

IFAH
Annual
Report
2009

Caring
for animals

Protecting
animal and
human health

Supporting
global food
production

—About IFAH

The International Federation for Animal Health (IFAH) represents manufacturers of veterinary medicines, vaccines and other animal health products around the world.

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

To fulfil its mission, IFAH will:

- Act as the voice of the industry in dialogue with 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;
- Facilitate the international harmonisation of regulatory guidelines governing animal health products.



IFAH's strategic priorities in 2009

1. Leadership

Maximise the effectiveness of IFAH at global, regional and national levels in both established and emerging markets in order to achieve our mission.

2. Value

Enhance perceptions of the animal health industry's value and contribution to society, building trust and acceptance among fellow food chain stakeholders and the public.

3. Regulation

Foster the development of a regulatory framework that supports the needs of both a sustainable animal health industry and of society as a whole.



— A message from IFAH's President

The past decade was one of tremendous change for our industry. Now, in a precarious economic climate, and with merger deals transforming the competitive landscape, the challenges we face have never been greater. Against this background, securing an environment capable of fostering a sustainable, innovative industry is crucial. In our strategic plan for 2009-2011 we identified three main objectives that will enable us to fulfil that goal.

First, we must maximise the effectiveness of IFAH by making best use of the resources at our disposal. By restructuring activities at global level, providing renewed guidance to our members and establishing a 'best practice' structure through which to address key issues, we have already taken an important step down that road. The re-organisation will allow us to focus more effectively on other key goals. Experience shows we can count on the goodwill and dedication of both our members and secretariat as we pursue the implementation of additional measures at global, regional and national level.

Second, we must secure improvements in the regulatory framework governing our industry. Here, our aim must be the establishment of workable rules that balance the concerns of society and the requirements of a small but highly innovative industry. This has always been a key goal for IFAH, and is an area in which we have achieved some notable successes. There is still much to be done, but we continued to make significant headway through 2009, guided by our new Regulatory Strategy Team.

Finally, we must promote a broader understanding of our industry's value to society. Media and consumer attitudes affect both the way in which veterinary medicines are perceived and approaches to their regulation. By shifting our approach, from the reactive to the proactive, we aim to gain the trust of both the public and fellow stakeholders, and to secure a full understanding of the role played by animal health products.

Without doubt, this is our greatest challenge. It is one we should approach with confidence, however, for the facts are clear: our industry is crucial not only to the preservation of animal health and welfare, but also – and increasingly – to the protection of human health and our ability to feed a rapidly-expanding population.

To keep pace with anticipated growth in demand for food, global production of meat and dairy products must double by the middle of this century. This will not be possible unless best use is made of products that enable farmers to increase their efficiency and minimise losses from disease.

Veterinary medicines have transformed both the health status of animal populations and the productivity of livestock agriculture in developed countries over the past 50 years. New products will deliver further improvements in future, while better access to veterinary medicines will have a dramatic impact on the economic fortunes of developing

countries, where many people rely on livestock not just for food, but as their sole means of income. In doing so, it can lift them out of poverty and help to tackle chronic hunger, which currently blights the lives of more than one billion people around the world.

These are simple truths – and yet they are lessons the world has been slow to learn. Thus, despite the clear link between livestock health and economic improvement among poor rural farmers, just 4% of international aid has been invested in agricultural development over the past 15 years. If our industry is to fulfil its potential, we must drive home our key messages effectively.

IFAH gained real momentum under my predecessor, George Gunn. My aim is to make sure we build on that progress, working together cohesively and effectively as a 'global industry team'. Looking back on developments in 2009, I am confident that we can rise successfully to the challenges facing our industry. I thank all those who have contributed to the federation's recent achievements, and look forward to working with you in 2010.



— *Eric Marée*
IFAH President

—A message from IFAH's Executive Director

My first full year as Executive Director of IFAH was an intense but highly rewarding one. I witnessed at first hand the level of commitment that exists – not only among the federation's secretariat, core teams and working parties, but also within the member companies and associations responsible for the execution of IFAH policies at national and regional level and in the international organisations with which IFAH interacts.

It was an opportunity to begin building personal ties – not only with regulatory bodies, government representatives and fellow stakeholders, but also with IFAH member associations such as AHI, BfT, JVPA, KAHPA and potential future members like the China Animal Health Products Association. Links between IFAH and many of these organisations are well established but were strengthened further in 2009, as readers will note elsewhere in this annual report.

We continued to cooperate with the OIE on a range of topics of mutual interest, while the development of our relations with the FAO represented a notable advance. Alongside the OIE, IFAH held detailed discussions with the Animal Health Service (AGAH) of the organisation's Animal Production and Health Division during the year. The federation was also involved in preparatory meetings with other private sector stakeholders in the run-up to the FAO's World Food Summit, which took place in Rome in November.

Global organisations such as the OIE, Codex Alimentarius, WHO, and the FAO co-operate with IFAH on a range of issues relevant to animal health, and to their wider implications. As we pursue broader recognition of our industry's value to society, we must interact with a growing range of other stakeholders. Establishing stronger links with other communities involved in health issues affecting people, animals and the environment is particularly important. Communication with the medical community is a priority, as we seek to highlight the interdependence of human and animal health and the potential synergies that can be achieved by pooling expertise in the two sectors.

Ultimately, our ability to achieve the federation's goals will depend on the successful dissemination of our core messages, so I am pleased to say we are in great shape where effective communication is concerned. Kim Hardie, who joined the secretariat as Communications Director in April 2009, has been quick to make her mark. Our new website went live during the year, while the new IFAH Value Team, which spearheads our drive to win broader recognition for the animal health industry, has made excellent early progress.

My first year with IFAH has been a strong reminder of the reasons I chose to study veterinary medicine, and of the common basic aims that we share with all of our fellow stakeholders: protecting the health and welfare of animals; safeguarding public health; and enabling the production of safe, quality food in quantities sufficient to feed a growing population. In this report, we offer you an insight into the role played by animal health products in achieving those aims, and into the activities and achievements of our federation at global, regional and national level during 2009.

—*Barbara Freischem*
IFAH Executive Director





— 'One World - One Health'™¹ : an integrated approach to the fight against infectious disease

Why pooling expertise is vital if we are to deal effectively with the growing threat posed by infectious disease.

'Medical and veterinary science', wrote one commentator recently, 'are like siblings who have grown apart.'² If that's the case, then the two certainly have a lot of catching up to do. And as recent infectious disease trends show, it's high time they began to get reacquainted.

