London, 29 January 2010
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European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

Report of a meeting held on 25 November 2009 at the EMEA (currently European Medicines Agency)

Summary
The meeting was the first meeting of the EMA project on monitoring of sales of veterinary antimicrobial (AM) agents in Europe[1].

The main objective of the meeting was to discuss a common approach for the collation of harmonized data on sales of veterinary antimicrobial agents in Europe.

The meeting follows a request from the European Commission (DG ENTR and DG SANCO) to the EMA to take the lead on collating at Community level the data collected by Member States on the use of AM agents in animals.

Participants
The meeting was attended by representatives from

- Member States, Norway and Switzerland
- The European Commission (EC): Directorate General for Enterprise and Industry (DG ENTR) and Directorate General for Health and Consumers (DG SANCO)
- Community Reference Laboratory on Antimicrobial Resistance (CRL AMR)
- European Centre for Disease Prevention and Control (ECDC)
- European Food Safety Authority (EFSA)
- European Surveillance of Antimicrobial Consumption (ESAC
- WHO Collaborating Centre for Drug Statistics Methodology
- European Group for Generic Veterinary Products (EGGVP)
- International Federation for Animal Health Europe (IFAH-Europe)

The full list of participants is attached to this document as an Annex.

[1] The meeting is a continuation of a Joint HMA/EMEA Meeting on Promoting Prudent and Responsible Use of Antimicrobials in Veterinary Medicine held on 19 – 20 May 2009 in Marienbad, Czech Republic where an outline of the intended project on collection of sales was already presented to stakeholders (http://www.emea.europa.eu/pdfs/conferenceflyers/hma_emea_19-20_may/Report_HMA-EMEA_meeting.pdf).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Introduction

The EMA Head of Unit of Veterinary Medicines and Data Management, David Mackay, welcomed all participants.

The meeting was co-chaired by Jordi Torren (EMA) and Kari Grave (EMA).

Summary of the presentations

Terms of reference
A summary of the terms of reference (TOR) from the Commission were presented by K. Grave (EMA).

The main aims of the collection of the data as presented in an Annex to the TOR are to obtain reliable data for

- Input into risk profiling regarding antimicrobial resistance (AMR)
- Input into risk assessment regarding AMR.
- For setting risk management priorities regarding AMR
- As a basis for evaluation of control measures being implemented
- To assess the impact of measures taken in relation to prudent use
- To identify emerging use of veterinary AM agents, e.g. of specific classes of AM agents such as those identified by WHO as critically important for human medicine
- To aid comparison of usage of AM agents between time periods, countries etc.

The EMA is asked 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), to collect the data from MS and manage the database, to draft a summary annual report with the data from MS and finally to ensure those data to be comparable with the data on use of antimicrobial agents in humans. In order to guarantee an integrated approach the Commission asked the EMA to consult the ECDC, the EFSA and the CRL.

Legal basis for collection of data
Representatives from the EC (M. Nagtzaam and L. Rasanen) indicated that there is a clear political mandate by the Council to start collecting data on use of antimicrobial agents in veterinary medicine. EC also stated that there is sufficient legal basis to request the pharmaceutical industry to provide data on sales of antimicrobial agents to the national authorities (Directive 2001/82/EC and Regulation 726/2004). If data are to be collected from veterinarians, farmers and/or pharmacies, which are likely sources for collecting data per species, there might be a need for additional legislation.

Suggestion by EMA on collating data on use of veterinary AM agents in Europe (ESVAC)
The suggestion by EMA on how to collate data on use of veterinary AM agents in Europe – the Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project - was presented by K. Grave.

EMA intend to follow a multiphase approach including four partly overlapping phases

- Phase I: investigation phase
- Phase II: pilot project
- Phase III: collect and report overall national data from all MS,
- Phase IV: collect and report data per species.

EMA suggests establishing a technical consultative group (TCG) with the role to provide advice to the EMA with respect to the ESVAC project, i.e.

- On how to develop a harmonised approach for the collection of data on veterinary AM agents at national level as this will be vital for collating harmonized data in the ESVAC database
- To assist the ESVAC management team in advisory activities as requested by MS setting up surveillance programs on veterinary AM agents for the first time.

