IFAH
Representing the
Animal Health Industry

# 2006
# ANNUAL REPORT

Improving the quality of life for animals and people

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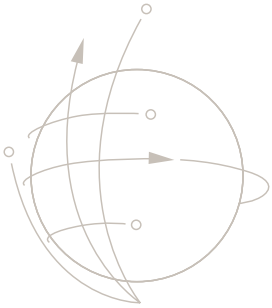
# About IFAH

The International Federation for Animal Health (IFAH) is an organisation representing manufacturers of veterinary medicines, vaccines and other animal health products in both developed and developing countries across five continents.

IFAH's mission is to foster a greater understanding of animal health matters and promote a predictable, science-based regulatory environment that facilitates the supply of innovative and quality animal medicines, vaccines and other animal health products into a competitive market place. These products contribute to a healthy and safe food supply as well as a high standard of health and welfare for animals and people.

To fulfil that mission, IFAH will:

- Act as the voice of the industry in dialogue with the major international bodies that have an impact on the animal health industry (OIE, FAO, WHO, Codex, WTO and others);
- Encourage and assist the development of predictable, science-based regulatory procedures and standards;
- Represent the industry with a unified, global voice in dealings with governments, food-industry partners and consumers; and
- Facilitate the international harmonisation of regulatory guidelines governing animal health products.



IFAH is lead by a 19-strong Board of Directors comprising representatives from member companies and industry associations across five continents. Headed by George Gunn, who began a two-year term as IFAH President in November 2006, the Board is the federation's decision-making body. It receives support from a Brussels-based secretariat, national and regional member associations, and from core teams, task forces and working groups focused on issues identified by the federation as strategic priorities for the animal health industry.

## IFAH's strategic priorities in 2006

**Regulatory affairs:** Ensuring the efficiency of regulatory procedures, international harmonisation of regulatory guidelines and the consistent application of science-based risk/benefit analysis.

**Antimicrobials in veterinary medicine:** Communicating the need to ensure the availability of all classes of antimicrobials in veterinary medicine as invaluable tools to treat diseases, and so support animal health and welfare as well as a safe food supply.

**Avian influenza:** Seeking increased recognition of the animal health industry's role in providing tools to prevent, control and eradicate this disease, and positioning IFAH as a voice of authority that can offer expertise on avian influenza.

# A message from IFAH's President

**The two-year 'road map' that we drew up for our federation through 2006 and 2007 was both challenging and complex. It charted a course that might have defeated lesser navigators, but I am pleased to report that - thanks to the outstanding effort put in by colleagues from member companies, associations and our dedicated secretariat over the past year - we are firmly on course to reach many of our objectives.**

George Gunn

Structural changes implemented at the beginning of 2006 were designed to increase the flexibility of our federation, allowing us to pursue a more proactive approach to achieving key goals, and to respond rapidly to emerging issues at local, regional and global levels.

The extensive list of achievements reported by national and regional associations during the year indicate clearly that we are already beginning to reap the rewards of these changes. Positive progress was also reported by each of our two global core teams, while both the Codex Working Party and the Avian Influenza Task Force, which were set up to execute IFAH policies in specific fields, have already made their mark.

The Avian Influenza Task Force in particular has helped to drive home the message that there is an integral link between good animal health and good human health. Our profile has also been raised by Global Antimicrobial Core Team activities - most notably through its contribution to the OIE's 'critical list' initiative and its success in delivering key messages to human health professionals.

As a result of these efforts, we have moved animal health to centre-stage in a range of debates at global level. Our positive, responsible approach to these debates has not gone unnoticed. By gaining the trust and respect of fellow stakeholders, regulators and political decision-makers, we have obtained a 'seat at the table' that will give us the chance to make a real impact on future discussions.

Nor should we overlook achievements in the regulatory sphere, where our Global Traceability Team has successfully piloted the introduction of a new, harmonised product identification system, and where the Global Regulatory Core Team (GRCT) has had a positive impact on developments in international arenas such as VICH and Codex.

Armed with an array of valuable new data generated by our industry benchmarking survey, the GRCT is ready to press home calls for a more proportionate, predictable and harmonised approach to the regulation of our industry. This will be a key target for IFAH in the coming year, during which we must capitalise on the progress made during 2006.

I thank the Board of Directors for giving me the opportunity to lead IFAH through what promises to be an exciting and rewarding period for our industry, and look forward to working with the dedicated teams that have already achieved so much for our members.

# A message from IFAH's Executive Director

**IFAH achieved much of what it set out to do in 2006, responding to the change in direction called for by the Board by tackling a number of new policy initiatives and building on progress towards the accomplishment of more established goals.**

**It has been an extremely active and exciting twelve months, and at the outset I want to acknowledge the tremendous collaboration and support of colleagues from both member companies and national and regional associations, who have made such an important contribution to the work of the federation over the past year.**

Peter G H Jones

Avian influenza is the first panzootic in animals, and has dominated the headlines once again. The threat that it may lead to a human pandemic is a very real one, and the responsibilities that the animal health community has to bear in managing this disease in poultry are enormous. IFAH, through the work of its Avian Influenza Task Force, has played an important part by developing and disseminating accurate and up-to-date information about the disease. The positive collaboration with international bodies such as OIE, FAO and WHO, as well as governments and regulators, highlights the contribution that our federation and its member companies are making in the global effort to contain this disease. Our measured intervention on the role of vaccination is respected at a time when vaccination is increasingly moving to the forefront as a tool for controlling this disease, alongside stamping out and effective bio-security, not only in emergency situations but also in prevention as well.

The Global Regulatory Core Team has made great strides towards its goal of encouraging the development of an operating environment capable of stimulating industry investment in new medicines. Efforts undertaken by IFAH to improve the efficiency of the VICH process were welcomed by the Steering Committee, and recommendations are to be considered for inclusion in the VICH charter. The benchmarking survey was close to completion at the time of writing, and regulatory authorities have been kept informed of progress throughout its development. The results provide a wealth of information on which to base key messages and a communications strategy is in place.

Progress was achieved in advancing compounds through the Codex process at the last CCRVDF in May 2006. The IFAH Codex Working Group worked closely with the JECFA secretariat on measures to provide improved protection of confidential data submitted to JECFA in support of establishing Codex MRLs. The group has also been active in supporting and ultimately achieving the setting up of the Codex Intergovernmental Task Force on Antimicrobial Resistance.

Elsewhere, debate on the development of strategies to manage potential human health risks from non-human use of antimicrobials continued throughout 2006, with IFAH playing an active and constructive role in discussions. Our federation remains convinced that any risk management measures applied to the use of veterinary antimicrobials must be rooted firmly in science-based risk assessment, and continues to oppose efforts by some parties to pursue alternative approaches.

