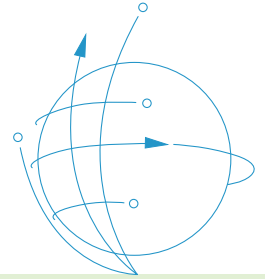


2005

**ANNUAL REPORT**







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

IFAH-Europe represents both corporate members and national animal health associations across Europe. These associations comprise local companies, SMEs, and international companies. IFAH-Europe's membership covers 95% of the European market for veterinary medicinal products.

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

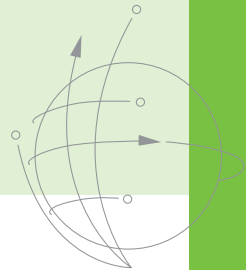
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**IFAH-Europe's mission is to promote a predictable, harmonised, science-based and innovative market place for the provision of quality animal medicines, vaccines and other animal health products, and so contribute to a safe food supply and to a high 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 agricultural sector, the food chain, consumers, and other stakeholders.

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

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**Whilst our industry has much to contribute to society, we can only deliver new, innovative medicines if the regulatory and business environment allows research and development to thrive. An efficient regulatory framework is essential to ensure that the EU enhances its position as a knowledge based economy. We look forward to continuing to work with European regulators to ensure that we have a licensing system that guarantees safety without incurring unnecessary complications and costs. Therefore we applaud the use of the Impact Assessment concept in the regulatory area, a process which requires any regulatory initiative to be subjected to a detailed 'needs' analysis including the option of taking no action. We also look forward to the review of legislation and guidelines on the interpretation of legislation over time, which allows all parties to assess the benefit or otherwise of each legislative proposal.**

The critical role of the animal health industry came into sharp focus in Europe during 2005 due to the spread of the H5N1 form of Highly Pathogenic Avian Influenza (HPAI). The socio-economic impact of epidemic zoonotic diseases such as HPAI is high. Society is very concerned from consumers at one end of the food chain to farmers at the other end. In addition, such diseases may also have a severe economic impact on the food chain. In this case the industry already produces vaccines that protect birds from this devastating disease. IFAH-Europe is actively involved with the European authorities in discussing suitable control strategies that the industry may help to deliver.

It is clear that society needs long-term planning for combating epidemic diseases and the development of new animal health products will be an important part of this strategy. Industry has been proactive in running the European Technology Platform for Global Animal Health (ETPGAH), which in July 2005 published a 'Vision 2015' paper describing the areas where research is needed in the animal health world. Experts were given the task of identifying the most important diseases and the critical research needs by disease. The outcome of these expert meetings is an action plan called the Strategic Research Agenda (SRA), which was released in May 2006.



**Brian Clark**  
Chairman



**Declan O'Brien**  
Managing Director

As many of the research priorities are likely to concern diseases that occur rarely, industry funding alone may not be sufficient. Public funding should be an important constituent in the overall funding of such research.

2005 has been another busy year for IFAH-Europe. Highlights included our conference in June focusing on the Lisbon Agenda and imparting the message that we have a significant contribution to make to the future growth of the EU economy via employment and exports. We also welcomed the opportunity to participate as a stakeholder in a number of meetings with the EU institutions including the DG SANCO Advisory Group on the food chain and animal health, and the consultative platform of the European Food Safety Authority (EFSA). We look forward to strengthening our relations with DG SANCO and EFSA in 2006. We also appreciated the opportunity to work with other stakeholders to highlight the safety of food from vaccinated animals. This initiative was started by COPA/COGECA in response to the concerns expressed by UK consumers at the idea of vaccinating food-producing animals against Foot-and-Mouth Disease. It is vital to highlight the fact that produce from vaccinated animals is perfectly safe.

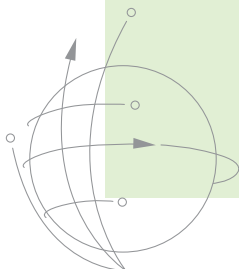
We very much value working with the European Medicines Agency (EMA) and are pleased they regard us as a key stakeholder in the regulatory process. We look forward to continuing to organise joint Information Days as we did in 2005 and in previous years.

IFAH-Europe also initiated a stakeholder dialogue called EPRUMA (European Platform for the Responsible Use of Medicines in Animals) towards the end of 2005 with the intention of creating 'Best Practice Guides' on the use of different types of animal health products. At the outset, we are working with the European farming (COPA/COGECA) and veterinary (FVE) organisations and look forward to broadening this dialogue during 2006. The outcome will be framework guides that can then be expanded at individual Member State level leading to common best practice guides across the EU.

The November IFAH-Europe first General Assembly underlined the renewed vigour of the animal health industry on the European level. By December, we also had a full team on board who look forward to delivering a busy programme of activities in 2006.

Finally, we appreciate working with very diverse contacts across the EU from the Commission to the Parliament to Member States and a wide range of animal health related stakeholders. We also thank our members for their continued and dedicated input and we will strive to carry out their wishes to the best of our ability into the future.

# ACTIVITIES AND ACHIEVEMENTS IN 2005



## **IFAH-Europe focuses its resources on three strategic areas:**

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

## **Regulatory Affairs**

The main aim of the work in Regulatory Affairs is to improve regulatory process efficiency, with a particular emphasis on reducing time and cost to market. During 2005 this work focussed on the implementation of the new veterinary medicines legislation, monitoring the functioning of the regulatory procedures, and responding to draft guidelines, monographs, legislative proposals, and other documentation. The impact of both packaging and guidelines were identified as key areas.

## **New pharmaceutical legislation:**

IFAH-Europe has focused on the implementation of the new EU veterinary pharmaceutical legislation (Directive 2004/28/EC) to ensure that the new legislation is transposed into national legislation in the 25 EU Member States in the most efficient, harmonised and workable way possible. The association's work in this area included:

- Comments on veterinary mutual recognition facilitation (VMRF) best practice guidelines for the decentralised procedure;
- Response to the proposed scope of the application of Good Manufacturing Practices (GMP) for active pharmaceutical ingredients (API) including an exemption for ectoparasiticides;
- EMEA agreement for a phase-in implementation of EudraVigilance Vet for Gateway users;
- Response to the Commission's draft penalties regulation;
- Response to the Commission's draft guideline on defining serious risk in the context of the mutual recognition and decentralised procedures;
- Response to Official Control Authority Batch Release (OCABR) proposals for veterinary vaccines.