Of the 1,461 diseases recognised in humans in 2005, 60% were due to multi-host pathogens³ that can affect people as well as animals, and that can pass from one species to another. Many are long-established. New infectious diseases such as SARS are being identified with increasing regularity, however, and about 75% of emerging human infections originate from animals⁴. At the same time, existing pathogens are mutating, resulting in the emergence of new threats such as the H5N1 and H1N1 influenza virus strains, while climate change is driving the spread of infections into new geographical areas.

The increasingly crowded nature of our planet – on which man and animals live in growing proximity – has enhanced the ability of zoonotic infections to jump between species. And once present in human populations, the unprecedented flow of commodities and people across the world enables pathogens to spread as never before.

The threat to human health posed by these diseases has grabbed most recent headlines. But their impact on animal health and food production has equally significant implications as we struggle to feed a rapidly growing population.

The One Health Initiative and One Health Commission

The need for an integrated approach to the fight against disease has been espoused by a number of organisations. Among them is the One Health Initiative (OHI): a movement set up to forge collaboration between medical and veterinary science. By doing so, it aims to enhance both human and animal health, expanding our understanding of infectious disease and accelerating the development of products that will prevent, control and eradicate zoonotic pathogens.

The OHI has won praise from key figures in both human and veterinary medicine, and has been endorsed by a growing number of organisations. Most notably, national associations representing both physicians (American Medical Association – AMA) and the veterinary profession (American Veterinary Medical Association – AVMA) have signed up as fully committed supporters.

Elsewhere, moves towards the adoption of a more integrated approach to infectious disease control have seen the establishment in the US of a national "One Health Commission". Its Executive Officer, Dr Roger Mahr, is a past president of the AVMA and a long-term advocate of the One Health concept.

A more holistic approach is also being pursued by international bodies with responsibility for human health, animal health and food production. Alongside several other international partners, the FAO, OIE and WHO are targeting the establishment of a strategic framework to combat infectious disease risks⁵. In March 2009, the Canadian Government – through its Public Health Agency of Canada – hosted a One World One Health™ Expert Consultation in Winnipeg⁶, at which international experts, including participants from IFAH and CAHI, discussed strategies for the implementation of this initiative. Delegates at the meeting called for the development of public-private partnerships in a bid to pool expertise.

¹ One World One Health is a registered trademark of the Wildlife Conservation Society

² Martin Enserink in Science Vol 316 No 5831 p 1553

³ TORREY EF and YOLKEN RH: Beasts of the Earth. New Brunswick, NJ: Rutgers University Press, 2005

⁴ TAYLOR et al.: Risk factors for human disease emergence. Philos Trans R Soc Lond B Biol Sci 2001

⁵ See «Contributing to One World – One Health™» at <http://un-influenza.org/node/2341>

⁶ See "One World – One Health™: from ideas to action" at <http://www.phac-aspc.gc.ca/owoh-umus/index-eng.php>



Ahead of the curve

The animal health industry is ahead of the curve where the pursuit of a more integrated approach to infectious disease control is concerned. Under the European Technology Platform for Global Animal Health (ETPGAH), it has brought together a range of stakeholders – including the OIE and FAO – in a bid to identify major disease risks and accelerate the development of tools capable of controlling them effectively. The federation’s call for the establishment of a global version of this initiative won support at the One World One Health™ Expert Consultation.



Because it is at the sharp end of the challenge posed by established, emerging and migrating infectious disease pathogens, IFAH recognises the need for an integrated approach to combating the threat they pose. The federation’s members have played a key role in the control of many infectious agents, ranging from rabies to food-borne pathogens such as salmonella. Animal vaccines against both of these pathogens have been developed, and are used around the world to limit their impact on human health, animal health and food production.

More recently, the animal health industry has developed novel tools enabling effective control of new threats posed by pathogens such as the H5N1 avian influenza virus, bluetongue and West Nile virus. A mosquito-borne pathogen, West Nile virus (WNV) had not previously been recorded in the US, but spread rapidly following its arrival there in 1999. The first vaccine for the protection of horses against WNV was approved by US regulators just

three years later, but no vaccine for use in humans is available to date. In the meantime, close to 30,000 human cases have been confirmed in the US, with over 1,000 proving fatal.

“At least 60% of all human diseases have their origin in animals. Effective prevention and control of infectious diseases at the animal-human-ecosystems interface are key to combating the spread of diseases in animals and humans, enhancing food security, and fostering poverty reduction. Increased transparency in the animal health situation contributes to better public health.”

