

2005

ANNUAL REPORT



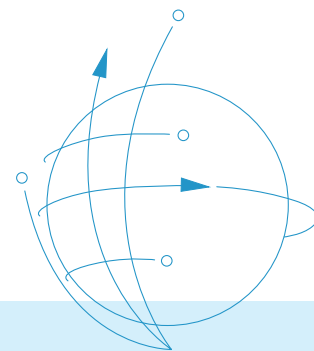
The International Federation for Animal Health (IFAH) is an organisation representing manufacturers of veterinary medicines, vaccines and other animal health products in both developed and developing countries across five continents.

Its goal is to promote a harmonised, science-based regulatory and trade framework and a commercial environment capable of supporting an economically viable, innovation-driven industry that makes vital contributions to the protection of animal health and welfare, and the supply of safe, healthy food.

To fulfil that goal, **IFAH'S MISSION** is:

- To act as the voice of the industry in dialogue with the major international bodies that have an impact on the animal health industry (FAO, WHO, Codex, OIE, WTO and others);
- To encourage and assist the development of predictable, science-based regulatory processes and standards;
- To represent the industry with a unified, global voice in dealings with governments, food industry partners and consumers;
- To facilitate the international harmonisation of regulatory requirements governing animal health products.





IFAH is lead by a 17-strong Board of Directors comprising representatives from member companies and industry associations in four geographical regions (North America, South/Central America, Europe and Asia/Pacific/Africa). Headed by Pedro Lichtinger, who began a two-year term as IFAH President in November 2005, the Board is the federation's decision-making body. It receives support from a Brussels-based secretariat, national and regional member associations, and from 'Global Core Teams' focused on the areas identified by the federation as strategic priorities for the industry.

IFAH'S STRATEGIC PRIORITIES IN 2005 :

Regulatory affairs: Ensuring the efficiency of regulatory procedures, international harmonisation of regulatory requirements, the employment of science-based risk/benefit analysis, and medicines availability, including the availability of antimicrobials.

Food chain: Positioning our industry as a widely-recognised, credible voice that influences decision-making in the food sector where animal health issues are concerned, and focusing on the supply of safe and wholesome food.

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

A MESSAGE FROM IFAH'S PRESIDENT

Pedro Lichtinger



In future, our industry may well look back on 2005 as a watershed year. It was a year during which the outstanding efforts of outgoing President Pat James and his team paid real dividends, delivering a stronger, more focused federation capable of rising to the challenges posed by the global environment in which we operate. It was also a year during which both the public and many of our fellow stakeholders began to sit up and take notice of the very real contributions made by our industry - not only to the health and welfare of animals, but also to the protection of human health and the global supply of healthy, wholesome food.

Internally, IFAH is now in better shape than it has ever been, having regained its global focus and been strengthened by a succession of key appointments. It now has a talented, highly motivated team in place, capable of making real progress toward its goals and, in the process, providing substantial benefits for its members. In Peter Jones we have an Executive Director with unmatched experience of both our industry and the regulatory framework within which it operates, while in Bernd Halling we have secured an individual with the expertise and determination required to drive home IFAH's key messages to a broad global audience.

At this time, the spread of the H5N1 Avian Influenza (AI) virus from Asia into Europe, and warnings of a possible human pandemic by organisations such as the WHO have trained the international media spotlight firmly on animal health. We are proud of the IFAH member companies whose poultry vaccines are already helping defend against this devastating disease. To identify the most productive additional ways our industry can contribute to the control of AI and a broad range of other animal diseases, we are actively undertaking productive collaboration with national, regional and global governmental, human health, veterinary and scientific organisations.

In addition to striving to control the H5N1 virus and other disease outbreaks, our industry must also undertake a sustained educational initiative to inform regulators, food-chain partners and the general public about some of the procedural hurdles, hidden costs and financial risks that our industry encounters in

any effort to develop innovative new vaccine and pharmaceutical technologies to protect against or treat emerging diseases.

Looking ahead and with key IFAH staff in place, and having now received guidance from the IFAH Board, we have articulated our strategic objectives.

Obtaining extended periods of marketing exclusivity to reward the investments and risks required to develop innovative animal health products is one of IFAH's key medium-term goals. We also plan to highlight the major differences between our industry and the human pharmaceutical business, and the potentially damaging effect of regulations that fail to take account of those distinctions. We can only hope to achieve these goals, however, by communicating effectively with our target audiences.

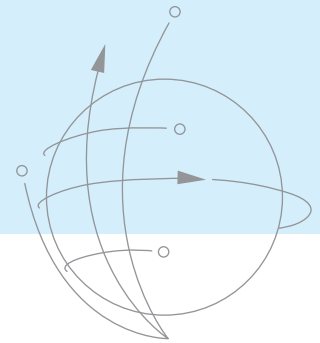
That is why, in recent months, the IFAH Board has called on the Global Core Teams responsible for executing the federation's strategies to reconsider their objectives and approaches. Following close scrutiny of those reviews, the Board has approved new goals and approaches to achieving them. The result is an IFAH 'Road Map', which plots a strategic course for the federation through the next two years.

Its emphasis will be firmly on the development of a more proactive approach to our dealings with regulators and all stakeholders, especially those involved in the food chain. By taking the lead in global debates surrounding animal health and food safety, I believe we will be better able to influence their outcome. And by doing so we will improve the financial and regulatory environment in which our members operate.

I am proud to be leading the federation and excited by the challenges that lie ahead. I look forward to working with our members and partners over the next two years as we strive collectively to build on the considerable progress that IFAH has already achieved on behalf of our industry in improving the quality of life for animals and people.

A MESSAGE FROM IFAH'S EXECUTIVE DIRECTOR

Peter G H Jones



Experience shows that it can be difficult for organisations to embrace change, and it is sometimes easier to stay with the familiar than to find the courage and determination to tackle new challenges. IFAH shows no sign of being stuck in the past and 2005 has undoubtedly proved that to be the case. The federation has clearly demonstrated its ability to very effectively manage the changing environment within which it operates.

Pedro Lichtinger was elected President of IFAH in 2005 and has shown, since his arrival in office, a firm commitment to ensure IFAH's success and influence in today's global operating environment. He and the Board quickly realised the need to define a more strategic focus in identifying IFAH's objectives and working proactively to achieve them.

IFAH's international activities have in recent years been coordinated by Global Core Teams. The federation fully acknowledges and appreciates their achievements in increasing international awareness of the safety, high quality and efficacy of the medicines and vaccines our industry brings to the market. Veterinary medicines and vaccines have an important role in securing an adequate supply of safe food derived from healthy animals through the prevention and treatment of animal diseases.