### **Mutual recognition procedure :**

In November 2005, IFAH-Europe in collaboration with the Veterinary Mutual Recognition Facilitation Group (VMRFG) published a survey on the 2004 mutual recognition procedures (MRPs) for veterinary products. There were significantly fewer applications during 2004 compared to 2003 and 2002, particularly with regard to companion animal pharmaceutical products (55 MRPs in 2004 vs. 87 and 94 in 2002 and 2003). A number of key issues identified by the survey were followed up with the VMRFG.

### **Review of residue legislation :**

IFAH-Europe participated in a stakeholders meeting organised by the Commission to discuss 'avenues to explore' on proposed revisions to the legislation on residues in foodstuffs of animal origin. IFAH-Europe also provided input to the impact assessment for these outline proposals, including supporting the establishment of a list of 'other legitimate factors' for certain justified risk management decisions as long as they are based on scientific criteria, and using Codex MRLs (maximum residue limits) for substances not having EU MRLs.

**EMEA fees:** IFAH-Europe is pleased that the EMEA will limit increases in veterinary fees to 10%. The association had presented a comprehensive position paper in 2004 objecting to the initial proposed change in fees, which would have been equivalent to a 100% increase on current fees.

### **EU level partnership to reduce animal testing :**

In December 2005 IFAH-Europe joined forces with the European Commission and six other industry associations in the 'European partnership to promote alternative approaches to animal testing'. The partnership launched its '3Rs' declaration aimed at refining, reducing or replacing animal use in November 2005.

**Antimicrobials :** IFAH-Europe was very active in the area of antimicrobials during 2005. The federation responded to a number of guidelines including :

- CVMP (Committee for Medicinal Products for Veterinary Use) draft guideline VICH GL 27 (CVMP/VICH 644/01) on antimicrobial resistance;
- CVMP Concept Paper on revision of the current guideline on the SPC for antimicrobial products.

In addition, IFAH-Europe commented on the make-up of the Special Advisory Group on Antimicrobials (SAGAM) and its relationship with CVMP, resulting in a meeting between IFAH-Europe, the CVMP and SAGAM. The outcome of the meeting was a confirmation that more clinicians would participate in the work of SAGAM on an ad-hoc basis and that the SAGAM role is to advise the CVMP.

IFAH-Europe has also monitored developments of the VETCAST (Veterinary Committee on Antimicrobial Susceptibility Testing) group and encouraged the group to consider clinical breakpoints for antimicrobials



as well as epidemiological cut-off points. In taking this position, IFAH-Europe has also raised this issue at the VICH and collaborated with the Clinical and Laboratory Standards Institute (CLSI) with regard to their approach for setting epidemiological breakpoints.

In Autumn 2005, the WHO decided to identify the antimicrobials which are critical for human therapy. IFAH-Europe prepared a general critique on the WHO critical list of Antimicrobials that was passed on to the IFAH Global Antimicrobial Core Team (GACT). IFAH-Europe updated previous Prudent use guidelines for use by the GACT and the EPRUMA (European Platform for the Responsible Use of Medicines in Animals) group.

The Association has monitored and provided input to the Antimicrobials Volumes Collection managed by CEESA (European Animal Health Study Centre), which collects data on the volume of antibiotics sold by IFAH-Europe/CEESA member companies. Surveys were undertaken in 2002 and 2004. In addition it has reacted to developments in Member States such as the Danish government's antibiotics 'list', the German bacterial collection, and the Spanish Authorities' requests for local isolates.

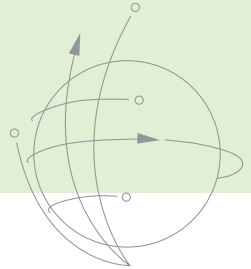
**Biologicals :** The association organised a meeting of interested parties on immunological standards and control bringing together the European Pharmacopoeia, the European Commission DG Enterprise, and the EMEA's Committee for Veterinary Medicinal Products (CVMP)'s Immunological Working Party (IWP). IFAH-Europe actively engaged

the European Commission and the European Pharmacopoeia in ongoing discussions aimed at the proportionate implementation of articles of the new European pharmaceutical legislation relating to the official control authority batch release of vaccines. An important aspect of these discussions is the elaboration of appropriate risk assessment criteria and impact assessment. In particular, the meeting addressed the necessity of full compliance with monographs, the six month time delay for compliance (agreed to be too short), and the possibility of adopting a system of concept papers for new monographs.

**Packaging :** IFAH-Europe published a discussion paper on packaging issues and organised a seminar with the Veterinary Mutual Recognition Facilitation Group (VMRFG) to examine possible solutions. The aim is to improve regulatory process efficiency and medicines availability, particularly in the smaller Member States. A follow-up workshop with the authorities will be organised in April 2006.

**Innovation :** IFAH-Europe published its position on innovation entitled '*IFAH- Europe perspective on the Lisbon agenda – enhancing innovation for the benefit of animals, people and the environment*', which was launched at the IFAH-Europe conference on the Lisbon agenda in June 2005. This paper identified the efficient transfer of research results and a predictable, science-based and harmonised regulatory framework as key elements to ensure competitiveness, innovation and sustainability in the European animal health sector.





IFAH-Europe successfully ran an EMEA/IFAH-Europe info-day on '*Nurturing innovation and sustainability in the European animal health sector*', which took place in October 2005. The association also conducted a survey on the impact of guidelines on innovation and sustainability giving examples of good and bad guidelines and suggesting points for future discussion, which was presented at the info-day.

**International Harmonisation:** In November 2005 the meeting of the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) Steering Committee discussed procedures for the maintenance of VICH guidelines, received regional reports on the implementation of VICH guidelines, reviewed the progress of several active VICH working groups, approved a number of key guidelines, and took decisions on proposed future VICH topics.

The Committee endorsed two Quality Guidelines (GL) for implementation by November 2006:

- VICH GL 39 on test procedures and acceptance criteria for new veterinary medicines and substances;
- VICH GL 40 on test procedures and acceptance criteria for new biotechnological/biological veterinary medicines.

