



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ESVAC strategy 2016-2020 including benefits of the collection of data on sales and use per species

Data collection on consumption of veterinary antimicrobials in Europe – achievements, challenges and way forward

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An agency of the European Union





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ESVAC mandate

The ESVAC mandate is *"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 (poultry, pigs, veal, other ruminants, pets and fish)"*.



Communication from the Commission to the European Parliament and the Council Action plan against the rising threats from Antimicrobial Resistance (COM (2011) 748)

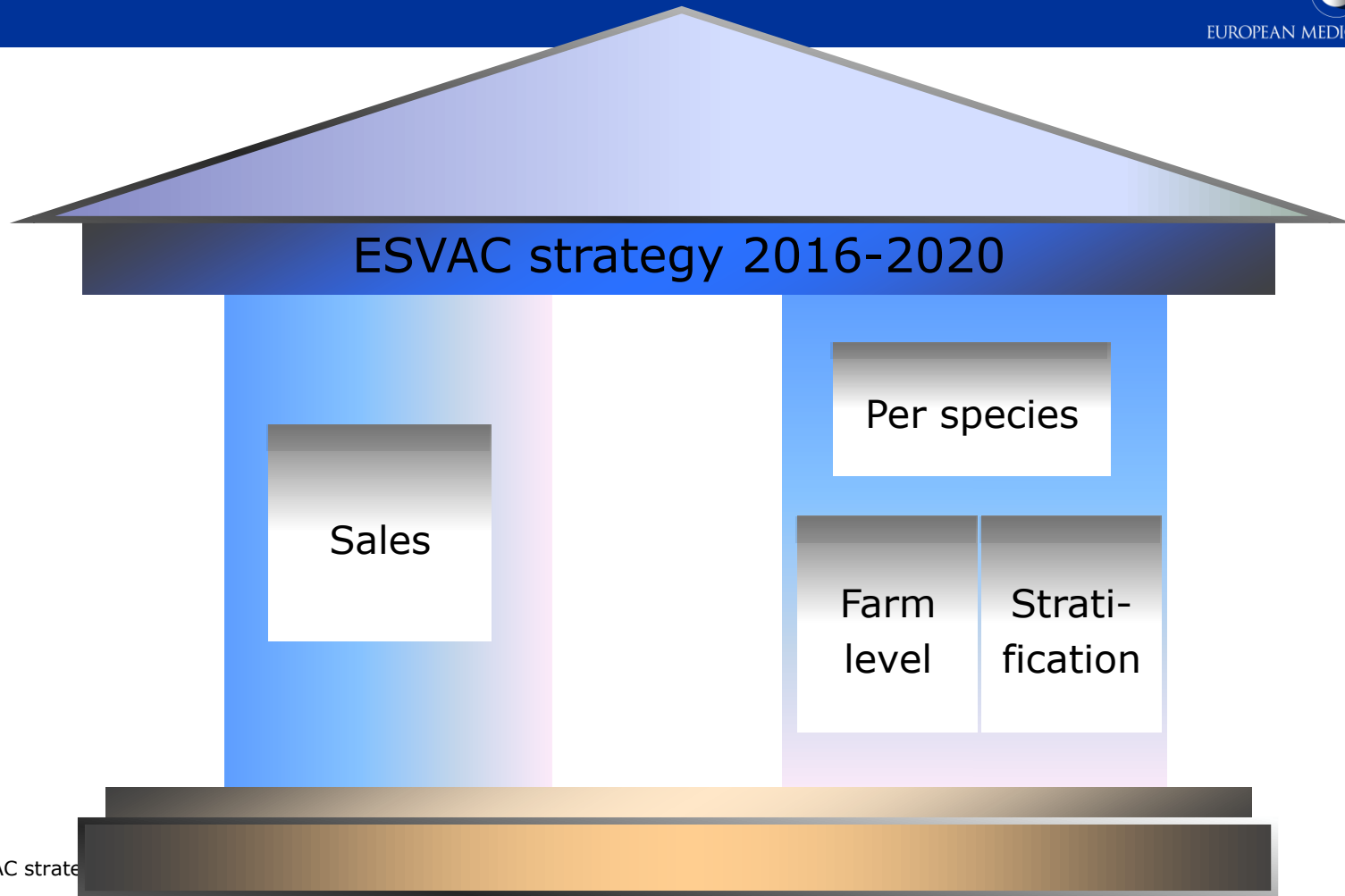
Action n° 10: Strengthen surveillance systems on AMR and antimicrobial consumption in animal medicine

