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Veterinary Medicines and Product Data Management

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project - 2nd annual network meeting, EMA, 14-15 February 2012

Agenda

Chair/co-chairs: Kari Grave (KG), Jordi Torren Edo (JTE), Arno Muller (AM)

Item	Agenda 14 February	Initials	Min
1.	Opening of the meeting	Executive Director Guido Rasi	10
2.	Adoption of draft agenda	All	5
3.	ESVAC results and state of play	KG	25
4.	Collection of ESVAC 2010 data – approaches and difficulties. Experience by MSs	Belgium, Ireland, Portugal, Spain, United Kingdom	100
5.	2010 data – validation procedure and usual errors/problems in the data provided	KG/AM	30
6.	Call and validation of for 2011 data. Discussion on WHAT and HOW to improve	KG/all	30
7.	Conclusions of discussion	JTE/all	20
Item	Agenda 15 February	Initials	Min
8.	Report 2010 data. Procedure and draft outline/content of the report	KG/JTE/AM/all	45
9.	Presentation of reflection paper on collecting data by animal species Discussion	Jeroen Dewulf/all	30
10.	Presentation of reflection paper on technical unit of measurement. Discussion	Gerard Moulin/all	30
11.	Conclusions of discussion	JTE/all	20
13	Preparation meeting with stakeholders	KG/JT	10
14	A.O.B	All	10
15	Closing of meeting	JTE/KG	5

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Summary of the meeting

Introduction

The Agency Executive Director, Professor Guido Rasi, welcomed the participants joining the second ESVAC annual network meeting that took place at the EMA in London 14-15 February 2012. He highlighted the Agency's commitment to fight against antimicrobial resistance of which the ESVAC project is an important part.

The 2nd annual meeting of the EMA European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) network took place in London on 14-15 February 2012. Representatives of the ESVAC network *and ad hoc* working groups were present as well as the European Commission , ECDC and observers from international organizations (FAD and WHO Europe).

The main objective of the meeting was to update the network on the current status of the project, to discuss challenges at MS level to obtain valid data with 100% coverage and the preparation of the report of the 2010 data to be published at the end of 2012.

ESVAC results and state of play

Collection of aggregated historical data

- collection of already existing data on aggregated overall sales, in tonnes of active ingredient, of veterinary antimicrobial agents by class in a harmonised manner from 9 European countries
- in order to report the sales by the 9 countries in a harmonized manner taking and into account the animal population at risk of being treated with veterinary antimicrobial the production correction unit (PCU) was developed by support from the Technical Consultative Group (TCG)
- the report on trends in the sales of veterinary antimicrobial agents in 9 European countries for the period 2005-2009 was published in September 2011[1]

Collection of standardized data at package level

- the ESVAC protocol and the ESVAC data collection form (ESVAC template) have been developed in order to obtain standardised and valid data on the sales of veterinary antimicrobial agents at package level from the MSs[2]
- an ESVAC data program has been developed for the purpose of quality check of the data in terms of standardization and the ESVAC data base for the storing of the validated data
- a program for the semi-automatic calculation of PCU have been developed
- call for data according to ESVAC template sent out to 23 EU/EEA countries that agreed to provide the data for 2010
- 19 EU/EEA countries have delivered the data, one will deliver shortly
- the data provided have been validated by the ESVAC data program and by manually validation - i.e. checking in particular strengths and for outliers for those countries that had data for earlier years

[1] Available from http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/09/WC500112309.pdf
[2] Available from http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580153a00

Collection of 2011 data

- call will be launched in March 2012
- for those Mss that have provided data to ESVAC for 2010 the country speific register will be used for data collection; amendments and deletion on basis of this register will make work easier for MSs and the ESVAC team

The technical support provided by the Technical Consultative Group (TCG) the WHO Collaborating Centre for Drug Statistics Methodology in the provision of ATC codes for use in the ESVAC Network work was acknowledged.