The ESVAC management team will process, analyse and summarize the data obtained from the various countries and it is suggested to ask the MS to validate their own data prior to publication.

Brief summary of the existing systems on collecting data

Representatives from 9 countries gave a brief presentation on their existing programs for collecting data. Only minor variations with regard to variables collected for each product were reported which indicate that it may be feasible to agree upon a common protocol and template for collection of data in the MS for the purpose of also collating standardized data in the ESVAC database. There are significant differences amongst the countries in the comprehensiveness of the surveillance programs implemented, sources selected for collection of the data as well as the extent to which the data are used at national level for the containment of AMR.

Representatives from 5 MS indicated that they have started or are about to start collecting data. Discussions took place on how to provide support to those countries; the first action should be to provide a template and protocol for collecting data (see conclusions).

Considerations from industry

A representative from IFAH-Europe, V. Thomas, gave a presentation on behalf of the veterinary pharmaceutical industry indicating that they would support the collection of data. The industry suggested that objectives of the collection should be agreed beforehand and that confidentiality of the data should be respected. All marketers should be involved to obtain complete data coverage. Animal population data should be considered from the outset to allow for interpretation of the data. The industry regarded it as essential to implement the same or similar methods for collection of the data in all MS and they suggested consulting stakeholders on the validation of the methodology and interpretation of the data. The industry also recommended that the system should be simple and robust and fit for risk assessment purposes. Representatives from EGGVP gave support to the presentation and conclusions.

Presentation of European Surveillance of Antimicrobial Consumption (ESAC) in human medicine

The experience from the ESAC project in collecting data on use of antimicrobial agents in human medicine was presented by A. Muller. The ESAC project is considered as very successful and could be used as an example for the ESVAC project. The ESAC project consists of a data management team and a unique network of 35 different countries that has delivered comparable and reliable data on use of antimicrobial agents in human medicine in Europe since 2001. Dr. A. Muller underlined that the data are delivered on a voluntary basis but that the different countries are enthusiastically delivering the data. He also emphasised that it is very important that a common template and protocol is adopted to obtain comparable data. Presentation from ESAC.

ECDC – future perspectives and integrated approach

The representative from the ECDC, O. E. Heuer, reported on the future perspectives and integrated approach for collection of surveillance data by ECDC in general and that the ECDC will shortly take over the collation of data on consumption of antimicrobial agents in human medicine. All the data will be collated into a common database (The European Surveillance System) that will allow for integrated analysis of the data in the database such as data on AMR. It was emphasised that the ESAC project in human medicine is regarded amongst the most successful of the ECDC surveillance programs and that the major reasons for this are the strong national networks of experts (ESAC network) representing a variety of fields of knowledge as well as the use of the data for the containment of AMR at national level.

Experiences from collection of data on sales of AM agents in human medicine at national level

A representative from the Norwegian Institute of Public Health/WHO Collaborating Centre for Drug Statistics Methodology, H. S. Blix, gave a presentation on experiences from collection of data on sales of AM agents in human medicine at national level. She stressed the need of broad knowledge on how the medicine distribution is organized at national level to ensure that the data sources included in the surveillance program covers the complete population. Furthermore, Dr. Blix underlined the importance of making sure that all antimicrobial agents are included in the reporting. It was also indicated that ATC/ATCvet codes have to be be linked correctly to the product on the package level (i.e. using the last version of the ATC/ATCvet index), procedures for updating the register according to the latest version should be implemented and this task should be allocated to a national centre in each country and done by competent experts with proper knowledge of the methodology.

The ATCvet system and its application for surveillance of drug use

The ATCvet system (Anatomical Therapeutic Chemical classification – veterinary) and its application for surveillance of drug use were reported by C. Berg from the WHO Collaborating Centre for Drug

Statistics Methodology. ATCvet is a common understanding/language to identify which AM agents to include in surveillance programs. It allows the comparison of use between time periods, countries, sectors (e.g. human – and veterinary medicine) for setting risk management priorities and to identify the use of AM agents defined by WHO as critically important AM agents (CIA) for human medicine. The ATCvet is recommended by WHO, OIE and FAO as a medicine classification system in surveillance programs for AM agents. The WHO Collaborating Centre is willing to provide support to those countries wanting to implement the ATCvet system.