—Bernard Vallat, OIE Director General

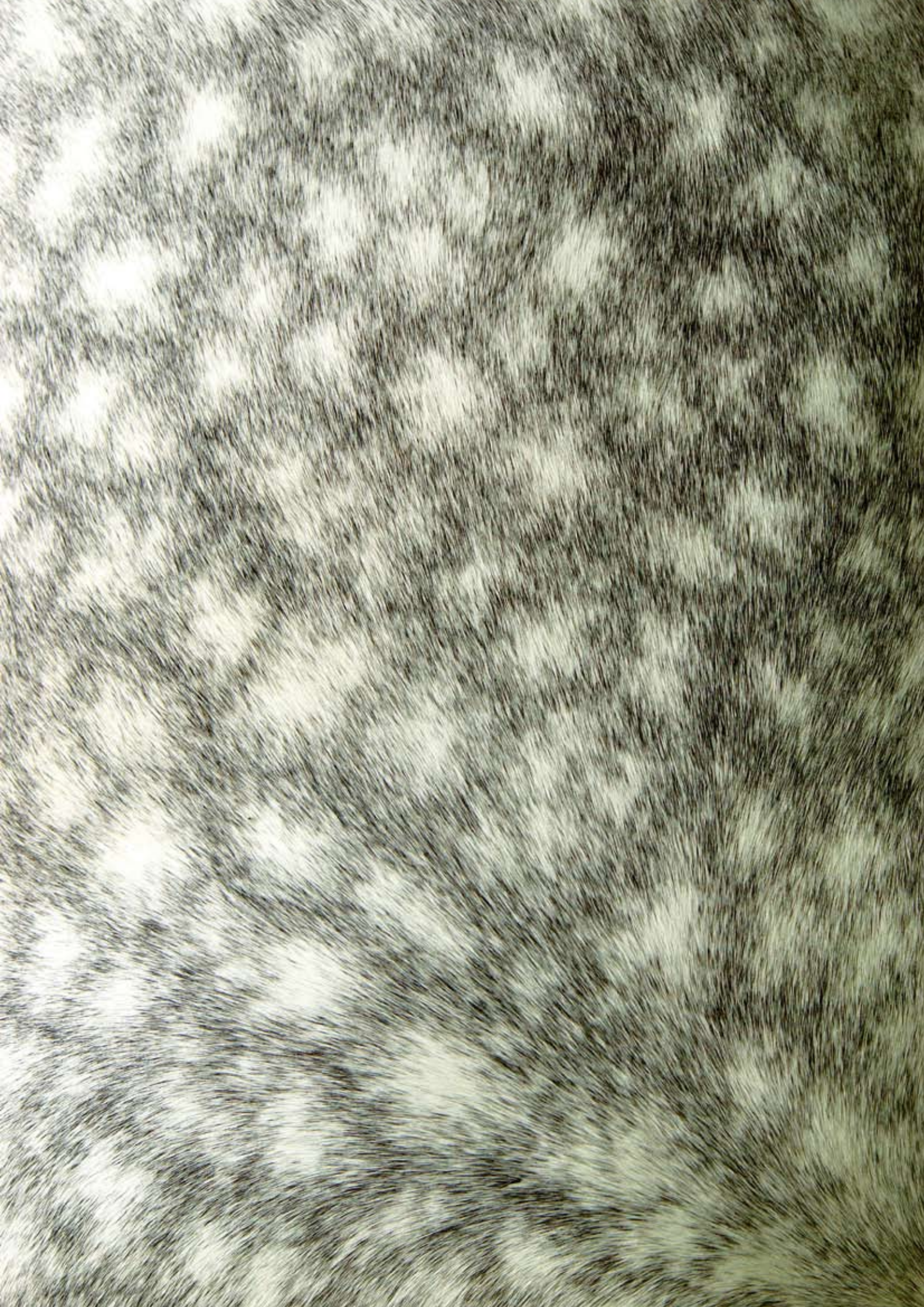
One of the first equine WNV vaccines was based on a technology platform which allowed for the concurrent development of products for use in both humans and horses. An equine version was subsequently developed and brought to market by one of IFAH's member companies. The human version, which is in late-stage clinical trials, is the most advanced vaccine candidate for the protection of people against WNV.

The use of a common technology platform for concurrent development of veterinary and human vaccines against the same pathogen exemplifies the potential offered by integrated approaches to the fight against infectious disease. By harnessing the combined expertise of medical and veterinary science we can transform our ability to control and eradicate a range of pathogens that pose major threats

to both human and animal health, and that undermine the viability of livestock agriculture and food production in parts of the world.

Key developments in 2009

- An IFAH delegation participates in the One World - One Health™ expert consultation, convened in Winnipeg, Canada during March 2009 to discuss a 'Strategic Framework for Reducing Risks of Infectious Diseases of the Animal-Human-Ecosystems Interface.' Delegates call for the development of public-private partnerships, citing the federation's European Technology Platform for Global Animal Health (ETPGAH) scheme as a model initiative.
- IFAH produces a statement and Question/Answer document addressing some common misconceptions about the H1N1 influenza A outbreak in humans, and explaining how swine influenza is managed and controlled effectively.



—Where would we be without them?

Have you ever stopped to consider the magnitude of the role played by animals in our society – or the extent to which veterinary medicines have transformed their health and welfare?

How to place a value on animals? Where the millions of cattle, pigs, sheep and poultry raised to meet global demand for animal protein are concerned, it is the market that decides, with values usually measured in tens or hundreds of euros.

Commercial considerations also determine the financial worth of performance animals, though here, the value of outstanding individuals can be measured in millions. Sea The Stars, winner of two English classics and the 2009 running of Europe's richest horserace – the Prix de l'Arc de Triomphe – may have been retired from the track, but is now about to embark on a career at stud that will net his owners more than € 12 million a year.



Beyond value

Market forces do not apply in parts of the world, where for millions of subsistence farmers, animals are part of more fundamental equations. The size and quality of livestock herds or flocks can determine social status. Raising livestock is also the main source of both employment and income in rural areas of many developing countries. More importantly, animals represent the only source of affordable food for populations in the world's poorest regions, providing a vital buffer against chronic hunger.

Nor would many owners care to place a monetary value on the much-loved pets that add an extra dimension to family life in millions of households around the world. And what about animals like Hunter, the seven-year-old



border collie who located three young girls, subsequently pulled alive from the rubble of a collapsed building in Port-au-Prince days after the Haitian capital was hit by a devastating earthquake?

Hunter was one of six search and rescue dogs deployed to Haiti with their handlers by the US Search Dog Foundation (SDF). Between them, they were responsible for saving ten lives in the days following the disaster. The SDF has been involved in around 30 major search and rescue efforts over the past decade, in the course of which its highly-trained dogs have helped to locate both survivors and victims of catastrophes. How can we possibly place a value on animals like these?

Less dramatic perhaps, but invaluable nonetheless, are the day-to-day roles played by a host of other animals: guide dogs, which transform the lives of their physically impaired owners; police horses; and the 'therapy' animals that we now know can have such a profoundly positive impact on severely disabled children.

The animal health revolution

Like the millions of animals they benefit, the role played by veterinary medicines is often overlooked. They help to keep equine athletes like Sea The Stars fit and healthy to race and breed. They shield canine



“Livestock are an income source, insurance policy, a source of basic nutrition, of dignity and self-determination for millions of people living in some of the Earth’s most challenging conditions. The widespread loss of animals through disease devastates these communities. GALVmed is working with partners, including IFAH, to make livestock vaccines, medicines and diagnostics available to those who need them most.”

—Steve Sloan, GALVmed Chief Executive Officer

heroes like Hunter from life-threatening infections, and they help keep your own beloved pet healthy too.

The impact of animal health products over the past 60 years has been truly revolutionary. Poultry production has been transformed by products that can control coccidiosis in broilers – a development that has helped to protect the health of millions of animals and enabled farmers to provide an affordable source of protein for millions of consumers. Highly effective parasite controls have enhanced the health and welfare of cattle, sheep and pig populations, and have helped farmers to combat the huge losses that can be caused by worm and fluke infections. And foot-and-mouth disease – which is among the most feared of all ruminant infections – has been controlled or eradicated in many regions, thanks to the development of effective vaccines and to concerted efforts on the part of policy makers, public health officials and veterinarians.

