EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

"Progress in the area of Antimicrobial Resistance – Veterinary Medicines"

European Medicines Agency

EMA-HMA conference 15-16 Sept 2011

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EMA work on AMR

- Supporting the scientific groups on their work on AMR (CVMP, SAGAM, ESVAC experts).
- Collaborating with international organisations on AMR: HMA, the European Commission, EFSA, ECDC, EURL-AMR, FDA, WHO, OIE, Codex Alimentarius, stakeholders…
- Providing input into review of veterinary medicines legislation on issues linked to AMR.
- ESVAC project

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

- ESVAC collects data on the use of antimicrobial agents in animals
- Well established pilot project
- Report on historical data from 9 countries – report to be provided by K. Grave
- ESVAC protocol and ESVAC data collection template available
- Collecting data for 2010 according to protocol and template
- Population correction unit (PCU) used as term for the estimated weight of livestock and slaughtered animals

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

- Trends in sales of veterinary antimicrobial agents in 9 European countries: 2005-2009

- "New countries"
  - Belgium (http://www.belvetsac.ugent.be/),
  - Ireland (http://www.imb.ie/images/uploaded/documents/Report%20on%20Consumption%20of%20Veterinary%20Antimicrobial%20Drugs%20in%20Ireland%20in%202009.pdf) and
  - Spain (http://www.aemps.gob.es/en/informa/notasInformativas/medicamentosVeterinarios/2011/docs/ventas-antimicrobianos_Espana-2009.pdf)

- Other countries already sending data for 2010.

Collaboration with other organisations

- Meetings with EC/EFSA/ECDC/EURL-AMR to progress on integrated analysis of data on resistance and sales of antimicrobials.

- Participation at TATFAR (Transatlantic Taskforce on Antimicrobial Resistance)

- Part of the EU delegation preparing the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance prepared by Codex Alimentarius

- International Symposium - Alternatives to Antibiotics: Challenges and Solutions, Paris, 26-28 September 2012

Collaboration with other institutions
Joint opinions

- Joint Opinion on antimicrobial resistance (AMR) focused on zoonotic infections from the ECDC, EFSA, CVMP/EMA, SCENIHR (October 2009)

- Joint scientific report of ECDC, EFSA and EMEA on meticillin resistant *Staphylococcus aureus* (MRSA) in livestock, companion animals and food (June 2009)

Collaboration with other institutions Contributions

Participation at preparation of:

- EFSA Scientific Opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases and/or AmpC β-lactamases in food and food-producing animals (2011)

- WHO booklet tackling antibiotic resistance from a food safety perspective in Europe (2011)

TATFAR

The purpose of the taskforce is to identify urgent antimicrobial resistance issues that could be better addressed by intensified cooperation between the US and the EU within the following key areas:

1. Appropriate therapeutic use of antimicrobial drugs in the medical and veterinary communities;

2. Prevention of both healthcare- and community-associated drug-resistant infections;

3. Strategies for improving the pipeline of new antimicrobial drugs.

TATFAR Recommendation 3- Collaborate on collection of data on sales and use of veterinary antimicrobials in food prod. animals

The US and EU to work with WHO AGISAR and OIE.

To address the development of common units of measurement of antimicrobial drug use.

Preferably, data collection should allow stratification by product type.

The ESVAC project could serve as an opportunity to share experience on such data collection.

A long-term goal of this work would be to lay the foundation for methods to interpret the information in relation to antimicrobial resistance data in the US and EU and to explore the link between use of antimicrobials and the development of resistance.

TATFAR Recommendation 4: Collaborate on implementation of the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance prepared by Codex Alimentarius

- to promote consistency between the US and the EU in implementing the internationally accepted guidelines

- an area of particular concern in both the EU and US is the "extra/off-label" use of antimicrobials, particularly those critically important to human health, in food-producing animals

TATFAR Recommendation 5: Enhance information sharing on approaches to promoting appropriate use in veterinary communities

- ESVAC
- risk management measures to restrict certain uses of critically important antimicrobials
- animal health programmes aiming to improve animal health in order to reduce the need to use antimicrobials

Marketing Authorisations and Antimicrobial Resistance

• Regulatory authorities authorise antimicrobials that are needed for animal health.

• Antimicrobials needed for animal health might have some negative impacts in animal health and human health.

Are we progressing?

• Delicate balance for regulatory authorities that authorise MA and establish conditions of MA

The CVMP Scientific Advisory Group on Antimicrobials (SAGAM) currently supporting CVMP on the assessment of many Marketing Authorisations for antimicrobials

Human Medicines -findings of the Gap Analysis

- Infections caused by multidrug-resistant bacteria are associated with a high cost.
- Very few antibacterial agents with new mechanisms of action are under development to meet the challenge of multidrug-resistance.
- There is a particular lack of new agents to treat infections due to multidrug-resistant Gram-negative bacteria.
- A European strategy to address this gap is urgently needed.

Human medicines – current challenges

- There has been a considerable amount of failures of new antibacterials at marketing authorisation in recent years due to a number of different factors mainly related to inadequate development plans.
- Appropriate use of antimicrobials drugs is essential to minimise selective pressure and preserve effectiveness of these dwindling agents.
- There are multiple scientific, regulatory and economic factors that are believed to have contributed to the decline in development of new antibacterial drugs.

Human medicines –Next Steps

- The Agency is engaged in developing further guidance to industry on development of antibacterials.
- EMA is engaged in the process of harmonisation of Product Information for established antibacterials approved across Europe by decentralised routes to avoid inclusion of indications and posology lacking adequate clinical evidence.
- policy makers should consider the option to put in place adequate incentives to stimulate developers filling the current gap in antibacterials.

Further considerations

- Increased concerns about MRSA & ESBLs including AMR from pets.
- More data on sales of veterinary medicinal products and resistance are now becoming available from Member States which will allow for detailed analysis
- Lack of innovation on new antibiotics for human and veterinary medicine
- Increased collaboration between institutions (HMA, ECDC, EFSA…)

"The scourge of antimicrobial resistance will not go away, but with a concerted multimodal approach, there is the potential to limit its impact on animal and human health."

Weese JS. Antimicrobial resistance: time for action. *Vet Rec* 2011; **169**: 122-3.