The range of issues confronting our industry remains both broad and challenging. But when I look at the progress we have made over the past year I am convinced, more than ever, that we are firmly on track to succeed in the creation of an environment within which the contribution that animal health products make to society at large is understood and appreciated. There has never been a greater acknowledgement of the fundamental contribution made by animal health to human health as in the context of avian influenza. IFAH and its member companies have shown in the last year that veterinary medicines and vaccines are valuable tools to prevent, control and eradicate diseases.

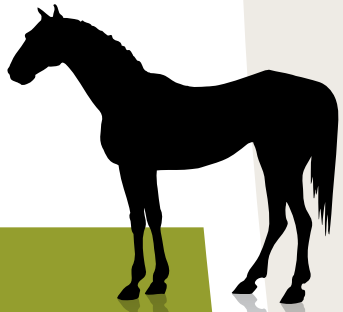
# Strategic activity report

Towards the end of 2005, the IFAH Board of Directors announced an overhaul of the federation's operations at global level. Designed to sharpen its focus and allow a more strategic, proactive approach to key issues, the move resulted in the creation of an Avian Influenza Task Force and a Codex Working Group - both charged with the development and execution of IFAH policies in specific fields. At the same time, responsibility for communication and food-chain related issues was decentralised, with regional and national associations now fulfilling IFAH goals in these areas.

The Board also called on its two main global core teams to update and realign their strategic priorities. New goals drawn up by the Global Regulatory Core Team (GRCT) and the Global Antimicrobial Core Team (GACT) were reviewed and approved by the Board in January 2006.

Key activities and achievements in each of IFAH's three main strategic priority areas at both international and regional level are described in the main body of this report.

# International activities



## Regulatory affairs

IFAH actively promotes the rigorous, science-based regulation of veterinary medicines, which is essential in order to protect the health of animals, those who administer such products, animal owners, consumers of food derived from animals and the environment. Since substantial investment is required to discover, develop and bring innovative new products to market, the regulatory framework must be harmonised, proportionate and predictable, enabling a fair return on such investment.

Working towards the establishment of such a framework is one of IFAH's main priorities. Activities in this area are spearheaded by the Global Regulatory Core Team (GRCT) and a newly-established working group set up to deal specifically with issues related to developments in the Codex Alimentarius arena.

**Regulatory process efficiency:** IFAH members operate in a segmented, highly competitive market. In this challenging commercial environment, efficient and proportionate regulation is essential if they are to continue delivering the innovative new products that have done so much to improve the health and welfare of animals and to guarantee the availability of safe, high-quality food for consumers.

Unfortunately, the regulatory framework governing our industry has become increasingly restrictive - to the extent that it has begun to erode the range of existing products available to the veterinary profession and animal owners. Worryingly, it has also begun to stifle innovation, threatening to deny our customers access to the potential benefits offered by the next generation of innovative new products. While it recognises the paramount importance of consumer protection, IFAH believes that, by adopting increasingly risk-averse approaches to such a broad range of products, regulators have not always ensured that animals and their owners are guaranteed access to a sufficient supply of safe, efficacious and quality medicines.

A major cause of this trend has been the propensity of regulators to apply identical standards to both human and animal health products. Not only does this approach overlook the many significant differences between the two sectors, it also ignores the gap in financial resources that exists between the human pharmaceutical and animal health industries. IFAH is determined to highlight the dangers of this situation, and to pursue potential solutions to existing problems by cooperating with regulators and other stakeholders.

To gauge the nature and extent of those problems, the federation has commissioned a major study benchmarking regulatory efficiency and industry competitiveness in the EU, the US, Canada, Japan and Australia. The GRCT has also been gathering information from IFAH member companies on individual instances where the imposition of inappropriate or disproportionate regulatory requirements has affected the time and cost involved in bringing new products to market.

Both initiatives were largely complete by the end of 2006, and IFAH now possesses a host of both quantitative and qualitative data in support of its campaign. Pleasingly, regulators have taken a keen interest in the results of this research. Indeed, the regulatory authorities in the countries concerned have already requested details of data generated by the benchmarking survey, and in some cases have asked the federation to submit its views on areas where it believes changes to existing regulations are required.

IFAH will communicate the results of the benchmarking study at a series of meetings throughout 2007, delivering key messages to both regulators and other stakeholders. In doing so, it will endeavour not only to highlight current problems, but also to put forward constructive proposals on how these can best be resolved.

Thanks to the work of the GRCT and the active cooperation of IFAH member companies, we now have a unique opportunity to raise our concerns with policy makers, ensuring that the regulatory framework governing our industry is both more efficient and more proportionate in future. An updated benchmarking study is already planned for 2011, so that we can assess how far regulators have responded to the challenges we set before them.

**International harmonisation:** International bodies such as VICH and the Codex Alimentarius Commission have the potential to exert a major impact on the regulatory and commercial environment facing IFAH members. As such, ensuring that standards adopted in these arenas are conducive to the future development of a viable, sustainable and innovative animal health industry is high on the list of IFAH's priorities.

# International activities

VICH is a tri-lateral (EU-Japan-USA) initiative involving regulators and the industry. Its aim is to harmonise international guidelines on technical requirements for the registration of animal health products. Having adopted almost 40 guidelines on drug safety, quality and efficacy since its establishment in 1996, VICH embarked on the second phase of its programme in 2006.

IFAH saw this as an appropriate stage at which to review the VICH process, and has resolved to pursue improvements in both the efficiency and usefulness of the programme as a vehicle for driving international harmonisation. It has also looked at the cost/benefit impact of VICH on the animal health industry.

There is no doubt that VICH provides a unique forum in which our industry can communicate directly with regulators, and IFAH remains fully committed to the initiative. Its potential value was highlighted by the excellent start to discussions on standards governing metabolism and residue kinetics achieved by the VICH Steering Committee at its 18th meeting in London at the end of May 2006. The federation will ensure that resources being committed to the initiative are being put to the best possible use.

Like VICH, the Codex Alimentarius Commission is a global initiative with the potential to exert a major impact on the operating environment facing IFAH members. Charged with the development of standards, guidelines and related texts under the joint FAO/WHO Food Standards Programme, Codex has become increasingly influential as developing nations participate more actively, with a growing tendency among such countries to adopt Codex standards on issues such as drug residues. As a result, Codex MRLs can have a significant impact on the commercial prospects of individual products.

Also like VICH, Codex procedures can often be long and challenging. IFAH believes there is room for improvement in the efficiency of the Codex system, which could limit the time and costs involved in reaching final decisions. The federation also has concerns regarding statistical approaches to MRL calculation methods being proposed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which advises the Codex on MRLs, and on the confidentiality of data submitted by originator companies in support of MRL development.

IFAH established a dedicated Codex Working Party during 2006, and embarked on the development of plans to address key issues of concern to the industry. It also resolved to pursue closer interaction between industry representatives and Codex officials in order to improve channels of communication. A meeting with JECFA's secretariat and its participation at the meeting of IFAH's Board of Directors in November marked a significant positive step down that road.

