EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 May 2016
EMA/CVMP/EWP/29236/2016
Veterinary Medicines Division

Agenda - Focus group meeting

Revision of the reflection paper on anthelmintic resistance EMA/CVMP/EWP/573536/2013

13th June 2016, 9.30-16.15, Room 3F

Chairs: G. Hahn and F. Hultén, CVMP Efficacy Working Party

	Draft agenda	Speaker	Mins
	First Session- Background		
09.30	**Welcome and introduction**.	G. Hahn /F. Hultén	10
09.40	**Anthelmintic resistance in Europe** *Overview of the anthelmintic resistance situation in Europe in main target species (cattle, sheep and horses).*	A. Bottger	15
09.55	**Factors influencing development of anthelmintic resistance**. *Current practices in animal husbandry, use of veterinary anthelmintics.*	E. Claerebout	15
10.10	Discussion	All	40
10.50	*Coffee break*		20
	Second session –Prudent use		
11.10	**Current knowledge of best practices for prudent use** *What is "best practice" in husbandry management in different target species in regard to helminth control?* *How should anthelminthics be used correctly?* *Are there alternative husbandry (e.g. refugia) or treatment options to the use of pharmaceuticals?*	L. Stubbings	15
11.25	**Regulatory tools (SPC and product information)** *Regulatory view* *What are current regulatory requirements when authorising anthelmintics?*	S. Steuber	5

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	Draft agenda	Speaker	Mins
	What information is currently included on product information as standard?		
11.30	**Regulatory tools (SPC and product information)** *Veterinary view* *Is the product information appropriate and sufficient for all target species?* *Should there be more information, e.g. need for diagnosis prior to treatment, specific management practices?*	FVE R. van Dobbenburgh/ N. De Briyne	5
11.35	Discussion	All	30
12.05	*Lunch break*		75
	Third session **Development and authorisation of anthelmintics**		
13.20	**Impact of VMPs on resistance development** *What is the impact of using multiple active products with overlapping activity to prevent or delay the development of resistance?*	IFAH-Europe T. Geurden	15
13.35	**Impact of specific formulations of anthelmintics on resistance development** *What is the impact of dose regimen, route of administration (e.g. topical/oral/injectable) and formulation (e.g. slow release) on the development of resistance?* *Is there a lack of effective antiparasitic substances (or formulations) for some (minor) target species?*	D. Murphy	10
13.45	Question and discussion	All	60
14.45	*Coffee break*		15
	Fourth session - Monitoring tools for resistance development		
15.00	**Monitoring methods and systems** *What suitable and validated tools/tests are currently available for monitoring resistance in main target species?* *Where are the problem areas concerning monitoring systems?* *Which monitoring systems for anthelmintic resistance are available or needed in Europe?*	G. von Samson-Himmelstjerna	10
15.10	**Regulatory tools: report on lack of efficacy** *What could be done to monitor resistance development?* *How can the reporting of "lack of efficacy" be further encouraged?*	P. Ekström	10
15.20	Question and discussion	All	40
16.00	**Conclusion and recommendations**	G. Hahn/F. Hultén	30
16.30	End of the meeting		