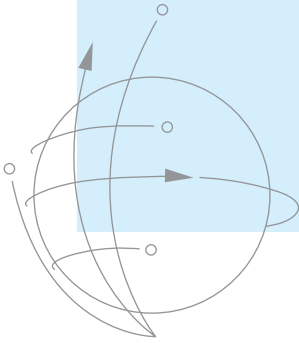
The future can often arrive unannounced and the federation is adapting to new challenges ahead. At the close of 2005 the Board therefore agreed that IFAH must focus more on regulatory issues and matters relating to the use of antimicrobials in animals. The priorities are as follows:

- to clarify the distinct differences between the animal health industry and the human pharmaceutical sector and the implications of these differences;
- to assess the impact of guidelines;
- to further define and implement the future policy of IFAH involvement in international fora such as VICH and Codex;
- to address specific issues relating to the use of veterinary antimicrobials and their inherent value in combating bacterial diseases in animals.

Furthermore, IFAH is now committed to demonstrating the benefits of new, innovative veterinary medicines and vaccines to the outside world through a more proactive approach to specific issues. A good example of the latter is our industry's current exploratory efforts to collaborate with international organisations and regulatory authorities in capitalising on our industry's expertise in the battle against Avian Influenza.

In conclusion, it is clear that much progress has been achieved in 2005, which puts IFAH on a firm footing to manage the issues that will come about in the short to medium-term. Having recently completed just over 10 very rewarding years working in the European veterinary environment, I had little hesitation in accepting an offer to change my professional activities and to come and work with this exciting and dynamic organisation. IFAH's vision is to ensure that animal health products are licensed according to science-based, reasonable and predictable regulatory requirements, firmly rooted in the principles of risk assessment, and that products can be marketed without restriction in all regions of the world.

STRATEGIC ACTIVITY REPORT



Another busy year for IFAH ended with the federation able to report considerable progress, not only towards the achievement of its strategic goals, but also towards the establishment of a stronger internal platform.

A string of key appointments, including additions to the secretariat's technical and communications teams, culminated with the arrival in October of Peter Jones as IFAH's new Executive Director. Bernd Halling joined IFAH as head of the federation's communications department, while the technical department was also strengthened by new appointments and restructuring.

Towards the end of the year, the Board called on its Global Core Teams to update and realign their strategic priorities, taking account of achievements and developments in their respective areas. New objectives identified by the teams were reviewed and approved by the Board in January 2006, and will guide the federation's future strategic direction.

Major activities and achievements in each of IFAH's three strategic priority areas at both international and regional level in 2005 are described in the following sections of this report.



INTERNATIONAL ACTIVITIES



1. Regulatory affairs

IFAH aims to promote a predictable, harmonised, science-based and innovation-friendly operating environment that encourages investment in the development and provision of safe, efficacious animal medicines. To fulfil that goal, the federation works closely with regulators, fellow stakeholders and a range of international NGOs, helping to shape regulations governing the development, manufacture, approval and sale of veterinary products. Its efforts are focused on improving the efficiency of existing regulatory processes; harmonising national and regional regulatory requirements; and ensuring that veterinary professionals and animal owners have access to a broad range of effective medicines.

International harmonisation

VICH: IFAH is a major contributor to the VICH (Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) initiative. VICH is a trilateral (EU-Japan-USA) programme - launched in April 1996 - aimed at harmonising international guidelines for veterinary medicinal products.

In a keynote address to the third VICH conference, held in Washington DC during May 2005, Pedro Lichtinger (now IFAH President) told delegates the initiative was crucial to the future development of a sustainable, research-based animal health industry.

The Washington conference marked the conclusion of the first phase of the VICH programme, during which time 33 guidelines on veterinary drug safety, quality and efficacy have been adopted in the USA, the EU, Japan and the observer countries: Canada, Australia and New Zealand. A further 11 are currently in development, including two important draft guidelines on adverse event reports (AERs), which were endorsed by the VICH steering committee at its 17th meeting, held in Kyoto, Japan, towards the end of the year.

IFAH will continue to support and participate actively in the VICH process as it moves into a second phase, which will provide a basis for wider international harmonisation of registration requirements. VICH will not only monitor and maintain existing guidelines, but will also update these and ensure that procedures are in place to allow consistent interpretation of data requirements in participating regions.

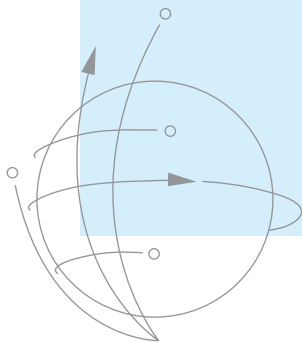
Within the unique forum provided by VICH, IFAH will continue to support constructive dialogue between regulatory authorities and the industry, encouraging the provision of technical guidance that will enable a positive response to emerging issues affecting regulatory requirements in the VICH regions.

Codex MRLs: Progress was made towards the establishment of maximum residue limits (MRLs) for several veterinary drugs under the Codex Alimentarius programme during 2005.

The Codex Alimentarius Commission was created in 1963 by FAO (Food and Agriculture Organisation of the United Nations) and WHO (World Health Organisation) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting consumer health, ensuring fair practices in food trade and promoting the coordination of all food standards work undertaken by governments and NGOs.

IFAH remains firmly committed to the Codex initiative and recognises the importance of global standards in this area. The federation has, however, proposed some major improvements to the system by which Codex MRLs are generated to ensure its future effectiveness.

For example, the confidentiality of data submitted for scrutiny by JECFA (Joint Expert Committee on Food Additives), the FAO/WHO committee that advises the Codex on MRLs, needs to be better protected to allow companies to submit the necessary data. Additionally, the statistical approaches to MRL calculation methods being proposed by JECFA and the plans to establish a Codex 'negative list' for veterinary drugs that are the subject of health or trade concerns are major issues for IFAH.



Encouragingly, FAO and WHO officials have told IFAH that JECFA experts will in future be subject to a new code of conduct regarding data confidentiality, and have given assurances that efforts are being made to speed up Codex MRL procedures. They have also conceded that risk assessments should be shared with the sponsors in a bid to reduce the frequency with which requests for information to address perceived data gaps are generated.

