

20 December 2010
EMA/706703/2010
Veterinary Medicines and Product Data Management

Report– Meeting with stakeholders on monitoring sales of veterinary antimicrobial agents in Europe

28 September 2010 09:00-13:00, Fougères, France

Introduction

A meeting on collecting data on sales of antimicrobial agents took place in Fougères (France). The meeting is part of an initiative from the European Medicines Agency and followed an invitation from the French Agency for Food, Environmental and occupational health and safety (ANSES) to hold a series of 3 meetings all related to the collection of data on sales of veterinary antimicrobial agents in Europe¹.

The meeting was attended by representatives from the European Medicines Agency project on European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), EU Member States, Norway and Switzerland, representatives of the European Commission, EFSA and representatives from the following organisations: International Federation for Animal Health Europe (IFAH-Europe), The European Association of Full-line Wholesalers (GRIPS), Federation of Veterinarians of Europe (FVE) and Association of Veterinary Consultants (AVC).

The meeting was chaired by Dr D. Mackay (European Medicines Agency).

Opening of the meeting and update on the ESVAC project

The Director of the French Agency, Jean Pierre Orand, opened the meeting welcoming all the participants.

Dr Mackay provided, together with Prof. K. Grave (EMA) an update on the current status of the ESVAC project. The report explained the resources available to the project, the different phases in which the project has been divided (pilot, operational and onwards), the achievements and the next steps of the project.

¹ Meetings of the ESVAC Technical Consultancy Group and training for Member States.

Report from countries recently started or starting to collect data shortly

Dr. D. Persoons (University of Gent) reported on the approach, aims and output of the Belgian BELVET-SAC (Veterinary Surveillance of Antimicrobial Consumption) programme. In Belgium data are collected monthly from wholesalers and reported as sales in nationally assigned animal daily doses.

Dr. G. Beechinor (Irish Medicines Board (IMB)) reported on the experience in Ireland on collecting for the first time data on sales. Following the decision not to request the sales data from wholesalers (due to legal reasons), data will be requested from Marketing Authorisation Holders. Problems encountered during the request were reported and discussed.

The experience by Spain in collecting data for the first time was reported by Dr. A. Muller on behalf of Dr. C. Muñoz. Following contact with stakeholders Spain has successfully obtained data according to the ESVAC template for 2009.

Considerations from stakeholders

Declan O'Brien presented the point of view of IFAH Europe on the collection of data on sales of veterinary antimicrobial agents. A better communication between stakeholders was requested. A scientific publication in the Journal of Antimicrobial Chemotherapy (JAC) comparing sales of antimicrobials from 10 European countries was criticised as the publication used as the denominator data on slaughtered biomass per country. IFAH Europe pointed out that this measure does not take into account import and export of animals for slaughter as well as other factors such as differences in dosing between the various antimicrobial agents. IFAH-Europe considered that if comparative data are to be published it is important that all relevant factors are taken into account and offered to collaborate with the ESVAC project to develop methods to present such data in a truly comparable manner.

Dr. J. Vaarten presented the point of view of the Federation of Veterinarians Europe (FVE). He described the activities of the veterinarians in relation to AMR concluding that now is the time for veterinarians to take further action themselves with respect to the threats posed by AMR. Such action will minimise the risks that other parties, less familiar with veterinary practice, will seek to limit the availability of antimicrobials to veterinarians in future.

Conclusions and next steps

Following the presentations discussions on the collection of data on sales of antimicrobial agents took place. A summary of the conclusions is included below, for full details refer to the slides with the conclusions of the meeting.

- The ESVAC project is well defined and implementation is ongoing.
- The standardised data collection form (template) is published on the EMA web page and has already been applied by some Member States.
- An EU call for harmonised data for 2010 will be shortly launched.
- Historical data from those European countries already publishing data is being collated and a report will be published during 2011.
- There is strong interest from Member States on collecting data on sales of veterinary antimicrobials. In addition to the 10 European countries already publishing data (Czech Republic, Denmark, Finland, France, Germany, The Netherlands, Norway, Sweden, Switzerland and United Kingdom) other countries such as Austria, Belgium, Cyprus, Estonia, Hungary, Ireland, Italy, Lithuania, Luxemburg, Poland, Portugal and Spain have started or starting to collect data.
- Data published on the EMA web page will not contain confidential information about sales of specific products. The EMA is developing a confidentiality policy that will ensure this.
- Further work on interpretation of data (indicators) is required to place data in context considering for example;
 - Biomass of slaughtered animals, when used as denominator data, should be refined to take into account factors such as the transport of animals to other countries for slaughter.
 - Differences in doses between the substances and administration route
 - Differences in use of antimicrobials by different species.
- Data should aim at 100% coverage without duplication or gaps. This will require all suppliers of data to be treated equally (e.g. companies producing pioneer products, generics and other types of product as well as all other sources of data).
- Activities to promote the prudent and responsible use of veterinary antimicrobials are being actively pursued by different parties, including the European Platform for the responsible use of medicines in animals (EPRUMA) guidance on responsible use of antimicrobial agents.
- Further information from the field on use of antimicrobial agents is required, in particular there is a need to monitor prescription patterns to obtain “real data” on the actual use of veterinary antimicrobials.

Closure of the meeting

The meeting was closed thanking the organisation ANSES and the participants at the meeting.

PARTICIPANTS:

Name	Representing
Nico Bondt	Netherlands
Linda Puister	Netherlands
Klemens Fuchs	Austria
Davy Persoons	Belgium
Lionel Laurier	Belgium
Marios Genakritis	Cyprus
Lucie Pokludová	Czech Republic
Marju Sammul	Estonia
Leena Rasanen	European Commission
Pierre-Alexandre Beloeil	European Food Safety Authority
Katariina Kivilahti-Mantyla	Finland
Gérard Moulin	France
Josa Preuß	Germany
János Kovács	Hungary
Cedric Muentener	Switzerland
J Gabriel Beechinor	Ireland
Delia Forte	Italy
Andra Sarguna	Latvia
Ugne Zymantaite	Lithuania
Marcel Bruch	Luxembourg
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Rodica Morcov	Romania
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Christian Berg	WHO Collaborating Centre for Drug Statistics Methodology
Hege Salvesen Blix	WHO Collaborating Centre for Drug Statistics Methodology
Irene Litleskare	WHO Collaborating Centre for Drug Statistics Methodology

Stakeholders

Declan O'Brien	IFAH-Europe
Valérie Thomas	IFAH-Europe
Stephanie Rief	IFAH-Europe
Olivier Espeisse	IFAH-Europe
Jan Vaarten	FVE
Vincent Dedet	AVC
Manuel Boehmer	GRIP (Wholesalers)

EMA

Arno Muller	
Kari Grave	
David Mackay	
Jordi Torren	