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Status quo and current challenges related
to antimicrobial resistance:
Veterinary consultants view

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at Joint HMA/CVMP Interested Parties Meeting
Antimicrobial Resistance in Veterinary Medicine
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- ~ 50 members throughout EU
- Consulting feed, food and animal health industry
- No member is selling VMPs
- We are happy to comment and contribute

Items 
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- **What has been achieved in the last 18 months**
- What are the plans for the next 18 months, highlighting the priority areas
- Suggested areas of greater collaboration

Achievement of last 18 months 
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Data Collection and Evaluation

- Data collection on volumes used started
- Data collection on resistance in food born path.
- Data collection on resistance in clinical disease
- More evidence, better understanding of MRSA, MRSP, ESBL and AmpC encoded resistance
- More clinical and epidemiological cut off breakpoints established, but CLSI vs. EUCAST
- Lack of understanding, how resistance occurs due to individual active ingredients

Achievement of last 18 months 
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Measures targeted at prescriber/user:

- EPRUMA/prudent use guidance updated
- SPC warnings implemented (still not completely)
- Lots of generics of FQ and Ceph registered
 - Prices have gone down per treatment
 - Use has increased
- Constantly more paperwork
- Constant evidence of misuse
- But: constant lack of control of prescribers/users by national competent authorities

Achievement of last 18 months 
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Measures targeted at MAH:

- SPCs of FQ and Ceph harmonised by research based companies, still some lack of implementation in member states
- Revised Guideline for 3rd/4th generation Ceph
- Concept paper for macrolides ...
- Concept paper on guidance on the efficacy testing of antimicrobials in the target species ([EMA/CVMP/EMA/760764/2010](#)), see AVC comments
- And many others

Achievement of last 18 months

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Other observations:

- Retailers selling products claiming „not treated with antimicrobials“, „FQ free raised“, „no antimicrobials in the feed during raising“, but limited to small market of consumers
- 90 % of consumer care about food price only
- Trying to gather data, some published, called „trends“, „concept papers“ etc.

Results from Measures

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- ➔ Awareness has grown
- ➔ AMR: still lack of data in target pathogens
- ➔ Patience of non-scientific parties involved gone down albeit actions taken
- ➔ Were measures taken until now valuable?
- ➔ Will they answer the questions of the public?
- ➔ Based on experience with the ban of AM feed additives: is a ban of certain classes a solution?
- ➔ Did we make sufficient progress in a science based approach, to answer the questions?

Reliable data on AMR still missing in EU!

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Why?

Items 

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Objective for next 18 months 

- It is likely that animal health is not a major problem for AMR in humans
- We need to produce data that proves or disproves this!
- Public is unlikely to accept data based on assumptions or trends

Needs for next 18 months 

- First of all we need to generate science based, sound data, also in the target pathogens
- Why not present? Lack of will/resources/money?
 - Public data in many MS not available
 - Industry data: not trusted?
 - Other data: just covering spots of EU
- Join the forces (e.g. Germap2008: 16 federal states, BVL and industry shared approach and costs!)
- Produce data that gives clear evidence and convinces the public based on science

Hopes for next 18 months 
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- ⇒ Stay scientific, and pragmatic
- ⇒ Collect reliable data, that is relevant for the evaluation
 - ⇒ Volume of AM use
 - ⇒ Resistance patterns in MS and EU
- ⇒ Draw conclusions and initiate actions based on scientific knowledge
- ⇒ Invest further into understanding of development/ occurrence of AMR in individual active ingredients (shoot at mass use, not at minor use!)
- ⇒ Progress on „responsible use“ activities: get the farmers/owners involved, inform the public!

Hopes for next 18 months 
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- ⇒ Ensure infrastructure for diagnosis (labs)
 - ⇒ If animal health does not matter, but only food hygiene, we should tell the public
- ⇒ Encourage R&D in prevention, control and treatment of infectious disease
 - ⇒ Diagnostic test kits
 - ⇒ Products (e.g. vaccines, feed additives, biocides, antimicrobials)
- ⇒ Define „go“ and „no go“ for applicants
- ⇒ Create an environment allowing innovation to go invest in marketable products

Hopes for next 18 months 
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- ⇒ Take one step after the other
 - ⇒ Before implementing non-science based stricter obligations to stakeholders, assure that all have delivered what was planned
- ⇒ Define criteria of use and control them:
 - ⇒ animal and possibly disease specific following pharmacological and microbiological principles
- ⇒ Train/teach responsible use for farmers/vets etc.
- ⇒ Implement requirements
- ⇒ Monitor/Control requirements
- ⇒ Set incentives or penalties

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Manenbad, CZ 20.05.2009

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↪ Suggested areas of greater collaboration

Anything to achieve less bacterial disease, to support responsible use of Antimicrobials, but keeping the balance!



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CORE is to WORK on FACTS

- Panic is not the correct adviser
- Science driven by reliable sound data
- Target first factors that are most obvious but keep effects controlled (e.g. use of Ceph in poultry)
- Implement EU requirements on animal husbandry/welfare/hygiene: insist on this!
- Implement incentives to improve health and reduce use of antimicrobials (e.g. milk SCC, NL)
- Support availability of other products (e.g. vaccines), but also innovation for antimicrobials


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CORE is to WORK on FACTS

Avoid:

- that measures are implemented in panic without appropriate risk assessment
- Whatever is implemented, it will have known and unexpected consequences (“adverse events”)
 - „After a plague is before the (next) plague“ (J. Hacker, president of Leopoldina)
 - „Bacteria will always have the last word“ (L. Pasteur)
 - Ban of Feed Additives: was it successful? Did we reach, what was foreseen/wished regarding AMR?
- No drawing of un-justified conclusions !


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While looking at antimicrobial use in animals, do not forget to also observe the effects caused by implementing any new measures; at all steps

- AMR is related use and „selection pressure“
- Effects of launch of new concepts
- Feed / Management / Environment
e.g. What was the true influence of the ban of AM FA?
What is the influence of the permanent increased recommendation and use of „desinfectants“?
- Produce reliable data, that convince the public!


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If we do something, set incentives right

Incentives for improvement of husbandry

- Political and financial support

Incentives for better health of animals (retailers)

- Higher price? (measured as reduced use of AM?)

Incentives for innovation of VMP replacing AM:

- For products avoiding/replacing AM use?
 - Accelerated/provisional marketing authorisation?
- Define influence on risk assessment

What we wish



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- Any action must strive to balance, on the one hand, the need for the affordable availability/development of effective (new) products (including novel actives) to ensure the future health and welfare of animals (pets and food producing species), and the security of supply of human food derived from animals with, on the other hand, concerns regarding safety including antimicrobial resistance.
- It is imperative that the legal requirements do not raise the (data) requirements for the use/development of products to a point where availability/development of (new) products is no longer affordable (low RoI compared to risk)
- To do so would risk creating far greater concerns for both animal and human welfare through the lack of safe and effective antimicrobial products to treat ill animals.
- Join forces to create the data we need to draw conclusions

AVC members will be happy to support creating sound scientific data and help to implement any such measures



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Thank you for the support of the working party on antimicrobial resistance of AVC, esp. discussions with M. Pott, D. Burch and T. Rowan

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