Following an initial public consultation, the Committee also agreed on the following draft guidelines, which have since been subject to a second three-month consultation period:

- VICH Draft GL 24 on the pharmacovigilance of veterinary medicinal products: management of adverse event reports (AERs);
- VICH Draft GL 42 on the pharmacovigilance of veterinary medicinal products: data elements for submission of adverse event reports.

### **Pharmacovigilance**

IFAH-Europe actively contributed to a TAIEX (Technical Assistance and Information Exchange) meeting on Pharmacovigilance as part of the Commission's programme to provide technical assistance to the 'new' Member States and candidate countries.

Considerable efforts have been made by industry (Gateway users) and EMEA towards implementing the EudraVigilance system for electronic reporting of Serious Adverse Reactions.

IFAH-Europe initiated the revision of its Good Veterinary Pharmacovigilance Practice Guide (GVPPG); it is expected to be released in 2006 once additional implementation guidance is available, e.g. the guideline on compliance monitoring and inspection.

### **Quality/Inspections**

IFAH-Europe engaged some discussion with the CHMP/CVMP Quality Working Party (QWP) towards reviewing Quality guidance to better reflect the specificities of the animal health sector, some of which have already been acknowledged by the QWP.



## Food Chain

**IFAH-Europe has three key priorities for food chain issues:**

- **Food safety;**
- **Responsible use of animal health products;**
- **Animal health and welfare.**

**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 on the food chain at European level. The association interacts closely with regulators such as the European Food Safety Authority (EFSA) and food chain stakeholders such as the agricultural sector, food producers, retailers and consumers.**

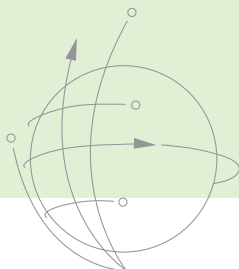
**Relations with regulators:** IFAH-Europe has been successful in obtaining associate member status of the EFSA stakeholder consultative platform. An IFAH-Europe representative attended the inaugural meeting of the consultative platform, which took place in October 2005 and the 'Stakeholder colloque' in November 2005. The platform is instrumental for our Federation to undertake dialogue with EFSA and other food chain related stakeholders on issues that have an impact on the animal health industry.

IFAH-Europe became a member of the European Commission DG SANCO Advisory Group on the Food Chain and Animal and Plant Health and attended its meeting in July 2005. Through this committee, IFAH-Europe was able to convey to the Commission industry's concerns about the negative consequences of the introduction of fees for EFSA's work and to express support for the view that EFSA should not charge fees.

**Stakeholder alliances:** IFAH-Europe built on contacts with the European consumer federation BEUC and the European retail federation EuroCommerce to promote a better understanding of the role played by the animal health industry.

IFAH-Europe is involved in several stakeholder alliances with organisations from the agricultural and agri-food industries, the veterinary profession and other branches of the pharmaceutical industry. In 2005, IFAH-Europe discussed issues such as the responsible use of medicines and the Community Animal Health Policy within the European Agri-Food Network (EAFN).

As a member of the European Initiative for Sustainable Development in Agriculture (EISA), IFAH-Europe has been active in EISA's working group on animal husbandry and has contributed to guidelines on integrated farming obligations.



**EPRUMA:** During 2005 IFAH-Europe joined forces with COPA-COGECA (farmers) and FVE (veterinarians) to create EPRUMA, the European Platform for the Responsible Use of Medicines in Animals. EPRUMA held its inaugural meeting in October 2005 and its second meeting in December 2005. EPRUMA's mission is to facilitate and promote a coordinated and integrated approach, involving all stakeholders, to ensure best practice in the responsible use of medicines in disease prevention and control. It aims are:

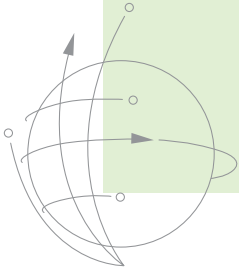
- To promote animal health and welfare through the responsible use of medicines in animals;
- To facilitate and promote a coordinated and integrated approach involving all stakeholders in order to ensure best practice in the responsible use of medicines in the prevention and control of animal diseases.

EPRUMA Plans for 2006 include communicating the initiative to further stakeholders and developing a best practice framework on antimicrobial use.

**Product Identification initiative:**

IFAH-Europe's commitment to greater transparency concerning the origins of animal-derived food products led to a 2004 decision to implement a product identification system by the end of 2007. During 2005 IFAH-Europe member companies undertook pilot projects to prepare for implementation of a product identification data matrix ECC 200. The data matrix for veterinary products will contain among other things, the registered selling unit (pack), details of the marketing authorisation holder, the batch number and expiry date. IFAH-Europe national associations conducted training sessions for IFAH-Europe member companies to explain how to implement it. One of the advantages of the data matrix is that it contains substantial product information in a very reduced space (4.5 x 4.5 millimetres).

**Position papers:** IFAH-Europe developed position papers on the contribution of the animal health industry and its products to food safety and animal welfare, as well as on the responsible use of animal medicines.



## Communications

**IFAH-Europe's communications strategy aims to ensure that the association is seen not only as the voice of the animal health industry, but also as a recognised, reliable and respected source of information on animal health issues.**

**Throughout 2005 IFAH-Europe has continued to undertake communications activities designed to support work in the areas of Regulatory Affairs and Food Chain in order to enhance dialogue with stakeholders and to consolidate IFAH-Europe's position as a responsible and effective partner in animal health matters.**

In doing so, IFAH-Europe has focused on optimising communication channels with other stakeholders such as the EU institutions and regulators as well as animal health related associations, for example those representing agricultural interests, consumers and veterinarians amongst others.

**New Communications tools:** During 2005 IFAH-Europe's work on communication tools included a number of publications and several events.

2005 IFAH-Europe **publications** include an updated '*Facts and Figures on the Animal Health Industry*', a leaflet explaining marketing authorisation procedures '*The Marketing Authorisation Process for Veterinary Medicinal Products in Europe*' and a dossier on animal vaccines '*Vaccines – protecting our animals*'. In addition several position papers related to food chain issues were published (see page 9 for more details).

IFAH-Europe's **events** in 2005 included the organisation of a successful conference on the animal health industry's contribution to the Lisbon Agenda in June 2005. Representatives of the animal health industry, the European institutions, national governments and other stakeholders including the agricultural sector and the veterinary profession discussed the importance of innovation for developing new products. IFAH-Europe stressed the importance of a predictable, science-based and harmonised regulatory framework as key elements to engender competitiveness, innovation and sustainability in the European animal health sector.

