



IFAH-Europe
A division of IFAH
International Federation for Animal Health:

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Introducing IFAH-Europe



What is IFAH-Europe?

IFAH-Europe is the representative body of manufacturers of veterinary medicines, vaccines and other animal health products in Europe.

IFAH-Europe represents the national animal health associations in Europe, comprising both local small and medium-size enterprises and international companies, and corporate members.

IFAH-Europe is a major operating division of a broader organisation – the International Federation for Animal Health* (IFAH).

Europe is a major centre of investment and activity for animal health companies. Companies that are members of IFAH-Europe and of national associations have headquarters, research and development facilities, production units and marketing functions in Europe. They support licensed animal health products across the European countries.

Equally Europe is an important regulatory centre and generates regulatory and social policies which not only impact member countries, but which also have high international significance. The European market represents 30.5% of the worldwide animal health market. This makes IFAH-Europe a key player within the International Federation.

What is IFAH-Europe's mission?

IFAH-Europe's mission is to promote a harmonised and science-based regulatory and trade framework for the marketing authorisation of quality medicinal products. These products contribute both to a healthy and safe food supply,

and to a high standard of health and welfare for all animals. IFAH-Europe aims to maintain and build an effective dialogue with the food chain stakeholders and to provide information to support science-based decisions.

IFAH-Europe wants to ensure that the contribution of the animal health industry to the quality of animal and human life through the advancement of sound science is fully understood in the context of growing regulatory constraints and social and political concerns. As a responsible industry we want to ensure that our stakeholders understand the work we do and the wide range of benefits we accord to society at large.

What are the foundations of IFAH-Europe?

In recent years the animal health industry has faced complex and challenging issues, which are increasingly global. In order to improve communication and representation with authorities and other organisations at all levels, in 2000 the industry began a review of its representational structures.

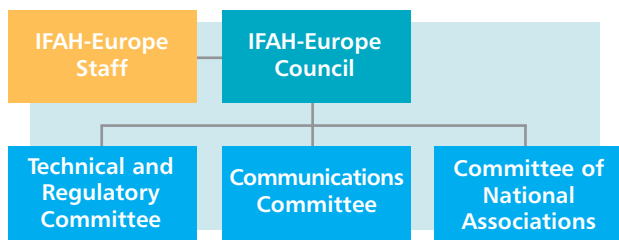
This led to the formation at the beginning of 2001, of IFAH – a new international federation for the animal health industry. At the beginning of 2003 IFAH-Europe was formally created as a distinct division within that federation, as a result of the integration of FEDESA (the European Federation of Animal Health), which had been until 2002 the representative body for the animal health industry in Europe. IFAH-Europe represents the interests of national associations and member companies at European level, by establishing a consensus position on common issues and European views at national level. Equally while representing European interests in the region, IFAH-Europe defends the European animal health industry worldwide, and acts as the conduit by which

Structure of IFAH-Europe and Facts about the Industry



international issues are brought to the attention of its European members. This multi layered and faceted dialogue enables the European animal health industry to participate fully and actively in policy debates and decisions that have an impact on its work.

How is IFAH-Europe structured?



IFAH-Europe is governed by a Council, the IFAH-Europe Council (IEC), which is composed of five representatives from companies established in Europe, five Secretary-Generals from European national animal health industry associations and the IFAH-Europe Chairman. The companies' representatives have senior management responsibilities within the EU and have the authority within their organisations to exercise leadership and manage European issues. The Secretary-Generals are elected by their European peers and represent all the national associations within the European region.

The IEC represents the European industry in its dealings with European authorities and other organisations. Members of the IEC are appointed for two years. To ensure an effective decision-making process, a network is established between the IEC members and all European national associations and companies. A representative of IFAH-Europe is a member of the IFAH Board. Final approval of plans is the responsibility of the IFAH General

Assembly, which includes all the member companies and associations.

The IEC is supported by the IFAH-Europe staff based in Brussels and by three operating committees - the Technical and Regulatory Committee, the Communications Committee and the Committee of National Associations.

The activities and projects of IFAH-Europe are funded by companies and national associations based in Europe.

Facts about the European Animal Health Industry...

Employment

In 2001 more than 50,000 jobs in Europe were related to the animal health industry.¹

Sales

In 2002 the sales of animal health products in Europe amounted to an equivalent of 3.3 billion euros, 30.5 % of the worldwide sales.²

Percentage of revenue invested in research and development

More than 10 % of its worldwide sales is invested in research and development (R&D) by the animal health industry in Europe.¹

Development time and cost of a new product

New animal health products containing a new substance for a major food producing species take between seven to ten years and cost 80 million to 100 million euros to develop and obtain regulatory approval. Other products can take four to seven years and cost 30 million to 50 million euros to develop and obtain regulatory approval.¹

¹ Source: Business Decisions Limited, 2001

² Source: Wood Mackenzie, 2003



The following highlights of activity in 2002, demonstrate the significance of Europe to the animal health industry, and of the industry to the region.

Global harmonisation of representational structure for the industry

In 2002 FEDESA built on dialogue with its members concerning the global alignment of the animal health industry, in accordance with the recommendations of the IFAH Board in 2001. This resulted in a decision of the FEDESA members at the General Assembly in October 2002 to merge its activities with IFAH as from 1 January 2003. Over 97% of the votes cast by FEDESA supported this integration and the subsequent new IFAH-Europe structure.

Regulatory harmonisation

European industry representatives participated actively in the discussions within the key international organisations: Codex Alimentarius, the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH). For example, they voiced the position of the European animal health industry at the meeting of the VICH Steering Committee and the 2nd public VICH Conference, held on 7-12 October 2002 in Tokyo, concerning antibiotics, pharmacovigilance and risk assessment.