Antimicrobial availability

International debate: IFAH continued to defend proactively the therapeutic use of antimicrobials in animals, maintaining a constructive dialogue with key organisations such as the WHO, OIE (World Organisation for Animal Health) and Codex, and striving to ensure that the global debate on this vital issue is both informed and science-based. Those efforts paid dividends, most notably in the case of WHO-sponsored meetings on antibiotic resistance, where industry participation contributed to a balanced debate.

The concerns inherent in some of the WHO's approaches to the antimicrobial resistance debate were highlighted in a paper by respected microbiologist Trudy Wassenaar, which was published recently in the peer-reviewed journal *Critical Reviews in Microbiology*. Dr Wassenaar concluded that the role of veterinary drugs in the development of resistant human pathogens has been widely exaggerated, and that opinions were being formed and decisions taken without proper risk analysis. Her views echoed comments made by a representative from the field of human medicine at the WHO's Berlin conference.

IFAH also contributed significantly to the setting up of an OIE critical list of antimicrobials for animals, which will support the OIE position in forthcoming discussions on resistance with WHO in the frame of a special Codex Task Force on Antimicrobials.

Antibiotic use survey: IFAH's efforts to promote informed debate on antimicrobial resistance have seen the federation embark on a number of initiatives designed to improve the availability of empirical data on veterinary antimicrobial use and its impact. These already include resistance monitoring programmes

and risk assessment activity. Definitive data on the volumes at which these products are used in veterinary medicine will also be generated in a survey that will be conducted by the European Animal Health Study Centre (CEESA). The survey will be based on the data provided by IFAH member companies.

Regulatory efficiency

New legislation: IFAH has played a major role in ensuring that new legislation introduced recently on both sides of the Atlantic has a positive impact on the efficiency of regulatory procedures, minimising the time taken to bring new veterinary drugs to market. The success of those efforts was reflected in final texts of the US Animal Drug User Fee Act (ADUFA) and updated legislation adopted by the EU and its member states in 2005 (see regional activity reports for more details).

Monitoring the implementation and impact of new legislation continued during 2005, and will be maintained throughout 2006.

Benefit/risk assessment: IFAH is determined to increase the recognition and application of proper benefit/risk analysis in regulatory procedures governing veterinary medicinal products. In so doing, its aim is to eliminate the 'precautionary' approach to regulation that has become so pervasive and disproportionate in recent years, and to drive a return to systems based firmly on empirical analysis of the benefits and risks attached to regulatory decisions.

IFAH has undertaken a thorough review of risk analysis procedures and terminology and has produced a position paper on benefit/risk management.

Industry benchmarking: IFAH has decided to conduct a study in 2006 that will benchmark the competitiveness of the animal health industry in different regions of the world. Comparison with the results of previous surveys undertaken in 1996 and 2001 in the EU and US will allow an accurate appraisal of changes in the operating climate over the past decade.



2. Food chain

IFAH is committed to the responsible use of animal health products, the health and welfare of animals, and the production of safe, quality food. It aims to position the animal health industry as a widely-recognised and respected contributor to debates surrounding animal health and food production. To achieve that goal, the federation is building relationships with stakeholders at all levels and in all sectors of the food chain; developing and disseminating industry positions on a range of key issues; and contributing proactively to food safety through the development of new product identification systems.

Dialogue with stakeholders

The animal health industry makes vital contributions, not only to the health and welfare of animals, but also to the quality of the world's food supply and the protection of human health. By building relations with fellow stakeholders at all levels of the food chain, IFAH aims to drive home this basic message, positioning the industry as a widely-recognised and credible contributor to debates on food and animal health policy.

IFAH has established strong relationships with global organisations such as the WHO, FAO, OIE and Codex, and provided valuable assistance to these bodies during the year - notably in the formulation of international responses to the emergence of Avian Influenza. The federation is determined to build broader contacts and alliances throughout the food chain. IFAH continued intense dialogue with bodies representing a range of agricultural producers, processors and retailers at international level, such as IAFN (International Agri-Food Network).

Position papers

IFAH has developed position papers on a range of issues, including the food chain, food safety, responsible use of animal medicines, sustainable agriculture and the contribution of animal health products to society.

Product identification

IFAH worked on ideas and systems designed to facilitate the identification of veterinary medicines. As one of its major projects, IFAH has developed a 'data matrix' bar code system that will allow easy identification of animal health products. This has attracted positive feedback from a variety of stakeholders, including wholesalers and veterinary surgeons as well as regulators. It will be introduced in Europe during the next two years, and has the potential to be used throughout the world.



3. Communications

IFAH aims to position the federation as a widely-recognised, reliable and respected source of information on animal health issues. Its communications strategy is designed to promote the exchange of information and the development of a shared set of values among member companies and associations, and to convey the values and opinions of the industry to a broad external audience. Activities in this sphere also provide valuable support for initiatives designed to convey industry messages on regulatory and food chain issues. Key achievements in 2005 included the development of new and improved communication tools, the establishment of a statement of principles to which IFAH and its members are committed, and the development of a position paper on benefit/risk analysis.

Benefit/risk analysis paper

IFAH produced a document that sets out in clear and concise terms the need for a measured, empirical approach to the assessment, management and communication of benefits and risks associated with decisions concerning the use of animal health products.

IFAH is a staunch advocate of risk analysis, and has been encouraging its use by authorities charged with the regulation of animal health products throughout the world.

Statement of principles

A document outlining the shared values to which IFAH and its members are committed was endorsed by the federation in 2005. The IFAH *statement of principles* underlines the animal health industry's commitment to animal health and welfare, food quality, public health and the conservation of natural resources.

Communication tools

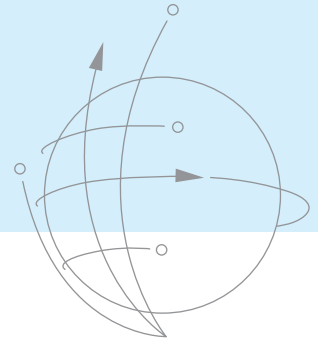
Throughout 2005, IFAH continued to work on the development of tools designed to improve the quality and range of communication materials to enhance levels of communication both within the federation and between IFAH and its external audience.

Changes to the IFAH website have made it a more attractive, accessible tool for those wishing to learn more about our industry. The documents mentioned above are available on the website.

REGIONAL ACTIVITIES

1. EUROPE

IFAH-Europe



1. Regulatory affairs

During 2005 the IFAH-Europe technical group organised 45 internal meetings of its expert working groups, and prepared 47 position papers in response to draft guidelines, concept papers, Regulations or other official proposals. In addition, the technical group and IFAH-Europe experts provided input to 75 external meetings (meetings with the authorities and conferences/workshops).