The animal health industry’s impact on the health and welfare of pets and leisure animals has been equally significant. Parvovirus, once such a common cause of canine deaths, is now prevented routinely – alongside a growing range of other potentially fatal infections – by safe, effective vaccines. Cats, horses and other

companion animal species have benefited from similarly dramatic developments in veterinary immunology, while revolutionary new products have enabled the effective control of parasites such as fleas and ticks to which companion animals are exposed.

The effective prevention of so many diseases in such a wide range of species is one of the animal health industry’s greatest achievements. The scale of that success is reflected by comparative figures, which show that while vaccines account for about 1% of medicines used in human healthcare, their share of the animal health market has reached almost a quarter.

While the range of preventative products available to veterinary surgeons and owners continues to grow, animals still get sick. And a sick animal, like a sick person, needs treatment. Here again, the range and complexity of available products continues to grow, spanning anti-infectives, parasite controls, reproductive aids and metabolic drugs, as well as novel treatments for chronic conditions such as osteoarthritis, cardiovascular disease and even cancer.

The animal health industry remains both innovative and dynamic, ploughing well over a billion dollars a year into

the research and development of novel products, and responding rapidly to new or emerging disease threats.

When a new strain of bluetongue virus began to ravage Europe’s sheep flocks in 2006, the industry set about the development of new vaccines targeting the strain. Developing and registering a new or improved vaccine serotype normally takes between five and seven years. But with co-operation from regulators, who expedited review procedures, the industry presented Europe’s sheep farmers with vaccines against bluetongue serotype 8 in less than two years.

New operational models designed to help address animal health needs in emerging markets are also beginning to emerge. Among the most notable is GALVmed – the Global Alliance for Livestock Veterinary Medicines – a charitable foundation that promotes public-private partnerships to tackle specific needs in Africa and Asia. IFAH is very supportive of GALVmed and some members contribute considerable expertise to the alliance’s projects.

As new disease challenges emerge, the industry is playing a growing role in the protection of both human and animal health. And just like the animal populations it serves, its value to society deserves broader recognition.

Key developments in 2009

- IFAH establishes a new Value Team, tasked with enhancing recognition of the animal health industry’s contribution to society, and with managing key issues faced by the federation’s members.
- IFAH launches its new website, offering external audiences access to an expanded range of information spanning animal health issues, the industry, its products, and the role it plays in protecting animal health and welfare, human health and food safety.
- IFAH is an active participant at major conferences organised by global bodies such as the FAO, WHO and OIE, and builds on existing relations with a range of other key stakeholders.



—Rising to the global food security challenge

Animal health products have already transformed livestock agriculture in the developed world. Now they can play a major role securing the availability of safe, healthy food for all.

In 1996, 180 nations gathered at the FAO's Rome headquarters for a World Food Summit. They left having pledged to eradicate hunger, and set a basic target of halving the world's malnourished population by 2015.

Fourteen years later, chronic hunger is more widespread than at any time over the past 40 years, and is rising. One in every six of the global population is malnourished. The figure rose by 100 million to 1.02 billion in 2009 – a year in which the FAO convened its most recent World Food Summit – driven up by a combination of high food prices and the global economic crisis.

Already struggling to tackle hunger, the world will face an even greater challenge in future. UN forecasters expect the global population to exceed 9 billion by the middle of this century, while the FAO says the nutritional needs of a growing population will require a 70% increase in food protein production by 2050. Meat production alone will need to rise by 200 million tonnes.

The FAO has calculated that farming new land and increases in cropping intensity will contribute only 30% of the required increase in output. Accordingly, it concludes that 70% of the world's additional food needs can be met only through the adoption of new and existing agricultural technologies that will make production more efficient. Put simply, feeding the world will not be possible unless optimal use is made of key inputs, including veterinary medicines and vaccines.

Meeting the challenge

Alongside advances in livestock breeding and nutrition, animal health products have helped to transform livestock agriculture and food production in developed countries over the past 50 years. By cutting mortality rates and reducing losses from disease, they have contributed to significant increases in productivity.

Access to highly effective vaccines, parasite controls, anti-infectives and a range of other veterinary medicines helped Europe's farmers respond to calls for increases in both output and efficiency in the second half of the 20th century. They helped fuel a similar surge in production and productivity in the US, where meat production rose by almost 90% in less than 50 years, and where egg and poultry output increased by over 400% in the same period.

The industry has continued to invest in the development of innovative products that protect animals from a growing range of diseases and allow farmers to get the best from their stock. New vaccines have been used to tackle emerging infections and to prevent food-borne diseases, while novel technologies have enabled farmers to produce more milk and meat from fewer animals, saving huge amounts on feed – the production of which would have tied up hundreds of thousands of acres of scarce agricultural land.

By controlling and eradicating a range of animal diseases – including many zoonotic infections – animal health products have made a major contribution to food safety. And by eliminating losses caused by those infections they have also helped to make food more affordable, contributing to a 75% fall in global food prices, relative to wages, over the past 60 years.

The global-local disconnect

Despite these advances, food remains neither affordable nor readily available to more than a billion people worldwide. And 2008 – a record year in terms of global agricultural output – was also a year blighted by food shortages and rising prices in some of the world's poorest countries.

This fundamental disconnect was addressed by global food industry representatives, who met with the FAO in the run-up to its World Food Summit in November 2009. Our failure to tackle hunger more effectively since 1996 reflected problems not with food production, but with its distribution, they said, highlighting the impact of losses sustained within the food chain in developing countries.

A sizeable chunk of those losses occur at producer level. The OIE estimates that animal disease reduces global output of animal protein by 20%. Its impact is greatest in developing countries, where two-thirds of the world's poor are reliant on livestock as their main source of food and income.

Co-operation and co-ordination

The declaration signed at the end of the 2009 World Food Summit called for urgent action at national, regional and global level, but stressed the need for better co-ordination of initiatives designed to tackle hunger.

IFAH is determined to ensure that the animal health industry plays its part in efforts to feed the world more effectively. Established products and new technologies will help farmers in the developed world produce animal protein more efficiently and effectively, contributing to required increases in global food production. Clearly, however, problems in many developing countries require local rather than global solutions.

The federation and its members are realistic. Some of the technologies that have driven the revolution in livestock agriculture across Europe and North America will not be applicable in developing countries, where production is still dominated by small-scale farming. Better access to effective, quality animal medicines, could have a hugely positive impact for many producers, however.

IFAH is already working alongside the FAO on projects aimed at improving access to quality products in parts of Africa. At a broader level, it is helping to pool scientific knowledge in a bid to develop vaccines and other new drugs that will be targeted specifically at problems faced by livestock farmers in developing countries. For it is here that developments enabling the production of quality food can exert the biggest impact – reducing losses, boosting incomes and – as a result – helping to break the existing cycle of poverty and hunger.

“The FAO Animal Health Service and IFAH have developed joint activities related to the quality of veterinary drugs, initially focusing on treatments for Nagana. Counterfeit drugs are a worldwide problem, particularly felt in developing countries, with severe implications for animal health, food safety as well as public health.”

*—Juan Lubroth,
Head of the Infectious Diseases Group,
Animal Health Service, FAO*



Key developments in 2009

- IFAH delegations participate in major preparatory meetings for the FAO's 2009 World Food Summit, including a high-level expert forum on 'How to Feed the World in 2020', and an FAO/private sector dialogue designed to build a consensus on approaches to global food supply challenges.
- IFAH representatives discuss improving access to high quality animal health products with representatives from developing countries at the OIE conference on veterinary medicines in the Middle East, held in Syria at the beginning of December 2009.
- The federation produces a new brochure on veterinary medicines and food safety. Underlining the basic message that healthy animals make safe food, it explains how rigorous scrutiny by regulators and strict adherence to residue limits and withdrawal periods ensure the safety of food for consumers.



—In search of a new regulatory paradigm

How does the regulatory framework governing veterinary medicines affect the animal health industry – and how is IFAH working to improve current legislation?

Disease poses a growing threat, not only to the health and wellbeing of human and animal populations, but also to the efficiency – and in places even the viability – of livestock agriculture. The need for products that can treat, control or eradicate these infections has never been greater, and yet the availability of some established veterinary medicines is also under threat. So too is the ability of the animal health industry to provide farmers and veterinary surgeons with innovative new products, as it grapples with a challenging regulatory framework.

Animal health products are subjected to exhaustive testing in the course of their development, and rightly so. Requests for permission to market a veterinary medicine are granted by independent regulators only when they are satisfied that the product has demonstrated required levels of efficacy, safety and quality.

The potential impact of a product on the environment is also assessed where this is deemed necessary, while maximum residue limits and withdrawal periods must be established if it is intended for use in food-producing animals. Nor does regulatory scrutiny cease upon approval, with post-marketing surveillance representing an integral part of the regulatory process.

Regulatory impact

IFAH supports fully the application of rigorous, science-based regulatory standards to all veterinary medicines. Legislation must be proportionate, however, and must be applied consistently if it is to support a sustainable, innovative industry capable of delivering new products and technologies that address the needs of animals and their owners.

A comparative study of legislation undertaken by the federation in 2007 revealed a number of shortcomings. IFAH is now working on preparations for a repeat survey that will take place in 2011.

Existing problems stem partly from the tendency to apply common regulations to both human and veterinary medicines, ignoring major differences in terms of product requirements, the conditions under which they are used and – crucially – the gulf in resources that exists between the two industries. This trend has imposed a growing, often unnecessary burden on the animal health industry, which has also been hampered by divergent approaches to the way regulations are applied in particular markets.

The impact of these failings on the industry has been dramatic. Product development costs have risen by 150% since the 1990s. Over the same period, the average time taken to bring a new veterinary medicine to market has increased by almost five years, while companies are now spending more than a quarter of their entire R&D budgets on defensive research required simply to maintain approvals for existing products.

Politics have also been allowed to creep into the regulatory process, overriding science-based considerations where the use of some veterinary medicines and animal health products is concerned. This has denied farmers in some markets access to novel products and technologies capable of improving production efficiencies. It also threatens the future availability of some long-established products with proven track records in terms of safety, efficacy and quality.

IFAH goals

Encouraging and assisting the development of predictable, proportionate, science-based regulations has been high on IFAH's agenda since its inception. It has assumed added importance in light of survey results that have quantified the impact of existing regulations on the industry.

Over the years, the federation and its members have highlighted a number of shortcomings in the existing regulatory framework. It has always pursued a constructive approach, however, tabling proposed solutions to current problems and working alongside regulators to improve procedures and standards.

“Codex standards ensure that public health is protected, that developing countries have access to required public health tools, and that trade issues precluding the movement of food are minimised. I look forward to working with the animal health industry and others in CCRVDF to forge new approaches to these global health challenges.”

*—Steven D Vaughn,
CCRVDF Chairman*



This positive approach has reaped rewards in several areas, eliciting the amendment of key regulations in major markets. The federation has also played a central role in initiatives designed to harmonise regulatory approaches. Where the world’s biggest markets are concerned, this has involved participation in the tripartite VICH initiative, through which industry and regulators from the EU, the US and Japan have defined and implemented a series of harmonised regulatory guidelines.

Adherence to common standards at a broader, global level is required in order to protect the health of both animals and consumers, and to ensure the availability of safe, quality animal health products. Accordingly, IFAH and its members are active participants in the work of Codex Alimentarius, which has developed a range of harmonised food safety standards impacting on the regulation of animal health products. These have been adopted by many smaller countries which lack the resources required to generate their own national standards.





Key regulations have been simplified and harmonised in a number of markets as a result of IFAH's work but the federation continues to pursue further improvements. It has turned its attention to issues such as product identification, and to the provision of incentives for innovation through appropriate protection of data linked to the registration of animal health products.

Adequate protection of proprietary products and data generated in support of their approval is vital if companies are to reap fair rewards for the significant risk attached to their development. Product patents are now recognised widely around the world, but data protection remains inadequate in many countries.

The degree to which data protection is available varies widely between individual markets. It is non-existent in some countries and remains deficient in others, while approaches to implementation still vary where explicit legislation has been established.

Exclusivity periods must be increased to reflect the time required to develop and register new animal health products. A new IFAH working group, established in 2009, will pursue the implementation of stronger data exclusivity provisions over the next two years.

Key developments in 2009

- IFAH's Regulatory Strategy Team co-ordinates the dissemination of key industry messages in a range of international fora, reporting positive developments in all major regions.
- While challenges remain, the VICH initiative achieves further significant progress towards improvements in levels of regulatory harmonisation and efficiency.
- Some headway is also made in the Codex Alimentarius forum, where IFAH highlights the need for the adoption of more timely assessment procedures during the development of global standards.
- IFAH publishes a new brochure on maximum residue limits (MRLs), outlining the steps involved in the establishment of MRLs and their contribution to consumer safety.





Antimicrobials

Maintaining access to antimicrobials

IFAH-Europe produced a paper detailing its views on future volume collection systems as a contribution to the ongoing work of the European Medicines Agency. Very fruitful discussions were held with the Agency, the Member States and other agencies. It is anticipated that a very functional system will be introduced in the coming two years.

In preparation for a report from the relevant European agencies, IFAH-Europe published a report entitled "Review of European Surveillance Programmes" to help inform the discussion and debate. The report from the agencies is balanced and recognises the need for responsible use along with data gathering concerning volumes and resistance patterns as a means of obtaining good information on which to make informed decisions.

Responsible use of antimicrobials

Partners in the European Platform for the Responsible Use of Medicines in Animals (EPRUMA), of which IFAH-Europe is a founding member, agreed to develop a range of new communication tools – including a dedicated website – which will be made available in 2010. New versions of EPRUMA's booklet outlining a best practice framework for the use of antimicrobials in food-producing animals were published in Italian and Polish.

—Regional activities: North America

AHI, US – CAHI, Canada – INFARVET, Mexico

Regulatory affairs

Efficient regulation

CAHI President Jean Szkotnicki continued to chair an advisory committee set up by Canadian regulators to advise on how best to increase the efficiency of veterinary drug review procedures there. Significant improvements have been witnessed recently, but further progress is required.

Health Canada's Veterinary Drugs Directorate (VDD), which cleared the last of a decade-long registration backlog in 2009, plans to pilot phased reviews of some submissions as it looks to streamline review procedures further. The Canadian Centre for Veterinary Biologics (CCVB) of the Canadian Food Inspection Agency is also pursuing procedural improvements – including the possible implementation of phased review procedures for vaccines that have been approved in the US.

CAHI and fellow stakeholders continue to press for regulatory reforms that would ensure Canadian livestock producers have access to management tools that are available to their counterparts in the USA bill consistent with that goal was lost after Parliament was suspended in December 2009. CAHI remains confident that momentum on this issue will be maintained, however, resulting in more

timely approvals for new veterinary drugs and vaccines.

In the US, AHI continued to monitor implementation of amendments to the Animal Drug User Fee Act (ADUFA) which were introduced in 2008. Fees paid by the industry have already enabled the Food and Drug Administration's Center for Veterinary Medicines (CVM) to hire more reviewers and invest in improved procedures and systems. In return, regulators must comply with timely review targets, and vowed to reduce review periods further under the 2008 agreement.

Quality standards

Illegal compounding of veterinary medicines poses a growing threat to sales of legitimate, authorised products in both the US and Canada. In the US, AHI established a new working group to press for FDA action against violators and educate veterinary surgeons about the danger of administering compounded products of unknown quality. In Canada, CAHI continued to advocate tighter regulation of compounding, and of the import of unlicensed products for 'personal use'. Both activities have reached such levels that the association believes loopholes in existing legislation – representing Can \$100 million a year in opportunity

values – will be addressed when the government modernises legislation pertaining to food and medicines.

In the US, AHI established a new working group that will initiate consultations with the Environmental Protection Agency (EPA) on the evaluation of adverse reaction reports concerning spot-on flea and tick controls. In the biologicals sector, the association coordinated discussions between manufacturers, regulators and producer groups regarding H1N1 influenza vaccine requirements.

INFARVET worked closely with the Mexican government on the development of technical guidelines that will be annexed to a major revision of the country's Federal Animal Health Law. Many of its recommendations have been taken up, and will be included in the new regulation when it is published in 2010. The association also lent its support to moves that will see the application of good manufacturing practice (GMP) standards to veterinary medicines, calling for the creation of certification procedures that guarantee the quality of manufacturing operations. Elsewhere, INFARVET was involved closely in the revision of guidelines for avian influenza vaccines, and drew up detailed proposals on the regulation of autogenous vaccine products.

Antimicrobials

Maintaining access to antimicrobials

The AHI joined forces with other stakeholders in a bid to educate lawmakers on the role played by antimicrobials in livestock agriculture, and on the essential differences between animal and human medicine. This followed the introduction of draft

legislation which threatens to deny veterinary surgeons and farmers access to products that play a vital role in disease control and prevention. The American Farm Bureau said proposals contained in the draft Preservation of Antibiotics for Medical Treatment Act (PAMTA) would jeopardise both animal health and food safety.

Antimicrobial usage

CAHI prepared and submitted a summary of antimicrobial volumes sold by its members to the Canadian Integrated Program on Antimicrobial Resistance Surveillance (CIPARS). In the US, AHI developed a new form for the collection of data on antimicrobial use.



Communication

Value

AHI initiated a major communication and education campaign designed to broaden understanding of the role played by veterinary medicines in protecting both animal and human health. A dedicated website, www.HealthyAnimals.org, was launched alongside a range of other materials designed to deliver key messages. The initiative also included a stakeholder and media outreach element.

Stakeholder initiatives

In Mexico, INFARVET organised and took part in conferences which brought together a broad range of stakeholders with interests in animal health. The association's annual conference,

which addressed challenges and opportunities facing the animal health industry, was a great success, while a forum on the responsible use of veterinary medicines was also well attended.

Assisting pet owners

CAHI members produced and distributed new 'tear-off' information slips for vets to give to owners following the vaccination of companion animals. Designed to help owners distinguish between adverse reactions to vaccines, which require veterinary follow-up, and transient but harmless reactions to vaccination, the initiative received strong support from the veterinary profession, with the Canadian Veterinary Medical

Association requesting the inclusion of its logo on future materials as a mark of their support. In the US, more than 650 Members of Congress, congressional staff and other delegates attended AHI's Pet Night on Capitol Hill.

Product disposal

Working with pesticide manufacturers, the provincial government, agricultural retailers, vets and producer groups, CAHI participated in a province-wide collection of unwanted/expired products and used sharps from farms across Ontario.



—Regional activities: Asia / Africa

AAHA, South-East Asia – ASOHI, Indonesia
– JVPA, Japan – KAHPA, Korea – MAI, Israel
– SAAHA, South Africa

Regulatory affairs

Efficient regulation

The AAHA liaised with national industry associations and governments across south east Asia as part of its strategy to encourage regulatory reform in the region.

Campaigning by the MAI's animal health division paid off in 2009, when guidelines for the fast-track approval of veterinary medicines were adopted by Israel's Health and Agriculture ministries. The industry continued to work with regulators and the veterinary profession on the development of policies governing extra label use and regulatory requirements for companion animal products.

In South Africa, SAAHA has initiated legal action against regulators, citing delays in the registration of animal health products under Act 36 of 1947. Livestock health products are still regulated under this legislation, despite the recent passage of a new Medicines Act. The association has called for a single act to be applied to the registration of all animal health products.

Regulatory standards

A mutual recognition agreement was signed under which the EU will recognise GMP certifications issued by Israel's Ministry of Health for veterinary pharmaceutical

manufacturing plants. MAI is pursuing an extension of the agreement to cover veterinary vaccines.

In Indonesia, ASOHI continued its dialogue with the government regarding regulation of the animal health sector. New legislation designed to clamp down on illegal veterinary medicines was introduced, while responsibility for licensing distributors was devolved from central government to provincial level. ASOHI was also involved in discussions with government officials on GMP standards.



Antimicrobials

Prudent use

Dr Jan Koesling represented the AAHA and IFAH at an FAO expert

workshop on improving biosecurity through prudent and responsible use of antimicrobials in aquaculture.

Communication

Stakeholder initiatives

Alongside its parent association, the animal health division of the MAI embarked on a campaign designed to highlight the quality and safety of locally-manufactured pharmaceuticals in Israel. The group maintained regular contacts with the food industry in a bid to improve awareness and understanding of issues such as safety, quality and traceability.

In Indonesia, where ASOHI celebrated its 30th anniversary, the association organised a road-show which toured the country's universities, and conducted a seminar on prospects for the poultry industry. The 7th edition of the Indonesian Veterinary Drug Index and a new feed additive compendium were launched, along with a publication marking the association's anniversary.

In South Africa, SAAHA continued to work with partners from the crop protection sector and the Department of Environmental Affairs on the implementation of a sustainable waste management programme. The industry will eventually submit an integrated waste management plan for approval under the National Waste Management Act.

[Efficient regulation](#)



—Regional activities: Australia / New-Zealand

AGCARM, New-Zealand – The Animal Health Alliance, Australia

Regulatory affairs

Highlighting efficiency failings in the regulatory framework governing animal health products in Australia, the Animal Health Alliance launched a campaign for change. In a position paper addressing the issue, the association noted structural, procedural and legislative weaknesses in the existing system. It has called for the establishment of a fast-track approval process for products already approved in the EU or the US, and for improvements in the transparency and efficiency of the system.

Regulatory efficiency and the duplication of resources were also high on the industry's agenda in New Zealand, where revised registration requirements for branded veterinary medicines and new legal classifications have increased the regulatory burden. The authorities responded to AGCARM's calls for change by organising two workshops at which potential improvements were explored. AGCARM also completed a detailed submission on intellectual property issues. The association expressed support for the extension

of patent terms where exclusivity periods have been eroded by regulatory delays. It also called for the introduction of stronger data exclusivity provisions for animal health products, branding current levels of protection 'woeful'.

Antimicrobials

Managing resistance

Alliance CEO Dr Peter Holdsworth was part of the Australian delegation to the 3rd session of the Codex

Alimentarius taskforce on antimicrobial resistance, held in Jeju, Korea. Major goals were to ensure that guidelines being developed by the taskforce

focus on food safety issues, are usable in developing countries, and focus on risk assessment/management methodologies.

Communication

Stakeholder initiatives

In meetings with regulators and fellow stakeholders, the Alliance highlighted shortcomings in Australia's regulatory framework. Addressing the country's cattle producers, it described how over-restrictive, inefficient registration procedures were denying them access to important management

tools. Key industry messages were also disseminated in meetings with regulators, and at the annual 'Science Meets Parliament' event.

Increased visibility

AGCARM revamped its communications strategy, targeting a more visible presence for the

industry in both print and audio media. The association launched a new website, offering improved tools for members and a broader range of information – including a regular newsletter – aimed at external audiences.





— Animal health industry profile

2009 Animal health industry



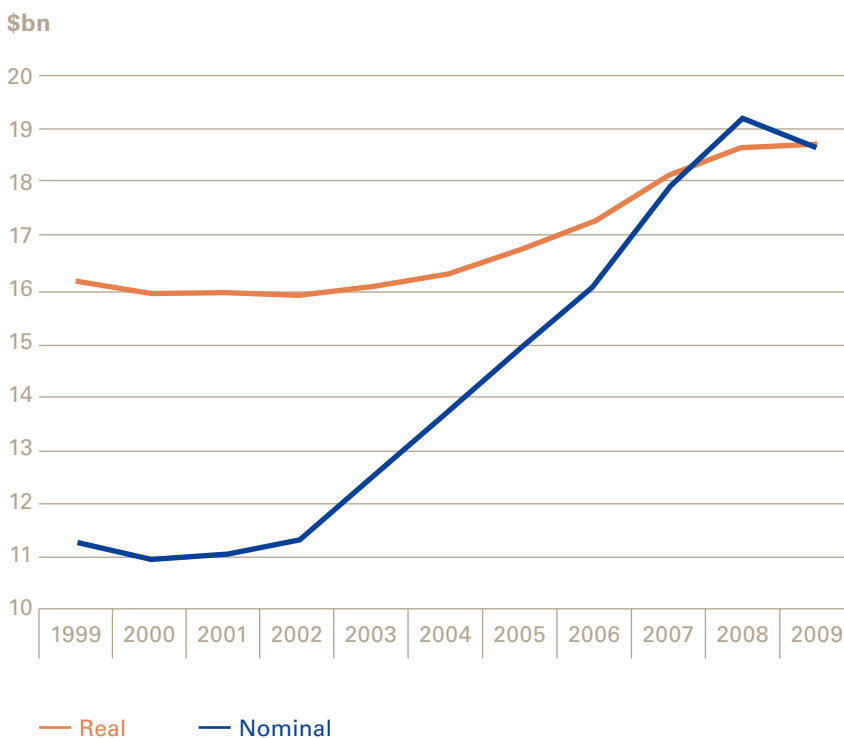
18.6
\$ billion

-2.8%
Nominal growth

+0.3%
Real growth

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Global animal health market evolution



| Time Period (Years) | CAGR % p.a.* | |
|---------------------|--------------|------|
| | Nominal | Real |
| 10 | 5.2% | 1.4% |
| 5 | 6.3% | 2.8% |
| 1 | -2.8% | 0.3% |

*Compound annual growth rate percentage per annum

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2009 Animal health market by product group

Medicinal feed additives

2.2 \$ bn
1.6 year over year % (nominal)

Biologicals

4.7 \$ bn
-0.3 year over year % (nominal)

Anti-infectives

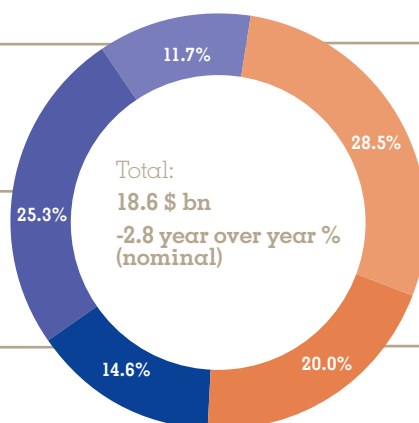
2.7 \$ bn
-6.4 year over year % (nominal)

Parasiticides

5.3 \$ bn
-2.6 year over year % (nominal)

Other pharmaceuticals

3.7 \$ bn
-6.1 year over year % (nominal)



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2009 Animal health market by region

North America

6.1 \$ bn
-2.6 year over year % (nominal)

Latin America

2.3 \$ bn
0.7 year over year % (nominal)

West Europe

5.8 \$ bn
-7.1 year over year % (nominal)

East Europe

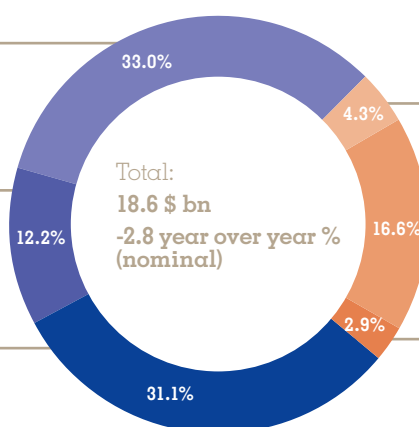
0.8 \$ bn
-9.6 year over year % (nominal)

Far East

3.1 \$ bn
4.4 year over year % (nominal)

Rest of the world

0.5 \$ bn
0.9 year over year % (nominal)



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2009 Animal health market by species

Cattle

4.7 \$ bn
-8.8 year over year % (nominal)

Sheep

0.8 \$ bn
-8.7 year over year % (nominal)

Pigs

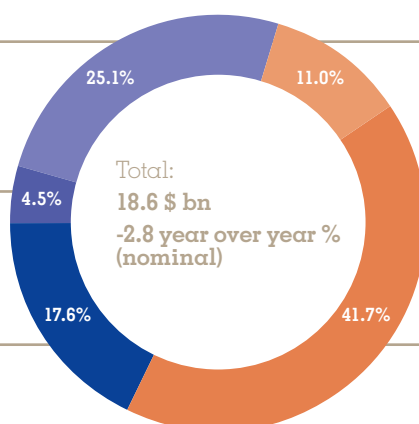
3.3 \$ bn
4.9 year over year % (nominal)

Poultry

2.1 \$ bn
-0.2 year over year % (nominal)

Companion animal / Other

7.8 \$ bn
-2.1 year over year % (nominal)



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—Who's who at IFAH

IFAH is led by a 17-strong Board of Directors comprising representatives from member companies and industry associations throughout the world. Headed by President Eric Marée, the Board is the federation's decision-making body. It receives support from a Brussels-based secretariat, national and regional member organisations, and from global teams, task forces and working groups focused on issues identified by IFAH as strategic priorities for the animal health industry.

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Peter Holdsworth, the Animal Health Alliance, representing Australia-New Zealand

Raul E. Kohan, Intervet/Schering Plough Animal Health

Alexander S. Mathews, AHI, representing North America

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Stewart Cairns, AAHA, representing South-East Asia

Jeff Simmons, Elanco Animal Health

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Florentina Pardo, Executive Assistant

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Kim Hardie, Communications Director

Myriam Alcaín, Communications Manager

Laurence Leclercq, Public Relations Manager

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Technical Affairs

Rick Clayton, Technical Director

Sylvie Meillerais, Technical Project Manager

Yara Antonissen, Technical Assistant

Marie-Hélène Delvaux, Executive Secretary

Administration and IT

Linda Moortgat, Administration Manager and IT Coordinator

Corporate members

Alpharma Animal Health Division

Bayer HealthCare Animal Health Division

Boehringer Ingelheim Animal Health

Elanco Animal Health

Intervet/Schering-Plough Animal Health

Janssen Animal Health

Merial Ltd

Novartis Animal Health

Pfizer Inc. Animal Health

Vétoquinol

VIRBAC SA

Member associations*

Argentina

CAPROVE, Cámara Argentina de la Industria de Productos Veterinarios

Australia

The Alliance, Animal Health Alliance (Australia) Ltd

Belgium

Pharma.be, Association Générale de l'Industrie du Médicament

Brazil

SINDAN, Sindicato Nacional da Indústria de Produtos para Saúde Animal

Canada

CAHI, Canadian Animal Health Institute

Denmark

VIF, Veterinærmedicinsk Industriforening

Europe

IFAH-Europe, International Federation for Animal Health-Europe

France

SIMV, Syndicat de l'Industrie du Médicament Vétérinaire et Réactif

Germany

BfT, Bundesverband für Tiergesundheit

Indonesia

ASOHI, Indonesian Veterinary Drugs Association

Ireland

APHA, Animal & Plant Health Association

Israel

MAI, Manufacturers Association of Israel

Italy

AISA, Associazione Nazionale dell'Industria della Salute Animale

Japan

JVPA, Japan Veterinary Products Association

Korea

KAHPA, Korea Animal Health Product Association

Mexico

INFARVET-CANIFARMA, Industria Farmacéutica Veterinaria

The Netherlands

FIDIN, Vereniging van Fabrikanten en Importeurs van Diergeneesmiddelen in Nederland

New Zealand

AGCARM, New Zealand Association for Animal Health and Crop Protection

Portugal

APIFARMA, Associação Portuguesa da Indústria Farmacêutica

South Africa

SAAHA, South African Animal Health Association

South East Asia

AAHA, Asian Animal Health Association

Spain

Veterindustria, Asociación Empresarial Española de la Industria de Sanidad y Nutrición Animal

Sweden

LIF, Läkemedelsindustriföreningen

Switzerland

SGCI Chemie Pharma Schweiz, Swiss Society of Chemical Industries

United Kingdom

NOAH, National Office of Animal Health

United States

AHI, Animal Health Institute

* Contact details are available on the IFAH website (www.ifahsec.org)



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