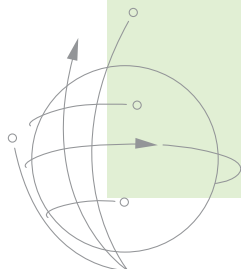


*IFAH-Europe's 'Healthy Happy Horse'*

IFAH-Europe participated in the 2005 Belgian Horse Parade with its 'Healthy Happy Horse', a model horse artwork designed by Belgian artist Véronique Sabban with the message 'Animals are good for you – be good to them'. This showed the animal health industry's commitment to improving the quality of life for both animals and people. In November 2005, the 'Healthy Happy Horse' was auctioned and the proceeds of the sale went to the Belgian charity Dyasis, which trains assistant dogs to help disabled people.

IFAH-Europe co-sponsored the TELLUS mission project led by the European Council of Young Farmers (CEJA) to promote knowledge of agriculture amongst primary school pupils in EU Member States. This included communicating the benefits of animal medicines in agriculture at a teacher seminar organised by CEJA at the European Parliament in Brussels in December 2005.

# EUROPEAN TECHNOLOGY PLATFORM FOR GLOBAL ANIMAL HEALTH



**More information on the ETPGAH is available at:**  
<http://www.ifaheurope.org/EUPlatform/Platform.htm>

**Encouraged and supported by the European Commission, IFAH-Europe has formed the European Technology Platform for Global Animal Health (ETPGAH) along with a wide range of stakeholders at national, EU and international level. The ETPGAH brings together different partners and organisations to define and promote a common research agenda that leads to the development of effective products for treating animal diseases, to improve animal health and to limit the negative social and economic impact that animal diseases can have on human health.**

The ETPGAH was launched at an event with European Commissioners Janez Potočnik (DG Research) and Louis Michel (DG Development). Its core aim is:

**‘To facilitate and accelerate the development and distribution of the most effective tools for controlling animal diseases of major importance to Europe and the rest of the world, thereby improving human and animal health, food safety and quality, animal welfare and market access, contributing to achieving the Millennium Development Goals.’**

Members of the ETPGAH include agricultural sector stakeholders such as COPA-COGECA (farmers), EFFAB (animal breeders) and EuropaBio (biotech), representatives of the EMEA (European Medicines Agency), international agencies such as the WHO, the OIE and the FAO, universities and research institutes, national government ministries and animal welfare groups.

The ETPGAH has a steering committee, an executive board, and a secretariat which is provided by IFAH-Europe. Three working groups have been established on (1) Mapping Research, (2) Technology Exchange and Transfer, and (3) Horizontal Issues.

In July 2005, the ETPGAH presented the ‘Vision 2015’ document outlining how the platform plans to move from innovation to delivery in order to achieve its core aims. The ETPGAH working groups met in 2005 to discuss the development of a Strategic Research Agenda (SRA).

## FUTURE CHALLENGES



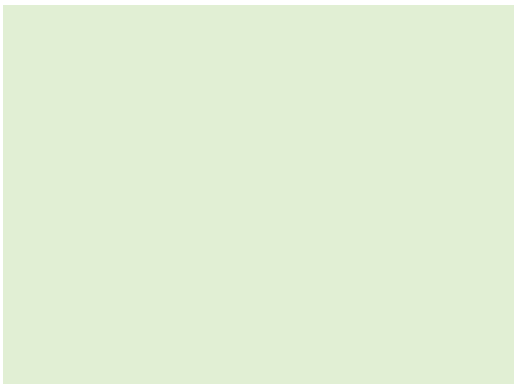
### Regulatory Affairs

IFAH-Europe's challenges in the area of regulatory affairs fall into a number of categories, some connected to existing legislation or regulatory procedures, and others related to areas where future regulation is likely to occur.

With regard to **existing regulation**, IFAH-Europe will pay close attention to the new decentralised procedure (DCP), introduced with the review of pharmaceutical legislation in 2001, which is designed to overcome some of the problems of the mutual recognition procedure. The Federation plans to conduct a survey amongst its members on the implementation and functioning of the DCP. Of particular interest is the issue of 'automatic arbitration', a procedure triggered when a serious issue raised by a Member State cannot be resolved during the DCP. It is not yet known how many DCPs will be delayed by arbitration, but it should be less than 10% and should result in long term improvement through greater harmonisation. IFAH-Europe is also negotiating for more flexible implementation of packaging rules, particularly where these limit the availability of products in small markets.

IFAH-Europe will follow with interest the debate on the review of the annex to Directive 2001/82/EC on veterinary pharmaceuticals and the review of Regulation 2377/90, which lays down procedures for the establishment of maximum residue limits for veterinary medicines in the EU. The Federation has recently submitted comments to the new annex to European Directive 2001/82/EC and hopes that this will lead to improvement. For the review of Regulation 2377/90, it is expected that the Commission will publish proposals during 2006 and IFAH-Europe hopes that points raised by industry will be taken into account. In addition, IFAH-Europe will respond with renewed effort to the European Commission's announcement of a review of the variation Regulations (governing procedures whereby marketing authorisation holders can vary a product license rather than apply for a new one), which is expected to begin in 2006.

With regard to advances in the international harmonisation of technical requirements through **international regulation**, IFAH-Europe plans to continue working to further enhance the CODEX system and to get the best out of the VICH. A large amount of effort is required to reach a harmonised guideline via the VICH process. It might be necessary to look at the cost-benefit ratio to ensure that the process delivers a positive balanced outcome. The challenge is to identify new areas that can be harmonised with a positive cost-benefit ratio, and to identify ways of improving the VICH process itself.

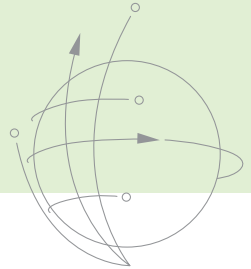


IFAH-Europe will monitor developments in several areas where **future regulatory challenges** might arise. In the short term, these efforts are likely to concentrate on guaranteeing the development of an appropriate accelerated assessment procedure and exceptional circumstances procedures, so that for example, Avian Influenza vaccines can be registered quickly without unnecessary regulatory or bureaucratic barriers. Another field is environmental risk assessment, where the science continues to grow and new technical issues may be found that could lead to new regulatory requirements. A further area is that of antimicrobial resistance where there are already several guidelines for the development of therapeutic indications. Future development may see similar regulation on antiparasiticides (anthelmintics and ectoparasiticides) and it will be important for the industry to work with regulators to ensure appropriate and proportionate requirements that help to combat the development of resistance.

