

IFAH-EUROPE NEWS RELEASE



IFAH-Europe launches its Good Veterinary Pharmacovigilance Practice Guide

FOR IMMEDIATE RELEASE

Brussels, Belgium, 21 April 2004: IFAH-Europe launches its Good Veterinary Pharmacovigilance¹ Practice Guide at its Info Day organised to underline the animal health industry's responsible attitude towards its obligations concerning pharmacovigilance².

IFAH-Europe has invited experts from the industry, FVE and the EU institutions and authorities to the Brussels-based event that represents the official launch of the animal health industry's Guide on Good Veterinary Pharmacovigilance Practice.

The Guide forms an important part of the animal health industry's strategy to promote veterinary pharmacovigilance. The industry began its initiatives in this area in 2002 with a joint FEDESA/EMEA/FVE³ workshop on pharmacovigilance in Madrid. This was organised in response to its acknowledgment of an urgent need to communicate and to heighten the awareness and understanding of the pharmacovigilance procedure to different audience segments, namely directly interested parties (animal owners, veterinarians and the animal health industry), EU institutions, authorities and the general public.

The Guide explains the obligations of each party responsible for the pre- and post-approval surveillance of veterinary medicinal products. It is written in a Question and Answer format, completed by two annexes containing links to the relevant legal texts and official documents, and a reporting decision tree.

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¹ Pharmacovigilance is the systematic collection, collation and analysis of reports, principally from veterinarians and animal owners, of adverse reactions or events connected to the use of a veterinary medicinal product.

² Pharmacovigilance is provided for by Directive 2001/82/EC of the European Parliament and the Council on the Community code relating to veterinary products (OJ L 311, 28.11.2001, p.1) and remains an integral part of the recently reviewed regulatory process. The Guide is a significant contribution from the industry side to apply pharmacovigilance in an efficient, effective and consistent way.

³ FEDESA was the European Federation of Animal Health (now IFAH-Europe), EMEA is the European Agency for the evaluation of Medicinal Products and FVE is the Federation of Veterinarians of Europe.

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Jean-Louis Delforge, Chairman of the IFAH-Europe Council, introduced the Guide by saying *'IFAH-Europe is delighted to launch its Good Veterinary Pharmacovigilance Practice Guide that addresses all the major issues on the pre- and post-approval surveillance on veterinary medicinal products'*. He continued, *'The Guide makes pharmacovigilance understandable by answering the following questions: what, when and how. It is an essential tool for anyone involved in pharmacovigilance and an excellent demonstration of how our industry's responsible attitude results in the introduction of best practices in the veterinary pharmaceutical sector'*.

The Info Day was well attended by all stakeholders, and presentations were made by representatives from the European Commission, EMEA, CVMP⁴, HEVRA⁵ and FVE as well as IFAH-Europe. Speakers warmly congratulated IFAH-Europe on its initiative and commitment to pharmacovigilance, and expressed their desire to continue to work together with the industry to promote the health and welfare of animals and people.

The Good Veterinary Pharmacovigilance Practice Guide can be ordered upon request from IFAH-Europe for € 10 plus postage by using the following e-mail address: techsec@ifahsec.org.

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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 (IFAH) - an international non-profit organisation registered under Belgian law.

For further information on IFAH and IFAH-Europe, please visit <http://www.ifahsec.org/>

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⁴ The CVMP is the Committee for Veterinary Medicinal Products of the EMEA.

⁵ The HEVRA is the Heads of European Veterinary Regulatory Authorities.