Implementation of the HMA Strategic Plan on Antimicrobial Issues

CZ / SE HMA-v - EMEA - Stakeholders Co-ordination meeting Marienbad, CZ May 2009

This presentation brings the personal views of the author and cannot be considered as representing the official position of the HMA

HMA Strategic Plan

- SPC update following the EMEA/CVMP conclusions regarding fluoroquinolones
 - HMA meeting July 08 → decision
 - ask HMA Management Group to draft a strategic plan
 - contact non respondents

HMA Strategic Plan

- First draft for discussion
 - HMA / 7 November 2008, Paris, FR
- Second draft for discussion
 - HMA / 27 January 2009, Prague, CZ
- Third draft for adoption
 - HMA / 19 May 2009, Marienbad, CZ

HMA Strategic Plan – ideas behind

- Complement the EMEA/CVMP Strategy and actions
- Consider international recommendations
 - Responsible and prudent use of antimicrobial agents in veterinary medicine OIE Terrestrial Animal Health code Chapter 6.7
 - Code of practice to minimize and contain antimicrobial resistance CAC/RCP 61-2005
- Take into account Council conclusions (10 June 08)

HMA Strategic Plan – Overview

- I Introduction
- II Vision
- III Responsibilities of NCAs
- IV Responsibilities of HMA
- V Strategic plan

II- Vision

- Maintaining the efficacy of antimicrobials
- Containment of the development of resistance is essential for PH and AH.
- A global approach is needed.
- Necessary risk based and proportionate approach for maintaining availability
- The focus of all actions should be based on the prudent and responsible use of the antimicrobials in Veterinary Medicine, with better cooperation and coordination

III - Responsibilties of NCAs

- Marketing authorisations /assessment of potential for selection
- Quality control
- Control of Therapeutic efficacy
- Establishment of ADI/MRLs, withdrawal periods
- Protection of the environment
- Establishment of SPC
- Post marketing surveillance
- Supply and administration of antimicrobial agents used in veterinary medicine
- Control and advertising
- Training of antimicrobials users
- Research
- In some ares responsibilities of NCA are complementary to the responsibilities of other (official) bodies

IV – Responsibility of HMA

HMA

- informal network
- no direct responsibilities in the implementation of the NCAs' duties,
- HMA role of facilitator in this area. Help its members identifying areas and ways of actions
 - Follow up of implementation of decided measures,
 - Assistance to the network,
 - Development of a comprehensive communication in and out of the network,
 - Strengthening actions with regards to availability of medicines according to the HMA Task Force Report on Availability of Veterinary Medicines published in April 2007.

V – Strategic Plan

- Finalisation of the (fluoro)quiolone exercise
- Adequate co-ordination with EMEA
- Ensure appropriate legal status for antimicrobial VMPs
- Use of the results of the survey on consumptions
 - Risk assessment
 - Tool in the communication strategy directed towards users / prescribers of ATM VMPs.
- An HMA action plan should be implemented after further discussion and coordination with the EMEA.

Conclusions – HMA attitude

- HMA assumed strategic / pro-active approach to the issue of AMR in the veterinary area
 - Involvement of both HMA-h and HMA-v deemed as critical

Conclusions - prerequisits

- AMR is of global (complex) nature
 - Comprehensive solutions are needed
 - There are (probably) no simple solutions on this issue
 - Any actions (risk management measures) need to be based on up-to date science
 - Active involvement of different stakeholders is critical

Conclusions - goals

- Regulatory measures appropriate to identified risks
- Minimisation of the "side effects" while getting the maximum yield – due consideration (non-exhaustive) :
 - Availability of VMPs, animal health / welfare, innovation, veterinary profession, farmers, rural development, trade, industry
- Concerted actions leading to the implementation of the scientific conclusions / regulatory measures in practice followed by positive effects on public health and animal health
 - Feedback to the regulatory authorities on the efficiency / impact
 - Affection of users / prescribers of veterinary antimicrobials
 - Joint efforts needed

Conclusions – further steps

- Internal activities of the network
 - Implementation of Strategic Plan as outlined in the Part V of the Strategic Plan
 - Development of the HMA Action Plan
 - Inputs from the stakeholders essential

Conclusions – further steps

- Activities outside the network
 - 3Cs
 - Communication / co-ordination / co-operation
 - To be further considered
 - ? Topic for a new format for HMA meetings with stakeholders
 - under discussion / development at the HMA level
 - Effective co-ordination in the regulatory area
 - Clear roles / responsibilities
 - Involvement of stakeholders
 - industry (IFAH, EGVVP etc) to develop their own action plans to address this issue.

Thank you for your attention!