Discussions and conclusions

Country coverage
Ten European countries are already collecting data. In addition, there are 5 MS that have just started or that are ready to start collecting data shortly and representatives from those countries emphasized the need to be informed as soon as possible about the format, template/variables to be collected for each product for collection of the data preferred by the ESVAC to obtain harmonized data

Protocol/Template for collecting data on sales
The templates used by those countries already collecting data were relatively similar.

To obtain standardized data in the ESVAC database the various countries would have to provide data to the ESVAC database according to agreed (and appropriate) protocol/templates for the collecting of the requested data.

The data requested for each product should be justified (e.g. why identity number of products, ATCvet code etc). The TCG, the pharmaceutical industry and other relevant stakeholders will be consulted regarding the template.

It was agreed that the EMA should prepare a draft template for comments by the TCG, the pharmaceutical industry and other relevant stakeholders. The template should be ready for use by the MS by March 2010.

Inclusion criteria
The inclusion criteria for AM agents to be included in the surveillance programs at national level and reported to ESVAC will have to be agreed upon. The ESAVAC project will ask TCG and the pharmaceutical industry to provide advice on which AM classes to include.

It was suggested to not include coccidiostat feed additives and biocides in the project.

Capacity building
It was agreed that further discussion on how to support those MS that are starting to collect data is required, i.e. on how to ensure that the collected data covers the complete animal population, how to analyze and report data in a meaningful way as well as how to use the data on national level for the containment of AMR. It was suggested that the EMA organise a workshop (in 2010) where countries with broad experience, e.g. TCG, from such activities use their knowledge to assist countries with little or no experience in the field.

Objectives of collecting data
It was emphasized that there is a need to further explain in more detail the intended use of the collected data. It is noted that those objectives are detailed described in the mandate from the Commission (see above).

It was suggested that to enhance the understanding of the objectives MS already collecting data could report on how they use the data to fight antimicrobial resistance.

It was concluded that the ESVAC project should to the extent possible make use of the great amounts of experience from the MS, the ESAC project as well as of the experience of the WHO Centre of Drug Statistics Methodology.

Animals at risk (denominator)
It is considered vital to also consider data on animals at risk (denominator) when analysing the data.

Confidentiality issues

The ESVAC project will be responsible for the confidentiality of the data in the ESVAC database.

The data will usually be presented at ATCvet 3rd level in the annual reports and similar reporting, while when data are used by the EMA, the EFSA or the ECDC or for inter-agency activities (EFSA, ECDC and EMA) e.g. following requests from the European Commission, on risk profiling and risk assessments at Community level the data may also be analyzed at ATCvet 4th and 5th level if required, however, the confidentiality of the data will have to remain.

Establishment of national networks. Use of data at national level

Similar to the ESAC project it is thought that the ESVAC project would benefit from strong national networks of experts representing a variety of fields of knowledge such as in collection of reliable data on medicine use, clinical pharmacology, microbiology and epidemiology. Therefore, in the pilot phase ESVAC should facilitate the building up of networks in the various MS and encourage collaboration with the national ESAC network and the network on collecting data on AMR (those providing data to EFSA on resistance).Such networks are vital to ensure optimal use of the data at national levels, which is regarded as the most important arenas for activities for the containment of AMR but also to increase the reliability of the data. It was suggested to explore the possibility that the ESVAC network convene annual meetings with the annual meetings of ESAC network.

Use of data at Community level

The EMA will initiate a discussion amongst the Commission and the relevant EU agencies (EFSA, ECDC and EMA, including CVMP and SAGAM, as required) with regards to reporting of the data for the optimal use of these at the Community level for the containment of AMR. This may include reporting that allow for integrated analysis with data on AMR in animals, humans, food and feed as well as with data on use in animals and humans.