Promotion and extension of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) with the collaboration of EMA to obtain harmonised data on the usage per animal species and production categories as well as for different indications from all Member States.



Roadmap Commission's Communication on a One-Health Action Plan to support Member States in the fight against Antimicrobial Resistance (AMR)

Developing expertise on methodologies, indicators and instruments **to monitor trends** in resistant infections and **antibiotics consumption**, both in humans and **animals**.





ESVAC strategy 2016-2020

Sales



Sales coverage

In the period 2016-2020, ESVAC intends to continue collecting and publishing overall sales data from as many EU/EEA countries as possible

Next report:

Data from 30 European countries.
Nearly full coverage.





Evolution

Grave, K., Torren-Edo, J., & Mackay, D. (2010). Comparison of the sales of veterinary antibacterial agents between 10 European countries. *J Antimicrob Chemother*, 65(9), 2037-2040. doi: 10.1093/jac/dkq247

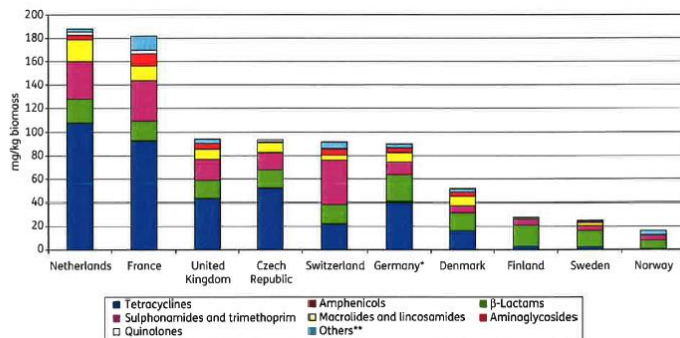
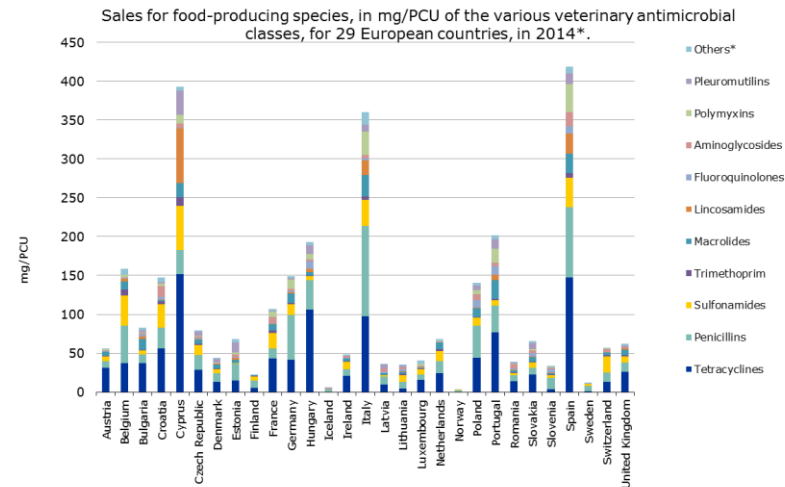
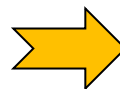


Figure 1. Amounts, in mg, of veterinary antibacterial agents sold in 2007 per kg biomass of pig meat, poultry meat and cattle meat produced plus estimated live weight of dairy cattle. *2005 data. **The substances included vary from country to country.



