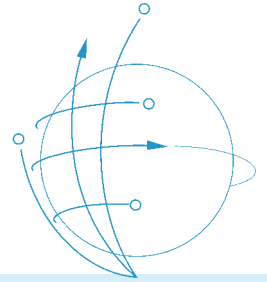


Improving the quality of life for animals and people

**ANNUAL REPORT 2004**







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

**It represents both corporate members and national animal health associations in Europe. These associations comprise both local and medium-size enterprises (SMEs) and international companies. IFAH-Europe's membership covers 95% of the European market for veterinary medicinal products.**

## **IFAH-EUROPE'S MISSION**

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IFAH-Europe's mission is to promote a predictable, harmonised, science-based and innovative market place for the provision of quality animal medicines, vaccines and other animal health products, and so contribute to a healthy and safe food supply and to a high standard of health and welfare for animals and people.

As a responsible industry we want to ensure that our stakeholders understand the work we do and the wide range of benefits we give to society at large. To achieve this, IFAH-Europe, as the voice of the European animal health industry, encourages constructive dialogue with governments, public policy makers, legislators, regulators, non-governmental organisations, the veterinary profession, the food chain, consumers and other stakeholders.

## A JOINT MESSAGE FROM IFAH-EUROPE'S CHAIRMAN AND MANAGING DIRECTOR

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**Brian Clark**, Chairman

**The political map of Europe was transformed between May and November 2004 - a period during which ten new Member States joined the European Union, a new European Parliament was elected and a new European Commission took office.**

**The past year also marked a potential turning point in the fortunes of our industry, with the adoption of a revised regulatory framework governing the sector in the EU, publication of the EMEA's regulatory 'Road Map' and commitments to develop new or improve policies in other key areas such as the regulation of minor-use products and legislation governing residues.**



**Susanne Zänker**, Managing Director

IFAH-Europe and its members have campaigned tirelessly for many of these changes, but there remains much to be done if we are to ensure that the potential benefits offered by new policy initiatives are delivered in practice. Only then will we be in a position to reverse the fortunes of this sector.





Our industry plays a critical role in the protection of animal health and welfare, public health and the environment. It also makes a substantial contribution to the European economy by providing over 50,000 full-time jobs in the region. This figure has declined in recent years, however, and the industry's sales have remained flat while its costs have continued to rise.

Too often, regulations governing our industry have been modelled on those developed for the human pharmaceutical sector. While the two industries may share close scientific links, they are very different in terms of financial resources and market size<sup>1</sup>. For example, the research and development (R&D) budget available to the world's leading human pharmaceutical company is seven-times higher than R&D funds available to the whole of the animal health industry.

2005 marks the mid-term review of the Lisbon Agenda, under which Member State governments have vowed to reform European markets. Their goal is to transform the region by 2010 into 'the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs, greater social cohesion and respect for the environment'.

If its potential contribution to this transformation is to be realised, our industry must remain both competitive and innovative. That is why IFAH-Europe supports fully the establishment of a regulatory framework capable of safeguarding animal health and welfare, public health and the environment, but proportionate and efficient in nature, enabling the continued development of the industry.

With a new European Parliament and Commission in place, ten new governments participating in EU debates, and new initiatives being pursued in the fields of innovation and research, we have a unique opportunity to help determine the nature of the operating environment that our industry will face in future.

We look forward to leading IFAH-Europe in this exciting period, and to working with the many dedicated representatives of our member companies and associations, who are the basis of the federation's work and contribute so much to it.

*March 2005*

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<sup>1</sup> See page 14

# ACTIVITIES AND ACHIEVEMENTS IN 2004



**IFAH-Europe focuses its resources on three strategic areas in which, by co-operating with regulators and other stakeholders in the pharmaceutical and agricultural sectors, it aims to promote a predictable, harmonised, science-based and innovation-friendly operating environment that encourages the development and provision of quality animal medicines, vaccines and other animal health products.**

**The three strategic areas are:**

- **Regulatory affairs**
- **Food chain issues**
- **Communications**

The federation's major activities and achievements in each of these areas during 2004 are discussed in this document.

## **Regulatory affairs**

**New legislation:** The most significant event in the regulatory sphere during 2004 was the adoption on 31 March of revised EU legislation governing pharmaceutical products. IFAH-Europe's efforts to secure changes that will benefit the animal health industry were rewarded in several areas.

