European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

2006 EMEA/IFAH-Europe Info Day

'Stimulating innovation and managing risk in market access to the veterinary sector'

The EMEA hosted the 2006 EMEA / IFAH-Europe Infoday on the 9-10 November. This regular event provides an opportunity for in depth discussions between members of the Committee for Medicinal Products for Veterinary Use (CVMP), the EMEA Secretariat and IFAH-Europe as a representative body of the European animal health industry.

On this occasion the meeting was entitled 'Stimulating Innovation and Managing Risk in Market Access to the Veterinary Sector' and the whole of the first day was devoted to discussing aspects of benefit:risk assessment in the authorisation of veterinary medicines. Rick Clayton, Technical Director of IFAH-Europe, underlined the importance of recognising the unique nature and drivers of the animal health sector. He considered that there is a consequent need to ensure that regulation developed in the human sector is not automatically transposed to the veterinary sector without due consideration as to whether or not it is 'fit for purpose'. Dr Gérard Moulin, Chairman of the CVMP, updated the meeting on the work of the Committee to develop systematic methodology for benefit:risk assessment. Dr Karin Krauss of the European Commission emphasized the commitment that DG Enterprise now placed on 'better regulation' and supporting the objectives of the Lisbon Agenda. There was extensive and lively discussion raising a number of constructive points that will be useful to both industry and regulators in the future approach to benefit:risk assessment.

The meeting discussed how to implement the requirements of the revised pharmaceutical legislation in relation to environmental risk assessment (ERA). It was recognised that this is a complex issue on which the CVMP has consulted extensively with industry in developing technical guidance to complement VICH GLs 6 & 38. The CVMP is expecting to provide advice to the Commission in December 2006 as to how the technical requirements may be implemented in practical terms in compliance with legislation whilst not adversely affecting product availability. Industry emphasized the need for a pragmatic, flexible approach to be consistently applied throughout the European Regulatory Network.

The user safety guidelines for veterinary immunological and pharmaceutical products were discussed. IFAH-Europe will provide comments on the draft guideline for immunologicals and may submit a request to CVMP to consider revision of the pharmaceutical guideline with suggestions as to how it may be improved.

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The EMEA updated the meeting on a number of areas such as progress with the EMEA Roadmap, accelerated assessment, authorisation under exceptional circumstances, readable EPARs and the Sunset Clause. The various initiatives by regulators and industry to reduce the use of animals in the development and testing of veterinary medicines were discussed. There was agreement that both parties need to work together in their efforts to apply the 3Rs (reduction, refinement & replacement).

Overall, participants agreed that the meeting had provided a useful forum for exchange of views on issues of current regulatory interest.

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