*Differences between countries can be partially explained by differences in animal demographics, in the selection of antimicrobial agents in dosage regimes, in type of data sources, and veterinarians prescribing habits and prices

From 9 countries in 2009 to 30 countries in 2015.



Advantages sales

- To aid interpretation of patterns and trends regarding antibacterial resistance
- Trends and patterns available
- To serve as a basis for risk profiling and risk assessment regarding antibacterial drug resistance
- E.g. CVMP/AWP recommendations make extensive use of ESVAC data
- To serve as a basis for setting risk-management priorities
- Colistin/prioritisation of referrals
- To serve as a basis for evaluating the effectiveness of control measures being implemented.
- Colistin

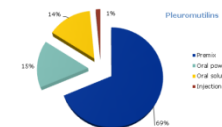
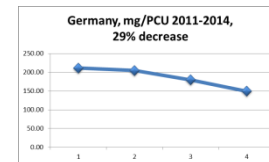
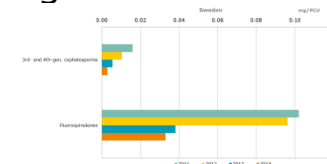


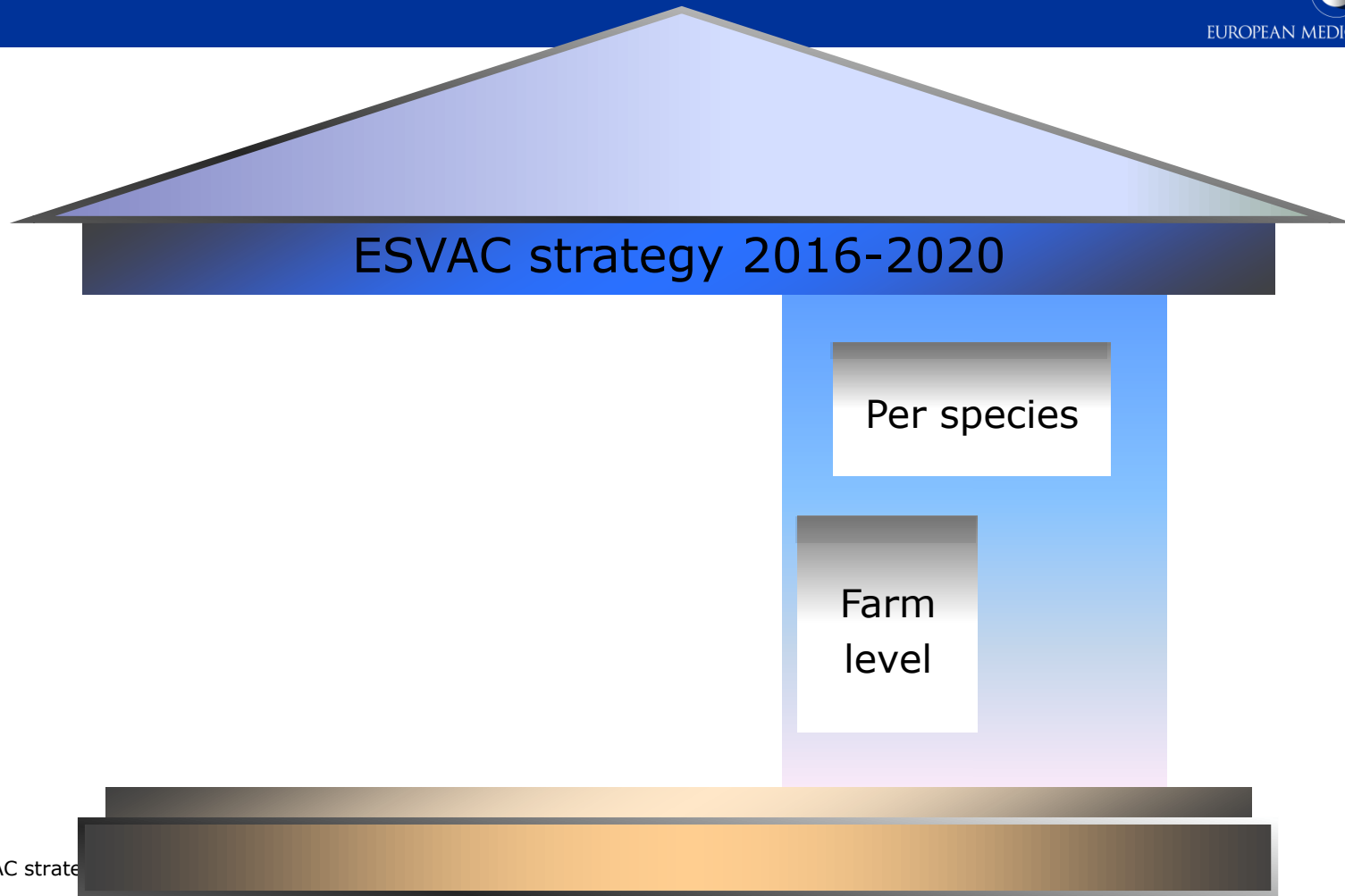
Figure 3. Sales of pneumococcal conjugate vaccine in 2011 by pharmaceutical form in 25 countries – expressed as percent of total sales in tonnes (EMA/ESVAC, 2013).