Major achievements included:

- Obtaining harmonised ten-year data protection and other incentives to support investment and innovation;
- Maintaining access to a choice of licensing procedures; and
- Securing the provision of streamlined marketing authorisation, renewal and referral procedures.

Since the publication of final texts, the federation has conveyed its position on key issues where interpretation of the new regulations will have a major bearing on its impact for the animal health industry, including the operation of new mutual recognition and decentralised registration procedures, avoiding repeated renewals, promoting good manufacturing practice for active substances and strengthening pharmacovigilance.



IFAH-Europe will continue to liaise closely with regulators during the implementation phase of the new legislation. Its efforts have already paid dividends, with the new Regulation on fees; in response to the convincing case put forward by the federation, there will be no significant increase in fees levied on the animal health industry. An 'initiator pays' clause has also been inserted for referrals from the decentralised and mutual recognition procedures and referral time-lines have been halved.

**EMEA road map:** In anticipation of the adoption of a new Regulation governing its activities and responsibilities, and in preparation for the accession of 10 new Members States, the EMEA released proposals for its strategic Road Map to 2010. IFAH-Europe responded positively to this initiative during 2004, welcoming measures that will encourage innovation and lead to a stable and predictable regulatory environment. The federation will continue to address the need for a reduced regulatory burden while maintaining a high level of safety.

**MUMS policy:** During 2004 the EMEA Committee for Veterinary Medicinal Products (CVMP) issued a policy paper on minor use/ minor species (MUMS) veterinary medicines. The paper, which sets out a strategic action plan for improving the availability of these medicines, recognises almost all of the key points raised by IFAH-Europe during discussions on this issue, and represents a major step towards addressing the veterinary medicines availability issue.

#### **Review of residues legislation:**

The review of EU residues legislation during 2005 announced by the European Commission will present further opportunities to improve regulatory process efficiency. IFAH-Europe responded to the 'Reflection Paper' during 2004 and subsequently submitted detailed proposals to the Commission on this issue. The federation will make the case for inclusion in the final proposals of measures that encourage broader use of maximum residue limit (MRL) extrapolations, a more consistent approach to residue monitoring in the Member States, and appropriate protection for MRL data.

#### **Commitment to pharmacovigilance:**

The most important element of product safety is monitoring in the marketplace. IFAH-Europe is committed to the implementation of a comprehensive and responsible pharmacovigilance system across Europe. With this in mind, in April 2004 the federation launched a Good Veterinary Pharmacovigilance Practice Guide for the European Animal Health Industry.



**Technical guidelines:** IFAH-Europe continued to liaise closely with regulators on the development of technical guidelines during 2004 with the aim of ensuring that guidelines and standards applying to the industry are fair, practical and workable.

As an example, the federation negotiated the redrafting of proposals for vaccine batch testing which, had they been adopted in their original form, would have increased manufacturer costs by around € 150,000 per batch. Furthermore, regulators agreed to conduct a full impact assessment of amended provisions before they are adopted. This highlights the need for a revised approach to the development of guidelines applying to the industry.

IFAH-Europe has also called for the introduction of a 'need' clause where guidelines are concerned, and the implementation of rigorous, transparent impact assessments before new guidelines are developed and implemented.

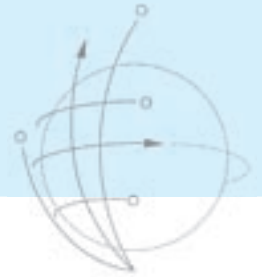
**Co-operation and communication:**

The federation's commitment to co-operative partnerships with regulators and fellow stakeholders saw it involved in a succession of formal and informal meetings during the year. These included meetings with the CVMP and its working parties, the heads of Europe's medicines regulatory agencies and the Veterinary Mutual Recognition Facilitation Group (VMRFG). IFAH-Europe undertakes regular joint surveys of the MRP and centralised procedures in partnership with the VMRFG and CVMP respectively, to measure and improve regulatory process efficiency.

Results of the most recent surveys were presented at a joint EMEA/IFAH-Europe 'Info Day' in December. This was one of several such events held during the year, at which regulators and the industry exchanged information and ideas on a range of key issues.

IFAH-Europe also played a lead role in the development of an initiative designed to deliver improved vaccines and diagnostics for the control of animal diseases. The federation and its members met with regulators, research institutions, the biotechnology industry and other interested parties in December with a view to encouraging and accelerating the development of innovative disease control tools within the framework of the industry-lead European technology platform for global animal health.





