



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

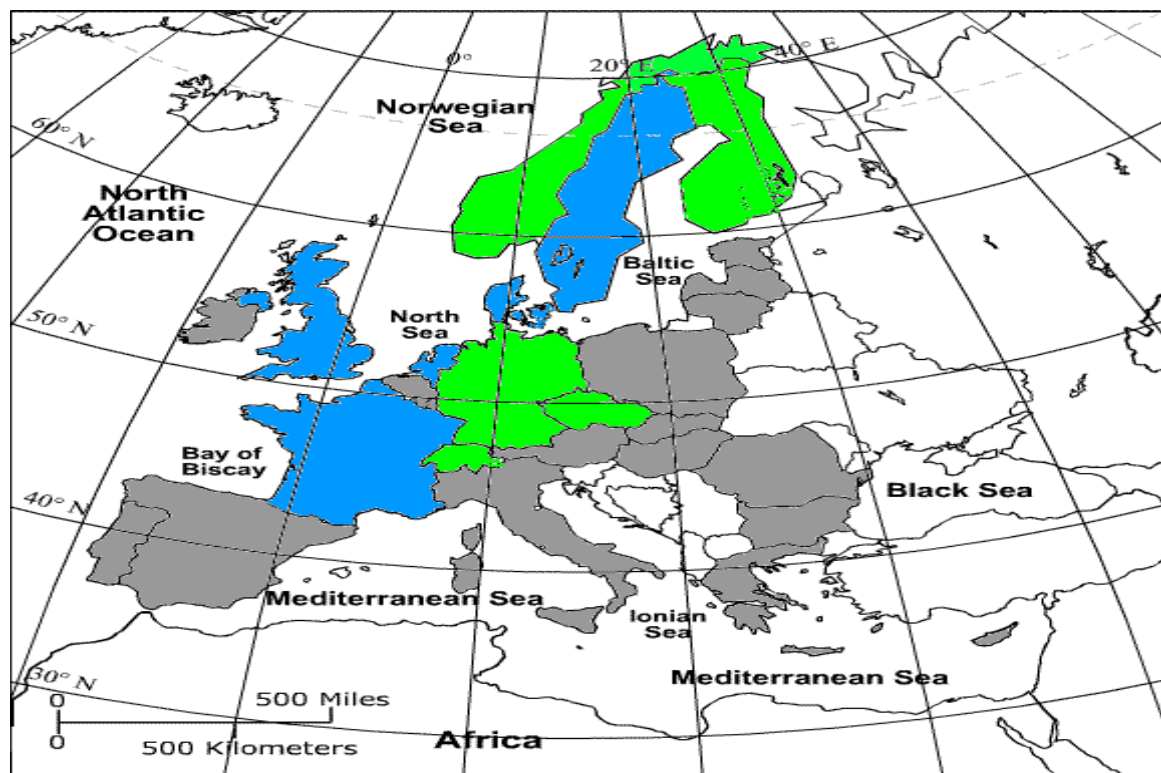
Update on the ESVAC project

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



“State of the art” before the ESVAC project was initiated



10 countries (8 MS)
5 collect per species

Coverage of > 50 %
(slaughtered) biomass
in MS

 Total sales
 Total sales + per species



Outline

1. ESVAC Project Team
2. ESVAC project plan - revised
3. Achievements September 2009 - September 2010
4. Next steps



ESVAC Project Team

- Project Coordinator - work shared equally between a national expert and a temporary agent, each working 50% on the project (1 September 2009....)
- Data Manager – 50% position in 7 months (1 September 2010)
- Administrative Assistant – 20% position (1 September 2009)
- EMA Trainee - 100% for 6 months (1 October)



ESVAC project plan - revised

- **ESVAC I**. Pilot project (2009-2011)
- **ESVAC II**. Operational Phase: Collating overall sales data from all Member States (2012-onwards) and on estimations per species
- **ESVAC III**. Collating data on overall sales, estimates per species and on actual usage of antimicrobials by animal species, production category, indication etc (2013-onwards)



ESVAC I. Pilot project (2009-2011)

- Develop/adapt software to store, validate, process and analyse overall sales data for 2010 collected according to ESVAC template (September 2010-January 2011). **In this phase the system will be manual, requiring limited IT resources**
- Development of recommendations for an operational system (ESVAC II), including the ESVAC database



ESVAC I. Pilot project (2009-2011) cont.