New pharmaceutical legislation: IFAH-Europe focused on the implementation of the new EU veterinary pharmaceutical legislation (Directive 2004/28/EC and Regulation EC 726/2004) to ensure that new requirements are transposed into national legislation in the 25 EU Member States in the most efficient, harmonised and workable way possible.

This work included efforts to ensure: that best practice guidelines for the decentralised procedure are workable; that Good Manufacturing Practices (GMP) for active pharmaceutical ingredients (API) included an exemption for ectoparasiticides; that a phased approach is taken to implementation of Eudravigilance Vet for Gateway users; that penalties for non-compliance are proportionate; that the guideline on defining serious risk in the context of the decentralised procedures is effective; and that the impact of Official Control Authority Batch Release (OCABR) for veterinary vaccines is minimised.

Mutual recognition procedure: In November 2005, IFAH-Europe in collaboration with the Veterinary Mutual Recognition Facilitation Group (VMRFG) published a survey on the 2004 mutual recognition procedures (MRPs) for veterinary products. A number of key issues identified by the survey were followed up with the VMRFG.

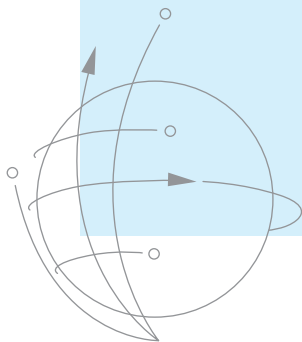
Review of residue legislation: IFAH-Europe participated in a stakeholders meeting organised by the European Commission to discuss proposed revisions to the legislation on residues in foodstuffs of animal origin, and provided input to the impact assessment for these outline proposals.

EMEA fees: Following IFAH-Europe's intervention, the Commission will limit increases in veterinary fees to 10% (their initial proposal was for a 100% increase).

EU level partnership to reduce animal testing: In December 2005 IFAH-Europe joined forces with the European Commission and six other industry associations in the '*European partnership to promote alternative approaches to animal testing*'. At its launch the partnership released a '3Rs' declaration aimed at **refining, reducing** or **replacing** animal use in experiments.

Antimicrobials: IFAH-Europe remained active in the area of antimicrobials during 2005, responding to two CVMP concept papers addressing guidance on the interpretation of data from VICH GL27 (studies to assess the potential development of resistance) and revisions to the guideline on the Summary of Product Characteristics (SPC) for antimicrobial products. Following IFAH-Europe's comments on the first of these papers, the CVMP granted a hearing with the federation during which it confirmed that the role of its Special Advisory Group on Antimicrobials (SAGAM) is to advise the CVMP, and that its composition would be broadened to include clinicians.

In addition, IFAH-Europe engaged in the topics of the VETCAST group and raised the issue of clinical breakpoints for antimicrobials at the VICH, and the WHO critical list of antimicrobials. The federation also updated its Prudent Use guidelines for use by the Global Antimicrobial Core Team and the EPRUMA group. It also monitored and provided input to the Antimicrobials Volumes Collection managed by CEESA and reacted to developments in Member States such as the Danish government's antibiotics 'list', the German bacterial collection initiative and the Spanish authorities' requests for local isolates.



Biological standards: The association organised a meeting between the authorities and industry to discuss various issues concerning immunological standards and control. A follow-up meeting will be organised in 2006.

Packaging: IFAH-Europe published a discussion paper on packaging issues and organised a seminar with the VMRF Group to examine possible solutions. A follow-up workshop with the authorities will be organised in 2006.

Innovation: IFAH-Europe published its position paper on innovation entitled '*IFAH-Europe perspective on the Lisbon agenda - enhancing innovation for the benefit of animals, people and the environment*'. EMEA and IFAH-Europe jointly organised an info-day on '*Nurturing innovation and sustainability in the European animal health sector*'; A key topic was the association's survey on the impact of guidelines on innovation.

International harmonisation: IFAH-Europe remains an active member of VICH via several Expert Working Groups (EWG) and the Steering Committee.

During 2005 procedures for the maintenance of VICH guidelines were discussed, two quality guidelines were adopted for implementation, and two draft pharmacovigilance guidelines were adopted for consultation. In addition, a new EWG was established on Metabolism and Residue Kinetics and two potential new topics - harmonisation of antimicrobial 'breakpoints' and the common technical document - were discussed. These will be debated further in 2006.

2. Food chain

Relations with regulators: IFAH-Europe has obtained associate-member status of the European Food Safety Authority's (EFSA) stakeholder consultative platform. A representative of the association attended the platform's inaugural meeting in October and a meeting of stakeholders held during the following month. The platform will provide a valuable avenue of communication with both the EFSA and other food chain stakeholders on issues that affect the animal health industry.

IFAH-Europe also gained membership of European Commission DG SANCO's Advisory Committee on the Food Chain, Animal and Plant Health. At the committee's July meeting it used this forum to convey serious concerns about the impact that proposed EFSA fees would have on the industry's competitiveness and ability to innovate.

Stakeholder alliances: Contacts with European federations representing consumers (BEUC) and retailers (EuroCommerce) were strengthened during the year in a bid to promote a better understanding of the role played by our industry. Issues such as the responsible use of medicines and the Community Animal Health Policy were also discussed with fellow food-chain stakeholders through the European Agri-Food Network (EAFN), while the association contributed to guidelines on integrated farming obligations developed by the European Initiative for Sustainable Development in Agriculture (EISA).



IFAH-Europe's "Healthy Happy Horse"

IFAH-Europe was also involved in the creation of a new alliance involving the industry, farmers and veterinarians, having joined forces with COPA-COGECA and the FVE to establish EPRUMA, the European Platform for Responsible Use of Medicines in Animals. Its goal is to ensure best practice in the responsible use of animal medicines in disease prevention and control. EPRUMA plans for 2006 include communicating this initiative to further stakeholders and developing a best practice framework on antimicrobial use.

Product identification initiative: IFAH-Europe continues to spearhead the industry's commitment to product identification. National associations held training sessions on a data matrix product identification system that will be introduced in Europe by the end of 2007, while a number of member companies undertook pilot projects with the system. Regulators and fellow stakeholders have responded positively to this initiative, which demonstrates the willingness of our industry to take the lead in the provision of transparent information on the origins of animal-derived food products.

