EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Consultation meeting with stakeholders

Request from the European Commission for advice on the impact on public and animal health of the use of antibiotics in animals 28 February 2014

Summary of discussions

Presented by: Jordi Torren-Edo
Scientific Administrator, Public and Animal Health

Disclaimer

"The views expressed in these slides are the views expressed during the stakeholders meeting and may not be understood to be the view of, or reflecting the position of, the EMA or one of its committees or working parties".

General considerations

- AMEG is a collaborative effort with experts from CVMP (AWP), CHMP (IDWP), ECDC and EFSA.
- Opportunity for comments on the questions at two different stages:
  - Before publication of draft (1st April 2014 for Q3 and Q4)
  - After publication of draft for Q2, Q3, Q4 (draft intended to be published in June/July 2014).
- Comments from all stakeholders encouraged

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2013/12/event_detail_000809.jsp&mid=WC0b01ac058004d5c3

European Commission policy on AMR

- Referral on colistin as result of the first scientific advice of the EMA to EC.
- The EC will take measures taking into account the advice during the period 2015-2018, particularly when formulating legal proposals
- The scientific opinion will be a key document to inform the EC measures on AMR.
- EMA leading Agency but there is a need to have the involvement of ECDC and EFSA that also have competencies on the area. The Agency confirmed that those Agencies are already involved on the advice(s).

Question 2 (ranking of antimicrobials)

- Criterion 1 from WHO is one of the factors to establish a ranking of antimicrobials to answer the question from the EC.
- Concern was expressed that Criterion 1 (and 2) encompasses most antimicrobials and therefore other factors need to be taken into account including the importance of being able to treat infectious diseases successfully in animals.
- No new risk assessments to be performed by AMEG.
- There is an extremely high concern from ECDC about the lack of new antimicrobials for use in humans, and the alarming increase of bacteria resistant to antimicrobials used in human medicine.

Question 2

- The OIE has produced a list of CIAs and recommendations on fluoroquinolones and cephalosporins that takes into account human and animal health aspects.
- It is recognised that a global classification cannot take into account all cases, showing that such a list should only be taken as an element of any risk management decision and that there are other factors to consider (local resistance or availability of medicines)
- Any list should be flexible enough to take into account the field situation and to be applicable locally.
- To be workable any categorisation should be concise.

Question 2

- Treatment guidelines should be developed locally.
- Knowing the impact of implementing treatment guidelines is important.
- Flexibility on the implementation of the treatment guidelines is needed. The knowledge of the veterinarian must be brought into the decision of which antimicrobial has to be prescribed by the vet.
- Formularies also take into account other factors related to use and so are a risk management tool.

Question 2

- The value of formularies was the subject of some debate
- Stakeholders highlighted that some evidence exists that formularies can actually have the opposite of the intended effect if the range of antimicrobials recommended is so restricted that it drives the rate of development of AMR against those few agents that are recommended
- Some veterinary opinion however is that formularies can direct the use of critically important antibiotics more precisely and only when absolutely necessary thus overall resulting in a diminution in their use in animals
- Evidence on outcome of the use of formularies should therefore be considered.

Question 2

- Lists are useful for establishing risk management priorities, for hazard identification and for consequent risk assessment.
- The list provided by WHO could be used as a base to rank antimicrobials according to the relative probability of spread of resistance from animals to humans and the consequent risk to human health but it cannot be the sole base for treatment guidelines for veterinary use as such guidelines must consider numerous other factors of importance for effective treatment of animals.

Question 3 (new antimicrobials)

- The EMA expert group indicated that information from stakeholders is essential to answer the question from the EC.
- The stakeholders indicated that it might not be possible to answer to all questions proposed by the Agency before 1 April 2014
- The development of tools like
  - Medicinal products with new indications/species, possibly derived by extension of existing antimicrobials
  - Affordable antimicrobial testing kits (especially pen-side)

  is of importance and could be part of the answer to the EC
- It was indicated that restrictions placed on granting new classes for animals could seriously challenge successful treatment of zoonotic diseases in animals

Question 3

- It was indicated that the pharmaceutical industry requires predictability for the development of new products.
- For antimicrobials authorised only in human medicine some stakeholders indicate that they are not aware of any use in food producing animals, but there is some use described in companion animals and horses.
- Directly opposing views were expressed whether entirely new antimicrobials should by default be reserved exclusively for human use or whether the option for veterinary use should be left open until a risk assessment has been performed
- Several veterinary stakeholders spoke of the need to incentivise and support development of innovation in antibiotics for veterinary use.

Question 4 (measures for existing CIAs in veterinary medicine)

- There are concerns about the use of antimicrobials in animals and their impact on public health.
- Stakeholders presented examples on how reduction of consumption of antimicrobials has had a negative impact on animal health. Although there were no references made to the positive aspects of such reductions, there are several.
- In some MSs the physicians are significantly changing their prescribing habits for man to reduce the use of 'reserved' CIAs such as 3rd and 4th generation cephalosporins.

Question 4

- A strong suggestion was made by some of the stakeholders to extend the data protection for AMs for veterinary use.
- Veterinarians should have antimicrobials available both for welfare reasons and to treat sick animals, as healthy food comes from healthy animals (and vice versa).
- Since there appears to be no significant development of new antimicrobials, there is a need to use the existing antimicrobials in an extremely prudent manner.
- It was indicated that price should not influence veterinary prescription patterns.

Question 4

- It was indicated that a similar approach is needed in the EU and other regions of the world to avoid the EU merely importing the problem of resistance generated elsewhere.
- Cost of control measures, or the cost of failure to introduce them, is difficult to estimate.
- The importance of the use of fluoroquinolones, cephalosporins and macrolides was highlighted. Adequate measures should be in place to minimise negative impact on public health from their use. It was proposed that their use in animals should be maintained, albeit under strict circumstances.
- Effective and cheap diagnostic tools are urgently required, particularly pen-side sensitivity testing to drive the prudent choice of antimicrobial at the point of care.

Question 4
Difficulties to answer the EC request

Some of the difficulties to answer question 4 were listed as follows:

- Complexity in linking usage in animals to resistance in man;
- Often several actions are implemented at the same time. Difficult to identify the effect of each;
- It will be essential to define what are the key 'measurements of success' and desired outcomes for an effective policy and how they will be measured
- Risk-to-risk: Difficult to evaluate consequence of a specific action, e.g. replacement by other antibiotics and other practices which may impact on resistance;
- Use of, and risk of, the same antimicrobial in different animal species may be different;
- Control of off-label use should be considered as part of any package of control measures