



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Progress in the area of antimicrobial resistance

CVMP

EMA-HMA conference 15-16 Sept 2011

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An agency of the European Union





Progress -> CVMP -> future plans

- The CVMP strategy on antimicrobials 2011-2015
- Class referrals
- Final reflection papers
- Ongoing initiatives
- Suggested areas of greater collaboration



The CVMP strategy on antimicrobials 2011-2015

Development: The document was published for consultation in December 2010 as the 3rd 5-year strategy from CVMP.

The final strategy was published in July 2011 with minor changes.

Vision statement

To promote the continued availability of effective antimicrobials for use in animals whilst at the same time acting to minimise risks to animals or man arising from their use.



Summary of the CVMP strategy on antimicrobials 2011-2015 (1/2)

CVMP perceives the need for effective antimicrobial treatment for relevant indications in all species.

CVMP wishes to encourage an increased level of innovation on treatment alternatives for infectious diseases.

Authorised antimicrobials should have product information recommending the products to be used in a responsible way to avoid unnecessary selection pressure for AMR.



Summary of the CVMP strategy on antimicrobials 2011-2015 (2/2)

Pivotal clinical trials should be conducted according to responsible use principles.

Risk mitigation measures at a proportionate level are needed to contain risks for human health.

The need to allow off label use under some circumstances is acknowledged. However such use may constitute a non-assessed risk to public and animal health related to AMR.

CVMP work should be seen in a context as a part of an overall EU strategy on antimicrobials.



Highlights

- ESBL: Foodborne risks go beyond spread of zoonotic bacteria
- MRSA: A non foodborne, occupational risk implies a need for new thinking
- Risks related to direct contact comprises companion animals
- High quality risk analysis is important
- SPC recommendations need to be implemented in every day life



Class referrals

- Fluoroquinolones:
 - Warnings sentences now included in all SPCs for products containing a fluoroquinolone
 - Ongoing work on prioritization of referrals (combinations, wording of indications, posology...)
- Cephalosporins:
 - Ongoing referral on prudent use for 3rd-4th generation cephalosporins (systemic adm.)
 - Off label use needs to be addressed



Final reflection papers

- MRSA (Methicillin Resistant Staphylococcus Aureus) reflection paper adopted in March 2009.
- MRSP (Methicillin Resistant Staphylococcus Pseudintermedius), reflection paper adopted in January 2011.
 - Hygiene measures important
 - Antimicrobials should not be used for decolonisation
 - AMR risks for humans (mainly MRSA) should be considered when using products off label
 - “Last resort medicines” for humans should be avoided to the extent possible



Q & A document - SPC guideline.

July 2011

What does CVMP mean by “treatment and prevention”? (Section 4.2 - Indications for use)

...The term “prevention”, refers to the administration of the product at the same time to other in-contact animals, to prevent them from developing clinical signs, and to prevent further spread of the disease. The presence of the disease in the group/flock must be established before the product is used.



Ongoing initiatives

- Reflection paper on macrolides, lincosamides and streptogramins has been published for consultation until 28/2 2011. Revision after consultation almost finished.
- Revision of the efficacy guideline for antimicrobials. Concept paper consultation ended 31.07 (SAGAM together with EWP-v).
- Reflection paper on the use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health (under preparation in 2011)



Ongoing initiatives

- Reflection paper on data requirement for new veterinary medicinal products for companion animals with respect to antimicrobial resistance (under preparation in 2011)
- Impact of off-label use of antimicrobials on resistance in food producing animals (reflections/discussion ongoing)
- Intramammary guideline, revision ongoing. Concept paper consultation until Dec. 2010.



Suggested areas of greater collaboration^(1/2)

- Availability of the right AMs:
 - “Mapping” the needs of all member states and develop plan to fill gaps, in particular to avoid unnecessary use of antimicrobials that constitute a higher public health risk with regard to AMR
 - Define and ensure availability of AMs that constitute a lower risk, including the setting of MRLs for relevant species, and authorisation of products for relevant species and indications



Suggested areas of greater collaboration^(2/2)

- Ensure:

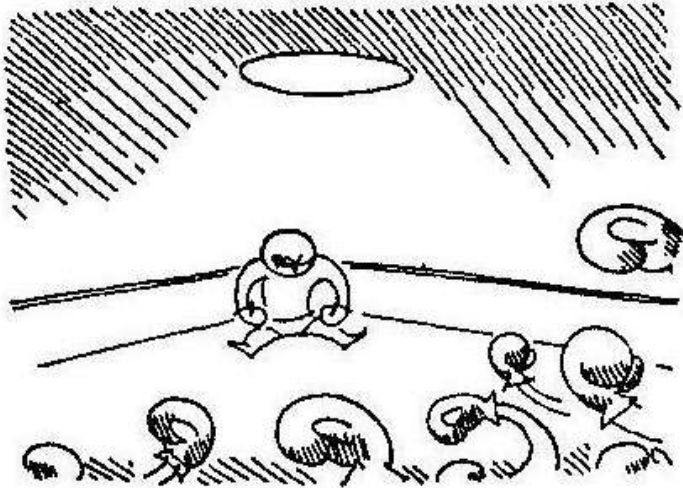
- correct use and attention by users via appropriate and updated product information
- good implementation in farming and vet practice

- Target our efforts better:

- Cooperate to understand the magnitude and impact of the flow of resistance of concern from (certain areas of) the veterinary field to the human field



Thanks for your attention! Questions?



PROBLEMS

Problems worthy
of attack
prove their worth
by hitting back.

Piet Hein