European Technology Platform for Global Animal Health:

Encouraged and supported by the European Commission, IFAH-Europe and a number of fellow national and regional stakeholders have established a European Technology Platform for Global Animal Health (ETPGAH). The initiative is designed to identify and promote a research agenda capable of fostering the development of effective tools for the control of animal disease. Fellow stakeholders include livestock breeders and producers, the biotech industry, regulators and international agencies such as the WHO, FAO and OIE, as well as public sector research organisations, government ministries and animal welfare groups.

3. Communications

New communication tools: IFAH-Europe continued to pursue enhanced dialogue with fellow stakeholders and the consolidation of its position as a reliable and effective food-chain partner. IFAH-Europe revamped its website and produced communication materials. These included an updated 'Facts & Figures' primer profiling the animal health industry, a dossier on veterinary vaccines and a leaflet outlining the marketing authorisation procedure for veterinary medicines.

Lisbon agenda conference: At its conference on the animal health industry's contribution to goals laid down in the Lisbon Agenda, IFAH-Europe identified a predictable, science-based and harmonised regulatory framework as the key to ensuring the future of a competitive, innovative and sustainable animal health industry in the region. Its message was heard and welcomed by a broad audience comprising representatives of EU institutions, member state governments and fellow stakeholders from the agricultural and veterinary sectors.

Horse parade: Our industry's commitment to improving the health and welfare of both animals and people was underlined at the Belgian Horse Parade, where IFAH-Europe entered a model designed by local artist Véronique Sabban carrying the message: 'Animals are good for you - be good to them'. The artwork was later auctioned for charity, with the proceeds donated to Dyasis, a Belgian charity, which provides specially-trained dogs to work with the disabled.

TELLUS mission: IFAH-Europe also co-sponsored the TELLUS mission, a project led by the European Council of Young Farmers (CEJA) that aims to teach primary schoolchildren in EU member states about agricultural issues. This included communicating to teachers the benefits of veterinary medicines in a seminar held at the European Parliament building in Brussels.

2. NORTH AMERICA

AHI, USA | CAHI, Canada | INFARVET-CANIFARMA, Mexico

1. Regulatory affairs

Product approval procedures: With US regulators now collecting \$10 million a year from the industry in user fees, the AHI is closely monitoring the impact of new legislation to ensure that it is delivering real improvements in the efficiency of regulatory procedures. The association's input was instrumental in determining that regulators will be judged against explicit performance criteria included in the Animal Drug User Fee Act (ADUFA). Joint industry/FDA teams set up following its introduction continue to check progress and pursue improvements in both the quality of submissions and the efficiency of the application review process.

Positive results are already evident in both regards. The Food and Drug Administration's Center for Veterinary Medicine (CVM) has now cleared the backlog of submissions that previously existed, and closer dialogue between regulators and the industry is helping to reduce delays in the approval process associated with questions relating to information contained in new animal drug applications. Further improvements in reducing the number of review cycles are being pursued through an assessment of regulatory procedures and improved communication between reviewers and applicants. Discussions on the desk review of residue method trials - an approach that could cut approval times for some new drugs by a year or more - are also being pursued by the AHI.

While review procedures in the US are improving, a backlog of submissions continues to cause delays in the approval process for companies operating in Canada. CAHI is pressing Health Canada's Veterinary Drugs Directorate (VDD) to reduce approval times, and the association worked with the VDD in 2005 on the development of guidelines for the management of regulatory submissions. It also hosted bilateral meetings with senior regulators aimed at closer adherence to performance standards and improved reporting on performances in the review of both veterinary biological and pharmaceutical products.

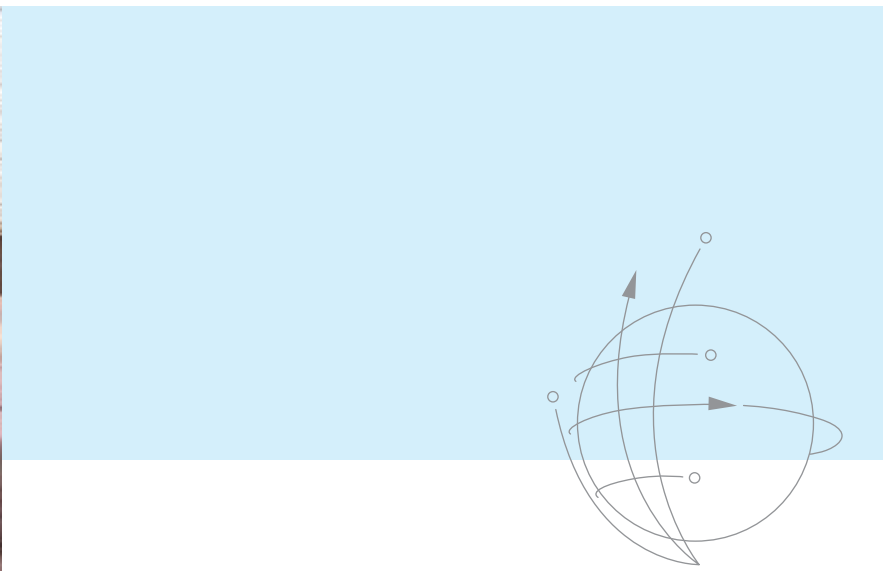
Other pharmaceutical regulations: AHI worked closely with the US Department of Agriculture on the development of a policy that means the Department will in future accept pre-harvest food safety vaccine products for regulatory review. It also petitioned for new incentives for the production of anti-terror countermeasures in the government's Bioshield II legislation.

In Canada, CAHI successfully advocated a review of Health Canada's policy on drug manufacturing and compounding. Updated regulations address industry concerns surrounding counterfeiting, and provide a clearer distinction between manufacturing and compounding of veterinary products. Industry calls for the prohibition of 'own use' drugs for use in food-producing animals were also heeded.

In Mexico, INFARVET contributed actively to discussions on a draft Federal Animal Health Law. The proposals were laid before the Senate in December, and are expected to receive final approval in the first half of 2006. The association was also closely involved in the development of new GMP guidelines for the veterinary pharmaceutical industry, which were published in January 2005, and worked closely with regulators on the development of new rules governing prescription status for veterinary medicines.

Antibacterial availability: After several years of debate, US regulators finally withdrew the approval for the use of the fluoroquinolone, enrofloxacin, in poultry. AHI expressed its disappointment at the decision which, it noted, has deprived poultry producers of an important tool for the treatment of sick birds. The association said all decisions on the approval and use of antibiotics should be based on sound, data-driven risk assessments, adding that it would work with the CVM to improve risk assessment procedures in a bid to ensure the continued protection of both animal and human health.

