EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 August 2010
EMA/472334/2010
Veterinary Medicines and Product Data Management
Direct Line +44 (0)20 7418 8432

To organisations

Dear Colleague,

Subject: Invitation to participate in a workshop: veterinary pharmacovigilance question time: better regulation for electronic reporting and periodic safety update reports (PSURs)

We are writing to invite a representative of your organisation to participate in a workshop on better regulation of veterinary pharmacovigilance. The main aim of the workshop is to provide an opportunity for representatives from industry and the Federation of Veterinarians of Europe and pharmacovigilance experts from the European Union national competent authorities to reflect on improving the regulation of veterinary pharmacovigilance, with specific focus on electronic reporting and periodic safety update reports (PSURs).

The workshop will take place from 12.30-16.30 on **24 November 2010** at the European Medicines Agency, London, as detailed in the draft programme enclosed. The meeting will comprise short presentations, panel and open discussion sessions for participants to exchange views concerning electronic reporting and PSURs, to identify common goals and to reflect on future prospects as part of a proportionate pharmacovigilance system. We will ask all participants to submit questions or comments for discussion in advance of the workshop and we will provide more information on the workshop with the meeting documentation in due course.

We would be grateful if you would confirm your attendance **by 10 September 2010** via email to Anna Vecellio (anna.vecellio@ema.europa.eu). Please note due to the security arrangements at the Agency, anyone who has not registered in advance will be turned away.

Please do not hesitate to contact me if you require any further information on the workshop.

Yours sincerely,

Dr. Kornelia Grein
Head of Sector - Veterinary Medicines

Encl.

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 August 2010
EMA/433980/2010-Draft
Veterinary Medicines and Product Data Management

Veterinary pharmacovigilance question time: better regulation for electronic reporting and periodic safety update reports (PSURs)

24 November 2010, 12.30-16.30, Room 2D, European Medicines Agency, London

Aim of workshop: to reflect on improving regulation of veterinary pharmacovigilance for a proportionate veterinary pharmacovigilance system with focus on electronic reporting and PSURs

	Item	Speaker	Duration	Time
1	**Opening of the meeting**	*Chair (Agency)*	5 mins	1230-1235
2	**Setting the scene: the Commission public consultation on better regulation** ▪ *CVMP proposals for the revision of the veterinary legislation on pharmacovigilance* ▪ *Industry illustration of the need for change: Presentation of the IFAH-Europe impact assessment data package*	 *TBD* *TBD*	 10 mins 10 mins	1235-1255
3	**Questions**	*All*	5 mins	1255-1300
4	**Electronic reporting: *reporting routes, time to report; proposed Member States and MAHs reporting obligations*** ▪ Industry ▪ NCA/Agency	 *TBD* *TBD*	 15 mins 15 mins	1300-1330
5	**Panel discussion**	*All*	30 mins	1330-1400
6	**Periodic safety update reports (PSURs): *frequency, content and assessment*** ▪ Industry ▪ NCA/Agency	 *TBD* *TBD*	 15 mins 15 mins	1400-1430
7	**Panel discussion**	*All*	30 mins	1430-1500
Coffee break			30 mins	1500-1530
8	**The way forward: future prospects for electronic reporting & PSURs – exchange of views** **a)** Common goals **b)** Practical measures for addressing issues/problem areas under current legislation **c)** Identification of topics to be addressed in future legislation	*All*	45 mins	1530-1615
9	**Summary of discussion and close**	*Chair*	15 mins	1615-1630

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DATE:		**REF:**	
TO:	Anna Vecellio	**PHONE:**	(44-20) 75 23 7714
	Euroepan Medicines Agency Secretariat	**FAX:**	(44-20) 74 18 8447
		E-Mail:	anna.vecellio@ema.europa.eu

Nomination for participation at a workshop

Veterinary pharmacovigilance question time: better regulation for electronic reporting and periodic safety update reports (PSURs)

12.30-16.30, 24 November 2010, European Medicines Agency, London

NAME:	
POSITION:	
ORGANISATION:	
ADDRESS:	
TELEPHONE:	
FAX:	
E-MAIL:	