**Antibiotics:** The federation and its members have strived to ensure that stakeholders' discussions on the use of antibiotics in animals are balanced and based on accurate scientific information. It is also working actively to improve our understanding of antibiotic resistance mechanisms and the prevalence of resistance. The federation is supporting a programme to monitor susceptibility of zoonotic bacteria in animals, while its members are undertaking risk assessments on several active ingredients used in veterinary medicine. IFAH-Europe is committed to the responsible use of these products, which are a valuable tool in the maintenance of animal health and welfare and the supply of safe food.

**International harmonisation:**

The federation represents the European industry in meetings with a range of international bodies, including the WHO, FAO, OIE and Codex Alimentarius Commission. It is also an integral part of the International Co-operation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) - an international initiative established in 1996 to harmonise approaches to the technical standards of animal health products in the world's major market regions. These activities aim to facilitate at long term the global trade of animal health products and of foodstuffs of animal origin.

IFAH-Europe sits on the VICH steering committee, which developed its strategy for the next five years at its 15th meeting, held in October 2004. VICH has adopted 33 harmonised guidelines since it was established, and will continue to develop new guidelines during the period to 2010. It will also step up monitoring and updating of existing harmonised standards, however, and will place increased emphasis on cost/benefit analysis of existing harmonisation initiatives. Discussion of existing guidelines and the elaboration of VICH's future work plans will take place at the VICH 3 international conference, to be held in May 2005.



## Food chain

**One of IFAH-Europe's main goals is to position the animal health industry as a widely-recognised and respected voice in debates and decision-making processes at European level. The federation already interacts closely with regulators in the sector, but is working to forge stronger links with other food chain stakeholders, encouraging dialogue between our industry and other interested parties, and building alliances where common interests exist.**

**IFAH-Europe prioritised three major categories of issues in the food chain, namely, food safety, responsible use of animal health products, and animal health and welfare. Responses to these issues will continue to be developed in 2005.**

**Stakeholder alliances:** Relationships with fellow stakeholders were strengthened significantly in 2004 through IFAH-Europe's active input to the European Agri-Food Network (EAFN) and its associate membership of the European Initiative for Sustainable Agriculture (EISA). Through EAFN, IFAH-Europe is encouraging the development of a European platform for the responsible use of veterinary medicines in agriculture.

**Relations with consumers and regulators:** Relations with other partners in the food chain, including regulators and consumers, were also strengthened in 2004. IFAH-Europe developed its relationship with the European Consumers Organisation (BEUC) in order to promote a better understanding of the role played by our industry. The federation also reinforced its relationship with the European Food Safety Authority (EFSA) through direct dialogue between IFAH-Europe's members and EFSA's Executive Director, Geoffrey Podger.



**Traceability initiative:** Our industry's determination to play a leading role in the development of initiatives that will benefit all stakeholders in the food chain was underlined in October, when the IFAH Board endorsed the introduction of a new bar code system that will allow identification of animal health products. The system will initially be implemented in Europe, where its introduction is expected within the next three years. The system chosen is designed to be applied throughout the world as a function of local requirements. The initiative, which has been welcomed by authorities and stakeholders in Europe, demonstrates the willingness of our industry to respond positively to calls for more transparent information on the origins of animal-derived food products.

## Communications

**Effective communication, both within our industry and with third parties, is vital if we are to contribute fully to debates and decision-making processes in the European animal health and food safety sectors. IFAH-Europe has enhanced the flow of information between its members and stakeholders to consolidate its position as a reliable and effective partner in animal health matters.**

**New contacts:** The changing political environment in Europe meant that 2004 was a particularly busy year for the federation, which oversaw the development of contacts with new Member State governments and regulators, new MEPs and the new Commission, in addition to managing a range of existing projects.

**New communication tools:** IFAH-Europe expanded its range of communication tools. An IFAH-Europe Facts Card providing key information on our industry was added to the existing communication tools, while an IFAH-Europe section was established on the EUpolitix website.

IFAH-Europe publications include a brochure on the marketing authorisation process for veterinary medicinal products in Europe, and a good veterinary pharmacovigilance practice (GVPP) guide for the European animal health industry.

IFAH-Europe co-sponsored a brochure on agriculture in the new EU Member States produced by the European Council of Young Farmers (CEJA).