The Federation commissioned a benchmarking study of the European regulatory environment for the animal health industry, which showed the need for a harmonised regulatory system, amongst others.

Food chain

The Federation built on dialogue and cooperation with the European food chain network, which comprises organisations representing food chain stakeholders (farmers, the food and drink industry, feed producers, veterinarians, amongst others) at European level.

The European animal health industry contributed to the debate on the establishment of the European Food Safety Authority (EFSA), within the context of the global issue management on Food Chain under IFAH.

Antimicrobial resistance

The Federation provided comments on the draft EMEA/CVMP¹ guidelines for the evaluation of antibiotic products, which are very important for the future of the licensing process of new antibiotic products. It worked in partnership with the European Animal Health Study Centre (CEESA) on this issue, as collections of bacteria are being undertaken for surveillance and resistance testing.



Other major achievements on specific European regulatory issues

Veterinary Regulation Review: A paramount effort of the Federation and its members was to provide input to the Review of the EU pharmaceutical legislation at the EU institutions - the Commission, the Council and the European Parliament (EP). The industry successfully put its messages across and had its position endorsed by the EP.

The main issues are:

- Obtaining sufficient data protection to guarantee a return on investment
- Having a free choice in the licensing procedures
- Getting a streamlined renewal process
- Maintaining national routes of distribution for certain food-animal medicines.

These changes aim to improve the regulatory framework in the EU for a faster registration of safe and efficient veterinary medicines.

Medicines Availability: The industry provided data to the EU institutions that supported the principle of extending existing Maximum Residue Limits (MRLs) to all food-producing animals. This was one of the interim measures proposed by the EU authorities to tackle one aspect of the medicines availability crisis in the short term. IFAH-Europe has actively supported other measures to improve medicines availability in the longer term, through proposals for the Review of the pharmaceutical legislation.

Communications achievements

The Federation was a partner of a coalition group of animal-related charities and non-profit associations who organised the second European Pet Night on 1 October 2002. The event gave an opportunity for European legislators to learn more about how animals improve the lives of thousands of people, and it was coupled to a meeting of the European Parliament Eurogroup on Animal Welfare, where MEPs acknowledged this vital social role of animals. This activity substantially elevated the knowledge of MEPs on the Animal Health Industry at the time when the veterinary legislation was being discussed in parliament.

The Federation was a partner in an ambitious Pan-European Educational Project, led by the European Committee of Young Farmers (CEJA), which aimed to educate children and make them aware of where food and other agriculture products come from. This helped in understanding the role of our industry.

IFAH-Europe Who is Who...

IFAH-Europe Council members

Hervé Catillon, *Pfizer Animal Health Group*
Brian Clark, *Laboratoires Virbac*
Santiago de Andrés, *VETERINDUSTRIA – Asociación Empresarial Española de la Industria de Sanidad y Nutrición Animal (Spain)*
Jean-Louis Delforge, *Chairman and IFAH Executive Director*
Jean-Louis Hunault, *SIMV – Syndicat de l'Industrie du Médicament Vétérinaire et Réactif (France)*
Peter McCarthy, *Schering Plough Animal Health*
Pierre Scarcériaux, *Janssen Animal Health*
Martin Schneiderreit, *BfT – Bundesverband für Tiergesundheit (Germany)*
Philip Sketchley, *NOAH – National Office of Animal Health (United Kingdom)*
Maritza van Assen, *FIDIN – Vereniging van Fabrikanten en Importeurs van Diergeneesmiddelen in Nederland (The Netherlands)*
Jochen Wieda, *Intervet International BV*

IFAH-Europe represents:

Member Companies

Alpharma Animal Health Division
Bayer AG, Business Animal Health Group
Boehringer Ingelheim Animal Health GmbH
CEVA Santé Animale
Elanco Animal Health
Fatro
Fort Dodge Animal Health
Intervet International BV
Janssen Animal Health
Laboratoires Virbac
Merial Limited
Monsanto Company
Novartis Animal Health Inc
Pfizer Animal Health Group
Schering Plough Animal Health
Vétoquinol, Laboratoire Pharmaceutique Vétérinaire

National Associations

Belgium: AGIM/AVGI - Association Générale de l'Industrie du Médicament
Croatia: VETERINA Animal Health
Denmark: VIF - Veterinaermedicinsk Industriforening
Finland: PIF - Pharma Industry Finland
France: SIMV – Syndicat de l'Industrie du Médicament Vétérinaire et Réactif
Germany: BfT – Bundesverband für Tiergesundheit
Greece: HAVEPHARM – Importers, Distributors, Agents and Manufacturers of Veterinary Products in Greece
Ireland: APHA – Animal and Plant Health Association
Italy: AISA – Associazione Nazionale dell'Industria della Salute Animale
The Netherlands: FIDIN – Vereniging van Fabrikanten en Importeurs van Diergeneesmiddelen in Nederland
Portugal: APIFARMA – Associação Portuguesa da Industria Farmacêutica
Slovenia: WAH – Working Group for Animal Health of the Slovenian Pharmaceutical Manufacturers Association
Spain: VETERINDUSTRIA – Asociación Empresarial Española de la Industria de Sanidad y Nutrición Animal
Sweden: LIF, Läkemedelsindustriföreningen
Switzerland: SGCI/SSIC – Schweizerische Gesellschaft für Chemische Industrie
United Kingdom: NOAH - National Office of Animal Health

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