Various

There are some technical issues to be further discussed which include

- The use of DDD_{animal} (or similar parameters) for the reporting of data per species ,
- The implementation of the use of the ATCvet code (some countries are already using the ATCvet system and those not using it yet expressed interest to learn how to implement it),
- How to ensure that AM agents subjected to parallel import are included
- How to ensure that use of human AM agents in companion animals are included,
- How to ensure that use of AM agents under the “cascade” is included

The IFAH-Europe report on volume collection dated September 30th, 2009 will be circulated by the EMA.

TIME	AGENDA TOPICS	
9.00 – 9.20	**Welcome and introduction** **Terms of reference from the Commission**	EMEA
9.20 – 9.30	**Legal basis for collection of data**	European Commission
9.30 – 10.00	**Suggestion by EMEA on collating data on use of veterinary AM agents in Europe (ESVAC)**	EMEA
10.00 - 11.00	**Brief summary of the existing systems on collecting data**	The Czech Republic, Denmark, Finland, France, Germany, the Netherlands, Norway, Sweden, Switzerland, United Kingdom
11.00 – 11.15	***Coffee break***	
11.15 – 11.45	**Considerations from industry**	Industry representatives
11.45 - 12.30	**Presentation of *European Surveillance of Antimicrobial Consumption* (ESAC*)* in human medicine**	Dr Arno Muller, ESAC
	ECDC – future perspectives and integrated approach	Dr Ole E. Heuer, ECDC
12.30 - 12.45	**Experiences from collection of data on sales of AM agents in human medicine at national level**	Dr Hege Salvesen Blix, Norwegian Institute of Public Health/WHO Centre for Drug Statistics Methodology
12.45 – 13.45	***Lunch***	
13.45 – 14.00	**The ATCvet system and it's application for surveillance of drug use**	Dr Christian Berg, WHO Collaborating Centre for Drug Statistics Methodology
14.00 – 15.30	**Discussions on the project – next steps** • Obstacles in Member States • Capacity building • Timelines	EMEA/all
15.30 – 16.00	**Summary of discussion**	EMEA/all
16:00	**Next meeting - Closure of meeting**	

LIST OF PARTICIPANTS

Lionel Laurier	Belgium
Davy Persoons	Belgium
Jiri Holy	Czech Republic
Lucie Pokludová	Czech Republic
Erik Jacobsen	Denmark
Vibeke Frøkjær Jensen	Denmark
Ole Heuer	European Centre for Disease Prevention and Control
Martinus Nagtzaam	European Commission
Leena Rasanen	European Commission
Pierre-Alexandre Beloeil	European Food Safety Authority
Gérard Moulin	France
Pascal Sanders	France
Josa Preuß	Germany
János Kovács	Hungary
Cedric Muentener	Switzerland
J Gabriel Beechinor	Ireland
Alessandra Perrella	Italy
Vita Zalcmane	Latvia
Nico Bondt	Netherlands
Wojciech Cybulski	Poland
Dorota Prokopiak	Poland
Maria Helena Ponte	Portugal
Rodica Morcov	Romania
Martina Péteryová	Slovak Republic
Miguel A Moreno	Spain
Consuelo Rubio Montejano	Spain
Kinfe Girma	Sweden
Christina Greko	Sweden
Nick Renn	United Kingdom
Arno Muller	ESAC - Universiteit van Antwerpen
Christian Berg	WHO Collaborating Centre for Drug Statistics Methodology – Norway
Hege Salvesen Blix	WHO Collaborating Centre for Drug Statistics Methodology – Norway
Irene Litleskare	WHO Collaborating Centre for Drug Statistics Methodology
Declan O'Brien	International Federation for Animal Health (Europe)
Valérie Thomas	International Federation for Animal Health (Europe)
Marie-Anne Barthelemy	International Federation for Animal Health (Europe)
Sybille Raddatz	European Group for Generic Veterinary Products
Inge Sandberg	European Group for Generic Veterinary Products
David Mackay	The European Medicines Agency
Kari Grave	The European Medicines Agency
Cristina Muñoz	The European Medicines Agency
Jordi Torren Edo	The European Medicines Agency