# CHALLENGES FOR THE FUTURE



**Many of the topics addressed by IFAH-Europe in 2004 have yet to be fully resolved, and will continue to feature in our plans for 2005 and beyond. In addition to the Lisbon agenda, new policies and issues are also emerging, notably the development of the Community Animal Health Policy and the implementation of the reformed Common Agriculture Policy. These will demand timely and incisive input from our industry. Priorities for 2005 will include:**

## Regulatory affairs

- Continued work on issues relating to the new legislation governing veterinary pharmaceuticals to ensure its implementation in a harmonised and positive manner.
- Following up our initial submission to the European Commission on the review of existing residues legislation, with a view to ensuring that our industry benefits from proposed changes.
- Monitoring technical guidelines for licensing and testing (i.e. vaccine batch controls) to ensure that they are practical, workable, and will not impose unnecessary regulatory or financial burdens on our industry.
- Progressing the harmonisation of international standards (VICH, Codex, OIE).







## Food chain

- Further development of the industry-led traceability project, with a view to the introduction of a bar code system for animal health products across the EU within the next three years.
- Consolidation of IFAH-Europe's position as an active member of alliances with other stakeholders in the food chain.
- Supporting the establishment of a Europe-wide initiative on the responsible use of veterinary medicines in agriculture.

## Communications

- Increasing the awareness of the authorities on the animal health industry's need to be competitive and innovative through the organisation of events, for example, with the European Parliament, the European Commission and the Heads of Medicines Agencies (HMA) in 2005.
- Elaborating a proposal for a Strategic Research Agenda to the European Commission to further develop the European technology platform for global animal health.
- Expanding the range of communication tools available to the federation and its members, including the publication of a new comprehensive booklet containing facts and figures on the European animal health industry and documents on the federation's food chain priority.

# FACTS AND FIGURES ON THE EUROPEAN ANIMAL HEALTH INDUSTRY



## Employment

The animal health industry supports more than **50,000** full-time jobs<sup>1</sup> in Europe, including:

- **+/-15,000** directly in production, marketing, sales, administration and research and development (R&D);
- **+/-18,000** indirectly as a result of the industry's purchases of goods and services, including contract R&D, logistics, capital equipment and raw materials;
- **+/-17,000** through its 'multiplier effect' on employment.

*(each € of expenditure on goods and services by direct employees of the industry creates additional employment in other sectors, especially services)*

## Sales

**Total European sales** amounted to **US \$ 4,800 million, 35 %** of the worldwide sales in 2004.

**Western Europe**<sup>2</sup> represented **30.9 %** and **Eastern Europe**<sup>3</sup> **4.3 %** of the total sales in Europe.

*(Source: Wood Mackenzie Ltd, 2005)*

<sup>1</sup> This estimate excludes the distribution of veterinary medicinal products in livestock farming.

<sup>2</sup> Western Europe includes EU-15, Norway, Switzerland, Iceland and Greenland.

<sup>3</sup> Eastern Europe includes: Central and Eastern European Countries and Former Soviet Union.



## Research and Development

### Investment

- **+/-12%** of turnover for multinational companies in Europe;
- **+/- 6%** of turnover for small and medium-size enterprises in Europe.

### Costs

- Time to bring a new product to market **5 to 11 years;**
- Costs to bring a new product to market **Up to € 50 million;**
- Percentage of R&D budget spent on keeping existing products on the market (defensive R&D) **35%** in Europe; **16-18%** in the USA.

## Animal health products and food animals

Only healthy animals produce safe and wholesome food.

A reduction in the use of veterinary medicinal products would require a larger food animal population to obtain the same production level. For example, veterinarians believe that in a situation without veterinary medicines, the poultry population would have to increase by **25%** and the cattle population by **89%** to maintain production at current levels.

In a situation without veterinary medicines, animals would suffer.

Considering the additional production that would be required, as well as the additional output in manure, it is obvious that veterinary medicines contribute significantly to animal health and welfare as well as to the protection of the environment.

*Conclusions of the study 'How do animal health products contribute to economic and environmentally-friendly livestock farming' by Prof. Jacques Viaene, Ghent University.*



## Animal health products and companion animals

Keeping our companion animals healthy and treating them with dignity is one of our objectives and is a contribution to society. This also applies to livestock and wild animals.

Recent research has demonstrated that the human/animal interaction benefits human physical, emotional and psychological well-being.

As an example:

- In the EU alone, more than 13,000 assistance dogs help blind and deaf people as well as other handicapped persons in their daily life.
- Therapy horses are used to help treat people with mental and physical disabilities.

## Comparison with the human pharmaceutical industry

The human and veterinary pharmaceutical industries share many close scientific links. This has encouraged regulators to impose similar regulatory requirements on the two sectors, and most of the legislation governing the European animal health industry is modelled on rules developed for its human pharmaceutical counterpart. The financial resources available to the two industries - and their ability to bear such a regulatory burden - are significantly different, however.

