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Veterinary Medicines and Product Data Management

## Report from the Workshop on collection of data on antimicrobial agents by species and on unit(s) of measurement

13 - 14 October 2011

Role	Name
Chair/Vice-chair	G�rard Moulin/Kari Grave
Present:	Klemens Fuchs, Boudewijn Catry, Erik Jacobsen, Claire Chauvin, G�rard Moulin, Roswitha Merle, Inge van Geijlswijk, Lourdes Garc�a Migura, Christina Greko, Cedric Muentener, Ana Mateus, Klaus Weist, Pierre-Alexandre Beloeil, Yvonne Ager�, Irene Litleskare, Scott McEwen, Christian Berg, Vittorio Fattori, Fran�ois Diaz
EMA:	Jordi Torren, Arno Muller
Apologies:	Hilde Kruse, Ole E. Heuer, Rosa Peran, Martinus Nagtzaam, David White

### Introduction

An expert meeting was held at the European Medicines Agency to explore the possibilities of collecting data on sales of antimicrobial agents per animal species and on the development of units of measurement in order to take into account differences in dosing when reporting the sales data. The meeting was divided in two work-streams (animal species and units of measurement) and held under the umbrella of the European Surveillance of Veterinary Antimicrobials Consumption (ESVAC) project. The experts were selected on basis of their expertise on the subjects of the meeting and on antimicrobial resistance and were primarily ESVAC national representatives, SAGAM and CVMP members but also from academia. Further information on the project can be found here [http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000302.jsp&murl=menus/regulations/regulations.jsp&mid=WCOb01ac0580153a00](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&murl=menus/regulations/regulations.jsp&mid=WCOb01ac0580153a00).

### Summary

The aim of the ESVAC is to collect harmonised data on sales of veterinary antimicrobial agents – overall and by species. The first step is to collect overall sales data and report these in a harmonised manner. The next step is to collect valid data by species that are harmonised between countries and to develop units for veterinary antimicrobial agents in order to harmonize the reporting of such data across Europe and time periods.



## Agenda - Workshop on collecting data by species 13 October

Item	13 October 14:00-18:30	Initials/Names
1	Opening of the meeting/adoption of draft agenda	Jordi Torren/Kari Grave
2	ESVAC project – where are we?	Kari Grave
3	Setting the scene	Kari Grave/Jordi Torren
4	National approaches/guidance on how to collect/estimate data per species	Austria, Belgium, France, Germany, Sweden, Switzerland
5	WHO AGISAR Draft guidance on how to collect data per species at farm level	Scott McEwen (by video conference)
6	Point prevalence studies in human medicine	Arno Muller
7	Discussion on guidance	All
8	Development of work streams? How?	All
9	Conclusions	Jordi Torren
10	Next meeting	Kari Grave/all
11	A.O.B or Tour de Table	Jordi Torren/all

### Discussions

Projects and surveillance programs on collecting data of veterinary antimicrobial agents per animal species in different EU countries were presented. The data sources and methods of data collection varied between the countries.

Longitudinal studies or point prevalence studies (PPS) were used to collect consumption data on antimicrobial agents by some countries. Advantages and limitations of both methods were discussed especially with regard to the feasibility and sustainability of longitudinal studies and PPS.

Repartition of overall sales data by species was an approach used by some other countries and various approaches on species repartition were presented.

### Conclusion

It was concluded that as a first step prior to the development of guidance on how to collect data by species there is a need to discuss how to establish a sustainable system to obtain valid surveillance data on sales/use of antimicrobial agents by species from the various countries taking into account that the data source will have to vary. An *ad hoc* working group was established with the aim to develop a reflection paper to address this.

#### Terms of reference

Describe what data is needed on overall use of antimicrobial agents by species and country, including criteria for acceptance for ESVAC such as the comparability, minimum level of precision (e.g. confidence limit of estimate), reproducibility etc.

Describe and discuss the applicability of:

- point prevalence studies (farm level, veterinary practices)
- longitudinal studies (farm level, veterinary practices)
- models for repartition of totals sales based on e.g. PSUR

- to obtain estimates of the needed data.

Emphasis should be placed on sustainability, possibilities for validation of the data and potential for improvement of the respective methods as well as comparability of results obtained with the different methods.

In principle the groups of animals to be addressed are: poultry, pigs, cattle, other ruminants, horse, fish and pets. The species to be addressed should be prioritised.

## Agenda - Workshop on animal DDD or equivalent 14 October

Item	14 October 08:30-14:30	Initials/Names
1	Opening of the meeting/adoption of draft agenda	Gerard Moulin/Kari Grave
2	National approaches/guidance on assigning animal DDDs or similar units	Austria, France, Belgium, the Netherlands, Switzerland
3	WHO draft guidance on assigning animal DDDs	Irene Litleskare
4	Discussion on guidance	All
5	How to organise work streams on assigning animal DDDs or similar units at European level	All
6	Conclusions	Jordi Torren
7	Next meeting	Kari Grave/all
8	A.O.B or Tour de Table	Jordi Torren/all

## Discussions

Different units of measurement to report antimicrobial consumption in food-producing animals were used by the countries. Units of measurement units included kilogram, ADDs (Animal Daily Dose), ACD (Animal Course Dose), DDDanimal (Defined Daily Dose animal), DCD (Defined Course Dose), DID (prescribed daily dose per 1000 animals), UD (Unit Dose), PDD (Prescribed Daily Dose). Identical units, e.g. DDD, was often defined and calculated differently in each Member State. The appropriateness of the various unit of measurements from the analysis of the data in the context of e.g. antimicrobial resistance and the evaluation of campaigns on prudent use was discussed

## Conclusions

It was agreed that as a first step prior to the development of guidance(s) on how to assign animal DDD or similar units there is a need to discuss what unit(s) of measurement is applicable for the reporting of the data depending on the purpose of the reporting – e.g. whether to evaluate management measures, prudent use campaigns or in the context of antimicrobial resistance. Also the terminology has to be standardized. An *ad hoc* working group was established with the aim to develop a reflection paper to address this topic. The terms of reference for this work have to be agreed during the 1<sup>st</sup> meeting (Vitero) 15 December 2011.