Advantages sales (cont.)

- To aid in identifying emerging use of antibacterial drugs, e.g. of specific drug classes such as critically important antibiotics.
- Fluoroquinolones, 3rd and 4th generation cephalosporins and colistin.
- To aid in comparing usage of antibacterial drugs between and within countries, and between time periods etc.
- Multiple examples available.
- To assess the spread and effects of environmental pollution through use of antibacterial drugs.
- Overall sales in tonnes by classes provides a proxy, but no data by substance.
- To serve as a basis for focused and targeted research and development.
- Need to have more “category 1” substances authorised.







Collection of use data by species – objectives and principles

The objective of this work stream is to foster the collection of harmonised and standardised data in the EU/EEA countries on the use of antimicrobials by species for the three major food-producing animal species; cattle, pigs and poultry.

- Should allow for the monitoring and analysis of trends in use of antimicrobials by species over time.
- Use of the standardised units of measurement (DDDvet and DCDvet).
- Should further support the preparation of countries for the expected requirements of the revised legislation on veterinary medicinal products as it relates to the collection and supply of data on antimicrobial use



Advantages of data by species

- Analysis of antimicrobial use and resistance data (collected by animal species).
- *Systems for monitoring antimicrobial consumption should preferably be integrated with national (or even farm-level) surveillance programmes for AMR. This would facilitate the establishment of an evidence base to identify the need for risk management measures/policies at the local level and to assess their effectiveness (RONAFA opinion*).*
- Exposure of animals to antimicrobials by animals species; identification of those with highest use of antimicrobials.
- *Sales data of antimicrobials by animal species/production sector would be helpful in establishing more precise patterns of use (RONAFA opinion*).*



Advantages of data by species (cont.)

- Trends of use of antimicrobials amongst animal species and age categories where available.
- *The sales data from the ESVAC project at present do not collect data at the species/production sector level or use a standardised measurement of consumption by species. This limits usefulness of the data for intercountry comparison due to differences in livestock profiles (RONAFA opinion*).*
- Use of refined units of measurement (DDDvet and DCDvet).
- *A common protocol should be considered which would enable a comparison of antimicrobial consumption data between all countries and over time. A meaningful, harmonised statistic (e.g. DDDvet) should be used in the analysis of use data (RONAFA opinion*).*



Advantages of data by species (cont.)