IFAH-Europe's involvement in a European Partnership between seven industry associations and the European Commission to promote alternatives to animal testing through the '3Rs' strategy – reducing, replacing and refining - will require some detailed investigation ('mapping') as a first step. One aim of the partnership is to develop and validate in-vitro tests that can replace existing in-vivo studies. Regulatory authorities will need to approve the use of such methods.

IFAH-Europe will continue to communicate the important differences between the animal health sector and the human health sector to regulators. The animal health sector is quite distinctive with different drivers, requirements and restrictions, and a market size much smaller than the human health sector. Despite this, current regulation for the animal health sector is often modelled on that designed for the human health sector. IFAH-Europe will seek to encourage more appropriate adaptation of regulation to the specificities of the animal health sector.





## Food Chain

There are a wide range of challenges in the food chain area and most of them provide an opportunity for the animal health industry to collaborate with other stakeholders.

In the area of **product identification**, IFAH-Europe will oversee the introduction of the data matrix bar code system on the packaging of veterinary medicines by all IFAH-Europe companies before November 2007. IFAH-Europe will monitor the introduction over time and draw attention to any lag in implementation.

In response to the current animal health pandemic of **Avian Influenza**, IFAH-Europe will undertake efforts to ensure that stakeholders in the food chain understand the role of vaccination and the safety of produce from vaccinated animals. These efforts will include close contact with other food chain stakeholders such as BEUC, EuroCommerce and the CIAA. The animal health industry will also consider developing a paper on Avian Influenza and food safety in collaboration with representatives of the agricultural sector (COPA/COGECA, FVE and others).

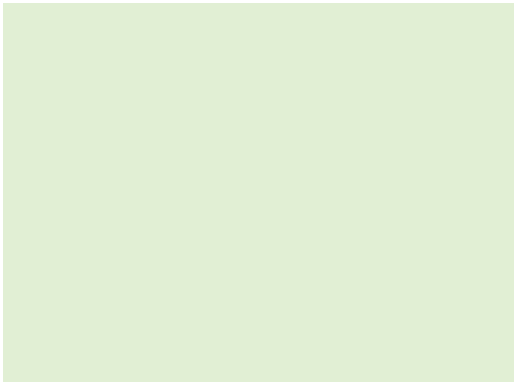
Specific stakeholder collaboration planned for 2006 includes:

- The development of 'Best Practice Guidelines' through the **EPRUMA** (European Platform for the Responsible Use of Medicines in Animals) initiative will be important to reinforce the need to use medicines carefully and to build understanding of the animal health industry's role;

- Working with the **EAFN** (European Agri-Food Network) forum to dialogue with stakeholders and ensure that relevant food chain issues are fully understood by all parties concerned;
- Dialogue with **EISA** (European Initiative for Sustainable Development in Agriculture) to help ensure that EISA standards in relation to animal health/husbandry are appropriate and reflect good practice;
- Participating in the **EFSA** (European Food Safety Authority)'s stakeholder platform, an activity which is vital to the Federation because of EFSA's responsibility to provide independent scientific advice and risk assessment on food safety issues some of which have an impact on the animal health industry;
- Providing input to the DG SANCO Advisory Group on the Food Chain and Animal and Plant Health.

The points above summarise the key activities in the area of the Food Chain group as we move into 2006 and look to the future. IFAH-Europe is committed to participating in various collaborative initiatives and platforms in order to conduct dialogue with members of the food chain and to build an awareness of the animal health industry as a responsible partner in the food chain. In turn, we value the contribution our stakeholders can make in providing informed feedback on our industry over time.

IFAH-Europe hopes that our activities in this area will contribute to raising awareness that the animal health industry is a responsible, reliable partner in the food chain that is willing to engage with others to find solutions to any concerns/problems that emerge over time.



## Communications

IFAH-Europe activities on communication in 2006 will focus on three main areas:

- the optimisation of existing communication tools and development of new tools to support the activities of industry's thematic activities;
- the expansion of IFAH-Europe's public affairs contacts with institutions and other stakeholders;
- the organisation of an IFAH-Europe conference 'The Animal Health Industry – an essential partner for Global Health'.

As part of its communication strategy in 2006, IFAH-Europe will optimise existing communication tools and develop new ones. This includes a revised version of IFAH-Europe's internal newsletter **In-sight** as well as the launch of a new external newsletter '**IFAH-Europe perspectives**' in Spring 2006. This year will also see a further update of the IFAH-Europe website to bring more information on Animal Health issues and policies to experts and interested members of the public.

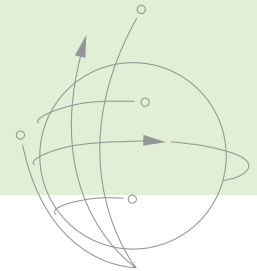
Supporting the thematic activities of its committees and working groups, IFAH-Europe will actively develop messages to ensure that decision-makers and the public understand the importance of the Animal Health sector for modern society. One major area of activity will be the **Avian Influenza threat**, where the animal health industry as vaccine producers have an important role to play in combating the disease and ensuring that the public is properly informed about the option of vaccination.

The successful launch of the **ETPGAH** as a stakeholder alliance will require a continuous effort in the area of communication and public affairs during 2006.

The IFAH-Europe communications department will work on the systematic mapping of decision-makers in European institutions and agencies to ensure that IFAH-Europe's messages reach their target with optimum efficiency and to ensure a coherent follow-up. In collaboration with the Food Chain Committee, the communications department will strategically extend its network of stakeholders to ensure that the animal health industry has close links to all interested parties in the animal health policy field.

As an important event in the middle of 2006, IFAH-Europe will organise a conference '**The Animal Health Industry – an essential partner for Global Health**' with a number of high level speakers from the EU institutions, industry and academia. The conference is not only an important opportunity to highlight the recent achievements of IFAH-Europe, but it is also a chance to present practical examples of cooperation between the animal health industry and other stakeholders to underline the benefit of collaborative activity for the long term sustainable development of the animal health sector and so to continue improving the quality of life for animals and people.