The Codex initiative delivered positive progress on a number of issues during the year. Most notable were the achievements of the CCRVDF, which advanced most MRL standards and related texts under review at its meeting in Mexico during May, prompting some industry delegates to describe it as one of the most productive meetings in the committee's history. Later in the year, the Codex Alimentarius Commission approved the establishment of a task force on antimicrobial resistance - a move that IFAH has recommended for some time (see antimicrobials in veterinary medicine for more details).

**Product identification:** IFAH is the driving force behind an industry-led initiative to upgrade and harmonise product identification systems. By allowing rapid and reliable traceability of registered animal health products, this will improve levels of animal and user safety. It will also help distributors, retailers and veterinary surgeons comply easily with legal requirements where record-keeping and the use of animal health products is concerned.

The initiative involves the adoption of the datamatrix identification standard, allowing the identity of a product, its batch number and expiry date to be verified with a single scan. The system, which has received widespread acclaim among regulators, and which is being adopted increasingly in other sectors, including the human health industry, also has the capacity to store additional information, making future development a viable proposition.

## Antimicrobials in veterinary medicine

Antimicrobials are essential to the health and welfare of animals. IFAH is concerned about the development of resistance to antimicrobials in animals and humans, but is determined to ensure that measures taken to manage this problem are informed, science-based and proportionate.

Veterinary antimicrobials undergo a rigorous regulatory review process - including a science-based risk/benefit analysis - designed to minimise the risk of both resistance building in animal populations and the transfer of resistance from animals to humans. IFAH member companies undertake continuous monitoring of antimicrobial products, which are also subject to surveillance programmes carried out in collaboration with regulatory authorities and independent scientific institutions.

In countries where surveillance systems have been implemented, results indicate that resistance of some organisms to veterinary antimicrobials is either stable or in decline. Nevertheless, some opinions on this vital issue are still being formed - and decisions taken - without recourse to proper, science-based analysis. As a result, the role of veterinary medicines in the development of resistant human pathogens continues to be exaggerated.

Led by the efforts of its Global Antimicrobial Core Team (GACT), IFAH continued to pursue balanced, science-based debate on the use of veterinary antimicrobials. By the end of the year it was able to report positive developments in several areas.

**Communication outreach:** Over 60 participants from the human medical profession attended a satellite symposium organised by IFAH during the 12th International Congress for Infectious Diseases (ISID), held in Lisbon, Portugal, on 18th June 2006. Representatives of the veterinary profession told delegates that antimicrobials played an essential role - not only in protecting animal health and welfare, but also in ensuring that healthy animals produce safe and wholesome food - while regulatory officials highlighted the broad range of measures in place to monitor, measure and minimise the spread of resistance.

The symposium was a success, eliciting broad agreement on, among other things, the shared responsibility of veterinary surgeons and physicians to ensure prudent use of antimicrobials, and the need for transparent risk assessment procedures to manage the challenges posed by resistance. It is clear that further communication with the medical profession will help to improve levels of understanding about the vital role played by veterinary antimicrobials, and the stringent controls that govern their use.

In a bid to build on the achievements of the Lisbon symposium, contacts and communications with the medical profession and scientific community will be stepped up through 2007 and into 2008.

**OIE 'critical list':** In 2005, the WHO drew up a list of antimicrobial products deemed critical to human health. The document has since been used in some quarters as a basis on which to campaign for a ban on the use of products on that list in animals. This approach fails to take account of available scientific evidence, the impact that a blanket prohibition would have on the health and welfare of animals, and its potential implications for human health.

The World Organisation for Animal Health (OIE) has drawn up its own list of antimicrobials deemed critical to the health and welfare of animals. An ad-hoc working group set up by the organisation to handle the development of that list has received input from a broad range of sources, including IFAH, which provided detailed information on products required in the treatment and control of individual diseases.

The ad-hoc group, which met twice during 2006, requested expert input from IFAH representatives at both of those sessions, and remarked on the balanced, non-partisan nature of our industry's contribution. It has now drawn up a critical list of antimicrobials used in veterinary medicine, categorised according to their importance for animal health and welfare. IFAH supports the ad-hoc group's conclusions, which will be tabled for adoption at the next General Session of the OIE in May 2007.

**Codex Task Force on Antimicrobial Resistance:** At its 29th session, held in Geneva, Switzerland, in July 2006, the Codex Alimentarius Commission agreed to establish a Task Force on Antimicrobial Resistance. The decision to create a dedicated task force within Codex is a welcome development. Codex is widely regarded as a transparent and open organisation, and IFAH is confident that the task force will approach its work in a measured fashion, with proper regard for the need to focus strongly on risk-assessment methodologies before assessing risk-management options.

## Avian influenza

Having caused losses of at least US$10 billion in South-East Asia since 2003, the highly pathogenic H5N1 strain of the avian influenza virus has emerged as a threat to poultry production in parts of the Middle-East, Africa and Europe.

# International activities

Human deaths resulting from infection with the virus have heightened concern surrounding the disease, with the WHO warning that a global pandemic is possible.

IFAH set up an Avian Influenza Task Force (AITF) early in 2006. Through the AITF, the federation has played a key role in developing and disseminating accurate, up-to-date information about the disease, has worked closely with governments, regulators and international bodies such as the OIE, FAO and WHO on control and eradication strategies, and has established co-operative links with a range of stakeholders in the poultry production chain.

In the process, IFAH's reputation as a knowledgeable, authoritative and trustworthy partner in the fight against animal disease has been further acknowledged. Our industry is now more widely - and rightly - recognised as a key player, possessing expertise and resources that can make a major contribution in the prevention, control and eradication of AI and other diseases that threaten the health of both animal and human populations.

**Education:** The AITF produced a comprehensive communications package on avian influenza during 2006, aimed variously at consumers, fellow stakeholders, regulators, governments and NGOs. It has also built up a broad electronic library of information on avian influenza for use by IFAH members.

An on-line resource providing answers to the most frequently-asked questions about the disease and information on the role of the animal health industry in avian influenza control was established at an early stage. This educational tool explains in simple terms the nature of the disease and approaches to its prevention, control and eradication. Importantly, it also sets broader risks posed by AI in context, and reassures consumers about the safety of poultry products.

The FAQ resource also provides information on the role of the animal health industry in avian influenza control. This has been addressed at a more technical level in a 'backgrounder' on AI vaccination, which explains in detail the nature of the virus, the types of vaccine currently available, and the technologies being researched as potential platforms for the development of new-generation vaccines. The backgrounder discusses the role of vaccination alongside bio-security and humane culling in the prevention and control of this disease.

Background papers on several other AI-related topics have been drafted, while the task force has drawn up an IFAH position paper on the potential contribution of the animal health industry to broader responses in the event of a human influenza pandemic.