AHI successfully defended the safe use of veterinary antibiotics from legislative attacks in the states of Ohio, Minnesota and Maine.



2. Food chain

CAHI is a key player in broad alliances that have brought together a range of food chain partners in Canada. By improving dialogue between producers, service providers, processors and regulators, these are helping to ensure the development of rational policies and adherence to high standards at all levels of the food chain. The association has also worked bilaterally with commodity producer organisations, providing valuable input into the development of quality assurance programmes.

CAHI is a board member of the Canadian Animal Health Coalition, which comprises producers, veterinary and processing industries as well as both provincial and federal governments. The coalition is building a comprehensive national animal health strategy and developing protocols for the management of emergency situations in the sector. CAHI is also a member of the Canadian Supply Chain Food Safety Coalition which, by encouraging dialogue between partners at all levels of the chain, facilitates the development and implementation of a coordinated national approach to food safety.

In the US, AHI continues to work with coalition partners such as the National Cattlemen's Beef Association in a bid to provide balanced, factual information about the use of antibiotics in agriculture to stakeholders further along the food chain. AHI is also addressing issues regarding the legal standing of animals, and has built a coalition of companion and food animal interests to oppose the expansion of damages available to plaintiffs in lawsuits involving animals. It has been instrumental in achieving resolutions by state legislators to check this trend, and to oppose proposed changes in US law that would have seen pet owners handed 'legal guardian' status.

AHI has played a significant role in IFAH's efforts to strengthen its relationships with other stakeholders in the food chain at national level. It is also spearheading moves to build contacts in the human health field, laying the foundations for a more open-minded approach to the debate on antimicrobials and resistance.

3. Communications

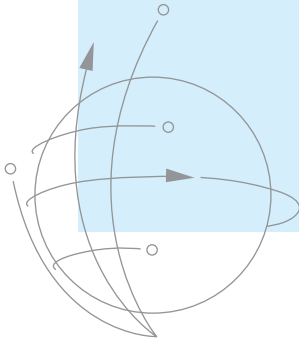
Industry associations across North America were responsible for co-ordinating surveys of the sector designed to provide transparent information on the size of the industry and, in the US, its commitment to continued investment in research and development.

The positive role played by the industry in animal health and welfare was also highlighted through a range of communication initiatives. In the US, these included the 9th annual AHI-hosted Pet Night on Capitol Hill, while in Canada, CAHI contributed on a regular basis to the Canadian Veterinary Journal and interacted with the media on current issues related to animal health. CAHI served on the steering committee of a national conference addressing the prudent use of antimicrobials and agriculture's role in managing resistance, where its involvement helped to ensure a balanced, informed debate. The association also pursued regular contact with political and bureaucratic decision-makers in a bid to ensure that emerging policies with an impact on the animal health sector are based on informed decisions.



3. SOUTH AND CENTRAL AMERICA

CAPROVE, Argentina | SINDAN, Brazil



1. Regulatory affairs

Regional harmonisation: Representatives from industry associations and regulatory authorities across South and Central America convened in Montevideo, Uruguay, during September, for the eleventh meeting of CAMEVET, an initiative designed to harmonise rules governing the registration and control of veterinary medicines in the region. The conference addressed a range of issues, including the inspection, verification and control of veterinary medicines, product labelling requirements, GMP guidelines and efficacy/safety standards for antiparasitics and biologicals. Panama will host the next meeting of CAMEVET in 2006.

National issues: In Brazil, SINDAN maintained regular contact with regulatory officials, during which legislation governing animal production and food safety was discussed in detail. The association's compendium of veterinary products approved for use in Brazil is now available in electronic form on both the SINDAN and Ministry of Agriculture websites. The number of hits registered for the compendium on SINDAN's site increased dramatically in 2005.

In Argentina, representatives of CAPROVE brought several areas of concern to the attention of the government during a meeting with officials from the Ministry of Industry and Commerce. Issues discussed during a highly productive session included the application of GMP standards to the animal health industry and the importance of keeping the country's livestock herds and flocks free from serious disease outbreaks. The association also called on the government to clamp down on unlicensed suppliers of animal health products by enforcing quality standards more rigorously.

2. Food chain

In Brazil, SINDAN maintained close contact with fellow stakeholders in the food chain during 2005 in a bid to ensure that all parties comply with the high standards required to protect the health of both animals and consumers. The industry has played a crucial role in the development of animal production for both domestic consumption and export - not least as a result of its ability to increase the supply of products such as Foot-and-Mouth Disease (FMD) vaccines. Demand for FMD biologicals has risen dramatically in recent years, and manufacturers produced over 400 million doses in 2005. Vaccines are subjected to strict quality control by regulators, and the industry works closely with farmers and veterinary surgeons, as well as the authorities, to ensure the protection of Brazil's livestock against the disease.

In Argentina, CAPROVE participated in a meeting that brought together representatives from all major links in the food chain and the biotechnology industry. It also strengthened established relationships with regulators and took part in a number of events that brought together various stakeholders in the food chain.

3. Communication

Efforts to eradicate FMD in South and Central America highlight the importance of the role played by our industry in the protection of animal and human health. With emerging infections such as highly pathogenic Avian Influenza presenting new threats in this regard, SINDAN worked hard during 2005 to highlight the industry's commitment to the control and eradication of serious zoonotics.

CAPROVE also stepped up communications with the media in a bid to achieve broader recognition of the vital role played by the industry in the protection of animal health and welfare. The association also established a new companion animal committee that will work to heighten awareness of zoonoses and the importance of pet health maintenance, and to encourage responsible use of animal health products.

4. ASIA-PACIFIC-AFRICA

Agcarm, New Zealand | The Alliance, Australia (Formerly Avcare) | ASOHI, Indonesia | JVPA, Japan | MAI, Israel | KAHPA, Korea | SAAHA, South Africa

1. Regulatory affairs

Veterinary product legislation: Like their counterparts in the US and the European Union, regulators in Japan have overhauled legislation governing animal health products recently. The JVPA was involved closely in discussions on the development of new regulations, which were implemented through major revisions to the country's Pharmaceutical Affairs Law in 2005. By replacing import and manufacturing approvals with a system of product-specific marketing authorisations, the new law will allow the animal health industry to adopt a much more flexible approach to business in Japan.

The JVPA has also contributed actively to the Japanese government's switch from a zero-tolerance policy on veterinary drug residues to the implementation of MRLs. This will see withdrawal periods for many animal health products revised during 2006.

