29 August 2018
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Veterinary Medicines Division

Draft agenda - Focus group meeting on the Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals (EMA/CVMP/AWP/706442/2013)

19 September 2018, 13:00 – 16:30

Meeting room 2E

Co-chairs: Helen Jukes, Christopher Teale

	Preliminary draft agenda	Speaker	Mins
13:00	Welcome Aims of the focus group meeting	Jordi Torren Christopher Teale	10’
13:10	High level overview of the guideline	Helen Jukes	10’
13:20	Industry view	AnimalhealthEurope	20’
13:40	Experience of the Danish researchers	Lis Alban, Johanne Ellis-Iversen	30’
14:10	Questions to Danish researchers	All	10’
14:20	Key updates made since first consultation	Helen Jukes	10’
14:30	General discussion	All	30’
15:00	*Coffee break*		*15’*
15:15	Categorisation of risk factors, risk assessment steps and overall risk estimation	Christine Schwarz	10’
15:25	Simplified consequence assessment	Damien Bouchard	10’
15:35	Direct contact as a route of exposure	Boudewijn Catry	10’
15:45	Discussion	All	30’
16:20	Summing up and closing remarks	Christopher Teale	10’
16:30	Close		

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Background to the focus group meeting with stakeholders to discuss the CVMP's draft Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals (EMA/CVMP/AWP/706442/2013)

The CVMP's antimicrobial veterinary medicinal product (VMP) risk assessment guideline aims to provide guidance to marketing authorisation applicants on the data requirements and methodology to be used for assessing the risk to public health from AMR due to the use of those products. The scope of the guidance applies to veterinary medicinal products (VMPs) intended for food-producing species, only.

The first draft guideline was published for public consultation on 21 January 2015, and comments were received from five stakeholders. These comments have now been addressed in the 'Overview of comments' document, and revisions made to the draft guideline as relevant (documents enclosed: Revised draft guideline and Overview of comments).

The CVMP's Antimicrobials Working Party, which has led on the development of the guideline, is holding a focus group meeting with stakeholders to discuss the revision of the guideline after the first consultation, concentrating on certain topics identified from the consultation. Comments that are considered to have been addressed in the 'Overview' without requiring revision to the guideline will not be re-opened for discussion at the focus group meeting, although there will be some time for general discussion around other revisions not specifically identified below.

The guideline is particularly important in relation to novel products and Animalhealth Europe (previously IFAH-EU) will provide a short presentation on the views of industry on the guideline. In addition, Lis Alban and Johanne Ellis-Iversen, as representatives of a Danish research group, will provide a presentation on their experience on the guideline in relation to their recently published risk assessment (ref. Alban et al, 2017).

Please note, although further revisions may be made to the enclosed GL draft, no significant changes to the overall structure of the guideline are foreseen following the focus group meeting.

Specific topics highlighted for discussion with stakeholders at the focus group meeting:

1. **Categorisation of risk factors, risk assessment steps and overall risk estimation**

   Some further guidance has been introduced on the categorization of certain risk factors, although these proposals may be refined by the applicant according to the conditions of use of their specific product. More detail has also been given on the overall categorization of the release, exposure and consequence assessments (from 'very low' to 'high'). For the overall risk estimation, consideration was given to use of a matrix, but it was decided that greater flexibility might be needed and would allow for expert judgement.

2. **Proposal for option of a simplified consequence assessment**

   Acknowledging the extent of the gaps in the data needed to perform the consequence assessment, an option is proposed for a simplified consequence assessment that would be based on the AMEG categorization for the antimicrobials substance and the extent of use of the AM class in human medicine. Please note that since the AMEG categorization is currently under review, the matrix in this section is subject to the outcome of the review.

3. **Direct animal contact as a route of exposure**

As knowledge around the risk for direct contact as a route for transfer of AMR from animals to humans is increasing, it was decided to retain this route in the scope of the guideline. It is acknowledged that there are still many data gaps, but the framework of the GL may still be followed.

Further detail and explanation of these topics are given in the revised draft GL and the Overview.

Reference

Alban L, Ellis-Iversen J, Andreasen M, Dahl J and Sönksen UW. 2017. Assessment of the Risk to Public Health due to Use of Antimicrobials in Pigs – An Example of Pleuromutilins in Denmark. Front. Vet. Sci. 4:74. doi:10.3389/fvets.2017.00074