**Cooperation:** From an early stage, the AITF pursued an open, co-operative approach, inviting external experts and international organisations to take part in its meetings and seeking dialogue with fellow stakeholders, regulators, governments and NGOs. It has also made industry experts available to participate in the formulation of policies being developed at national, regional and global level, while IFAH has agreed to provide support to the joint International Meeting on Emerging Diseases (IMED) to be held in 2007 organised by the International Society for Infectious Diseases and co-sponsored by ProMED-mail, ECDC, OIE, the European Commission and the WHO Regional Office for Europe. IFAH was also invited to become a member of the scientific panel of the 'International Conference on Vaccination: a Tool for the Control of Avian Influenza' hosted by OIE, FAO, IZSVe and the European Commission, to be held in Verona, Italy, in March 2007.

The task force has liaised with stakeholders in the food chain, including processors and retailers. It has also worked closely with the human health industry, looking at ways in which the resources of the two sectors can best be harnessed to ensure optimum production of influenza vaccines for use in both poultry and human populations.

The AITF has drawn up a position paper outlining the animal health industry's potential contribution to global control and eradication efforts in the event of a human influenza pandemic. This highlights the role already being played by vaccines for use in poultry, notes areas such as antigen production where it could co-operate with human-vaccine producers, and draws attention to some of the financial, regulatory and production issues that need to be addressed in order to make best use of available resources. The task force has worked on a joint position paper by IFAH and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) addressing influenza vaccines, which has now been completed.

The task force has also co-operated extensively with regulators and governments on issues ranging from the authorisation of vaccines against avian influenza

to the supply of vaccine stocks and vaccination strategies. IFAH was pleased to note that regulators in the European Union authorised two new avian influenza vaccines under an expedited review procedure to ensure their availability in advance of periods of greater risk for outbreaks of the disease in the member states.

**Consultation:** The policy of active consultation and information-sharing pursued by the AITF has been rewarded by invitations for IFAH and its members to participate actively in a range of initiatives at global level.

The task force was consulted by the WHO as part of its research into the potential for expanded vaccine production in the event of a human influenza pandemic. It provided a range of valuable data, outlining the industry's vaccine production capabilities and discussing the best use of IFAH member resources in control and eradication programmes. The AITF also liaised regularly with a number of other international organisations, and was invited to take part in a range of key initiatives.

IFAH and its vaccine-producing member companies provided input to both meetings in 2006 of the OIE's Ad-Hoc Group on Avian Influenza Vaccines, which is formulating guidance for countries on risk assessment and decision-making in relation to vaccination. In the same month, three industry representatives were invited to speak at a Symposium on Technical Requirements for AI vaccines organised by the European Directorate for the Quality of Medicines (EDQM).

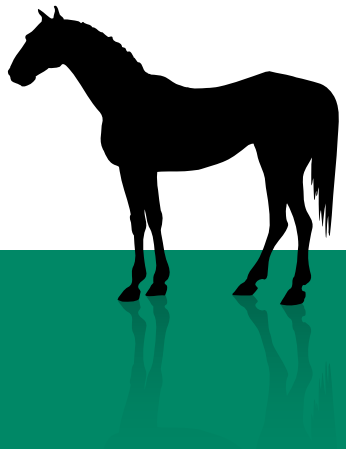
Towards the end of the year, the IFAH Executive Director, Peter Jones, was invited to address the IV International Conference on Avian Influenza in Mali, where he called on the international community to engage in greater coordination of research into animal medicines to combat the disease. He proposed the establishment of an international stakeholder alliance to help develop those products, and stressed the importance of public-private partnerships to drive forward vaccine research, citing the European Technology Platform for Global Animal Health (ETPGAH) as a model on which to base such an initiative.

# Regional activities

IFAH represents the interests of national and regional associations from five continents at global level. The federation broadened its reach in 2006, welcoming both the Malaysian national association, MAHNIA, and the recently formed Asian Animal Health Association (AAHA) as new members. It is actively pursuing broader representation in South and Central America, where discussions regarding the establishment of a stronger industry representation have begun.

Member associations play a key role in the execution of IFAH policies at national and regional level. At the beginning of 2006 they also stepped up their involvement in food chain and communications-related initiatives, following the IFAH Board's decision to devolve responsibility for activities in these areas.

The following section provides an overview of the main activities and achievements reported by member associations in 2006.



# Regional activities

## Europe:
IFAH-Europe

**Regulatory affairs:** The EU's new pharmaceutical legislation has improved the regulatory framework governing veterinary medicines in a number of respects. However, experience with the new laws and their implementation in the member states has highlighted several areas in which further change is required if the aims of recent reforms are to be achieved. IFAH-Europe's regulatory teams worked throughout the year on several 'implementing measures', the identification of shortcomings in the new legislation and the development of proposed solutions to these issues. They also submitted detailed responses to 42 official-consultation documents during 2006.

One major 'implementing' area has been the discussion on procedures and systems required to implement strengthened pharmacovigilance provisions. A second major topic was official batch-testing procedures for vaccines. Discussions on this issue were held with the European Commission and the European Directorate for the Quality of Medicines (EDQM) in order to ensure that procedures remain proportionate and practical. The federation also submitted a detailed response to proposals on the amendment of 'Annex I' on registration dossier requirements, seeking to balance the twin objectives of the legislation: medicines availability and safeguarding public health.

The EMEA/IFAH-Europe info day, 'Stimulating Innovation and Managing Risk in Market Access to the Veterinary Sector', held in November, was very successful. Using a new format of small parallel discussion groups, the event attracted a record attendance of representatives from industry and the authorities, and provoked lively debate on a series of key issues, including risk/benefit assessment, better regulation for animal health products and the need to differentiate between the human and veterinary sectors when drawing up legislation and guidelines.

The interpretation of requirements relating to environmental risk assessments (ERA) and the summary of product characteristics (SPC) under the new legislation are among other key areas of concern for the industry. IFAH-Europe outlined potential problems that guidelines on these subjects could pose for its members in meetings with regulators, stressing the need to guarantee a 'level playing field' for all product types where ERA is concerned, and warning against systematic calls for impact assessments. On SPC requirements, the federation warned that requests for a full list of excipients would undermine data-confidentiality rights.

Other key issues dealt with during 2006 included packaging requirements and the review of regulations governing variations to marketing authorisations. In a position paper on the variations review, IFAH-Europe called for the introduction of a more flexible, pragmatic approach to procedures in order to remove existing barriers to innovation and reduce the financial burden that current legislation imposes on the industry. Earlier in the year, the federation held a workshop on packaging requirements, at which a range of technical and practical issues were addressed.

Improving the competitiveness of the European industry was among the main goals of the EU's recent regulatory reform programme. Existing legislation still poses significant barriers to the ability of IFAH-Europe members to compete effectively at global level, however, and the federation will continue to pursue much-needed improvements into 2007. A study benchmarking the competitiveness of the industry commissioned by IFAH during 2006 will provide a valuable new source of quantitative evidence to back up its arguments.

