



18 November 2013
EMA/408480/2013
Veterinary Medicines Division

Draft agenda – Focus Group Meeting

Revision of the CVMP Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances
EMA/CVMP/261180/2012

9 December 2013, Room 3A

Chair: G. Hahn / H. Jukes

Preliminary draft agenda		Speaker
10.00	Welcome and introduction	G. Hahn / H. Jukes
10.15	Introduction to revised guideline ¹ (“ what has changed and why”) (EMA/709374/2013)	G. Hahn / H. Jukes
10:30	Overview impression of the draft guideline from the industry perspective	IFAH Europe
10:45	Coffee break	
11:00	Topics for discussions (identified by regulators) (Brief introduction by regulator expert, followed by discussions with stakeholders)	
11.00	<ul style="list-style-type: none">Characterisation of the susceptibility pattern of the target pathogen (section 5.3) (EMA/713355/2013)	S. Pyörälä
11.30	<ul style="list-style-type: none">Dose determination (sections 6.2 and 6.3) (EMA/709443/2013)	S. Vermouth
12.00	<ul style="list-style-type: none">Control methods in field trials (section 6.4) (EMA/709442/2013)	S. Vermouth
12:30	<ul style="list-style-type: none">Endpoints and timing of efficacy assessment (section 6.4.6) (EMA/709359/2013)	N. Bridoux

¹ Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances available on EMA website for consultation – deadline for comments 30 November 2013
(http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/05/WC500143698.pdf)



Preliminary draft agenda		Speaker
13.00	Lunch	
14.00	Topics for discussions (identified by regulators) (Brief introduction by regulator expert, followed by discussions with stakeholders)	
14:00	<ul style="list-style-type: none"> • Metaphylaxis (section 6.4.7) (EMA/709803/2013) 	F. Hulten
14.30	<ul style="list-style-type: none"> • Prevention claims (section 6.4.8) 	F. Hulten
15.00	<ul style="list-style-type: none"> • “Second line” antimicrobials (EMA/709804/2013) 	K. Törneke
15:45	Coffee break	
16:00	Discussions and proposals	G. Hahn / H. Jukes
16.45	Wrap up and conclusions	G. Hahn / H. Jukes
17.00	End of meeting	G. Hahn / H. Jukes