- Better analysis of efficacy of measures implemented.
- Benchmarking of farms; improve use of antimicrobials.
- *The minimum data collected should allow identification to the prescribing veterinarian, farm of use, animal species, formulation details and quantity to allow for benchmarking and tailoring of risk management measures (RONAFA opinion*).*
- Identification of off label use of antimicrobials.
- *Further research should be done into the nature and extent of off-label use of antimicrobials in food-producing animals in the EU... (RONAFA opinion*).*



Advantages of data by species

Depending on the system implemented at MS level some of the advantages might vary (e.g. benchmarking, collection of off-label data).



Collection of use data by species – intended actions

- Act as the networking hub within the EU/EEA area, bringing together the best technical expertise on collection and analysis of use data by species.
- Develop, in consensus with the ESVAC species EAG and with input from the ESVAC networks, guidance (including methodology) for the collection of harmonised and standardised data on use by species.
- Foster the conduct by EU/EEA countries of studies to ensure applicability of the guidance throughout the EU/EEA area and promote the uptake at national level.



Collection of use data by species – intended actions

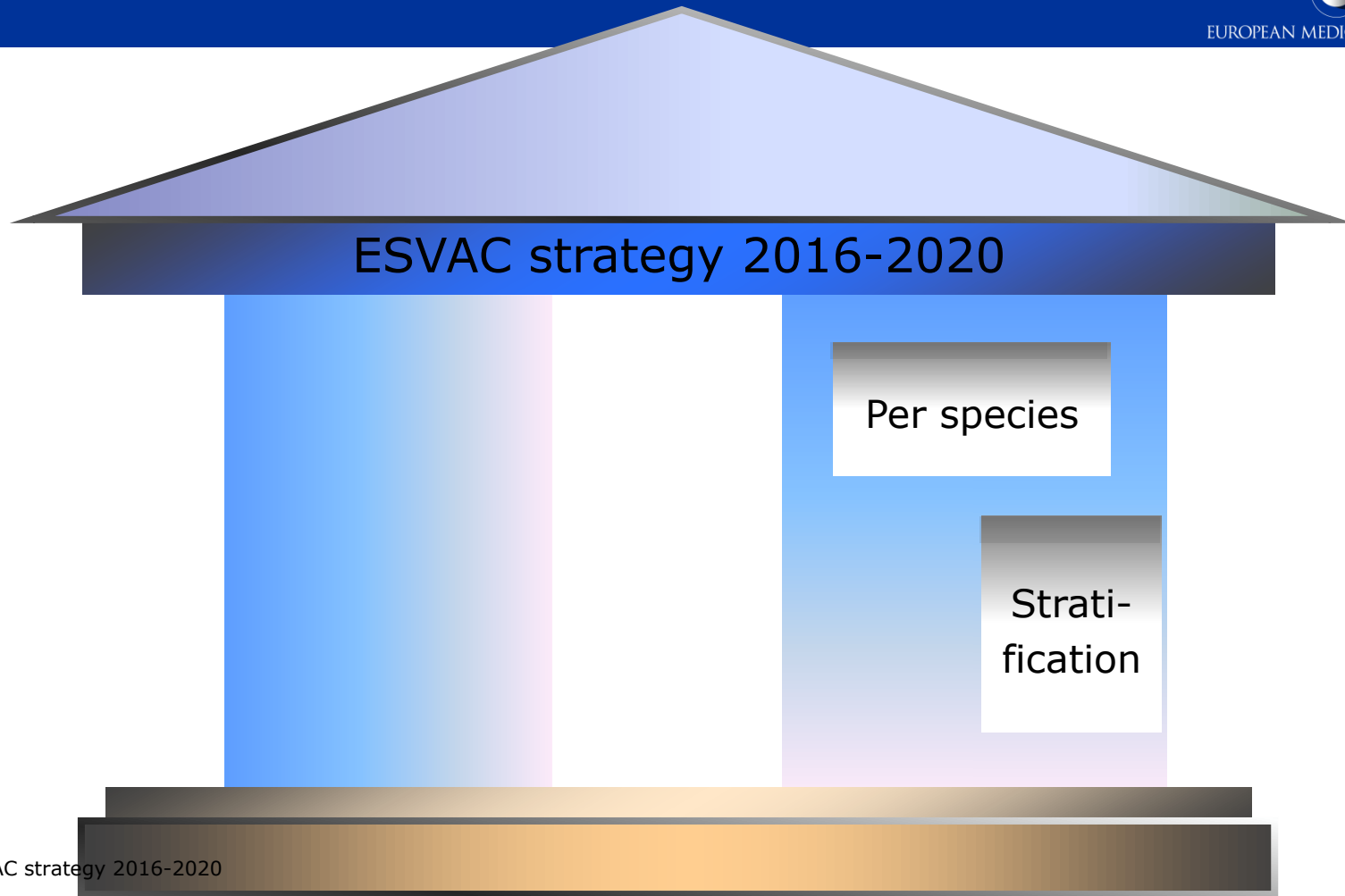
- The ESVAC work stream should help to ensure that existing schemes could provide data that are harmonised and compatible with the EMA databases.
- Data by species will be used as part of the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) reports.
- Guidance on provision of data on antimicrobial use by animal species from national data collection systems (EMA/489035/2016) recently published for consultation until 24/09/2017 -> all comments are welcome. The guidance will be revised at the end of the consultation period.