**Antimicrobials in veterinary medicine:** IFAH-Europe continued to participate actively in the debate surrounding the use of antimicrobials in veterinary medicine, cooperating with regulators and working with stakeholders to ensure the prudent use of antibiotics in animals. It also contributed to discussions at global level, most notably with regard to the 'critical lists' of antimicrobials being drawn up by international bodies (the WHO and OIE), and worked on the coordination of antibiotic-use surveys and monitoring programmes across Europe.

The EMEA's Committee for Medicinal Products for Veterinary Use (CVMP) published a reflection paper on the use of fluoroquinolone antibiotics in food-producing animals at the beginning of the year. The paper concluded that many of the problems with resistance in human medicine are correlated to the use of antimicrobials in humans, and acknowledged the importance of the fluoroquinolone class to veterinary medicine.

IFAH-Europe participated in this debate, calling for a more precise definition of antimicrobial breakpoints and endorsing proposals to include 'prudent use' wording in the summary of product characteristics (SPC) for fluoroquinolones. The federation is confident that the proposed measures, together with the introduction of new guidelines and resistance monitoring systems, will help contain the potential development of resistance to fluoroquinolones.

**Avian influenza:** Confirmation of outbreaks of avian influenza in member states of the European Union underlined the importance of efforts to prevent the spread of the disease and to develop adequate control and eradication plans. IFAH-Europe and its members have made vital contributions to the prevention and control of AI in Europe, and continue to cooperate fully with governments and regulators on the development of prevention, control and eradication plans.

Since 2005 both emergency- and preventative-vaccination programmes have been allowed in EU member states under defined conditions. In September 2006, European-level authorisations were granted for two AI vaccines developed by IFAH-Europe member companies, following a fast-track registration procedure introduced by the EMEA. Commenting on the decision, EU Enterprise Commissioner Günter Verheugen praised the industry's ability 'to innovate and address urgent challenges so quickly'. In a discussion paper on AI vaccination published towards the end of the year, the European Commission highlighted the economic benefits of vaccination as a tool against avian influenza.

**Food chain:** IFAH-Europe and its member associations have spearheaded the development of stakeholder alliances in the region, and continue to forge productive relationships with groups representing the veterinary profession, producers, processors, retailers and consumers. These are vital if the federation is to promote a better understanding of the valuable role our industry plays in the protection not only of animal health and welfare, but also of human health.

Joining forces with farmers' groups and the veterinary profession, the federation established a European Platform for Responsible Use of Medicines in Animals (EPRUMA) towards the end of 2005. EPRUMA members met on three occasions in 2006, finalising the organisation's mission statement and drawing up a 'best-practice framework' for the use of antimicrobials in food-producing animals. A workshop on stakeholder dialogue was also held in November, attracting participants from several other stakeholder groups as well as the European Food Safety Authority (EFSA).

The federation maintained close contact with the veterinary profession, distributors and users of animal medicines, ensuring that all parties are fully informed about the new datamatrix product identification system being introduced by manufacturers. IFAH-Europe member companies began introducing the new system at a number of major manufacturing plants during 2006, and most animal health products circulating in the region will bear the datamatrix bar code on packaging by the end of 2007. This will enable the identification of product batch numbers, manufacturing dates and use-by dates at all stages from the factory to the farm.

**Communications:** In line with the IFAH Board's decision to decentralise responsibility for communications, the European federation stepped up its activities in this area during 2006. IFAH-Europe held a succession of meetings with a range of stakeholders, and was a regular participant at conferences across the region. Presentations at these events helped to disseminate core industry messages and encourage future dialogue with a growing number of organisations. It also hosted key events that highlighted the positive role played by the industry, while communication with regulators was maintained throughout the year.

IFAH-Europe's June conference, 'The Animal Health Industry - an Essential Partner for Global Health', attracted close to 150 delegates from a range of stakeholders, and featured a presentation by Markos Kyprianou, European Commissioner for Health and Consumer Protection, on the EU's future animal health strategy. Commissioner Kyprianou said Europe's policy-makers intended to step up activities in the animal health field in order to provide additional direction, strategy and synergy. The conference also featured speakers from a range of other EU institutions, international organisations, NGOs and the animal health industry.

**European Technology Platform for Global Animal Health (ETPGAH):** With the active support of the European Commission and involvement of fellow stakeholders, the federation made significant headway with the European Technology Platform for Global Animal Health (ETPGAH). Established to identify and promote a research agenda capable of fostering the development of effective tools for the control of animal disease, the platform is chaired by IFAH-Europe. The ETPGAH launched a strategic research agenda (SRA), which lays out plans to ensure close cooperation between the public and private sectors designed to achieve better coordination of research activities and accelerate innovation in animal health.

# Regional activities

## North America:

AHI, USA
CAHI, Canada
INFARVET-CANIFARMA, Mexico

**Regulatory affairs:** Four years after the US Congress passed a user fee programme, the industry has begun to see a return on the substantial contribution it now makes to funding the Food and Drug Administration's Center for Veterinary Medicine (CVM). Product review times have improved and a survey undertaken by the AHI indicated that regulators are now meeting or exceeding the performance targets laid down under the user fee initiative.

AHI working groups continue to monitor review procedures and identify additional areas in which levels of regulatory efficiency can be improved. The association is preparing for discussions with regulators on new or modified performance standards that may be introduced when the existing user fee agreement expires in October 2008.

Progress was also witnessed on measures to improve the availability of new 'minor use/minor species' (MUMS) products. Proposals designed to facilitate the registration of MUMS products - including rules governing designation for specialised procedures and the establishment of expert review panels to rule on the use of unapproved drugs in minor species - were issued by the FDA. The AHI reviewed the new proposals, providing comment and feedback to regulators on how draft regulations might be improved in order to enhance medicines availability.

In Canada, Health Canada's Veterinary Drugs Directorate (VDD) came under the leadership of a new Director General in 2006. With the change in leadership, CAHI established a positive working relationship with regulators, leading to consultations on technical requirements for submissions, updating of labelling guidelines, pharmacovigilance reporting, antimicrobial growth promotant evaluation and their submission tracking programme. The VDD is committed to eliminating the backlog of submissions, having a review stream that is current, and cooperating with the CAHI. A similar undertaking has been made by officials at the Veterinary Biologics Section (VBS) of the Canadian Food Inspection Agency, who are responsible for reviewing animal vaccines.

CAHI consulted extensively with VDD officials on a range of issues during the year, including the establishment of a risk-based approach to the product review process that could improve levels of regulatory efficiency. The positive working relationship was cemented at a joint workshop held in November, and the two parties have already committed to repeat that exercise in 2007. Discussions on a new approach to managing the review stream for veterinary vaccine submissions will also be held at an early stage in 2007.