# THE EUROPEAN ANIMAL HEALTH INDUSTRY - FACTS AND FIGURES



## Employment

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

- **+/- 15,000 people directly employed by the animal health industry** in research and development, production, marketing, sales and administration;
- **+/- 18,000 people employed** in companies **supplying the animal health industry** with goods and services such as contract R&D, logistics, capital equipment, and raw materials;
- **+/- 17,000 people employed through the 'multiplier' effect** of the animal health industry's operations (each € of expenditure on good and services by the direct employees of the industry creates additional employment in other sectors, especially the service sector).

## Sales<sup>2</sup>

- **Total European sales** amounted to **US\$ 5.3 billion, 35.3%** of worldwide sales in 2005;
- **Western Europe**<sup>3</sup> represented **30.7%** and **Eastern Europe**<sup>4</sup> **4.6%** of the total worldwide sales.

## Research and Development

### Investment<sup>5</sup>

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

### Costs<sup>6</sup>

- Time to bring a new product to market **5 to 11 years**;
- Costs to bring a new product to market **€ 50 million** (NB: this figure can be higher in exceptional cases);
- Percentage of R&D budget spent on keeping existing products on the market (defensive R&D) **35%** in Europe, **16-18%** in USA.

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

<sup>2</sup> Source: Wood Mackenzie Ltd., 2005

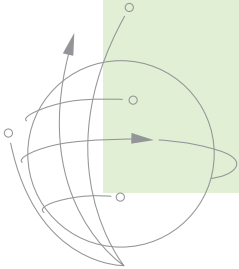
<sup>3</sup> Western Europe includes EU-15, Norway, Switzerland, Iceland and Greenland

<sup>4</sup> Eastern Europe includes Central and Eastern European countries and Former Soviet Union.

<sup>5</sup> Source: IFAH-Europe, 2001

<sup>6</sup> Source: IFAH-Europe, 2001

# IFAH-EUROPE'S STRUCTURE



During 2005 IFAH-Europe made some important changes to the structure of the organisation designed to enhance representation and efficiency. These changes included the consolidation of the IFAH-Europe Council (IEC) as the federation's decision-making body. In addition, Declan O'Brien was appointed as Managing Director of IFAH-Europe in July 2005. IFAH-Europe held its first General Assembly in November 2005.

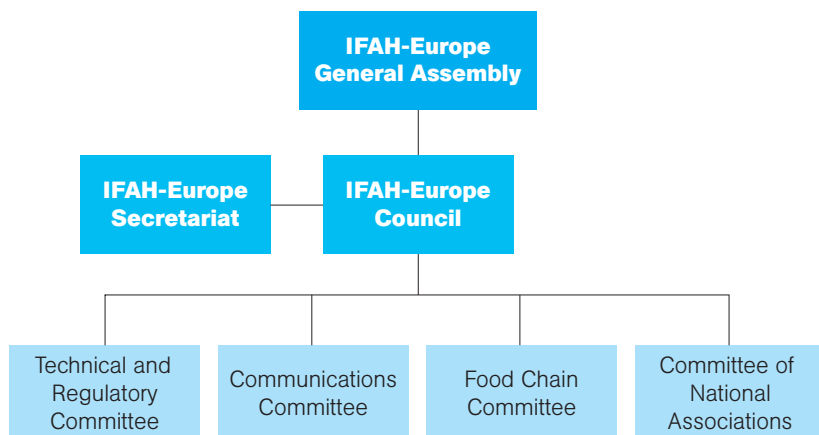
- Food Chain Committee (Chair: Jean Louis Hunault of SIMV);
- Committee of National Associations (Chair: Philip Sketchley of NOAH).

These committees are in turn supported by a series of working parties and ad hoc groups such as the biologicals working party and the pharmacovigilance ad-hoc group. For a full list of all IFAH-Europe committees, working parties and ad-hoc groups, please see annex 1.

The IEC is supported by a Brussels-based secretariat and four key operating committees:

- Technical and Regulatory Committee (Chair: Brigitte Boenisch of Merial);
- Communications Committee (Chair: Sabine Schueller of Intervet International);

IFAH-Europe is also a member of IFAH, the Federation representing the global animal health industry.



# MEMBERSHIP



## IFAH-Europe Council 2005

**Brian Clark** (Chairman)  
Virbac SA

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

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

**Albert Bourla** (Treasurer)  
Pfizer Animal Health Group

**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

**Henriette Pagh-Kohl**  
VIF - Veterinaermedicinsk Industriforening,  
Denmark

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

**Hugo Wahnish**  
Schering-Plough Animal Health

**Jochen Wieda**  
Intervet International BV

## IFAH Europe membership

### Corporate members as at January 2006

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

### National association members as at January 2006

#### BELGIUM

##### Pharma.be

(Association Générale de l'Industrie du  
Médicament)

Veterinary Medicines Group co-ordinator:  
Dr Tim De Kegel

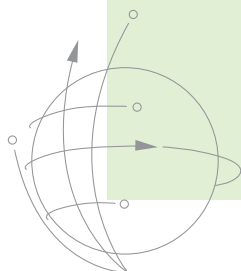
Chaussée de la Hulpe 166  
B-1170 Brussels  
Belgium

Tel: +32 2 661 9123

Fax: +32 2 661 9199

E-mail: [tdk@pharma.be](mailto:tdk@pharma.be)

Website: [www.pharma.be](http://www.pharma.be)



## **CROATIA**

### **VETERINA**

President: Dr Nenad Štiglić

Svetonedeljska 2, Kalinovica  
HR-10436 Rakov Potok  
Croatia

Tel: + 385 1 6120 999

Fax: + 385 1 6115 668

E-mail: nenad.stiglic@veterina.hr

Website: www.veterina.hr

## **CYPRUS**

### **CAVEMID**

(Cyprus Veterinary Medicines Importers and  
Distributors Association)

Managing Director: Dr Demetris Lapathiotis

c/o Cyprus Chamber of Commerce  
P.O.Box 21455,  
1509, Nicosia  
Cyprus

Tel: +357 22 88 97 22

Fax: +357 22 66 86 30

## **DENMARK**

### **VIF**

(Veterinaermedicinsk Industriforening)