Ad hoc Working Groups on collection of data by species and on technical units of measurement

Two ad hoc Working Groups on collection of antimicrobial consumption by species and of technical units of measurement were established in October 2011 with the task to develop combined reflection paper addressing these topics. The members of the two groups are selected on the basis of their expertise in the two fields, respectively. ECDC and EFSA as well as EURL-AMR have been invited to participate in the meetings in order to harmonise with the ESAC project and with the surveillance programs of AMR in the human and animal field. FAO, OIE, US FDA and WHO Europe participate as observers. The main objective of those groups is to produce a document summarising the state of art and produce recommendation for the ESVAC project on collecting data per animal species and on technical units of measurement to be used to report the data.

Collection of ESVAC 2010 data – approaches and difficulties. Experience by MSs

Belgium, Ireland, Portugal, Spain and United Kingdom gave presentation for this agenda item. The major challenge presented by these countries was how to obtain valid data in terms of obtaining 100 % coverage of the sales of veterinary antimicrobial agents by the reporting year but also how to avoid double reporting.

As sales between wholesalers are common, it is a challenge to trace sales to final users (e.g. farms, veterinary pharmacies, veterinary practices, feed mills). It was suggested that an important obstacle to obtain valid data could be the import of medicated feed form other MSs, i.e. it was questioned whether the premixes sold in one MS but used for the production of medicated feed transported to another MS could be counted in both countries giving rise to overestimate in the exporting MS. It was concluded that it is vital that each MS asks for sales of veterinary antimicrobial agents to end user in the country in question and that this topic should be highlighted in the call for 2011 data

One Member State representative reported that a change of national legislation will be necessary in order to be able to obtain valid sales data from stakeholders.

It was suggested that it takes at least 3 years in order to establish a valid baseline and this was supported by many of the MSs that had collected data for many years.

One MS reported that MAHs were unwilling to provide the data on sales of veterinary antimicrobial agents exported to the country due to confidentiality issues. This was later discussed with industry during the ESVAC stakeholders meeting, industry has agreed to try to sort those problems.

The MSs found very valuable to discuss problems collecting the data, problems that were more or less the same for all the countries. It was therefore suggested that for the next ESVAC network meeting the Agency should consider setting aside time to allow for bilateral discussions.

2010 data – validation procedure and usual errors/problems in the data provided

The approach used by the ESVAC data managers for the quality check of the data in terms of standardization and manual checking of the data was presented. It was reported that it takes from 2-5 days to validate the data by MS in order to obtain standardized data and to support the MS in question to obtain valid data with 100% coverage.

Report 2010 data. Procedure and draft outline/content of the report

The suggested procedure and in particular content of the report to be published by the end of 2012 was thoroughly discussed and the suggested changes and amendments have been included in the enclosed presentation.

The approach/procedure will be as follows

- The raw data used for calculation of PCU and the calculated PCU sent out for proof reading by the MSs (ESVAC National Representatives). Deadline 2 weeks from received
- The sales data that the MSs (ESVAC National Representatives (NRs)) have given their consent to save in the ESVAC database is considered as proof read and will be included in the analysis of the data
- The countries asked to provide brief information on data sources used, legal basis, assumed coverage
- The report developed by the ESVAC Project Team (PT). EMA experts to be consulted as appropriate
- The report sent out for proof reading and endorsement to involved MSs (ESVAC NRs/alternates). Deadline for comments 4 weeks
- The report (including data) to be handled *as confidential* by the ESVAC NRs/alternates until the report is published
- When the report has been endorsed by the involved MSs (ESVAC NRs) it will be sent to industry on embargo approximately one week before published
- Before published the report will be presented for one or more of Commission's Standing Committees
- The MSs will be send the final report and the Agency's press release two and one week, respectively.
- The issue of demographics, i.e. differences in contribution of each species to the pCU per MS will be discussed in the report;
- In tables and diagrams MSs will be listed alphabetically
- Provisional deadline for the publication of the ESVAC report for 2010 data is 15th September 2012. However, if delayed it was suggested that the report could be published on the 18th of November 2012 (Antibiotic Awareness Day).

Presentation of reflection paper on collecting data by animal species/Presentation of reflection paper on technical unit of measurement

The content of the 1st drafts of the reflection papers, respectively, were presented by the rapporteurs of the WG Jeroen Dewulf and Gerard Moulin. Due to time constraint these were not discussed but the final drafts will be sent out to the ESVAC network and relevant organizations for consultation as well as published for consultation on the EMA web page.

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