Collection of use data by species – intended actions

- Call for data by species (farm level) depends on revision of legislation (content/when into force).
- Depending on available resources EMA might explore application of guidance with volunteer countries.

The guidance document has been drafted for those MSs that would be willing to provide data on a voluntary basis. Accordingly, statements like "data to be provided to EMA" should not be understood as a requirement, but as the data to be provided once a MS has decided to provide such data.



ESVAC strategy 2016-2020

Per species

Stratification



Stratification of sales data

- Sales data as a proxy for consumption will continue to be collected for the foreseeable future as the core ESVAC activity, even whilst work is carried out to develop systems to collect data on actual use of antimicrobials by species.
- ESVAC will explore if it is feasible to estimate the consumption per species based on an approximate allocation of the proportion of total sales that are used in each species for which an antimicrobial is indicated (stratification of sales data).
- The stratification of sales data should be viewed as an interim approach until systems to collect data on use by species are in place.



Stratification of sales data (cont.)

- Could provide reasonable estimates of consumption with an acceptable coverage in terms of countries involved.
- Would allow for use of DDDvet and DCDvet.
- During the preparation of JIACRA II an estimation of sales by animal species has been produced, such work would be used as the basis for the stratification of sales data.
- Japan has produced data stratified by animal species for a number of years.
- FDA is preparing a similar approach.
- Pharmaceutical industry seems supportive of the initiative.
- Will depend on resources at the Agency (and Member States).



Overall considerations

- Antimicrobial sales data is a very cost/effective manner to support activities on prudent use of antimicrobials.
- It is of great importance that Member States dedicate the resources required to the sales data and that methodology and knowledge at Member State level are maintained and improved.
- Collection of use data by species is more refined but, pending on expected requirements from veterinary medicines legislation, unlikely to be completed at EU/EEA level in a short period of time.

Overall considerations (cont.)

- Collecting data from a representative sample of farms could be an alternative option for those countries that do not currently collect automated continuous data from all farms, but minimum sample size should be big.
- Stratification of sales data could be an interim approach – pending on EMA resources.
- Call for data by species (farm level) depends on revision of legislation (content/when into force) and resources.
- The Agency will further consider the current set up of the ESVAC activity to adapt to its growth and legislative changes.



The way forward

- Collection of sales of antimicrobials to continue with further improved data and full EU/EEA coverage.
- Legislative requirements for collection of antimicrobial data are outside the remit of EMA.
- If mandated to collect data at farm level, the revised guidance per animal species would be the basis for the request to MSs.
- Depending on resources, the feasibility/work on stratification will be taken forward.



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Thank you for your attention

Further information

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