In Indonesia, constructive dialogue between ASOHI and regulators has been instrumental in the updating and improvement of the registration process for veterinary products. ASOHI has also been involved closely in discussions surrounding the implementation of good manufacturing practice (GMP) standards, which has now been delayed until the end of the decade.

In Australia, the Alliance (formerly Avcare) has been involved closely in a regulatory review of sheep ectoparasiticides undertaken by the Pesticides and Veterinary Medicines Authority (APVMA). The association published a new book designed to contribute to the debate, which was launched formally by the Department of Agriculture, Fisheries and Forestry (DAFF) parliamentary secretary Susan Lee towards the end of the year.

In New Zealand, regulatory control of most animal health products is now between the Agricultural Compounds and Veterinary Medicines (ACVM) Act and the Hazardous Substances and New Organisms (HSNO) Act. Agcarm has monitored the transfer process closely, clarifying requirements and advising members of new responsibilities. Labelling requirements are prominent in this respect, and the association has prepared a labelling guide covering responsibilities in this area.

Agcarm maintained a close dialogue with regulators on the issue of prescription veterinary medicine dispensing, where a system of licensing of traders has been implemented in the wake of the transfer process. It also spearheaded the development of FAIRad, a forum for the regulation of advertising by the industry under which a code and charter for the promotion of veterinary medicines is being established.

Elsewhere, Agcarm made representations to the government calling for improvements to existing levels of intellectual property protection accorded to veterinary medicines. It highlighted inadequate data protection and generic spring-boarding provisions contained in existing legislation as particular areas of concern.





In South Africa, where responsibility for the regulation of veterinary medicines is still split between two government departments, SAAHA continued to push for the application of more uniform standards and the elimination of overlap between requirements imposed by the Health and Agriculture ministries. Significant progress has been achieved through regular liaison meetings with the Department of Agriculture, and the association is working closely with government officials on the drafting of new trial protocols and GMP guidelines. Staff changes at the Department of Health have hindered SAAHA's efforts to establish a working relationship with officials there, but a breakthrough was achieved during 2005 when the Veterinary Products Policy Committee met for the first time in over two years, enabling the association to discuss issues of concern with both government departments, as well as the veterinary and pharmacy professions.

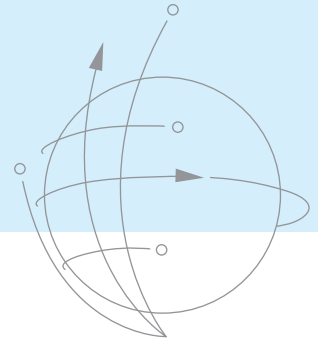
Further improvements in the regulatory environment are being targeted by SAAHA, which plans to brief the Parliamentary Working Group on Agriculture, highlighting the lack of capacity within the Department to deal with issues governing animal health products, and the detrimental impact that this has on the industry.

In Israel, MAI maintained a close and constructive dialogue with regulators on a range of issues, including amendments to existing requirements for the registration of insecticide products, which are designed to bring standards into line with those obtaining in the European Union. Regulations governing the import of veterinary medicines and the involvement of pharmacies in veterinary product distribution were also discussed during a series of meetings with representatives from the Agriculture Ministry's Veterinary Services Division and the Ministry of Health's Pharmacy Directorate.

Antimicrobial availability: With the help of materials provided by IFAH, the JVPA has prepared a series of position papers on approaches to risk assessment for antimicrobials used in animals. Emphasising the importance of a scientific approach to the process, these have been distributed to relevant parties in the run-up to an antimicrobial risk assessment programme that will be pursued by Japan's Food Safety Commission during 2006.

In New Zealand, Agcarm has participated in a government-led working group set up to address antimicrobial resistance issues, and has built positive contacts in the human health sector. This open approach has paid dividends, delivering a balanced debate and regulatory approaches that are acceptable to the animal health industry in New Zealand.

Safety and stewardship: The Alliance has spearheaded and participated in a number of initiatives designed to promote the safe, responsible use of animal health products and to limit their impact on the environment. It has developed guidelines on container design and labelling for liquid products, which will be released early in 2006, and played a central role in the development of Agsafe accreditation programmes for premises manufacturing and storing veterinary products.



2. Food chain

Avian influenza: While Avian Influenza (AI) has now spread beyond the Asia-Pacific region, countries there remain worst-affected by the disease. The animal health industry has played a vital role in assisting in educating and advising producers, the public and governments in the region about how best to deal with AI outbreaks and limit the risks posed to animal and human health by the infection. The Indonesian industry association, ASOHI, organised a seminar on AI and food safety issues during 2005, and supported government campaigns to educate the public about the disease.

Environmental impact: In Australia, the Alliance is involved in a number of initiatives designed to limit the environmental impact of animal health product use. It has lent its support to a new initiative designed to encourage broader participation by both farmers and local governments in the drumMUSTER programme, which involves the collection of empty containers for recycling. A similar initiative is being developed in New Zealand, where AGCARM is playing an active role. Back in Australia, the Alliance was also involved in the launch of ChemClear, a scheme set up to encourage the collection and responsible disposal of unused products from farms across the country.

Food safety: In Israel, MAI met with representatives of the slaughterhouse and food processing sectors in a bid to promote improved understanding of issues such as food safety, quality and traceability. Further dialogue with food chain partners is planned during 2006.

Sustainable product use: The Alliance has also lent financial support to the launch of WormBoss, a scheme developed with stakeholders representing Australia's sheep and wool producers that is designed to manage parasites and control resistance to anthelmintics. This comprehensive online resource pools the knowledge and expertise of the animal health industry, leading researchers in the field of parasitology, consultants and extension officers, offering advice to farmers on best practice for the control of parasites and the sustainable use of anthelmintics in livestock production. A similarly pro-active stance is being pursued by Agcarm in New Zealand, where the association is participating in the development of a national strategy to combat anthelmintic resistance.





3. Communications

Industry representation: Representation of our industry in Australia has been strengthened and simplified following the creation of the Animal Health Alliance (The Alliance), which now operates as a distinct division of Avcare - the national industry association which previously represented both the animal health and crop protection sectors. Preparations for this major new development dominated the association's communications agenda in 2005, and while the Alliance did not begin operating officially until the beginning of 2006, it has already established a comprehensive website.

In South Africa, SAAHA's status as the voice of the animal health industry was strengthened after it accepted three new associate members. The association now speaks directly on behalf of companies that represent more than three-quarters of the industry in terms of turnover.

