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# Latest developments in scientific review, legislation and marketing authorisation procedures

**London 13 March 2009: Representatives of European and national regulators as well as the Animal Health Industry met on the 12th and 13th March for the 2009 Infoday with the central theme "Latest developments in scientific review, legislation and marketing authorisation procedures" focussing on the core areas where regulatory professionals want to be kept up to date. 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.**

At the opening of the 'Infoday', Thomas Lönngren, Executive Director of the EMEA, welcomed the delegates by saying "The EMEA attaches great important to interactions with stakeholders and we are delighted to see so many participants from the animal health industry here today. EMEA and IFAH Europe have been holding joint infodays since the start of the agency. The attendance and agenda today show that they are still relevant and much appreciated by stakeholders."

Good science underpins the entire regulatory process, and is a subject of continual debate and evolution. Latest developments in this area were the subject of the 1st session. The basic scientific data required to obtain a marketing authorisation are laid out in Annex 1 of the Directive[1] that sets out the legal framework for veterinary medicinal products. This Annex has just been revised, and the impact and implications of the revisions were critically assessed by the first three speakers.

Other speakers provided the latest updates in discussions in the areas of oncology products, pharmacokinetic/pharmacodynamic modelling, biologicals (vaccines), environmental risk assessments, and the VICH[2] process for the global harmonisation of technical standards. Of particular importance is the draft guideline now adopted for consultation by CVMP laying out proposals aimed to facilitiate the authorisation of vaccines against Foot-and-Mouth disease, Bluetongue and avian influenza.

[1] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. OJ L311, p1-66, 28/11/2001

[2] VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. Its full title is the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

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Dr. David Mackay, Head of the Veterinary Medicines and Inspections Unit at EMEA, and chair of the session 2 on 'EMEA Bulletin board and procedures', welcomed everyone back for day 2 of the Infoday and noted "EMEA considers Infodays are an important way to have a two-way dialogue on the important issues of day, such as new scientific and procedural developments."

The session provided the delegates an opportunity to review the priorities of the CVMP 2009 work programme, to obtain the latest views on how to comply with renewals and the 'sunset clause', and how the agency and the network are preparing to accept dossiers in electronic format. The session also covered the outcome of a survey on the functioning of the centralised procedure for obtaining a marketing authorisation. The survey concluded that there is generally a high level of satisfaction with the centralised procedure but identified some areas of concern to industry, notably with respect to the way that some guidelines are interpreted.

The third and final session of the Infoday covered the latest developments in European legislation governing veterinary medicinal products. These included the new Regulations introducing improved procedures for obtaining variations to the terms of a marketing authorisation and the new Regulation governing the procedure to obtain a maximum residue of a pharmacologically active substance in foodstuffs of animal origin.

Looking to the future, the delegates also heard the ideas of industry on how the legislative provisions governing pharmacovigilance could be improved as part of the European Commission's "Better Regulation" initiative.

The last presentation of the day was given by co-organiser, Rick Clayton, Technical Director of IFAH-Europe, on IFAH-Europe's proposals for improvements to the veterinary legislation in anticipation of the assessment of the legislation announced by the Commission for reporting in 2010. He told the audience that "IFAH-Europe has one vision: to reach our goal of a true single European market for veterinary medicinal products through one final review of our legislation?"

This conference continues to be a popular event in the European regulatory calendar, with over 100 participants this year 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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