For example:

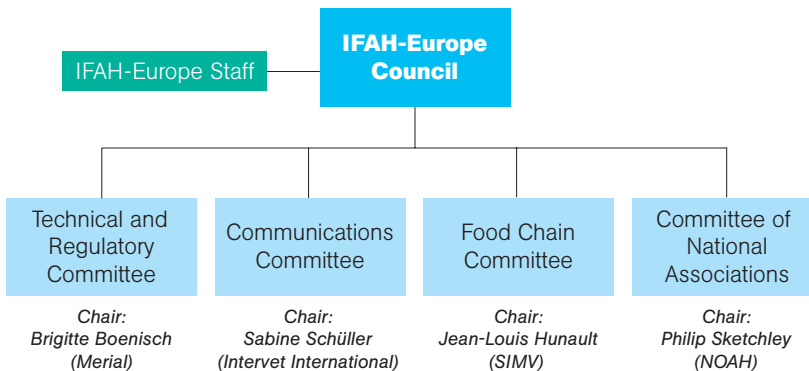
- At more than \$ 550,000 million, global sales of human drugs are some 40-times higher than those of veterinary medicines.
- Revenues generated by the world's best-selling human drug are equivalent in value to around three-quarters of the entire world market for animal health products.



# IFAH-EUROPE'S STRUCTURE



The IFAH-Europe Council (IEC) is the federation's decision-making body. It is supported by a Brussels-based secretariat and four operating committees (the Technical and Regulatory Committee, the Communications Committee, the Food Chain Committee, and the Committee of National Associations). These in turn are supported by a series of working parties and ad hoc groups.



# MEMBERSHIP



## IFAH-Europe Council from March 2005

**Brian Clark** (Chairman)  
Virbac

**Pierre Scarcériaux** (Vice-Chair)  
Janssen Animal Health

**Martin Schneidereit** (Vice-Chair)  
BfT - Bundesverband für Tiergesundheit,  
Germany

**Folkert Kamphuis** (Treasurer)  
Pfizer Animal Health

**Santiago de Andrés**  
VETERINDUSTRIA - Asociación Empresarial  
Española de la Industria de Sanidad y  
Nutrición Animal, Spain

**Jean-Louis Hunault**  
SIMV - Syndicat de l'Industrie du Médicament  
Vétérinaire et Réactif, France

**Declan O'Brien**  
APHA - Animal and Plant Health Association,  
Ireland

**Philip Sketchley**  
NOAH - National Office of Animal Health,  
United Kingdom

**Hugo Wahnish**  
Schering-Plough Animal Health

**Jochen Wieda**  
Intervet International

## IFAH-Europe membership

### Corporate members as at March 2005

Alpharma Animal Health Division  
Bayer HealthCare, Animal Health Division  
Boehringer Ingelheim Animal Health  
Ceva Santé Animale  
Elanco Animal Health  
Fort Dodge  
Intervet International  
Janssen Animal Health  
Merial  
Novartis Animal Health  
Pfizer Animal Health  
Schering-Plough Animal Health  
Vétoquinol, Laboratoire Pharmaceutique  
Vétérinaire  
Virbac

### National Associations as at March 2005

**Belgium:** PHARMA.BE - Association Générale  
de l'Industrie du Médicament

**Croatia:** VETERINA Animal Health

**Denmark:** VIF - Veterinaermedicinsk  
Industriforening

**France:** SIMV - Syndicat de l'Industrie du  
Médicament Vétérinaire et Réactif

**Germany:** BfT - Bundesverband für  
Tiergesundheit



**Greece:** HAVEPHARM - Hellenic Association of Veterinary Pharmaceutical Manufacturers

**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

**Poland:** POLPROWET - Polskie Stowarzyszenie Zagranicznych Producentów i Importerów Leków Weterynaryjnych

**Portugal:** APIFARMA - Associação Portuguesa da Indústria Farmacêutica

**Slovenia:** WAH - Working Group for Animal Health

**Spain:** VETERINDUSTRIA - Asociación Empresarial Española de la Industria de Sanidad y de Nutrición Animal

**Switzerland:** SGCI/SSIC - Schweizerische Gesellschaft für Chemische Industrie

**United Kingdom:** NOAH - National Office of Animal Health

## IFAH-Europe secretariat as at March 2005

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