Secretariat Director: Ms Henriette Pagh Kohl

Strødamvej 50 A  
2100 København Ø  
Denmark

Tel: +45 39 270925

Fax: +45 39 270918

E-mail: hpk@vif.dk

Website: www.vif.dk

## **FRANCE**

### **SIMV**

(Syndicat de l'Industrie du Médicament Vétérinaire  
et Réactif)

Secretary General: Mr Jean-Louis Hunault

11 rue des Messageries  
75010 Paris  
France

Tel: +33 1 5334 4343

Fax: +33 1 5334 4344

E-mail: simv@simv.org

Website: www.simv.org

## **GERMANY**

### **BfT**

(Bundesverband für Tiergesundheit)

Executive Director: Dr Martin Schneiderit

Annchenplatz 6  
53173 Bonn Bad Godesberg  
Germany

Tel: +49 228 318296

Fax: +49 228 318298

E-mail: bft@bft-online.de

Website: www.bft-online.de

## **GREECE**

### **HAVEPHARM**

(Hellenic Association of Distributors, Importers  
and Manufacturers of Veterinary Pharmaceuticals)

President: Mr Stamatis Barbatiotis

c/o Schering Plough Veterinary SA  
63 Agiou Dimitriou Street  
17455 Alimos, Athens  
Greece

Tel: +30 1 9897 432

Fax: +30 1 9887 925

E-mail: stamatis.barbatiotis@spcorp.com



## **IRELAND**

### **APHA**

(Animal & Plant Health Association)  
Director: Mr Brendan Barnes

8 Woodbine Park  
Blackrock  
Co Dublin  
Ireland

Tel: +353 1 260 3050  
Fax: +353 1 260 3021  
E-mail: [brendan@apha.ie](mailto:brendan@apha.ie)  
Website: [www.apha.ie](http://www.apha.ie)

## **ITALY**

### **AISA**

(Associazione Nazionale dell'Industria  
della Salute Animale)  
Director: Mr Giacomo Fortuni

Via Giovanni da Procida, 11  
20149 Milano  
Italy

Tel: +39 02 345651  
Fax: +39 02 3456-310  
E-mail: [aista@federchimica.it](mailto:aista@federchimica.it)  
Website: [www.aista.federchimica.it](http://www.aista.federchimica.it)

## **NETHERLANDS**

### **FIDIN**

(Vereniging van Fabrikanten en Importeurs van  
Diergeneesmiddelen in Nederland)  
Director: Mr Frederik Schutte

Hogeweg 16  
Postbus 80523  
2508 GM Den Haag  
The Netherlands

Tel: +31 70 7503100  
Fax: +31 70 3549766  
E-mail: [fidin@fidin.nl](mailto:fidin@fidin.nl)  
Website: [www.fidin.nl](http://www.fidin.nl)

## **POLAND**

### **POLPROWET**

(Polish Association of Veterinary  
Drug Producers and Importers)  
President: Dr Witold Klawe

c/o Bayer Sp. z o.o.  
Animal Health Division  
Al. Jerozolimskie 158  
02-326 Warszawa  
Poland

Tel: +48 22 572 36 59  
Fax: +48 22 572 36 53  
E-mail: [klawe\\_witold@lilly.com](mailto:klawe_witold@lilly.com)

## **PORTUGAL**

### **APIFARMA**

(Associação Portuguesa da Indústria  
Farmacêutica)  
Executive Director:  
Ms Isabel Saraiva Cristiano

Rua Pero da Covilhã 22  
1400-297 Lisboa  
Portugal

Tel: +351 21 303 1780  
Fax: +351 21 303 1798  
E-mail: [apifarma.board@mail.telepac.pt](mailto:apifarma.board@mail.telepac.pt)  
Website: [www.apifarma.pt](http://www.apifarma.pt)



## **SLOVENIA**

### **SPMA**

(Working Group for Animal Health (WAH))  
Director: Mr Jože Primc

c/o KRKA d.d.  
Marketing and Sales Animal Health  
Novo mesto  
Šmarješka cesta 6  
8501 Novo mesto  
Slovenia

Tel: + 386 7 3312371  
Fax: +386 7 3322631  
E-mail: joze.primc@krka.biz  
Website: www.krka.si

## **SPAIN**

### **VETERINDUSTRIA**

(Asociación Empresarial Española de la Industria  
de Sanidad y Nutrición Animal)  
Director General:  
Mr Santiago de Andrés Juárez

San Agustín, 15 1° dcha.  
28014 Madrid  
Spain

Tel: +34 91 369 2134  
Fax: +34 91 369 3967  
E-mail: veterindustria@veterindustria.com  
Website: www.veterindustria.com

## **SWEDEN** (as of April 2006)

### **LIF LÄKEMEDELSINDUSTRIFÖRENINGEN**

(Swedish Association of the Pharmaceutical Industry)  
Manager Veterinary Medicine: Mr Pär Tellner

Box 17608  
Ringvägen 100  
118 92 Stockholm  
Sweden

Tel: +46 8 462 97 00  
Fax: +46 8 462 02 92  
E-mail: info@lif.se  
Website: www.lif.se or www.fass.se

## **SWITZERLAND**

### **SGCI Chemie Pharma Schweiz**

(Swiss Society of Chemical Industries)  
Managing Director: Mr Dieter Grauer

Nordstrasse 15  
8035 Zürich  
Switzerland

Tel: +41 1 368 1711  
Fax: +41 1 368 1770  
E-mail: dieter.grauer@sgci.ch  
Website: www.sgci.ch

## **UNITED KINGDOM**

### **NOAH**

(National Office of Animal Health)  
Chief Executive: Mr Philip Sketchley

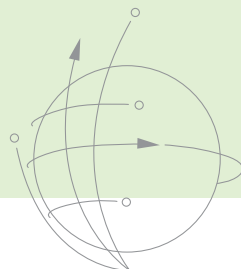
3 Crossfield Chambers, Gladbeck Way  
Enfield, Middlesex EN2 7HF  
United Kingdom

Tel: +44 208 367 3131  
Fax: +44 208 363 1155  
E-mail: p.sketchley@noah.co.uk  
Website: www.noah.co.uk





