European Medicines Agency
Veterinary Medicines and Inspections

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FOCUS GROUP MEETING - REVISION OF BIOEQUIVALENCE GUIDELINE
MINUTES OF THE MEETING
6 May 2009, EMEA, London

The chairman, Michael Holzhauser-Alberti (AFFSA, France, EWP chair), welcomed participants to the meeting. The meeting was attended by representatives from regulatory authorities, pharmaceutical industry, veterinary consultants and academia.

Main changes to the guideline

Representatives from CVMP and Working Parties presented the main changes to the guideline. Fredrik Hulten (MPA, Sweden, EWP member) introduced the revised (draft) guideline and highlighted the aim of the revision, i.e. to provide clearer / simplified guidance and also to harmonise the veterinary requirements with those for human products or other international guidance (FDA). K. Törneke (MPA, Sweden, CVMP member) addressed aspects related to the *in vivo* design such as the dosing, single versus multiple administration analysis, statistics and exemptions from requirement to provide *in vivo* data. P.H. Overhaus (National Institute of Public Health and the Environment, QWP veterinary vice-chair) gave a presentation on the newly introduced Annex to the guideline with the Biopharmaceuticas Classification System (BCS) allowing for biowaivers, which would allow to waive *in-vivo* testing for *in-vitro* studies. In addition, Henrik Wåhlström acting expert for the revisions of the human and the veterinary BE guideline was present to address issues related to harmonisation between these two documents.

A number of **topics had been identified by interested parties** and were presented by representatives from IFAH Europe who welcomed the revised guideline and appreciated the input of several disciplines/Working Parties into the document. However, some areas were highlighted where guidance was not clear or misleading and more clarity would be appreciated. Topics addressed in particular were in relation to biowaivers (E. de Ridder, Elanco), statistics (U. Sent, Boehringer Ingelheim), study designs (R. Hunter, Elanco) and the evaluation of enantiomers and complex study designs (M. Bobey, Merial). A number of suggestions were made to improve the wording of the guideline. Some areas of controversial views were highlighted which were discussed in detail. Particular consideration was given to the extrapolation of the new biowaiver approach for veterinary medicinal products. The principle is acknowledged but certain limitations will occur because of species differences and their difference in physiology when compared to Human medicine.

Discussions

Following the presentations, the individual sections of the guideline were discussed in detail and interested parties were invited to raise their views on each section. A number of issues were raised where further clarification would be useful or corrections would be necessary. Questions were raised to get clarification on certain areas in the guideline. The chairman also informed that work on the human guideline is currently still ongoing and changes made to the human guideline would also be considered for the veterinary guideline. In view of the number of comments made during the discussions, interested parties were reminded to send all their comments also in writing to the EMEA.

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Conclusions

The chairman thanked interested parties for their contributions and appreciated their careful checking of the guideline and the observations and comments made. The meeting highlighted differences of opinions not only between interested parties and regulators but also between experts and acknowledged the difficulties on developing a general guideline. A number of valuable comments and suggestions to improve the wording of the guideline were made which was considered very useful. Thanks were expressed for the opportunity to discuss the guideline in an open meeting.

List of Participants

Abbott Elizabeth	ECO Animal Health, UK
Beuvry Vincent	ORKEO, France
Bobey Marianne	Merial S.A.S (IFAH-Europe) , France
Brvar Nina	KRKA, Slovenia
De Ridder Erik	Elanco (IFAH-Europe), Belgium
Drury,Will	Cyton Biosciences Ltd, UK
Fraatz Kristine	Bayer (IFAH-Europe), Germany
Geneteau Anne	Ceva (IFAH-Europe), France
Goossens Lieve	Janssen Animal Health (IFAH-Europe), Belgium
Guàrdia Marc	HIPRA, S.A., Spain
Hahn Gesine	BVL, Germany, (EWP member)
Holzhauser-Alberti Michael	AFFSA, France (EWP chairman, CVMP)
Hugnet Christophe	Clinique Vétérinaire des Lavandes, France, (EWP member)
Hulten Frederik	MPA, Sweden (EWP member)
Hunter Rob	Elanco (IFAH-Europe), Belgium
Jukes Helen	Veterinary Medicines Directorate, UK, (EWP member)
Lees Peter	Royal Veterinary College, UK
Martano Marina	Universita degli studi di Torino, Italy, (EWP member)
Meijer Bert	Dopharma Research, Netherlands
Overhaus Piet-Hein	National Institute of Public Health and the Environment, Netherlands (QWP veterinary vice-chair)
Papelard Anne-Lise	Ceva (IFAH-Europe), France
Peyrou Mathieu	Novartis Animal Health (IFAH-Europe), Switzerland
Richez Pascal	Association of Veterinary Consultants (AVC), France
Sandberg Inge	EGGVP, Netherlands
Schefferlie Johan	Medicines Evaluation Board, Netherlands (SWP chair, CVMP)
Sent Ulrike	B.I.V. GmbH (IFAH-Europe), Germany
Speirs Graham	ECO Animal Health, UK
Törneke Karolina	MPA, Sweden (CVMP)
van Lieshout Roel	Eurovet Animal Health, Netherlands
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