SUMMARY REPORT INFO DAY:

Latest developments in scientific review, legislation and marketing authorisation procedures

<u>London 12 March 2010</u>: Representatives of European and national regulators as well as the Animal Health Industry met on the 11th and 12th March for the 2010 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 (The Agency) and the International Federation for Animal Health Europe (IFAH-Europe) in London at the Agency.

At the opening of the Infoday, David Mackay, Head of the Veterinary Unit of the Agency, welcomed the delegates: "The Agency attaches great important to interactions with stakeholders and we are delighted to see so many participants from the animal health industry here today. The Agency is in its 15th year, and this is the 14th Infoday. The attendance and agenda today show that they are still relevant and much appreciated by stakeholders."

Good regulatory decisions are based on sound science, which is continually evolving and consequently is a subject of continual debate. The first two sessions of the Infoday were devoted to scientific issues, with updates from CVMP[1] working parties and workshops, and the outcome of scientific discussions triggered by referrals.

Beginning with an area of broad interest, antibiotic resistance, the audience received an update on the activities of the Scientific Advice Group for Antimicrobial Resistance (SAGAM), followed by the perspectives of the animal health industry on the future of investment into research and development of this important class of veterinary medicine. Both speakers emphasised the need to actively promote the responsible use of antibiotics and their support for antimicrobial consumption using harmonised methodology and agreed criteria for interpretation.

Another area of intense scientific discussion is environmental risk assessment. The latest development in the form of a guideline on investigating the fate of veterinary medicines in manure was reviewed, and industry provided its viewpoint on the 'long mutual journey' leading to the current state of understanding of the regulatory requirements in this area.

Other speakers provided the recent activities in the Immunologicals Working Party, the Quality Working Party, and the Efficacy Working Party and of an Agency workshop on veterinary medicines for bees. Hot-of-the-press updates were provided on the adoption of new guidance on multistrain dossiers for vaccines (aimed to facilitate the authorisation of vaccines against Foot-and-Mouth disease, Bluetongue and avian influenza), on quality guidelines under development within VICH[2], and a call for comments on proposals to revise the efficacy guidelines for fish.

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[1] Committee for veterinary medicinal products, European Medicines Agency

[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

An important mechanism for the discussion and resolution of scientific issues is the procedure for referral to CVMP. IFAH-Europe provided a statistical analysis of the type, causes, and outcomes of referrals since 2008, and Ruth Kearsley presented 3 case studies to illustrate a range of issues that had arisen during CVMP referrals.

The third session provided the delegates with an opportunity to obtain the latest information concerning procedural issues and included updates in the areas of electronic submission of registration dossiers, on guidance covering pharmacovigilance activities, and on the updated procedural advice in Volume 6B of Notice to Applicants.

The Agency also took the opportunity to provide an overview of its draft Road Map to 2015, which is currently in public consultation, and a review of the Agency's interactions with the regulatory authorities in other regions, including the confidentiality agreements.

The final session of the Infoday covered the latest developments in European legislation governing veterinary medicinal products. These included a review of progress on the implementation of the new Regulations on the procedures for obtaining variations to the terms of a marketing authorisation and implementing the new Regulation governing the procedure to set a maximum residue limit for a pharmacologically active substance in foodstuffs of animal origin.

The last presentation of the day, given by the co-organiser of the event, Dr. Kornelia Grein, Head of the Veterinary Sector at the Agency, explained the new structure of the veterinary unit following the Agency's reorganisation.

The event was closed with some final words by Rick Clayton, Technical Director of IFAH-Europe, who identified "journey" as the key word for the day. In particular he pointed out that all stakeholders had been on a journey towards a single market for the last 30 years. "Surely it is time we finished that long journey! Why do we need several marketing authorisation procedures? We need just one procedure with a single scientific assessment and a single marketing authorisation for all products." he proclaimed. "With the next review of the veterinary Directive in 2011 we now have an opportunity to make this final last step to complete a single market for VMPs in Europe."

The conference focused on practical issues and experience in the field of regulation of veterinary medicinal products, and continues to be a popular event in the European regulatory calendar, with over 130 participants this year from both industry and the competent authorities.

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