

Improving the quality of life  
for animals and people





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 medium-size enterprises (SMEs) and international companies. IFAH-Europe's Membership covers 95% of the European market for veterinary medicinal products.

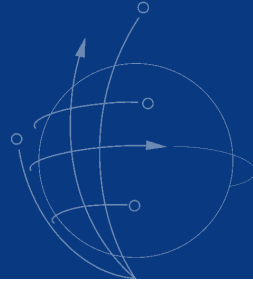
## **IFAH-EUROPE'S MISSION**

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 industry, encourages constructive dialogue with governments, public policy makers, legislators, regulators, non-governmental organisations, the veterinary profession, the food chain, consumers and other stakeholders.

# IFAH-EUROPE IN 2003

a message from the  
IFAH-Europe Council



In 2003, IFAH-Europe continued to work towards its goal of improving the quality of life for animals and people by successfully addressing the strategic priorities that were identified in 2002, namely:

**Regulatory Affairs**, comprising regulatory process efficiency, international harmonisation, risk/benefit analysis and medicines availability, including the availability of antimicrobials.

**Food Chain**, emphasising the positioning of our industry as a recognised credible voice that influences decision making in the food sector on animal health issues and working towards the supply of safe and wholesome food.

**Image Management**, IFAH-Europe being a source of reliable information for stakeholders that contributes to society within a shared set of values.



## **The Way Forward**

Medicines and other animal health products improve the quality of life and welfare for both animals and people. As such, IFAH-Europe is committed to ensure that the industry's core values are adhered to and that the benefits which the animal health industry offers to society are acknowledged.

As of 1 May 2004, the European Union increased its Membership from 15 to 25 Member States. This clearly has a significant impact on our industry and reinforces the need for us to continually strengthen our activities in the networking area.

Additionally, the election of the new European Parliament in June 2004, coupled with the appointment of a new European Commission in November offers our industry new opportunities to demonstrate its contribution to improving the quality of life for animals and people.

## **Acknowledgements**

We would like to thank both our Members and our employees for the excellent work and achievements accomplished throughout the year. We are sure that our efforts shall result in continued success this year and beyond.

# REVIEW OF ACTIVITIES 2003



The European Union is an important legislative centre generating regulatory and social policies that not only impact its Member States, but also have high significance throughout the world.

As such, our networking potential in the EU has been used efficiently and effectively on our three strategic priorities.

## REGULATORY AFFAIRS

### Regulatory process efficiency

- Veterinary regulation review: IFAH-Europe continued its efforts to provide input to the review at the EU institutions – European Commission, Council and Parliament – throughout 2003.

Our efforts were rewarded when final proposals were adopted by the European Parliament in December 2003 and by the Council of the European Union on 11 March 2004.

The major achievements for our industry include:

- Obtaining harmonised 10-year data protection and other incentives to support investment in innovation.
- Maintaining a choice in the licensing procedures.
- Streamlining of marketing authorisation renewal process.







An additional success was the avoidance of an extended period of legal uncertainty that may have resulted from a delay in the adoption of the package beyond EU enlargement on 1 May 2004.

- Technical guidelines on data requirements: Through dialogue with the EMEA and the European Pharmacopoeia, IFAH-Europe made a significant input in setting technical guidelines and monographs on data requirements for animal health products with regard to their quality, safety and efficacy. Forty position papers were delivered to the EMEA and the European Pharmacopoeia on this matter.
- Medicines availability: IFAH-Europe has actively participated in conferences on medicines availability and was the driving force in initiating alliance building with farmer and veterinarian organisations and minor species breeder groups.
- Pharmacovigilance: IFAH-Europe demonstrated the industry's strong commitment to the pre- and post-approval surveillance of animal health products. With this in mind, it developed the Good Veterinary Pharmacovigilance Practice Guide for the European animal health industry. This was launched in April 2004 and was welcomed by the Authorities as a positive contribution to the joint effort to promote veterinary pharmacovigilance in Europe.
- Info days: IFAH-Europe jointly organised info days with the EMEA and HEVRA to discuss improvements to the efficacy of the licensing procedures and to consider and explore important emerging issues. The discussions were based on the joint surveys aimed at measuring the qualitative and quantitative performance of these procedures.



## **International harmonisation**

- IFAH-Europe continued to participate actively in discussions within key international organisations. At Codex Alimentarius, industry's views on the risk assessment procedures and the importance of science-based decisions were emphasised. For the international harmonisation of technical requirements within the VICH process, several topics were successfully completed allowing for discussion on the future process, such as guidelines on antibiotic resistance and safety.

## **Antimicrobial availability**

- IFAH-Europe actively participated in the international symposium "Towards a Risk Analysis on Antibiotic Resistance" in Berlin in November 2003 and stressed the message that antibiotics contribute significantly to food safety, as only healthy animals should enter the food chain.
- During the year IFAH-Europe has continued to be proactive in investigating antibiotic resistance issues by:
  - Supporting a programme to survey and monitor susceptibility of zoonotic bacteria in animals.
  - Members undertaking risk assessments on several active ingredients.





## FOOD CHAIN

- One focus of IFAH-Europe's priorities in 2003 was to position our industry as a recognised, credible voice in decision making on animal health issues. In 2003 the basis was formed to actively interact with food chain stakeholders to ensure that they are aware of our industry's role and contribution to the sector by:
  - Identifying corporations and organisations in the food chain and developing the animal health industry's relationships with them.
  - Developing a database of these corporations and organisations in order to facilitate more effective communications and assistance to them.
  - Identifying key issues to the food chain and appropriate tools to address such issues.
- A concrete example of IFAH-Europe's engagement in this priority is its regular dialogue with the EAFN. The EAFN provides a

platform in the European Union at which senior Members of stakeholders' organisations are able to discuss items of common interest and create alliances.

