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IFAH-Europe hold a Reception for EU veterinary medicine legislators

Brussels, Belgium, 15th July 2003: The key decision makers within the European institutions gathered at the hotel Crown Plaza on Monday evening, 7th July 2003, to informally discuss the outstanding issues concerning the review of the pharmaceutical legislation with representatives from the European trade association, IFAH-Europe. All the delegates attending the Reception had a particular interest in the proposed changes to the veterinary medicines Directive (Directive 2001/82/EC).

“The Council has now reached a political agreement on the veterinary text. After the summer these texts will be resubmitted to the European Parliament for their second reading.” said Jean-Louis Delforge, Chairman of the IFAH-Europe Council, in his opening remarks. *“Therefore, at this critical stage in the process, we felt it would be useful to bring together the key players to discuss the main issues that have arisen.”* He continued. *“I am pleased this evening to welcome representatives from the European Parliament, the authorities from Member States, and the Committee of permanent representatives.”*

To set the scene for debate, the opinion of the European animal health industry was presented by Rick Clayton, IFAH-Europe Technical Manager. But first he reminded the audience not to forget the excellent work that has already been done by the European institutions in working towards a final text of the future pharmaceutical legislation. Putting specific issues aside, the Commission’s original proposals were well thought out and balanced. He noted, *“many issues have already been settled, and only a couple of difficult issues will need to be resolved between the Council and the European Parliament.”*

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Taking a broad perspective, Rick Clayton remarked *“Perhaps the most overriding message to come out of the debate over the last 2 years, is that the veterinary sector is very different from the human medicines sector. Our customer needs and market forces are very different. Quite often it is not appropriate to automatically transpose human medicinal rules onto the veterinary sector.”*

To illustrate this point, he described how different rules had now been agreed for the veterinary sector for the compulsory use of the centralised procedure for the registration of medicinal products. It was also necessary to have a tailored set of rules for regulatory data protection to support innovation in veterinary medicinal product development, particularly to encourage the extension of product indications to additional food-producing species.

The presentation was concluded with a few remarks on the one issue that was likely to be revisited by the European Parliament, namely whether medicines for food-producing animals should all be prescription only medicines (POM). Industry fully supports a category of POM products, but stresses the need to meet the practical conditions and the diversity of the European animal health market environment. The important element is to ensure traceability, which requires good record keeping.

The compromise proposal from the Council is for a list of criteria allowing certain products to be exempted from the “all-POM” clause. Industry points out that the necessary criteria for POM already exist in the current Directive and that when a product falls outside these criteria, the Member State decides how the product is controlled.

The Council Common Position will now be formally prepared over the summer, so that it can be submitted to the European Parliament in the autumn. The Parliament will then take a second reading of this legislative package, and are expected to deliver their opinion before the end of the year so that it could be adopted before the date of EU enlargement in April 2004.

Ends

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Notes to Editors:

IFAH-Europe is the representative body of manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It is a major operating division of a broader organisation – the International Federation for Animal Health, an international not for profit organisation registered under Belgian law.

For further information on IFAH-Europe including a list of members please see <http://www.ifahsec.org/>

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