Unlocking the potential for advances in animal health

ANNUAL REPORT 2007

IFAH
International Federation for Animal Health

Rue Defacqz, 1
1000 Brussels
BELGIUM

T +32 (0)2 541 0111
F +32 (0)2 541 0119

info@ifahsec.org
www.ifahsec.org

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About IFAH

The International Federation for Animal Health (IFAH) is an organisation representing manufacturers of 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 marketplace. These products contribute to the supply of safe, healthy food as well as 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 2007

For 2007, the IFAH Board set strategic goals for the federation in three priority areas:

Regulatory affairs: Ensuring the efficiency of regulatory procedures, international harmonisation of regulatory requirements 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, driving home the message that healthy animals are the key to healthy food – and by extension to consumer safety.

Communications: Underpinning the role of IFAH as a source of reliable information for stakeholders, and as a contributor to shared goals in terms of animal health and welfare and the production of safe, high quality food.

By the end of the year, the federation was able to report significant progress in each of these three areas. Key achievements at global and regional level are reviewed in this annual report.

IFAH is led by a 19-strong Board of Directors comprising representatives from member companies and industry associations throughout the world. Headed by President George Gunn, 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 IFAH as strategic priorities for the animal health industry.

A message from IFAH's President

Though we must never lose sight of the challenges that lie ahead, our federation can look back on 2007 as a year of remarkable achievement. Indeed, I believe that when the benefits of future advances in veterinary medicine are being reaped by animals, their owners and society at large, we may come to regard 2007 as the year in which the seeds of that harvest were sown.

Armed with powerful evidence to support its arguments, IFAH delivered a compelling case for a paradigm shift in attitudes towards our industry, which has been increasingly hamstrung by regulations that fail to recognise the unique nature of the sector. This has seen animal medicines subjected to a growing range of catch-all standards applied to human and veterinary pharmaceuticals alike – regardless of their very different requirements and the huge gulf in resources that exists between the two sectors.

The regulatory burden has snowballed, driving product development costs up by 150% since the early 1990s. The time taken to bring a new product to market has risen by almost five years in little more than a decade, while our member companies are now spending over a quarter of their entire research budgets on defensive projects designed to maintain approvals for established products.

Against that background it is hardly surprising that the flow of innovative new products to the market has slowed. Weighing up increasingly lopsided risk/reward ratios, companies are adopting more conservative approaches to research. As a result, we are failing to unlock fully the potential that exists for advances in the prevention and treatment of animal disease. In the process, animals, their owners and society are being denied access to new products and technologies that could transform animal health and food safety.

Recent trends will only be reversed when the use of a single benchmark against which to regulate both human and veterinary pharmaceuticals is abandoned. More than this, those in charge of framing regulations must pursue requirements that will actively advance the cause of veterinary research, developing a balanced framework that involves appropriate use of risk/benefit calculations. As a society, we must also look to harness fully the resources at our disposal, bridging the gap between institutional and commercial research and ensuring a fuller public understanding of issues surrounding animal health.

It was gratifying to hear regulators and fellow stakeholders acknowledge the need for change at the landmark conference held jointly by IFAH and the European Medicines Agency in London towards the end of the year. Feedback from discussions held with regulators in a number of key regions has been equally positive, and I am confident that our key messages have truly begun to hit home.

IFAH has emerged as a catalyst for change in many other areas, and our industry enjoys a growing reputation as a trusted partner in multiple-stakeholder forums. These achievements are a testament to the unstinting efforts of colleagues from member companies, associations and our secretariat. I thank those who have contributed to our recent success, and call on you all to maintain the sense of resolve and optimism upon which our industry has been built – and upon which our future achievements will depend.

George Gunn
IFAH President

A message from IFAH's Executive Director

In reviewing the work of the federation in 2007 I recall three significant quotes which illustrate admirably the importance of the contribution this industry makes to the health and welfare of animals as well as human health.

In his address to the New Delhi Ministerial Conference on Avian Influenza in December 2007 the Director General of FAO, Dr Jacques Diouf, said: "The acceleration of international trade will continue, as will climate change, and their impact on ecosystems is already causing the spread of vector-borne diseases into hitherto untouched regions." He continued: "Rift Valley fever, bluetongue virus and West Nile fever are instances of this for insect-borne diseases. But the spread of other epizootic diseases such as foot-and-mouth and African swine fever are, like avian influenza, other examples that are linked to the intensification of production systems and to the increase in commercial movements, whether controlled or not."

IFAH member companies have continued to be at the forefront of tackling avian influenza where governments have decided that vaccination is the appropriate method of control. As bluetongue now advances through countries hitherto not associated with the disease our industry has been working against the clock to develop a vaccine against the serotype 8 virus to protect animals in northern Europe before the summer, when the vector becomes active. As climate change allows further advances of what have up to now been called "tropical" diseases, it is difficult to predict which diseases will come next. If they have zoonotic potential, the challenge to our industry will be even greater, but meet those challenges we undoubtedly will.

This is why the second quote by Dr David Mackay, head of veterinary medicine at EMEA, is very relevant. In an interview with Animal Pharm just prior to the Global Animal Health Conference that he and I organised in London in November 2007, Dr Mackay notes that regulators need to be aware of industry concerns about the demands of the regulatory systems in place for veterinary medicines. At the conference these same concerns were revealed in the report of an IFAH benchmarking of regulatory requirements in major markets conducted in 2007.

Participants acknowledged that minimising the costs of new product development and time to market must be achieved if IFAH members are to respond to the challenges of new diseases through greater investment and innovation.

At the Global Animal Health Conference, which was the highlight of the IFAH calendar in 2007, many of the world's experts in animal health were gathered and essentially gave the same message: in short, the effective use and continued development of animal medicines should form a key component of any national, international, regional or global animal health strategy. To facilitate such development, regulatory agencies need to ensure that the requirements to authorise animal medicines are appropriate for the particular nature and constraints of the animal health industry, and this is where I want to include the third quote.

Professor Jim Riviere of North Carolina State Veterinary School in a visionary and insightful presentation concluded that the global regulatory environment must keep pace with the rapidly evolving science and emerging diseases. This without doubt was one of the key messages of this important gathering of the leading decision-makers in the animal health world. If it is heard and taken on board, it will undoubtedly provide the foundation that our members need to thrive and succeed in what they do best: the successful development of innovative and safe medicines for our livestock and companion animals throughout the world.

Peter G.H. Jones
IFAH Executive Director

The relationship between IFAH and OIE

During the course of 2007, OIE and IFAH strengthened their relations through a number of different activities.

A new formal agreement was concluded between the two organisations at the IFAH General Assembly. It was acknowledged that areas of mutual concern and interest have expanded, and we will endeavour to develop further cooperation through both formal and informal consultations on issues of common interest.

My participation at the IFAH General Assembly was an opportunity to illustrate OIE's activities, to underline the need for increased research into the development of veterinary vaccines and other animal medicines, and to address issues surrounding the availability of veterinary medicines in developing countries. Public-private partnerships were identified as a prerequisite for the successful development of new vaccines for orphan diseases.

In November 2007 the OIE was represented at the Global Animal Health Conference organised by IFAH, EMEA and DIA, where collaborative approaches to solving problems such as avian influenza and antimicrobial resistance were discussed.

The OIE has been represented on IFAH's Avian Influenza Task Force and IFAH was represented in the OIE Ad-hoc Group on the development of vaccination guidelines for avian influenza. Cooperation between the two bodies was also useful in the development of the OIE's list of critical antimicrobials for veterinary use, and IFAH has supported the further development of the OIE international standards on the antimicrobial resistance. IFAH is also a member of the scientific committee responsible for framing the "OIE Conference on Veterinary Medicinal Products in Africa: Towards the harmonization and improvement of registration and quality control" (Dakar, Senegal, 25-27 March 2008).

The OIE and IFAH are also both closely involved in the European Technology Platform for Global Animal Health, which aims to improve the availability of veterinary medicines by stimulating research. Led by industry, the platform has defined a strategic research agenda and drawn up an action plan to encourage research into products for the prevention and control of animal diseases, including zoonoses, which are a growing threat not just to Europe but to the world as a whole against the current background of globalisation and climatic change.

Bernard Vallat
OIE Director General

The OIE is the intergovernmental organisation responsible for improving animal health worldwide. It is recognised as a reference organisation by the World Trade Organisation (WTO) and as of January 2008, had a total of 172 Member Countries and Territories. The OIE maintains permanent relations with 36 other international and regional organisations and has regional and sub-regional offices on every continent.

International activities

Building on foundations laid in the previous 12 months, IFAH achieved remarkable progress during 2007 – to the extent that, by the end of the year, all of the key objectives laid down in its ambitious two-year 'road map' had been fulfilled. The federation consolidated its global presence and strengthened dialogue with international organisations, helping to place our industry firmly centre-stage in debates surrounding animal health matters. Levels of awareness regarding the vital role played by IFAH member companies in the fight against diseases such as avian influenza and bluetongue have increased sharply as a result.

Armed with the results of exhaustive benchmarking surveys, IFAH was able to disseminate core messages regarding the impact that over-regulation has had on the animal health industry. These triggered the start of a constructive debate with key stakeholders on changes that must be made to regulatory frameworks if they are to support a sustainable, innovative industry capable of delivering improved tools with which to tackle emerging disease threats across the globe.

Regulatory Affairs

IFAH's activities in this sphere are focused on the promotion of a proportionate, efficient regulatory framework which, whilst guaranteeing the safety, quality and efficacy of veterinary medicines, is capable of sustaining a viable, innovation-driven industry. Several notable successes were achieved in this field during 2007.

• **Gauging the impact of over-regulation:** In a bid to quantify the impact that over-zealous and indiscriminate regulation has had on the animal health industry, IFAH commissioned a major study benchmarking regulatory efficiency and levels of competitiveness in the EU, the US, Canada, Australia and Japan. The survey provided compelling evidence of the degree to which the growing regulatory burden has affected research activity. Results were shared with regulators at both national and regional level, prompting constructive dialogue on how best to tackle some of the most significant problems affecting the industry.

• **Stating the case for sector-specific regulation:** The case for sector-specific regulation of the animal health industry was crystallised in a booklet published by IFAH during the year. The booklet highlighted the growing tendency to impose rules developed for human pharmaceuticals on veterinary medicines without proper consideration of their very different requirements, the widely varying conditions under which they are used or the financial implications for the animal health industry. It highlighted examples of unnecessary or inappropriate legislation and put forward proposed solutions to the problems these have caused, emphasising IFAH's commitment to engage constructively with regulators in a bid to improve the legislative framework governing veterinary medicines.

• **Harmonising the international regulatory framework:** Excessive or inappropriate legislation is not the only problem faced by companies attempting to navigate what has become an increasingly complex regulatory framework. The existence of varying national requirements also adds significantly to the cost of developing new products and the time it takes to bring them to market. Under the VICH programme, IFAH has worked with regulators in the US, the EU and Japan for over a decade on the development of harmonised technical guidelines for animal health products. More than 40 VICH guidelines on safety, quality and efficacy have been adopted during that time, while significant progress on the development of harmonised standards governing pharmacovigilance and electronic dossier submissions was reported in 2007.

As VICH progresses through its second phase, IFAH is determined to make sure it focuses on key topics, where harmonisation will deliver real benefits for its members. It also favours closer monitoring of implementation and adherence to existing VICH guidelines in a bid to ensure the full benefits of harmonisation are being realised by regulators and the animal health industry alike. Working closely with OIE, a member of VICH, IFAH will continue to promote the use of harmonised guidelines by regulatory authorities around the globe.

• **Progress in the Codex arena:** Progress was also reported in meetings of the Codex Alimentarius Commission and its various committees. Charged with the development of global FAO/WHO food standards and guidelines, Codex has become increasingly influential as developing countries adopt its standards on issues such as drug residues. Codex procedures and decisions can affect both levels of investment required to support the establishment of maximum residue limits (MRLs) and the commercial potential of individual animal health products. As such, it is vital that they are as efficient and transparent as possible. IFAH has called for improvements in several key areas of the Codex decision-making process, and noted a number of positive developments during 2007.

MRLs for several molecules were discussed by the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) at its meeting in September in Colorado USA, with all except one progressing along the decision-making chain. Significantly, the committee agreed that MRLs may in future be progressed in the face of minority dissenting views unless objecting countries put forward new data to support their reservations. This promises to improve the efficiency of the process. Concerns raised by IFAH regarding the confidentiality of data submitted by companies in support of MRL development were also acknowledged, with the secretariat of the Joint FAO/WHO

Expert Committee on Food Additives (JECFA) agreeing to include explicit data confidentiality statements in relevant publications.

• **Spearheading improvements in traceability:** IFAH and its member companies are at the forefront of efforts to upgrade and harmonise product identification systems. This will not only improve traceability, but will also help distributors, retailers and veterinary surgeons comply easily with record-keeping requirements. Our industry is the first to adopt the datamatrix identification standard – which allows the identity of a product, its batch number and expiry date to be verified with a single scan – on a broad scale, and has risen impressively to the technical challenges this presents. By the end of 2007, implementation of the new system was 80% complete in Europe, while some companies were reporting almost 100% compliance. With a number of IFAH members integrating the new system into global packaging programmes, its benefits are already available in more than 80 countries around the world. The IFAH initiative has been monitored with growing interest by regulators and other industrial sectors alike. The human pharmaceutical industry has now agreed to implement datamatrix coding, while the French health authorities have requested its application to human medicines there by 2010.

Benchmarking survey delivers powerful messages

In 2006, IFAH commissioned the biggest-ever survey of the animal health industry. Designed to benchmark competitiveness and identify key drivers and constraints at work in the sector, it covered the US, Canada, the EU, Australia and Japan – markets which account together for around three-quarters of all animal health product sales.

Completed early in 2007, the study provided a valuable insight into the pressures impinging on an industry that has witnessed limited growth in recent years. And it delivered some stark messages about the degree to which regulatory burdens have affected the performance and strategic direction of companies operating in the sector.

The development of innovative new products was identified by an overwhelming majority of respondents as the main driver of long-term competitive success, while the regulatory framework was singled out as the single most significant obstacle to innovation. The survey revealed that regulatory requirements have driven up both the cost of developing new products and the time it takes them to reach the market. Regulatory-related development costs have risen by one-third in the past five years alone, and by as much as 150% in some regions since the early 1990s. At the same time, funds available to finance innovative R&D work have been eroded by the need to spend more on 'defensive' research, which now accounts for over one-third of the industry's total research spending in Europe. The growing regulatory burden has had a profound impact on the industry, driving more conservative approaches to research spending and, in some cases, prompting decisions to dispose of interests in the animal health sector. Over half of all respondents to the survey said they had narrowed both the scope and geographical coverage of their portfolios and had begun to focus more on established technologies, with regulatory factors cited by most as a significant driver of such strategic decisions.

IFAH has shared the results of the benchmarking study with regulators in each of the five regions, and their willingness and cooperation to acknowledge the need for change offers real hope that recent trends can be stalled. Regulators in the EU, Canada and Australia have already agreed to work with the industry to address a number of key issues, while discussions with the authorities in the US and Japan are ongoing.

The regulatory tide will not be turned overnight, but this important study promises eventually to help deliver a more proportionate framework. In turn, this will support a strong, innovation-driven industry capable of meeting disease-based challenges to food safety and the health of both animals and humans.

"The development of innovative new products was identified by an overwhelming majority of respondents as the main driver of long-term competitive success."

Antimicrobials in veterinary medicine

With two key international meetings scheduled for the year, 2007 promised to be a critical juncture in the long-running debate surrounding antimicrobial resistance and the use of these products in veterinary medicine. IFAH worked tirelessly to ensure that the case for continued access to antimicrobials – which play such a crucial role in protecting animal health and welfare – was heard, achieving highly satisfactory results.

• **Risk analysis is the key:** Misconceptions have dogged the global debate on antimicrobial resistance. It is vital that, in drawing up strategies to combat the problem, measures are based on proper scientific evidence. To that end, IFAH drew up a position paper on risk analysis that was central to its submissions at key meetings in 2007. In it, the federation called for the use of science-based risk analysis – in line with principles enshrined by international organisations such as Codex and the OIE. These recognise that risk-management measures should always be based on a prior and thorough risk assessment. IFAH also noted that risk analysis should be conducted at national rather than global level, and that risk-management options should be subjected to a thorough impact assessment before decisions on their implementation are made.

• **Codex Task Force embraces risk-assessment procedures:** The Codex Intergovernmental Task Force on Antimicrobial Resistance convened for the first time in Seoul, South Korea, in October 2007. In a technical workshop that preceded the main meeting, IFAH's firm rebuttal of inaccurate claims and assertions made by other participants received widespread support. Extreme views were aired by certain country delegations in the main meeting, but the final report issued by the task force was both measured and well balanced. It confirmed that risk-assessment principles will form the basis on which it addresses the issue of antimicrobial resistance and food-borne pathogens. It also emphasised that thorough risk assessment must precede the adoption of risk-management options, and that these should consider measures to be taken throughout the food chain rather than focusing simply at farm level.

The task force has established three inter-session working groups – on risk profiling, risk assessment and risk management – which will develop guidance on methodologies and procedures to be employed in the management of antimicrobial resistance. These groups will report to the task force, which is scheduled to meet on three more occasions before tabling proposals for adoption by the Codex Alimentarius Commission in 2010. IFAH will attend meetings of the working groups, at which it will continue to promote a balanced, science-based approach.

• **A measured approach to 'critical lists' is also anticipated:** IFAH is confident that WHO/FAO/OIE appointed experts, who met for the first time to discuss critical antimicrobial lists in November 2007, will recommend a similarly measured approach – ruling out the imposition of precipitate bans or other disproportionate measures. These had appeared a real threat following early responses to the WHO's list of antimicrobials deemed critical to human health back in 2005, with calls in some quarters for a blanket ban on the use of listed products in animals. A number of stakeholders challenged such proposals, and the OIE has drawn up its own list of antimicrobials deemed critical to the health and welfare of animals.

"Antimicrobials play a crucial role in protecting animal health and welfare."

The WHO/FAO/OIE consultation was originally due to take place prior to the meeting of the new Codex Task Force. The decision to postpone it until after the task force had convened was welcomed by IFAH – as was the selection of experts invited to participate in the consultation, which promised to produce a more balanced debate.

• **IFAH steps up human outreach activities:** Communication with the medical profession is essential if we are to improve levels of understanding about the vital role played by antimicrobials in veterinary medicine and the stringent controls which govern their use. In 2007, IFAH laid the foundations for a significant increase in levels of communication outreach. The federation will now be responsible for organising satellite symposiums at each of the world's two most important conferences addressing microbiological issues in 2008. Extensive programmes featuring a broad range of external speakers are being organised at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID, Barcelona, April 2008); and the 13th meeting of the International Society of Infectious Diseases (ISID, Kuala Lumpur, June 2008).

Communications

Encouraging constructive and open dialogue with fellow stakeholders has always been one of IFAH's key goals. Communication activities assumed added importance in 2007, however, as the federation attempted to drive home key messages on a number of issues that will shape our industry's future.

• **Disseminating results of the benchmarking study:** IFAH undertook the global coordination of strategies designed to communicate the results of surveys benchmarking the competitiveness of the animal health industry in five key regions. Working closely with national and regional associations in the US, Canada, Europe, Australia and Japan, it ensured that the main findings of the benchmarking report were conveyed clearly and concisely to regulators and other stakeholders.

• **Promoting a positive regulatory environment for veterinary medicines:** In a related project, IFAH produced a booklet outlining major differences between the animal health and human pharmaceutical industries and emphasising the need for sector-specific approaches to the regulation of veterinary medicines. It illustrated examples of 'catch-all' regulations, assessed their impact on the animal health industry and put forward constructive proposals for change.

• **Encouraging coherent debate on animal health policy:** IFAH's communications team played a key role in the organisation of the federation's landmark Global Animal Health Conference, held in association with the EMEA and DIA in London towards the end of the year. It was also responsible for producing a summary report of the conference and disseminating the views of keynote speakers, who included world-renowned figures from the regulatory, scientific and academic arenas.

• **Addressing misconceptions surrounding animal health:** In March 2007, IFAH established a new working group that will examine the discrepancies between public perceptions and the scientific reality where the risks and benefits of animal health products are concerned. The group will pursue a better understanding of how and why such discrepancies develop, and will take a pro-active approach to communicating the science behind new and emerging animal health technologies. By doing so, it will aim to allay existing concerns and pre-empt the emergence of distorted public perceptions surrounding emerging new technologies.

Landmark conference charts the future for animal health

Key messages emerging from IFAH's benchmarking survey were delivered by the federation at a landmark Global Animal Health Conference towards the end of 2007. Organised jointly with the European regulatory authority, the European Medicines Agency (EMEA), and overseen by the Drug Information Association (DIA), the event brought together many of the world's leading regulators, scientists, academics and opinion leaders, who took part in what many later said was the most important, in-depth and constructive debate the sector has ever witnessed.

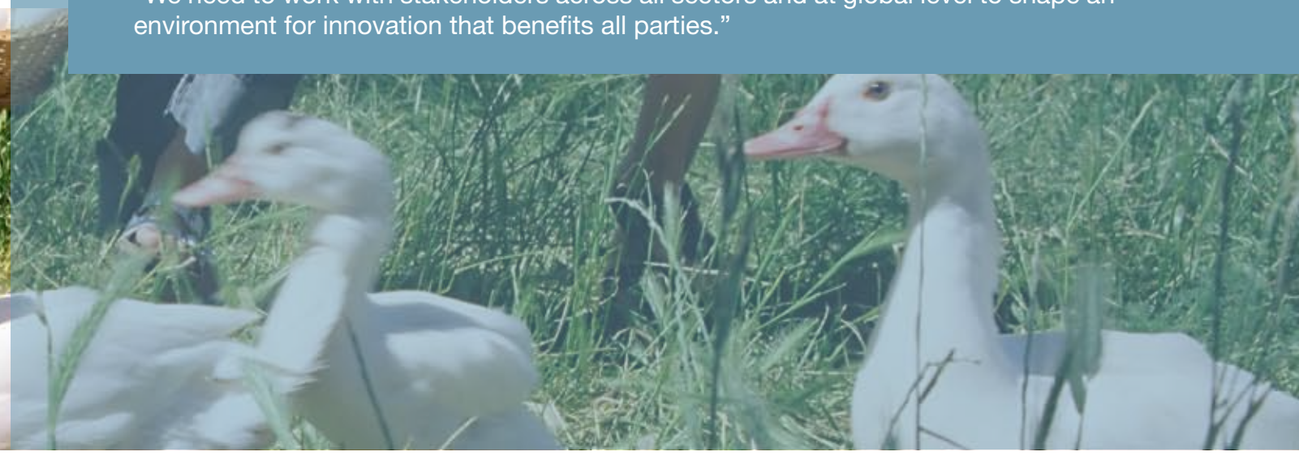
IFAH President George Gunn reiterated the federation's concerns, emphasising the need to simplify the regulatory framework governing the animal health industry. "We need to work with stakeholders across all sectors and at global level to shape an environment for innovation that benefits all parties," he said. European Commission representative Martin Terberger acknowledged that there was scope to simplify existing legislation without compromising the protection of animal and human health.

Professor Jim Riviere of North Carolina State College of Veterinary Medicine said that while regulators were struggling to control technologies already a decade old, new technologies currently being developed were set to transform the face of animal health. David Mackay, head of the EMEA's veterinary unit, said the importance of innovation to the maintenance of a sustainable animal health industry had been clearly identified, and agreed that regulators must be ready with appropriate guidance for the regulation of these new technologies.

Elsewhere, the wide-ranging conference debated how best to manage antimicrobial resistance, and discussed measures required to tackle existing and emerging diseases that threaten the health of both animal and human populations around the world. The European Technology Platform for Global Animal Health, in which IFAH plays a leading role, was held up as an example of the multiple-stakeholder approach that will be required to guarantee the success of such initiatives.

The conference organisers concluded that establishing effective partnerships between industry, academia, international animal health organisations and regulators was crucial in order to accelerate the progress to market innovative products for the prevention and treatment of these and other diseases. The effective use and continued development of animal medicines should form a key component of any national, regional or global animal health strategy, and those responsible for drawing up and implementing such strategies should ensure that all relevant stakeholders are involved, they said.

"We need to work with stakeholders across all sectors and at global level to shape an environment for innovation that benefits all parties."



Regional activities

IFAH represents the interests of national and regional associations across five continents at global level. Member associations play a key role in the execution of IFAH policies at national and regional level, and have stepped up their involvement in food chain and communications-related initiatives recently. An overview of the main activities and achievements reported by member associations in 2007 is contained in the following pages.

Europe

- IFAH-Europe

Regulatory affairs

Pursuing improvements in the regulatory framework: Reforms implemented by the EU since the beginning of this decade have gone some way towards improving the regulatory framework governing veterinary medicines, but further changes are required. During 2007 IFAH-Europe continued to monitor the impact of the new 2004-5 legislation, and has drawn up proposals that address a number of outstanding issues. The effect of new rules on the balance between innovative products and generics is a key issue, notably where the provision of safety data, including environmental risk assessments, is concerned.

Amending variation procedures: Proposals to amend legislation governing variations to existing marketing authorisations are being monitored closely by IFAH-Europe. Changes promise to deliver significant improvements, reducing administrative and financial burdens faced by applicants and promoting a more flexible approach. The federation is also pressing for the inclusion of shorter approval periods.

New MRL rules to aid product availability: Concrete proposals to amend the EU regulation on MRLs were tabled in April. These aim to clarify procedures and improve the availability of products for the treatment of food-producing animals. IFAH-Europe supports the changes, which will remove previously unreasonable requirements imposed on its members, whilst maintaining high levels of consumer protection. A task force established to monitor the issue has coordinated the development of IFAH-Europe briefing documents and position papers.

Safety and risk assessment: Limiting the burden imposed on the industry by new and existing legislation remains a priority. The federation's pharmacovigilance experts were involved closely in moves to synchronise periodic safety update reporting, which will enable work-sharing by competent authorities and reduce the administrative burden of these requirements for all concerned. Regulatory affairs specialists also held detailed discussions with the authorities on guidelines covering user safety and environmental risk assessment.

Feed additive regulations, the electronic submission of regulatory documents and international harmonisation initiatives also featured on the federation's busy agenda during the year.

Food chain

Collaboration with the EFSA: IFAH-Europe provided valuable input to the European Food Safety Authority (EFSA) through its consultative stakeholder platform, and continued to work closely with the organisation in a number of areas. Vaccination against diseases such as bluetongue and avian influenza was high on the agenda of one-to-one discussions. It is clear that vaccines are set to play an increasingly prominent role in the prevention and control of emerging disease threats in the region. Several of the federation's member companies have been developing vaccines against various serotypes of the bluetongue virus – including serotype 8 – which had such a detrimental impact on Europe's sheep and cattle farmers in 2007. EU funding for emergency vaccination programmes has now been agreed, and authorisations for novel vaccines have already been issued.

Animal Health Policy acknowledges key role played by the industry: Science, innovation and research is one of four pillars upon which the EU's new Community Animal Health Policy will be based. IFAH-Europe contributed to the work of the European Commission's DG SANCO, which outlined new approaches to animal health in a communication document published during 2007. The paper highlights the role played by veterinary products and recognises the need for a coherent regulatory framework to encourage investment in research.

Responsible use of medicines: The federation strengthened ties with fellow stakeholders – including farmers and the veterinary profession – through the European Platform for Responsible Use of Medicines in Animals (EPRUMA) initiative. Progress towards the adoption of a framework document on the use of antimicrobials in food-producing animals was made, while IFAH-Europe spearheaded efforts to broaden involvement in the EPRUMA initiative, discussing membership with a range of food-chain partners.

Communications

Answering the call for better regulation: At IFAH-Europe's annual conference, more than 100 delegates were invited to share the results of the federation's industry benchmarking survey, and heard calls for further action to improve the regulatory framework governing veterinary medicines in the EU. The survey showed that development costs and the time taken for new products to reach the market in Europe are higher than in any other major market region. IFAH-Europe Managing Director Declan O'Brien said the federation's goal was to see a 20% reduction in research costs and development periods and industry spending on defensive R&D to be reduced by 20%. The federation subsequently met with EU authorities, and has tabled constructive proposals designed to help meet the European Commission's call for better regulation across the region.

Dialogue with stakeholders: IFAH-Europe strengthened communications with European institutions and a range of other stakeholders, presenting keynote speeches at a variety of events and organising a European Pet Night, which was hosted by Members of the European Parliament and supported by animal welfare groups. Attended by over 100 people, the event is set to become an annual feature at the request of organisations involved in the initiative.

Sharpening communication tools: A thorough review undertaken during 2007 resulted in plans to expand and improve IFAH-Europe's online communication tools. The federation will launch a new website in 2008, offering both members and the public access to more information about the industry and its activities.

European Technology Platform for Global Animal Health

Following intensive and widespread consultation, the European Technology Platform for Global Animal Health (ETPGAH), of which IFAH-Europe is a founding member, finalised an action plan designed to deliver goals laid down in its strategic research agenda (SRA).

Both the ETPGAH and its action plan received a ringing endorsement from EU Science and Research Commissioner Janez Potočnik, to whom the document was presented in November. Describing the platform as "an excellent forum" for discussion on animal health research, he said the plan would be extremely valuable – not only for regulators and the industry, but also for those charged with prioritising European animal health research programmes.

The plan outlines measures required to encourage the development of new and improved tools for the control of major animal diseases. It also identifies key areas in which EU research funding is required if current gaps in the range of available vaccines and therapeutic medicines are to be plugged successfully.

Established to identify and promote a research agenda capable of fostering the development of effective tools for the control of animal disease, the ETPGAH is a joint initiative comprising industry and the research community. Led by IFAH-Europe, it brings together all relevant stakeholders at EU and national levels.

ETPGAH representatives with
European Commissioner for Science and Research Janez Potočnik

North America

- **AHI**, US
- **CAHI**, Canada
- **INFARVET-CANIFARMA**, Mexico

Regulatory affairs

US trends highlight the benefits of regulatory reform: IFAH members operating in the US have seen product approval times improve significantly under a five-year user fee programme, with surveys undertaken by the AHI indicating that regulators have met or exceeded all of the goals agreed under the initiative. The association continues to evaluate review procedures in a bid to identify additional opportunities for improvement. Some of these will be included in a new user fee programme, negotiated during 2007 and due to begin in October 2008. The impact of measures designed to improve the availability of new minor use / minor species (MUMS) products is also being felt for the first time, with new aquaculture treatments authorised and the first conditional approval of a minor species product issued during 2007.

Canadian regulators acknowledge need for change: The IFAH benchmarking survey demonstrated clearly that product review procedures in Canada are both inefficient and costly in comparison with those in many other major markets, including the US. Regulatory officials have acknowledged the need to address existing problems, and have asked CAHI to co-chair an advisory committee set up to pursue improvements in the capacity, efficiency and cost-effectiveness of the Canadian regulatory system. In the meantime, regulators are working to eliminate existing backlogs, while Health Canada has moved to close a loophole under which non-approved products were being imported on a huge scale, supposedly for 'personal use'. Along with compounding, this was costing IFAH members an estimated Can$100 million a year in lost sales. Improvements in the regulatory framework governing veterinary vaccines were also announced during the year. Staff numbers at Health Canada's Veterinary Biologics Section were increased, and the VBS said it would begin to accept phased reviews of biological products that have been approved in other countries.

Mexican regulatory framework strengthened: A new federal animal health law was ratified by the Mexican parliament in 2007. Its publication represented a landmark for INFARVET, which has worked closely with regulators on the development of texts that will bring national laws into line with international norms, and will ensure the safety and quality of animal health products circulating in the Mexican market. The association also maintained its commitment to the development of new Good Manufacturing Practice requirements – which promise to boost export opportunities for its member companies – organising and participating in a number of seminars addressing GMP issues.

Defending antimicrobial use: New antimicrobials for use in food animals were approved in the US using the FDA's qualitative risk-assessment guidance for the evaluation of antibacterial products, but the involvement of expert advisory committees in the review process emerged as a new challenge for the industry. The AHI liaised closely with regulators, recommending improved procedures to ensure that input from advisory committees is more objective and scientifically-based in future. The association maintained its successful opposition to calls for the introduction of legislation that would overrule FDA guidance by banning certain uses of antibiotics. In Canada, CAHI and the national feed industry agreed a science-based approach to the issue of drug carryover levels in feed.

Food chain

Stakeholder alliances: The value of stakeholder alliances built by the AHI was highlighted in 2007, with the Animal Health Coalition responding firmly to questions surrounding the use of antibiotics and certain veterinary vaccines, and the Healthy Pets Coalition heading off state proposals to grant 'pain and suffering' damages for animal owners. The AHI and its coalition partners also worked with the US Centers for Disease Control on its 'Get Smart on the Farm' programme, which is designed to promote responsible use of antibiotics. In Canada, CAHI continued to build relationships with producers, demonstrating its support and commitment to a livestock industry facing a tough economic environment.

Communications

Trusted providers of valuable information: The AHI, which is a valued source of data on the use of animal health products, published its annual statistical review of US sales, industry research spending and the amount of antibiotics sold for use in animals. CAHI organised a comprehensive survey of companion animal numbers designed to generate more consistent, reliable data on national pet populations, while in the US, the bond between companion animals and their owners was highlighted at the 11th AHI-sponsored Pet Night, held on Capitol Hill. In Mexico, INFARVET produced two video presentations designed to inform and educate fellow stakeholders about the role of the animal health industry. The association was also involved in a number of conferences and seminars during the year.

Coordinating opposition to restrictive state legislation: The AHI drew on the resources of both member companies and fellow stakeholders to oppose successfully the introduction of extreme or unnecessary legislative proposals at state level. These included measures that would have banned the use of animal vaccines due to concerns about mercury in products intended for human consumption, and proposals to allow plaintiffs to pursue damages for pain and suffering in litigation involving animals.

South and Central America

- **CAPROVE**, Argentina
- **SINDAN**, Brazil

Regulatory affairs

Harmonising regional regulations: Further progress towards the adoption of harmonised rules governing animal health products in south and central America was achieved under the joint industry/regulator initiative, CAMEVET, during 2007. IFAH member associations in Brazil and Argentina are major contributors to the harmonisation programme, and reported significant developments at the 13th annual meeting of CAMEVET, which was held in the Dominican Republic during August. Stability guidelines, Good Manufacturing Practice for ectoparasiticides and the development of guidelines governing good practice in the use of veterinary medicines were among the issues debated at the 2007 meeting. Problems relating to illegal distribution of veterinary products in the region were also discussed.

Antimicrobials: In Brazil, SINDAN reported widespread support among both regulators and other stakeholders for IFAH's position on the use of antimicrobials in veterinary medicine. The association is working closely with the Agriculture Ministry and the Oswaldo Cruz Foundation of the Health Ministry on plans for a third national seminar on antimicrobial resistance, to be held in 2008, at which best-practice guidelines, surveillance schemes and usage monitoring will be discussed.

Quality initiatives: SINDAN also supported the expansion of infrastructure required to ensure comprehensive control of animal health product quality. New procedures now in place mean that all product batches will be subjected to testing by both manufacturers and regulators. In Argentina, CAPROVE maintained a close dialogue with regulators on a range of issues affecting the animal health products sector. It also filed reports on illegal product distribution, helping regulators to achieve better control of the market.

Food chain

Fighting disease: Along with national associations representing farmers and meat producers, SINDAN was instrumental in funding and supplying vaccines for foot-and-mouth disease eradication efforts in border regions with Bolivia and Paraguay. Part of the 'Health Without Frontiers' programme, the initiative provides free FMD vaccines to subsistence farmers and native Indian communities in these areas, where vaccination coverage would otherwise be limited.

Livestock breeding and animal health: CAPROVE met with representatives of Argentina's livestock breeding associations to discuss the importance of animal health to livestock productivity, educating producers about the use of vaccines and veterinary medicines to prevent, control and treat disease. The association also lent its support to the country's National Livestock Breeding Congress, which took place in November.

Communications

Promoting animal health: CAPROVE met with a range of stakeholders to discuss the role of veterinary products in protecting and maintaining the health of livestock and companion animals. In collaboration with organisations representing the companion animal sector, the association produced a range of educational materials for pet owners, highlighting threats posed by zoonotic diseases and the importance of regular visits to the veterinary surgeon.

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 efficiency: Results of the IFAH benchmarking study were shared by member associations with regulators in Australia and Japan, where constructive dialogue with authorities promises to yield significant improvements. The survey revealed broad satisfaction with the existing regulatory framework in Australia, but the Animal Health Alliance is working with regulators to address areas where improvements are required. These include procedures designed to manage trade risks and approaches to risk assessment in general. In Japan, where the regulatory burden has traditionally been heavier, improvements in the efficiency of the review process are anticipated after the National Veterinary Assay Laboratory assumed sole responsibility for product authorisation in 2007. The switch by regulators from a 'zero residue' policy to the application of MRLs in 2006 is also yielding improvements.

Harmonising regulatory requirements: Australia is a leading market for parasite control products, and the Animal Health Alliance has played a key role in the development of harmonised international requirements for these products. Nine guidelines on efficacy data requirements for parasiticides have been drawn up by the World Association for the Advancement of Veterinary Parasitology. These are now being recognised by Australian regulators in a move that will enable 'pre-assessment' of efficacy data packages for generic companion-animal parasite controls prior to formal submission of dossiers to the APVMA.

At a broader level, the Asian Animal Health Association met with regulators in a number of countries, pressing the case for the harmonisation of standards governing veterinary medicines. Compliance is also a major issue in parts of the region, and AAHA is calling for regulators to tighten up monitoring and enforcement in markets where controls are currently limited. In Malaysia, MAHNIA has worked closely with the country's National Pharmaceutical Control Bureau on the development of new guidelines for the registration of veterinary products, which will be implemented in 2008.

Policy development: In Israel, MAI met with regulators and representatives of the veterinary profession to discuss extra-label drug use and recommend approaches to the formulation of policies on the issue. Amendments to existing GMP guidelines are also being discussed, while pressure from the industry has elicited a commitment from the Health Ministry to speed up product review procedures. In Indonesia, ASOHI maintained a regular dialogue with government officials regarding regulatory procedures, with rules governing the import of veterinary medicines high on the agenda.

Antimicrobials in veterinary medicine: Manufacturers in Japan are still awaiting the outcome of a review into the veterinary use of fluoroquinolone antibiotics. The Food Safety Commission, which was charged with undertaking risk assessments of veterinary antibiotic use in 2003, has made little progress, and delays are affecting the development of novel antimicrobials. The JVPA has stepped up calls for more rapid assessments.

Data protection: IIn New Zealand, AGCARM continues to press for improvements in the protection of data submitted in support of approvals for originator products. The issue is being discussed by a regulatory committee, and legislation may be introduced alongside anticipated amendments to pesticides regulations. Regulatory overview of both sectors is set to change following recent amendments to the Agricultural Chemicals and Veterinary Medicines Act. This includes a review of the prescription animal remedy (PAR) scheme under which rules governing the management of prescription veterinary medicines are set to be amended.

Food chain

Liaising with stakeholders: Discussions with regulators and fellow stakeholders are helping to shape regulatory frameworks, improve compliance and encourage the responsible use of animal health products across the region. In Japan, the JVPA organised seminars and published educational materials aimed at farmers, veterinary surgeons and distributors of animal health products in a bid to encourage a smooth transition from the country's 'zero residue' policy to the use of MRLs. In Indonesia, ASOHI liaised closely with stakeholders in the poultry industry, and organised a seminar outlining prospects for that sector in 2008.

Managing resistance: The need for prudent use of veterinary medicines is by no means limited to antimicrobials. Resistance is also an issue where antiparasitics are concerned, especially in some southern hemisphere countries where heavy parasite burdens necessitate the widespread use of such products. In Australia, the Animal Health Alliance provides financial support for the WormBoss initiative, which is designed to manage internal parasites of sheep and control anthelmintic resistance. In New Zealand, AGCARM is closely involved with the WormWise initiative, which promotes the sustainable management of internal parasites, providing information and training for farmers, veterinary surgeons and animal health advisers.

Safety, quality and traceability: MAI met with representatives from Israel's slaughterhouse and food processing sectors in a bid to promote improved understanding of issues such as safety, quality and traceability. Further discussions are planned in 2008.

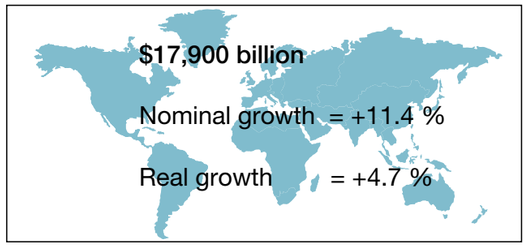
Communications

Educational initiatives: Member associations throughout the region are helping farmers, the veterinary profession and the public learn more about animal health products, encouraging both responsible use of veterinary medicines and a broader appreciation of their contribution to the protection of animal health, human health and the environment. In New Zealand, where AGCARM finances an annual scholarship for undergraduate veterinary students, the association has also funded the production of a wall chart that outlines best practice where drenching is concerned. The chart will be distributed to the country's farmers as part of broader efforts to manage resistance and preserve the efficacy of valuable animal health products. In Malaysia, MAHNIA distributes a quarterly magazine containing advice and information on animal health products to farmers across the country.

Antimicrobial messages: Communicating essential messages on the value of veterinary antimicrobials was high on the agenda of associations in both Australia and New Zealand in 2007. The Animal Health Alliance was involved closely in IFAH activities at the inaugural meeting of the Codex Task Force on antimicrobial resistance, held in Seoul during October. In New Zealand, AGCARM continued to liaise with NGOs and regulators in both the veterinary and human health sectors on issues relating to the management of antimicrobial resistance. The association, which reported beneficial results in terms of both attitudes and approaches to veterinary antibiotic use, is also involved in the development of best-practice guidelines and the establishment of a monitoring and surveillance programme.

Animal health industry profile

Animal health industry in 2007

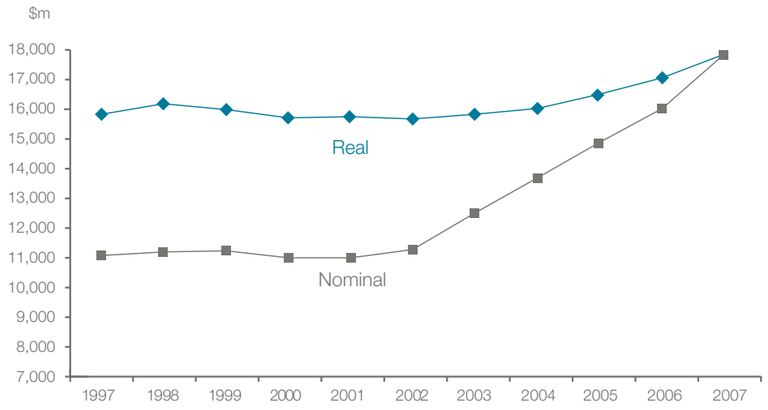


Animal health market by product group

Product group	2007 ($m)	YoY*(%)	Share (%)
Medicinal feed additives	2,095	5.0	11.7
Biologicals	4,175	14.1	23.3
Anti-infectives	2,775	9.3	15.5
Parasiticides	5,200	12.6	29.1
Other pharmaceuticals	3,655	12.5	20.4
Total	17,900	11.4	100.0

* Year over year percentage

Animal health market evolution/consolidation



Time period (Years)	CAGR (% p.a.*)				
	Nominal	Real	Currency	Price	Volume
10	4.9%	1.2%	-	-	-
5	9.6%	2.6%	-	-	-
1	11.4%	4.7%	4.3%	2.4%	4.7%

* Compound annual growth rate percentage per annum

Animal health market by region

Region	2007 ($m)	YoY*(%)	Share (%)
North America	6,095	8.8	34.1
Latin America	2,080	11.2	11.6
West Europe	5,670	16.9	31.7
East Europe	815	10.9	4.6
Far East	2,740	7.2	15.3
Rest of world	500	9.8	2.8
Total	17,900	11.4	100.0

* Year over year percentage

Animal health market by species

Species	2007 ($m)	YoY*(%)	Share (%)
Cattle	4,750	8.7	26.5
Sheep	830	7.8	4.6
Pigs	2,915	12.8	16.3
Poultry	1,935	11.8	10.8
Companion animals/other	7,470	13.0	41.7
Total	17,900	11.4	100.0

* Year over year percentage

Who's who at IFAH*

Board of Directors

President	**George Gunn** Novartis Animal Health
Vice-Presidents	**Joachim Hasenmaier** Boehringer Ingelheim Animal Health
	Patrick James Elanco Animal Health
	Raul Kohan Schering-Plough Animal Health
	Juan Ramón Alaix Pfizer Animal Health
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	Paul Derks Janssen Animal Health
	Sebastião Costa Guedes SINDAN, representing South and Central America
	Dominique Henryon Vétoquinol
	Peter Holdsworth The Animal Health Alliance, representing Australia/New Zealand
	Kevin Holloway Monsanto Company
	Alexander Mathews AHI, representing North America
	Declan O'Brien IFAH-Europe, representing Europe
	Yuhei Okamoto JVPA, representing Asia/Pacific
	Francisco Ortiz AAHA, representing South East Asia
	Ruurd Stolp Intervet International BV
	Carol Wrenn Alpharma Animal Health Division

* As of 31 December 2007

Secretariat

Executive Director's office	**Peter Jones** Executive Director
	Florentina Pardo Executive Assistant
Communications	**Bernd Halling** Communications Director
	Myriam Alcain Communications Manager
	Laurence Leclercq External Communications Officer
	Pamela Barcellona Senior 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 International BV
- Janssen Animal Health
- Merial Ltd
- Monsanto Company
- Novartis Animal Health
- Pfizer Animal Health
- Schering-Plough 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**
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
Malaysia	**MAHNIA** Malaysian Animal Health and Nutrition Industries 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).

Acronyms

APVMA	Australian Pesticides and Veterinary Medicines Authority
CAMEVET	Comité de las Américas para la Armonización del Registro y Control de los Medicamentos Veterinarios
CCRDVDF	Codex Committee on Residues of Veterinary Drugs in Food
DG SANCO	European Commission Directorate General Health and Consumer Protection
DIA	Drug Information Association
ECCMID	European Congress of Clinical Microbiology and Infectious Diseases
EFSA	European Food Safety Authority
EMEA	European Medicines Agency
EPRUMA	European Platform for Responsible Use of Medicines in Animals
ETPGAH	European Technology Platform for Global Animal Health
FAO	Food and Agriculture Organisation of the United Nations
FDA	United States Food and Drug Administration
FMD	Foot-and-mouth disease
GMP	Good manufacturing practice
ISID	International Society of Infectious Diseases
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MRL	Maximum residue limit
MUMS	Minor use / minor species
NGO	Non-governmental organisation
OIE	World Organisation for Animal Health
PAR	Prescription animal remedy
R&D	Research and development
SRA	ETPGAH strategic research agenda
VBS	Canada's Veterinary Biologics Section
VICH	Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organisation
WTO	World Trade Organisation

Credits