



14 May 2013  
EMA/CVMP/192734/2013  
Veterinary Medicines and Product Data Management

## CVMP Interested Parties' Meeting

15 May 2013, 17:00-19:00, Room 4C

Chair: David Mackay

Item	Preliminary draft agenda	Initials	Mins
1.	Adoption of agenda	All	5'
2.	Minutes of last meeting and report on actions arising	All	5'
3.	1. Antimicrobial Resistance <ul style="list-style-type: none"><li>Update on recent EMA/CVMP initiatives</li><li>Observations from IFAH-Europe on impact on innovation in the veterinary sector</li><li>Exchange of views</li></ul>	EMA/CVMP IFAH-Europe EGGVP, All	30'
4.	Residues of veterinary medicinal products: a global issue	EGGVP, CVMP	10'
5.	Update from CVMP on injection site issue	EMA/CVMP	10'
6.	2. Update on EMA/CVMP activities in relation to the 3Rs (details see annex) <ul style="list-style-type: none"><li>Progress with developing a new guideline on replacing animal tests</li><li>TABST</li><li>Update on progress with JEG 3Rs projects</li></ul>	ICAPPP/EMA	20'
7.	Update on IFAH-Europe activities relevant to CVMP	IFAH-Europe	15'
8.	3. Follow-up on developments for the treatment of bees diseases in the EU <ul style="list-style-type: none"><li>Availability of pharmacologically active substances for bees</li><li>Handling of veterinary medicinal residues in honey</li></ul>	FEEDM	10'



## **ANNEX: Items raised by CVMP Interested Parties**

### **Item 3: Innovation in the area of veterinary antimicrobials (raised by IFAH-Europe)**

- The focus will be on the elements that constitute market failure in antibiotics for the veterinary sector resulting in the wide range of on-going actions that combine to deter the industry from investing in innovative antibiotics and proposals for how to stimulate innovation.

### **Item 4. Residues of veterinary medicinal products: a global issue (raised by EGGVP)**

- Considering a more harmonized approach with international key players such as JECFA. The case of substances belonging to the tetracycline group and other examples.

### **Item 6. Update on EMA/CVMP activities in relation to the 3Rs (raised by ICAPP)**

- Progress with developing a new guideline on replacing animal tests following the consultation on the Concept paper on the Need for Revision of the Position on the Replacement of Animal Studies by in vitro Models (EMA/CHMP/SWP/169839/2011)
- Target Animal Batch Safety Test (TABST)-has the EMA sought guidance from the Commission as to whether companies can conduct the TABST for non-EU requirements under Directive 2010/63 (our legal advice is that it cannot, see Commission Q and A legal advice [http://ec.europa.eu/environment/chemicals/lab\\_animals/pdf/qa.pdf](http://ec.europa.eu/environment/chemicals/lab_animals/pdf/qa.pdf) ) and have they informed companies of this? Have all EU countries asked companies to update their market authorisations?
- TABST at the VICH- update on progress
- Update on progress with JEG3Rs projects as outlined in their 2011 work programme [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Work\\_programme/2011/10/WC500115627.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2011/10/WC500115627.pdf)