- Proactively provide advice and support to countries starting to collect data for the first time, including how to validate, process and analyse data collected according to the ESVAC template
- Issue a call for data for 2010 data according to template on sales of all veterinary antimicrobials included in ESVAC to all **countries agreeing to participate** (December 2010)

ESVAC II. Operational Phase (2012-onwards)

- Extend scope of project from pilot group to all 27 MS, plus EEA countries and other third countries willing to participate
 - Collation of overall sales data from all MS, EEA and other European countries according to template
 - Collating data on estimated use by species
- Depending on the resources available to the project
 - Development of a **semi-automated system** for data submission, collection, analysis and reporting, including the **ESVAC database**
- Develop a project plan for ESVAC III with the objective to collect and analyse data on the actual use of veterinary AMs in Member States



ESVAC III. (2013-onwards)

- ESVAC III. Collating data on sales, estimations per species and on actual usage of antimicrobials by animal species, production category, indication etc (2013-onwards)
 - This part of the project plan will be developed at a later stage based on the outcomes and decisions made for ESVAC I and II.



Achievements ESVAC (I)

- TCG appointed (includes DG Sanco and DG Enterprise, ECDC, EFSA and CRL)
- Identification of Stakeholders
 - International Federation for Animal Health (IFAH)
 - European Group for Generic Veterinary Products (EGGVP)
 - Groupement International de la Répartition Pharmaceutique (GRIP)/The European Association of Pharmaceutical Full-line Wholesalers
 - Federation of Veterinarians in Europe (FVE)
 - Association of Veterinary Consultants (AVC)



Achievements ESVAC (I) cont.

- Identification of other bodies etc to be kept informed about the ESVAC project
 - DG Environment, DG Agriculture
 - FAO
 - OIE
 - WHO
 - Codex
 - Consumers International



Achievements ESVAC (I) cont.

- Agreed on and published on EMA web pages
 - Which veterinary antimicrobial agents to be included in the ESVAC project (as a minimum)
 - ESVAC data collection protocol – including standardized conversion factors, classification system and names
 - ESVAC Data Collection Form
 - Brief description of the ATC/ATCvet system and relevant codes published at the EMA web pages



Achievements ESVAC (I) cont.

- Identified new MS that have started to collect data
 - Belgium
 - Ireland
 - Spain
 - Luxemburg
- Identified countries that plan to start collecting data soon
 - Cyprus
 - Estonia
 - Hungary



Achievements ESVAC (I) cont.

- **June 2010**
- Teleconferences/Vitro-meetings on the application/implementation of the template with
 - Belgium
 - Ireland
 - Spain
 - UK (already collecting data)



Achievements ESVAC (I) cont.

- Implementation of ESVAC template
 - Training to assist MS setting up surveillance for the first time (28 and 29 September 2010)



Presentation of ESVAC (I) on various meetings

- KSLA (The Royal Swedish Academy of Agriculture and Forestry) Conference. Stockholm 15 December 2009
- Heads of Medicine Agencies (HMA) April 2010
- Commission working group on antimicrobial resistance, Brussels, 25th May 2010
- ESAC-3 annual meeting. Stockholm, May 2010.
- APUA (Alliance on Prudent Use of Antimicrobials) Roundtable. Paris 28-29 May, 2010
- WHO-AGISAR (Advisory Group on Integrated Surveillance of Antimicrobial Resistance) 2nd meeting. Guelph 4-7 June 2010



Achievements cont./next steps

- Issued call for data according to data collection form on sales of specific classes of veterinary antimicrobial agents for 2008 to agreed participants (April 2010)
- Develop/adapt software to store, validate, process and analyse overall sales data from 2010 collected according to data collection form (September 2010 and onwards)



Achievements ESVAC I cont./next steps

- Issued call for data (April 2010)
 - Historical data on agreed veterinary antimicrobials (2005-2009) from the 10 countries already collecting data
 - 8 countries delivered; 2 will deliver data soon
 - Data on selected antimicrobials according to template (2008)
 - 9 countries delivered; 1 will deliver soon
- Analyse and report/publish aggregated data for 2005-2009 and species for 2008 (September 2010-February 2010)



Achievements ESVAC I cont./next steps

- Included in pilot on the applicability of the ESVAC template
 - Discussed at the TCG meeting
 - Experience be used in training 28-29 September



Next steps ESVAC (I)

- Evaluate use of denominator – e.g. use of biomass live animals vs biomass slaughtered animal to take into account transport of animals to other countries
- Agree format and content of report on historical data analysis
- Decide upon animal species categories
- Revise/amend ESVAC Data Collection Form
- Further implementation of ESVAC data Collection Form



• Next steps ESVAC (II)

- Based on a request from the Commission:
 - Conduct an analysis of advantages and disadvantages of voluntary vs compulsory schemes for submission of data into ESVAC, together with an appraisal of any need for change in legislation
 - Develop a draft working agreement with ECDC, EFSA and other relevant parties on integrated use of ESVAC data with data on AMR and on usage in human medicine.
 - Agree format and content for report of annual data analysis