In Mexico, INFARVET participated actively in the development and discussion of new legislation governing animal health and veterinary medicines. Significant progress was made during the year, and a new federal animal health law is expected to receive parliamentary approval in 2007. Norms governing good manufacturing practices (GMP) for veterinary products, on which the association held two seminars, are also expected to receive definitive approval during the year. Elsewhere, INFARVET was closely involved in the organisation of the Codex Alimentarius meeting held in Cancun during 2006.

**Antimicrobials in veterinary medicine:** Positive developments were also reported with regard to antimicrobial availability, against a background of continued debate surrounding antibiotic resistance. In the US, regulatory obstacles for food-animal antimicrobials were eased following the implementation of new qualitative risk-assessment guidance for evaluating the potential risk to human health of resistant bacteria. The first new therapeutic products for use in the treatment of bacterial infections in food animal species have already been approved under the new guidelines.

The AHI continued to successfully oppose federal legislative proposals that would overrule existing, science-based regulatory approaches by banning certain uses of antibiotics in animals. CAHI also headed off the potential withdrawal of performance-enhancing claims for a range of antimicrobials in Canada, which had emerged as a distinct threat following a blanket VDD call for the submission of new product-efficacy data in 2005. Following discussions between manufacturers and regulators, it was agreed to distribute an advisory notice to veterinarians and food-animal producers recommending the periodic evaluation of efficacy when using these products. In Mexico, INFARVET organised two technical presentations, and began preparing a video on prudent antibiotic use. It also worked closely with regulators on plans to step up controls on antibiotic use.

**Avian influenza:** Industry associations in the US, Canada and Mexico all played an integral part in the development of national approaches to the prevention and future control of potential avian influenza outbreaks. In the US, AHI representatives discussed the industry's technical capabilities with US Agriculture Secretary Michael Johanns, and discussed the coordination of key public messages with government officials and other stakeholders. In Canada, CAHI worked with federal and provincial governments under the Canadian Animal Health Coalition (CAHC) on the development of strategies to contain and eradicate avian influenza in the event of an outbreak. In Mexico, INFARVET contributed to discussions on the revision of regulations governing AI vaccines, which will be evaluated by the national centre for animal health (SENASA) in 2007.

**Food chain:** The AHI continued to build alliances with fellow stakeholders in a bid to spread key industry messages and gain broad support for IFAH policies. These efforts were instrumental in responding to both media and legislative threats to the use of antibiotics and certain vaccines in animals, and to adverse publicity surrounding the use of non-steroidal anti-inflammatory drugs in companion animals.

The association also collaborated with a range of producer and processor organisations on the development of quality-assurance programmes and the publication of guidelines on proper use of animal health products. A key dialogue with the Centers for Disease Control (CDC) was also initiated on how antimicrobials can be used to preserve the health and welfare of animals while protecting public health.

**Communications:** The value of effective communication was highlighted in the US during 2006, when AHI member companies and like-minded stakeholders worked together at state level to block proposed legislation that would have banned the use of animal vaccines due to concerns about mercury in products intended for human use. This state-level coalition also helped to defeat proposals that would have raised the cost of veterinary products and services by allowing plaintiffs to collect pain and suffering damages in litigation involving animals. In Mexico, INFARVET communicated extensively with a range of food chain partners through a series of conferences and seminars, and produced two videos outlining the association's work.

# Regional activities

## South and Central America:
CAPROVE, Argentina
SINDAN, Brazil

**Regulatory affairs:** Member associations in both Brazil and Argentina are committed to the implementation and enforcement of rigorous quality standards for veterinary medicines, and have cooperated closely with regulators on the development of new legislation in this sphere. Further progress was reported in both countries during 2006.

In Brazil, GMP inspections and audits for all plants manufacturing veterinary pharmaceuticals and biologicals were begun, while new legislation governing product stability and pilot batches was introduced. These initiatives will enhance levels of consumer confidence in the quality, safety and efficacy of animal health products.

In Argentina, CAPROVE continued to cooperate closely with regulators on initiatives designed to eliminate unfair competition from the market by rooting out tax evasion, demanding proper inspection of quality standards in the manufacturing sector and eliminating the unauthorised distribution of animal health products. Measures designed to enforce regulations governing marketing and distribution will be implemented in 2007.

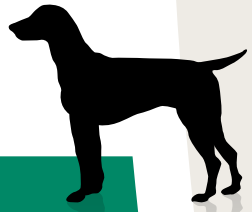
Both CAPROVE and the Brazilian association, SINDAN, are major contributors to CAMEVET, a joint industry-regulator initiative designed to harmonise rules governing veterinary medicines at regional level.

**Food chain:** Marking its 60th anniversary in November, CAPROVE tabled a major collaborative initiative designed to improve the quality and efficiency of food production in Argentina, with a view to improving prospects for the livestock and poultry sectors both domestically and in foreign export markets. Its plans received widespread support from regulators, the veterinary profession and producer organisations.

In Brazil, SINDAN continued to work with regulators, veterinary surgeons and farmers, ensuring that the country's extensive animal vaccination programmes - notably against foot-and-mouth disease (FMD) - are executed smoothly, and that vets and producers have access to adequate supplies of high-quality vaccines.

**Communication:** Strengthening communication activities and improving the image of the animal health industry are high on the list of CAPROVE's priorities for 2007. By cooperating closely with regulators, fellow stakeholders and the public, the association will look to drive home key messages and enhance the animal health industry's reputation as a responsible, trusted partner.

In Brazil, where the SINDAN Board was re-elected for a term spanning the period to December 2010, the association's president, Emílio Salani, now has five vice-presidents who will take on responsibility for key industry issues, including biologicals, feed additives, foot-and-mouth disease, pharmaceuticals and tax/ environmental measures.



# Asia-Pacific-Africa:

AAHA, South-East Asia
AGCARM, New Zealand
ASOHI, Indonesia
JVPA, Japan
KAHPA, Korea
MAHNIA, Malaysia
MAI, Israel
SAAHA, South Africa
The Animal Health Alliance, Australia

**Regulatory affairs:** Regulatory issues were high on the agenda of many associations in the Asia-Pacific region during 2006. The recently-established Asian Animal Health Association (AAHA) attended the OIE's regional conference on the harmonisation of veterinary drug registration procedures. The conference, held in Bogor, Indonesia, was used as a vehicle to set up meetings with regulatory officials from the region, at which AAHA representatives outlined the goals of the association and its future role in supporting regulatory reform efforts.

At national level, associations in several countries made vital contributions to the development and implementation of legislation governing the animal health sector, helping to ensure the introduction of practical, workable regulations and encouraging the enforcement of quality standards by the authorities in developing markets. In Indonesia, ASOHI met with government officials in a bid to resolve a range of issues affecting its members, including a recent slowdown in the regulatory approval process caused by funding problems, and measures to clamp down on the manufacture and distribution of illegal products. It also called on the government to issue official GMP certification for compliant manufacturers. The association is hopeful that continued dialogue will help to solve these issues.

