigs and poultry and this information is not giving 100%, fill in the remaining percentages in the column "All other animal species or unknown"
- d) Stratification data for other animal species (sheep and goats, fish, horses, rabbits, cats and dogs) will be highly appreciated, but is optional
- e) The estimate of the % of use in chicken and turkeys may be provided if known. This should be provided in % of the estimate for all species
 $\% \text{chicken in column W} + \% \text{turkey column X} = \% \text{poultry column P}$
- f) The estimated use in companion horses, should be included under "horses"
- g) If a country wishes to provide estimates of non-authorized product presentations in veterinary medicine, e.g. human medicinal products that are used in veterinary medicine through the cascade, this information can only be added if a clarification is provided in the column "Additional information" and under point 6 (Any other comments) of the questionnaire in Annex 2 of this protocol

Table 2. Additional columns added to the ESVAC template for the collection of data for stratification of sales data by species

PRODUCT INFORMATION		Stratification															
COUNTRY	YEAR	MA	PRESENTATION_ID	NAME	Cattle	Pigs	Poultry	Sheep & Goats	Fish	Horses	Rabbits	Cats & Dogs	All other animal species or unknown	Poultry chicken	Poultry turkeys	Additional Information	Total, %
			1	Presentation_1	5%	12%	80%						3%	20%	60%		100%
			2	Presentation_2	0%	0%	0%					95%	5%				100%
			3	Presentation_3	0%	0%	90%					10%					100%
			4	Presentation_4	0%	85%	0%						15%				100%
			5	Presentation_5	0%	0%	0%	23%		22%			55%				100%
			6	Presentation_6	25%	25%	25%	25%									100%
			7	Presentation_7	0%	0%	0%	100%									100%
			8	Presentation_8	0%	15%	0%		15%				70%				100%
			9	Presentation_9	0%	0%	20%						80%				100%

ANNEX 2: Questionnaire to be filled by all Member States

COUNTRY: _____

CONTACT POINT: Name: _____
 Organisation: _____
 E-mail: _____

INFORMATION RELATED TO THE STRATIFICATION DATA 2017

- 1) Source of the data (e.g. MAH, wholesalers, pharmacies):

- 2) Data coverage (100% or other %, including explanation about the missing data):

- 3) If relevant, validation of the data/quality assurance (e.g. by comparing with prescription data, farm data):

- 4) Use of the data in own country (e.g. own national annual report, or no publication of the data):

- 5) Short discussion about the results (please provide a short summary of the most relevant points):

- 6) Any other comments:

