EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 November 2016
EMA/634595/2016
Veterinary Medicines Division

Focus group on promotion of pharmacovigilance for food producing animals

23 November 2016, 11.00-17.00, Room 3F, European Medicines Agency, London

Chair: P. Ekström

Objectives: 1) Develop approaches for encouraging reporting on food producing animals and providing feedback to reporters; and 2) Establish collaborative network for veterinary pharmacovigilance of food producing animals

	Item	Presenter and objectives	Time		Time	Mins
1	Welcome and aims of meeting	Chair and I. Duarte (EMA)	11:00	-	11:05	00:05
2	Introduction • Overview of EudraVigilance Veterinary (EVVet) data and pharmacovigilance system • CVMP reflection paper on promotion of pharmacovigilance reporting	J. Olaerts (EMA) • Overview of current adverse event reporting system and reporting for food producing animals L. Woods (PhVWP-V member) • Overview of CVMP reflection paper	11:05	-	11:20	00:15
3	Outcome of Federation of Veterinarians of Europe (FVE) survey on adverse event reporting	N. de Briyne (FVE) • Presentation of survey results	11:20	-	11:35	00:15
4	Veterinarians experiences: cattle	I. Lorenz (Bavarian Animal Health Service) • Challenges of adverse event reporting • Feedback received	11:35	-	11:50	00:15
5	Veterinarians experiences:	K. Steen Pedersen (Ø-Vet A/S)	11:50	-	12:05	00:15

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	Adverse event reporting in pigs	• Challenges of adverse event reporting • Feedback received				
6	Veterinarians experiences: Pharmacovigilance in poultry experience from the field	J. van Erum (Galluvet) • Challenges of adverse event reporting • Feedback received	12:05	-	12:20	00:15
7	Veterinarians experiences: Pharmacovigilance and aquaculture	T. Wall (Fish Vet Group) • Challenges of adverse event reporting • Feedback received	12:20	-	12:35	00:15
8	Veterinarians experiences: other species e.g. horses	C. Scicluna (Clinique du Plessis) • Challenges of adverse event reporting • Feedback received	12:35	-	12:50	00:15
9	Communication/liaison between veterinarians and competent authorities – role of national veterinarian associations	T. Chambon (Union Européenne des Vétérinaires Praticiens) • Challenges of adverse event reporting • Feedback received	12:50	-	13:00	00:10
10	Stakeholders experiences – pharmacovigilance in food producing animals • Benefits of AE reporting • MAH view	D. O'Rourke (AVC) Tony Simon (IFAH-Europe)	13:00	-	13:15	00:15
11	Break		13:15	-	14:15	01:00
12	Discussion session: challenges of reporting adverse events: common factors and species differences	• Consideration of reporting tools, resources/incentives	14:15	-	14:45	00:30
13	Discussion session: measures to address challenges	• Identify feasible short-term and potential long-term measures to address challenges identified e.g. consideration of other mechanisms for reporting outside the 'traditional pharmacovigilance reporting route'	14:45	-	15:15	00:30
14	Discussion session: improving feedback to reporters	• Type and frequency of feedback received and desired	15:15	-	15:45	00:30
15	Discussion session: improving dialogue between veterinarians and the regulatory network	• Proposals for improving communication and collaboration for veterinary pharmacovigilance	15:45	-	16:15	00:30

	Item	Presenter and objectives	Time		Time	Mins
16	Next steps	• Conclusions	16:15	-	16:45	00:30
17	Close of meeting		16:45	-	17:00	00:15

Documents for information:

- List of participants (EMA/737712/2016)
- Reflection paper on promotion of pharmacovigilance reporting (EMA/CVMP/PhVWP/390033/2014)
- Veterinary pharmacovigilance 2015: Public bulletin (EMA/CVMP/818155/2015)
- Feedback form (EMA/765052/2016)