- In October 2003, the federation identified "traceability" as a strategic issue for our industry that should be managed by the IFAH-Europe Food Chain Committee. In November 2003, the Food Chain Committee created a Traceability Working Group, which has:
  - Clarified legal obligations and liabilities for the animal health industry regarding this topic.
  - Developed a concept project for the traceability of veterinary medicinal products, which it aims to develop in 2004 into a more defined proposal.
- The CEESA barcode project has received a favourable overall reaction by the European Commission's Services as a first stage of the traceability project.

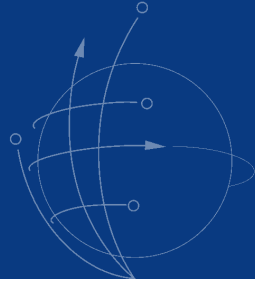


## IMAGE MANAGEMENT

- The Communications Committee (Comcom) focused on the development of basic communications materials and internal communications structures for IFAH-Europe.

Amongst the communications materials developed during the year were:

- A PowerPoint presentation and a booklet entitled "Introducing IFAH-Europe". These materials include a series of core messages reflecting our industry's values. Both the presentation and the booklet have been highly successfully used at internal and external events and meetings.
- The IFAH-Europe website ([www.ifahsec.org/Europe](http://www.ifahsec.org/Europe)).
- A new IFAH-Europe exhibition stand that was first used at the DIA International Animal Health Conference, which was held in October 2003 in Nice.
- Standard operating procedures (SOPs) detailing the preparation and approval of IFAH-Europe press releases, rapid response statements and supporting documentation.
- Internal consultation and approval procedure for political position papers.
- The Communications Committee is continuing to develop a facts and figures brochure and card as well as an issue and crisis management protocol, the latter having recently been adopted by the IEC.
- It supported IFAH-Europe in developing various press releases on animal health topics including the veterinary regulation review.



- A highly successful reception for Members of the European Parliament and representatives of the Member States' national governments was organised for July 2003 as a part of IFAH-Europe's input to the veterinary regulation review.
- During the year, a survey aimed at providing a snapshot of stakeholders' perceptions of the industry was developed. This survey will be conducted in 2004.
- The Committee began to develop a far-reaching Communications Plan for 2004-2005 with actions to be taken in support of the federation's three priority areas.



# CHALLENGES FOR THE FUTURE



Action plans have been developed for the strategic priorities identified in 2002, namely, Regulatory Affairs, Food Chain and Image Management. 2004 shall witness the continued implementation of these plans, including:

## Regulatory Affairs

- The implementation of the veterinary legislative package must be ensured in a harmonised and positive way, particularly in light of EU enlargement.
- The Services of the European Commission released a reflection paper on residues in foodstuffs of animal origin. The aim of the exercise is to balance consumer protection, animal health, welfare and trade requirements.

This represents a significant opportunity for IFAH-Europe to contribute to the process at an early stage.

- IFAH-Europe, with the support of its network of expert groups in each specialist area, will continue to develop position papers explaining the industry's views on regulatory process efficiency in Europe, particularly in view of EU enlargement. Special attention shall continue to be given to new or revised guidelines on the registration procedures and data requirements through both oral (hearings and info days) and written means.

## Food Chain

- IFAH-Europe's achievements shall be consolidated by actively interacting with other food chain stakeholders of strategic importance.
- IFAH-Europe's traceability project shall be further developed. The ability to trace our products represents the actions of a responsible industry.



## Image Management

- The actions already developed in IFAH-Europe's Communications Plan, addressing such diverse events as EU enlargement, elections to the European Parliament and the appointment of the new European Commission, shall be undertaken.
- IFAH-Europe shall ensure that the contribution of the industry it represents to improving the quality of life for animals and people is appropriately taken into consideration by decision makers in both the public and private sectors.

## ACRONYMS

CEESA - European Animal Health Study Centre

DIA - Drug Information Association

EAFN - European Agri-Food Network

EMA - European Agency for the Evaluation of Medicinal Products

HEVRA - Heads of European Veterinary Regulatory Authorities

VICH - International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products

# MEMBERSHIP



## Member Associations as at 31 December 2003

**Belgium:** PHARMA.BE – 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 – 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

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

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

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

**Sweden:** LIF – Läkemedelsindustriföreningen

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

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

## Corporate Members as at 31 December 2003

Alpharma Animal Health Division

Bayer Healthcare

Boehringer Ingelheim Animal Health

CEVA Santé Animale

Elanco Animal Health

Fatro

Fort Dodge

Intervet International

Janssen Animal Health

Merial

Monsanto

Novartis Animal Health

Pfizer Animal Health Group

Schering-Plough Animal Health

Vétoquinol, Laboratoire Pharmaceutique Vétérinaire

Virbac



## **IFAH-Europe Council as at 31 December 2003**

Hervé Catillon, *Pfizer Animal Health Group*

Brian Clark, *Virbac*

Santiago de Andrés, *VETERINDUSTRIA – Asociación Empresarial de la Industria de la Sanidad y de la Nutrición Animal*

Jean-Louis Delforge, *Chairman*

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

Peter McCarthy, *Schering-Plough Animal Health*

Pierre Scarcériaux, *Janssen Animal Health*

Martin Schneidereit, *BfT – Bundesverband für Tiergesundheit*

Philip Sketchley, *NOAH – National Office of Animal Health*

Maritza van Assen, *FIDIN – Vereniging van Fabrikanten en Importeurs van Diergeneesmiddelen in Nederland*

Jochen Wieda, *Intervet International*

## **Officers as at 31 December 2003**

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**Representing the European**  
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