In Japan, the JVPA published guidance documents on good quality practice and good pharmacovigilance practice and good vigilance practice for veterinary medicines designed to help manufacturers deal with regulatory changes implemented during 2005 under major revisions to the country's Pharmaceutical Affairs Law. Withdrawal periods for many veterinary drugs have also been revised following the introduction of maximum residue limits (MRLs), which have replaced the previous 'zero residue' policy operated by regulators. The JVPA liaised closely with the authorities on both issues, and made representations on behalf of the industry where MRLs adopted by regulators differ significantly from tolerances established under the Codex Alimentarius programme.

AGCARM has been a key player in the implementation of new legislation governing veterinary medicines in New Zealand, which has seen many products transferred into a new regulatory regime. The association was closely involved in discussions on labelling (incorporating new GHS provisions), and prepared a guide for the industry outlining new requirements, which now has statutory approval. It also liaised with the government on the development of a report addressing intellectual property, which the association is hopeful will be the prelude to improved protection periods for animal health products.
The Animal Health Alliance liaised closely with regulators in Australia to secure appropriate stakeholder involvement in the development of policies governing animal health products and ensure the continued efficiency and transparency of regulatory procedures. Discussions focused on issues such as sales levy percentage figures and revised product requirements and guidelines.

In Israel, implementation of new regulations governing the registration of insecticides, designed to bring national legislation into line with EU standards, began in 2006, while changes to GMP guidelines are being considered. The national industry association (MAI) held regular meetings with regulators on these and a range of other issues, including legislation governing pharmacies and veterinary drug import rules.

In Malaysia, MAHNIA is working closely with the National Pharmaceutical Control Bureau (NPCB), Ministry of Health, to formulate regulatory requirements for the registration of animal health products which have been gazetted. Seminars have been conducted by the association for the NPCB in relation to the assessment of veterinary products to demonstrate quality, efficacy and safety.

**Antimicrobials in veterinary medicine:** The AAHA liaised with governments across South-East Asia to drive home key messages regarding the importance of science-based decisions during the development of regulations governing the use of antimicrobials in food-animal species. Those efforts, which included a joint workshop with the Thai FDA on risk assessment, risk management and risk communication, helped to promote the continued availability of antibiotics for food-animal producers in the region.

In New Zealand, AGCARM liaised with NGOs and regulators in the human health sector, and made a detailed submission to the report of an expert panel on antibiotic resistance set up by the government. In cooperation with industry, including the veterinary profession, regulators are introducing best practice guidelines, programmes for monitoring antibiotic use and surveillance schemes.

In Malaysia, MAHNIA, in conjunction with Elanco, held a seminar for the Department of Veterinary Services addressing the scientific assessment of antimicrobial use in food-producing animals.

**Avian influenza:** While avian influenza has spread more widely around the globe in the past two years, countries in South-East Asia have borne the brunt of the disease, which has inflicted losses in excess of US$10 billion across the region. AAHA members provided a number of representatives from South-East Asia to participate in IFAH's global Avian Influenza Task Force during 2006, while individual companies also liaised closely with governments in the region to promote the implementation of effective prevention and control measures.

In Indonesia, ASOHI called on the government to prioritise the approval of products capable of contributing to avian influenza control efforts. The association confirmed its support for government vaccination programmes using H5N2 and H5N9 strains of the AI virus, and collaborated with regulators on the development of prevention, reporting and monitoring initiatives.

**Food chain:** IFAH member associations pursued dialogue and interaction with fellow stakeholders in a bid to encourage the responsible, prudent use of animal health products. Resistance to antiparasitic products is a significant problem in a number of southern hemisphere countries, and while research into new approaches to parasite control is being pursued, it is vital that existing product classes are used strategically in order to maximise their efficacy and limit the rate at which resistance develops.

In Australia, the Alliance continued to provide financial support for the WormBoss initiative, which is designed to manage internal parasites of sheep and control anthelmintic resistance. Resistance to anthelmintics is also an important issue in New Zealand, where AGCARM is closely involved with the implementation of the 'Wormwise' national worm management strategy. The programme aims to assist in the sustainable management of internal parasites through the provision of information and training for farmers and veterinary surgeons.

The veterinary profession and animal owners were also among the targets of information-based initiatives pursued by the national industry association in Japan, where veterinary drug residues are an issue of debate following the switch by national regulators from a 'zero tolerance' approach to the implementation of maximum residue limits (MRLs). The JVPA produced a publication for use by veterinary surgeons, distributors and producers, which aims to minimise the risks associated with residues of veterinary drugs in food by highlighting issues such as withdrawal periods and the need for responsible record keeping.

**Communications:** The ten founding members of the new Asian Animal Health Association (AAHA) will be joined by at least four more in 2007, as the association looks to broaden its influence in the South-East Asia region. AAHA commissioned an independent survey of salary levels for employees in the animal health industry, and reviewed the feasibility of conducting a sales audit based on data from member companies in specific markets.

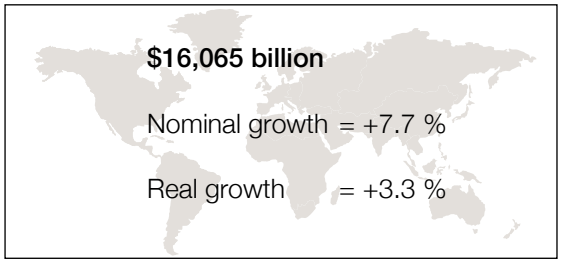
A detailed study on the use of ectoparasiticides was commissioned by the Alliance during the run-up to the release of the government's draft review on sheep ectoparasiticide products. Edited by Alliance Chief Executive Officer, Dr Peter Holdsworth, the publication underlined the value of these products to Australian livestock production. The Alliance also funded a study on the value of pets to Australian society. Launched in partnership with the Australian Veterinary Association, it focused on the statistical value of pets to the country, its economy and the structure of its society.

In Israel, MAI representatives met with the country's Agriculture Minister to discuss issues and opportunities facing the animal health industry, highlighting contributions made by the sector to the national economy and food safety.

In Malaysia, MAHNIA published a new quarterly magazine named 'Malaysia Livestock' with a circulation of 3,000 copies. The magazine is now the main channel to communicate veterinary health information, products, services and industry news to the livestock industry.

