



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2018
EMA/517715/2018
Veterinary Medicines Division

Draft agenda - Focus group meeting the pilot project on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation (EMA/CVMP/849775/2017)

12 October 2018, 10:00 – 16:00

Meeting room 3F

Chair: Johan Schefferlie

	Preliminary draft agenda	Speaker	Mins
10:00	Welcome Aims of the focus group meeting High level overview of the reflection paper	Chair	35'
10:35	Industry view		50'
11:25	<i>Coffee break</i>		15'
11:40	Pharmacokinetic/pharmacodynamic (PK/PD) modelling Discussion	Damien Bouchard, Pascal Sanders	20'
12:00	Target animal safety (TAS) Discussion	Helen Jukes	20'
12:20	<i>Lunch break</i>		60'
13:20	Environmental risk assessment (ERA) Discussion	Johan Schefferlie	20'
13:40	Withdrawal periods (WP) Discussion	Peter Hekman	20'
14:00	<i>Coffee break</i>		15'
14:15	General discussion Questions		90'
15:45	Summing up and closing remarks	Chair	15'
16:00	Close		

