European Medicines Agency
Veterinary Medicines and Inspections

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Towards an optimal balance between benefits and risks for veterinary medicines

London 14 March 2008: Representatives of European and national regulators as well as the Animal Health Industry met on the 13th and 14th March for the 2008 Infoday with the central theme "Balancing the benefits and risks of veterinary medicinal products" highlighting one of the core areas in the on-going discussion on 'better regulation' of veterinary medicinal products. The meeting was jointly organised by the European Medicines Agency (EMEA) and the International Federation for Animal Health (IFAH) Europe in London at the EMEA offices.

The conference tackled three elements of benefit-risk assessment: Participants debated firstly the draft benefit-risk assessment guideline, currently released by the Committee for Veterinary Medicinal Products (CVMP) for public consultation[1]. Secondly, regulators and industry discussed two of the recent and more challenging safety assessment guidelines: user safety and environmental safety. Thirdly, the Infoday provided an update on the implementation of the new legal provisions aimed to strengthen the post-authorisation surveillance of the safety of medicines, a process known as pharmacovigilance.

Beyond benefit-risk assessment, the conference also looked at the important issue of referrals made to the CVMP in the context of the decentralised authorisation procedures, highlighting the experience of industry, the national authorities at the Co-ordination Group for Mutual Recognition & Decentralised Procedures – Veterinary (CMDv), EMEA, and the CVMP.

Dr. David Mackay, Head of the Veterinary Medicines and Inspections Unit at EMEA opened the event and welcomed all the delegates noting that "EMEA considers Infodays are an important way for the agency to maintain a two way dialogue with stakeholders on the important issues of day such how best to assess the benefits and risks of veterinary medicinal products. Feedback from the meeting will be very helpful to CVMP in finalising its guideline on this topic."

The importance of these discussions between industry and the authorities was also stressed by Rick Clayton, Technical Director of IFAH-Europe and co-organiser. He said: "Getting the proper balance between the benefits and risks is a difficult process. It is the view of industry that all the important features of a veterinary medicine that contribute to its therapeutic efficacy in practice should be considered, and any potential risks from the use of the product must be identified, managed and minimised. It is the aim of both the authorities and industry to ensure that the right balance is achieved in the interests of animal welfare and public health."

The day concluded with the 'EMEA Bulletin Board' which provided the EMEA with the opportunity to update the industry on important new developments and initiatives at the Agency. It also provided industry an opportunity to pose questions directly to the senior management dealing with veterinary medicines.

[1] The CVMP Guideline on Benefit risk assessment is open for consultation until 31st March 2008 and can be found at http://www.emea.europa.eu/pdfs/vet/euleg/24849907en.pdf

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This event has always been very popular, but with 130 participants this year it has attracted a record number of delegates from both industry and the competent authorities. Both EMEA and IFAH-Europe considered the event to have been a success in terms of the level of the debate and the engagement of the audience in the topics under discussion.

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