



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2010
EMA/433980/2010 – Final
Veterinary Medicines and Product Data Management

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

24 November 2010, 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	<i>Chair: K Grein (European Medicines Agency)</i>	5 mins	1230-1235
2. Setting the scene: the Commission public consultation on better regulation			1235-1255
• <i>Industry illustration of the need for change: Presentation of the IFAH-Europe impact assessment data package</i>	<i>B Cornez (Huvepharma N.V)</i>	10 mins	
• <i>CVMP proposals for the revision of the veterinary legislation on pharmacovigilance</i>	<i>J Olaerts (European Medicines Agency)</i>	10 mins	
3. Question(s)	<i>All</i>	5 mins	1255-1300



Item	Speaker	Duration	Time
4. Electronic reporting: reporting routes, time to report; proposed Member States and MAHs reporting obligations - Industry - National Competent Authority	<i>K Quine (Elanco Animal Health)</i> <i>C Ibrahim (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit)</i>	15 mins 15 mins	1300-1330
5. Panel discussion Open discussion	<i>F Dyer (Veterinary Medicines Directorate)</i> <i>M Hendrickx (Pfizer Ltd)</i> <i>R van Lieshout (Eurovet Animal Health)</i> <i>L Vesterager Borge (Danish Medicines Agency)</i> <i>All</i>	20 mins 10 mins	1330-1400
6. Periodic safety update reports (PSURs): frequency, content and assessment - Industry - National Competent Authority	<i>C Torres (Ceva Santé Animale)</i> <i>A Werner (Bela-pharm GmbH)</i> <i>P Ekström (Läkemedelsverket)</i>	10 mins 10 mins 10 mins	1400-1430
7. Panel discussion Open discussion	<i>F Dyer (Veterinary Medicines Directorate)</i> <i>M Hendrickx (Pfizer Ltd)</i> <i>R van Lieshout (Eurovet Animal Health)</i> <i>L Vesterager Borge (Danish Medicines Agency)</i> <i>All</i>	20 mins 10 mins	1430-1500
Coffee break		30 mins	1500-1530

Item	Speaker	Duration	Time
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	<i>All</i>	45 mins	1530-1615
9. Summary of discussion and close	<i>Chair: K Grein (European Medicines Agency)</i>	15 mins	1615-1630