IFAH-Europe team



## IFAH-Europe Secretariat as at January 2006

**Declan O'Brien**, Managing Director,  
d.obrien@ifahsec.org

**Florentina Pardo**, Executive Assistant,  
f.pardo@ifahsec.org

### Communications Department :

**Bernd Halling**, Communications Director,  
b.halling@ifahsec.org

**Rebecca Taylor**, External Communications  
Manager, r.taylor@ifahsec.org

**Myriam Alcain**, Internal Communications  
Manager, m.alcain@ifahsec.org

**Pamela Barcellona**, Secretary,  
p.barcellona@ifahsec.org

### Technical Department :

**Rick Clayton**, Technical Director,  
r.clayton@ifahsec.org

**Sylvie Meillerais**, Technical Project Manager,  
s.meillerais@ifahsec.org

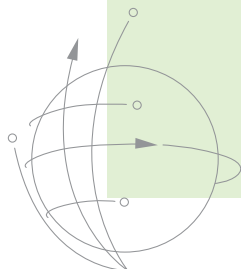
**Elena Miceli**, Technical Assistant,  
e.miceli@ifahsec.org

**Marie-Hélène Delvaux**, Executive Secretary,  
techsec@ifahsec.org

### Administration :

**Linda Moortgat**, Administration Manager and  
IT Coordinator, l.moortgat@ifahsec.org

## GLOSSARY



<b>AER</b>	Adverse Event Report
<b>API</b>	Active Pharmaceutical Ingredient
<b>BEUC</b>	The European Consumers Association ( <u>B</u> ureau <u>E</u> uropéen des <u>U</u> nions des <u>C</u> onsommateurs)
<b>CEESA</b>	European Animal Health Study Centre ( <u>C</u> entre <u>E</u> uropéen d' <u>E</u> tudes pour la <u>S</u> anté <u>A</u> nimale)
<b>CEJA</b>	European Council of Young Farmers ( <u>C</u> onseil <u>E</u> uropéen des <u>J</u> eunes <u>A</u> griculteurs)
<b>CIAA</b>	Confederation of the Food and Drink Industries of the EU ( <u>C</u> onfédération des <u>I</u> ndustries <u>A</u> gro- <u>A</u> limentaires auprès de l'UE)
<b>CLSI</b>	Clinical and Laboratory Standards Institute (formerly known as NCCLS)
<b>COGECA</b>	General Confederation of Agricultural Co-operatives in the European Union ( <u>C</u> onfédération <u>G</u> énérale des <u>C</u> oopératives <u>A</u> gricoles de l' <u>U</u> nion <u>E</u> uropéenne)
<b>COPA</b>	Committee of Professional Agricultural Organisations in the European Union (Comité des organisations professionnelles des agriculteurs)
<b>CVMP</b>	Committee for Medicinal Products for Veterinary Use
<b>DCP</b>	Decentralised Procedure
<b>DG</b>	Directorate General
<b>DG SANCO</b>	European Commission Directorate General for Health and Consumer Protection ( <u>S</u> anté et <u>P</u> rotection des <u>C</u> onsommateurs)
<b>EAFN</b>	European Agri-Food Network
<b>EAN</b>	European Article Numbering (European bar code association - now called GS1 following merger with North American counterpart)
<b>ECPA</b>	European Crop Protection Association
<b>EFFAB</b>	European Federation of Farm Animal Breeders
<b>EFPIA</b>	European Federation of Pharmaceutical Industries & Associations
<b>EFSA</b>	European Food Safety Authority
<b>EISA</b>	European Initiative for Sustainable Development in Agriculture
<b>EMA</b>	European Medicines Agency
<b>EPRUMA</b>	European Platform for the Responsible Use of Medicines in Animals
<b>ETPGAH</b>	European Technology Platform for Global Animal Health
<b>FAO</b>	Food and Agriculture Organisation
<b>GACT</b>	IFAH Global Antimicrobial Core Team
<b>GL</b>	Guideline
<b>GMP</b>	Good Manufacturing Practice
<b>IWP</b>	Immunological Working Party (EMA committee)



<b>MRL</b>	Maximum Residue Limits
<b>MRP</b>	Mutual Recognition Procedure
<b>OCABR</b>	Official Control Authority Batch Release
<b>OIE</b>	World Animal Health Organisation (Office Internationale des Epizooties)
<b>QWP</b>	Quality Working Party
<b>SAGAM</b>	Special Advisory Group on Antimicrobials
<b>SME</b>	Small and Medium Sized Enterprise
<b>SRA</b>	Strategic Research Agenda
<b>UCC</b>	Uniform Code Council (North American bar code organisation - now called GS1 following merger with European counterpart)
<b>VETCAST</b>	Veterinary Committee on Antimicrobial Susceptibility Testing
<b>VICH</b>	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
<b>VMRFG</b>	Veterinary Mutual Recognition Facilitation Group
<b>WHO</b>	World Health Organisation

## ANNEX 1

### IFAH-Europe Committees, working parties and ad-hoc groups

#### Committees

Food Chain Committee (FCC)  
 Technical & Regulatory Committee (TRC)  
 Communications Committee (ComCom)  
 Committee of National Associations (CNA)

#### Working Groups

**Supporting the Food Chain Committee:**  
 Traceability Working Group

**Supporting the Technical & Regulatory Committee (TRC):**

Anti-infectives Working Group  
 Biologicals Working Group  
 Regulatory Ad-Hoc Group

#### Ad-hoc Groups supporting the TRC:

In-feed Ad-hoc Group  
 Quality Ad-hoc Group  
 Good Manufacturing Practices (GMP) & Production Ad-hoc Group  
 Efficacy Ad-hoc Group  
 Pharmacovigilance Ad-hoc Group  
 Ecotoxicity Ad-hoc Group  
 Safety/Residues Ad-hoc Group  
 Regulatory Procedures Ad-hoc Group

#### Other Groups

VICH steering Committee (European delegates)  
 VICH representatives  
 European Technology Platform for Global Animal Health Working Group  
 Foot-and-Mouth Disease Working Group



**IFAH-Europe**

**Representing the European Animal Health Industry**

Rue Defacqz 1,  
1000 Brussels,  
Belgium

Tel.: +32 (0)2 543 7560

Fax: +32 (0)2 537 0049

E-mail: [info@ifahsec.org](mailto:info@ifahsec.org)

[www.ifahsec.org/Europe](http://www.ifahsec.org/Europe)

June 2006