# Animal health industry profile

## Animal health industry in 2006






## Animal health market by product group

| Product group | 2006 ($m) | YoY*(%) | Share (%) |
|---|---|---|---|
| Medicinal feed additives | 1,995 | 3.1 | 12.4 |
| Biologicals | 3,660 | 8.6 | 22.8 |
| Anti-infectives | 2,540 | 7.6 | 15.8 |
| Parasiticides | 4,620 | 9.1 | 28.8 |
| Other pharmaceuticals | 3,250 | 7.8 | 20.2 |
| Total | 16,065 | 7.7 | 100.0 |

* Year over year percentage



## Animal health market by region

| Region | 2006 ($m) | YoY*(%) | Share (%) |
|---|---|---|---|
| North America | 5,600 | 9.8 | 34.9 |
| Latin America | 1,870 | 10.3 | 11.6 |
| West Europe | 4,850 | 5.9 | 30.2 |
| East Europe | 735 | 7.3 | 4.6 |
| Far East | 2,555 | 5.6 | 15.9 |
| Rest of world | 455 | 4.6 | 2.8 |
| Total | 16,065 | 7.7 | 100.0 |

* Year over year percentage



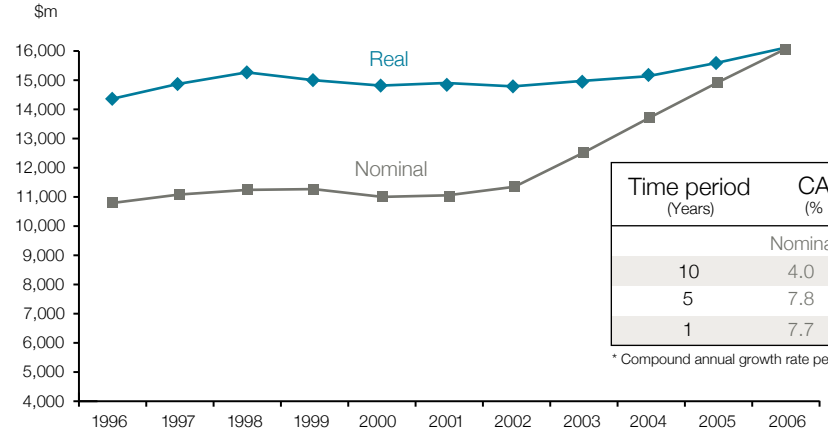
## Animal health market by species

| Species | 2006 ($m) | YoY*(%) | Share (%) |
|---|---|---|---|
| Cattle | 4,370 | 7.6 | 27.2 |
| Sheep | 770 | 1.3 | 4.8 |
| Pigs | 2,585 | 6.4 | 16.1 |
| Poultry | 1,730 | 3.3 | 10.8 |
| Companion animals/other | 6,610 | 10.4 | 41.4 |
| Total | 16,065 | 7.7 | 100.0 |

* Year over year percentage



## Animal health market evolution/consolidation




| Time period (Years) | CAGR (% p.a.*) | | | | |
|---|---|---|---|---|---|
| | Nominal | Real | Currency (%) | Price (%) | Volume (%) |
| 10 | 4.0 | 1.1 | | | |
| 5 | 7.8 | 1.6 | | | |
| 1 | 7.7 | 3.3 | 1.3 | 3.1 | 3.3 |

* Compound annual growth rate percentage per annum

# Who's who at IFAH

## Board of Directors*

**George Gunn,** President
Novartis Animal Health Inc

**Jerry Belle,** Vice-President
Merial Ltd

**Joachim Hasenmaier,** Vice-President
Boehringer Ingelheim Animal Health

**Patrick James,** Vice-President
Elanco Animal Health

**Raul Kohan,** Vice President
Schering-Plough Animal Health

**Eric Marée,** Treasurer
Virbac SA

**Ruurd Stolp**
Intervet International BV

**Stewart Cairns**
(representing South-East Asia)

**Peter Holdsworth**
(representing Australia/New Zealand)

**Carol Wrenn**
Alpharma Animal Health Division

**Lykele van der Broek**
Bayer HealthCare AG, Animal Health Division

**Declan O'Brien**
(representing Europe)

**Pierre Scarcériaux**
Janssen Animal Health

**Kevin Holloway**
Monsanto Company

**Alex Mathews**
(representing North America)

**Juan Ramón Alaix**
Pfizer Animal Health

**Sebastião Costa Guedes**
(representing South and Central America)

**Dominique Henryon**
Vétoquinol

**Yuhei Okamoto**
(representing Asia-Pacific)

* as at March 2007

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Novartis Animal Health Inc

Pfizer Animal Health

Schering-Plough Animal Health

Vétoquinol

Virbac SA

# Member associations

## Argentina

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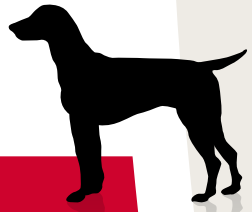
# Acronyms



| | |
|---|---|
| **AI** | Avian influenza |
| **AITF** | IFAH Avian Influenza Task Force |
| **CAHC** | Canadian Animal Health Coalition |
| **CCRVDF** | Codex Committee on Veterinary Drug Residues in Food |
| **CDC** | US Centers for Disease Control |
| **CVM** | US Food and Drug Administration's Centre for Veterinary Medicine |
| **CVMP** | Committee for Medicinal Products for Veterinary Use |
| **ECDC** | European Centre for Disease Control |
| **EDQM** | European Directorate for the Quality of Medicines |
| **EFSA** | European Food Safety Authority |
| **EMEA** | European Medicines Agency |
| **EPRUMA** | European Platform for the Responsible Use of Medicines in Animals |
| **ERA** | Environmental risk assessment |
| **ETPGAH** | European Technology Platform for Global Animal Health |
| **FAO** | Food and Agriculture Organisation of the United Nations |
| **FAQ** | Frequently asked question(s) |
| **FDA** | US Food and Drug Administration |
| **FMD** | Foot-and-mouth disease |
| **GACT** | IFAH Global Antimicrobial Core Team |
| **GHS** | Globally harmonised system of classification and labelling and chemicals |
| **GMP** | Good manufacturing practice |
| **GRCT** | IFAH Global Regulatory Core Team |
| **IFPMA** | International Federation of Pharmaceutical Manufacturers and Associations |
| **IMED** | International Meeting on Emerging Diseases |
| **ISID** | International Society for Infectious Diseases |
| **IZSVe** | Istituto Zooprofilattico Sperimentale delle Venezie |
| **JECFA** | Joint FAO/WHO Expert Committee on Food Additives |
| **MRL** | Maximum residue limit |
| **MUMS** | Minor use/minor species |
| **NGO** | Non-governmental organisation |
| **NPCB** | Malaysian National Pharmaceutical Control Bureau |
| **OIE** | World Organisation for Animal Health |
| **PROMED-mail** | A global electronic reporting system for outbreaks of emerging infectious diseases and toxins |
| **SENASA** | Servicio Nacional de Sanidad y Calidad Agroalimentaria / Mexican National Centre for Animal Health |
| **SPC** | Summary of product characteristics |
| **SRA** | ETPGAH strategic research agenda |
| **VBS** | Veterinary Biologicals Section of the Canadian Food Inspection Agency |
| **VDD** | Health Canada's Veterinary Drugs Directorate |
| **VICH** | Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products |
| **WHO** | World Health Organisation |
| **WTO** | World Trade Organisation |

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