



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ESVAC Strategy 2016-2020

ESVAC Stakeholders annual meeting 2016

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An agency of the European Union





Content of the presentation

- ESVAC mission.
- Overall sales data.
- Collection of consumption data by species.
- Stratification of sales data.
- Units of measurement.
- Publication of the strategy.
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ESVAC mission

The ESVAC mission is develop a harmonised approach for the collection and reporting of data based on national sales figures combined with estimation of usage in at least major groups of species (poultry, pigs, veal, other ruminants, pets and fish).

- Based specifically on the request from the European Commission.



Overall sales data

- Core of the ESVAC activity.
- Well established.
- Will continue in the future.
- Objective to report from all EU/EEA countries nearly achieved.
- New IT tools for collection and reporting of data implemented.
- ESVAC database will be linked to the Common EU Database of VMPs.



Collection of consumption data by species

Objectives

- To foster the collection of harmonised and standardised data in the EU/EEA.
- Pigs, poultry and cattle.
- Should allow to analyse trends of use of each species for which data are collected.
- Apply Defined Daily Doses (DDDvet) and Defined Course Doses (DCDvet).
- Should allow comparison of use of antimicrobials by species between countries.
- Should support the preparation of the countries for the requirements of the review of legislation on veterinary medicinal products (*and animal law*) on antimicrobial consumption.



Collection of consumption data by species

How to achieve the objective

- EMA/ESVAC acting as the networking hub within the EU bringing together technical expertise on collection and analysis of consumption by species.
- Key activity in preparing for the revision of the veterinary legislation to enable the EMA and NCAs to provide advice to the European Commission in preparing the necessary delegated acts.



Collection of consumption data by species

How to achieve the objective (cont.)

- Developing by consensus standard guidance and methodology, for collection of data on consumption by species and on animal population that are useful at a national level and that also allow collation of data at a European level;
- Fostering the conduct by Member States of pilot studies to validate the guidance and promote their uptake at national level.



Collection of consumption data by species

Lessons learnt

- Substantial resources and legal basis at Member States are needed to collect data on antimicrobial consumption by species.
- It will be a number of years before systems are in place to measure consumption by species on a routine basis in many Member States.



Next steps on collection of data by species

- ESVAC project will provide the minimum required variables to initially collect those data per species.
- ESVAC will produce guidance/protocols and templates for collection of harmonised and standardised data from MSs on the use of antimicrobials.

Considerations on collection of data by species

- Member States to populate templates either using data expressly collected for this purpose or data collected as part of national surveillance schemes.
- ESVAC foresees the implementation at EU level of schemes for collection of electronic prescriptions and associated electronic dispensing (unique packages IDs) which will considerably simplify and reduce the cost for Member States of supplying data on use of antimicrobials at farm level to the ESVAC project.



Considerations on collection of data by species (cont.)

- Ensure that those schemes produce data that are comparable.
- The guidance will be developed and approved in conjunction with the ESVAC Expert Advisory Group on collection of data per animal species.
- Integrated analysis with data on use of antimicrobials in humans, and on resistance in animals, humans and food.



Considerations on collection of data by species (cont.)

- EMA is not in a position to carry out surveys on consumption per species with the resources currently available.
- Those Member States wishing to take part will use a standard guidance and supply harmonised, quality controlled data to EMA that the EMA will then collate and report.



Stratification of sales data

- ESVAC project will, together with the MSs, 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.
- Would be based on direct attribution of sales to one animal species for those products for which only one animal species is authorised (circa 30% of products), and by attributing proportions of sales to each major animal species (pigs, poultry, cattle, companion animals and others).



Stratification of sales data (cont.)

- Estimates could be from the Marketing Authorisation Holders.
- Could enhance the analysis and reporting of the stratified sales data by use of the established DDDvet and DCDvet.
- Could provide an estimate of the use per species until such time as systems to measure actual use come on line.
- Parallel activity and not an alternative or competing system.



Units of measurement

- Objective:
 - To maintain the principles for the assignment of Defined Daily Doses animal (DDDvet) and Defined Course Doses animals (DCDvet);
 - To assign DDDvet and DCDvet for antimicrobials used in pigs, cattle and broilers and to maintain the system.
- DDDvet and DCDvets to be published shortly on the EMA web page.

Publication of the strategy

Agreed by the ESVAC network	29 March 2016 [*]
Adopted by ESVAC	31 March 2016 [*]
Start of public consultation	4 April 2016 [*]
End of consultation (deadline for comments)	31 July 2016 [*]

* These dates have been updated to reflect a revised timetable to allow time to take into account the conclusions reached at the Stakeholders meeting.



Conclusions

- Overall sales data will continue in the future.
- EC review of legislation likely to require antimicrobial consumption data per species from Member States.
- Consumption data per species is resource demanding and requires time and experience.
- ESVAC dedicating careful considerations on how to achieve systems at national level that are comparable at international (EU) level.
- Automated collection of continuous data will facilitate the collection of such data, but it will take years to be implemented in the EU.
- Complementary systems (stratification) will be explored by ESVAC.
- DDDvet and DCDvet to be published shortly.



Thank you for your attention

Further information

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