The industry's commitment to abide by the highest of standards was underlined by the introduction of ID cards, which have been issued to all qualified, accredited company representatives. The initiative was widely promoted in the local media. SAAHA produced new pamphlets - in both Afrikaans and English - designed as tools with which to spread industry messages, while its efforts to communicate with other stakeholders also included editorials placed in alternate issues of Pet's Health magazine.

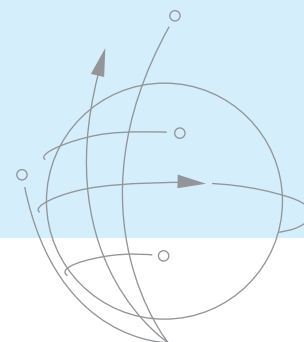
Encouraging debate and education: In Indonesia, ASOHI initiated a debate on the development of policies for monitoring and controlling outbreaks of animal disease, involving regulators, consumers and other parties operating in the food chain. The association also provided training courses for those involved in the handling and use of animal health products, and continued to develop the range of communication tools available to member companies. These now include a monthly news digest and bulletins addressing a range of topics.

In Israel, MAI worked to improve the government's understanding of issues, problems and opportunities faced by the animal health industry. Representatives of the association met with senior Agriculture Ministry and Veterinary Services officials on two occasions during the year, when government representatives visited ABIC Biologicals' new state-of-the-art vaccine production plant.

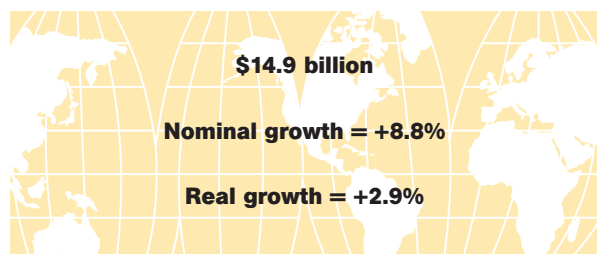
In Australia, the Alliance contributed to an initiative by the National Companion Animal Council designed to promote the benefits of socially responsible animal ownership. The association has also funded a study on the value of pets, which will assess the role of companion animals in society and the economic contribution of the sector. The study, which will include information on veterinary care and animal health products, will be published in 2006.

In New Zealand, Agcarm has established a scholarship to support third-year undergraduate veterinary students, while the association also provided financial assistance for the annual conference of the joint Australia/New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART).

ANIMAL HEALTH INDUSTRY PROFILE



The Animal Health Industry in 2005



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Animal Health Market by Product Group

Product Group	2005 \$bn	YoY* %	Share %
Medicinal Feed Additives	1.9	11.2	13.0
Biologicals	3.4	8.7	22.6
Anti-infectives	2.4	8.0	15.8
Parasiticides	4.2	7.9	28.4
Other Pharmaceuticals	3.0	9.2	20.2
Total	14.9	8.8	100.0

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* Year over year percentage

Animal Health Market by Region

Region	2005 \$bn	YoY* %	Share %
North America	5.1	8.5	34.2
Latin America	1.7	11.1	11.4
West Europe	4.6	8.1	30.7
East Europe	0.7	16.1	4.6
Far East	2.4	7.6	16.2
Rest of World	0.4	6.1	2.9
Total	14.9	8.8	100.0

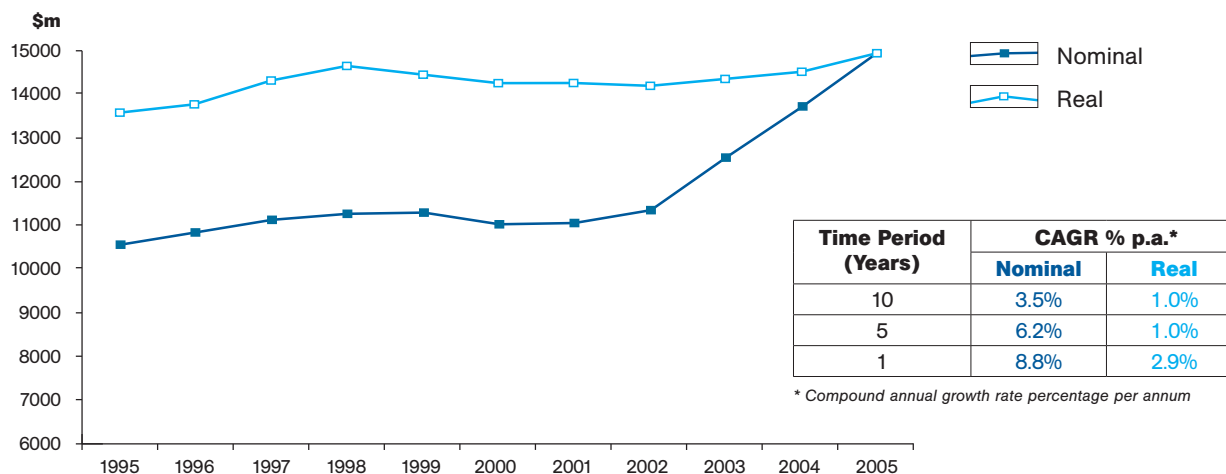
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* Year over year percentage

Animal Health Market by Species

Species	2005 \$bn	YoY* %	Share %
Cattle	4.1	10.5	27.2
Sheep	0.8	6.3	5.1
Pigs	2.4	7.5	16.3
Poultry	1.7	8.1	11.2
Companion Animal/Other	6.0	8.7	40.2
Total	14.9	8.8	100.0

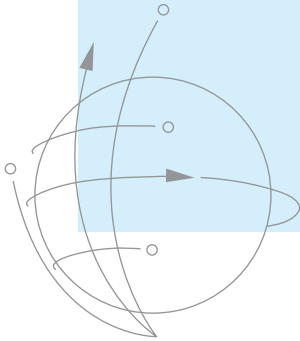
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* Year over year percentage

Animal Health Market Evolution/Consolidation



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Patrick James, Vice-President
Elanco Animal Health

Gunnar Riemann, Vice-President
Bayer HealthCare AG, Animal Health Division

Ruurd Stolp, Vice-President
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Eric Marée, Treasurer
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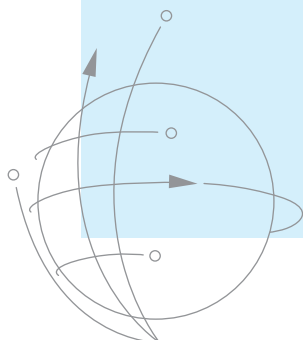
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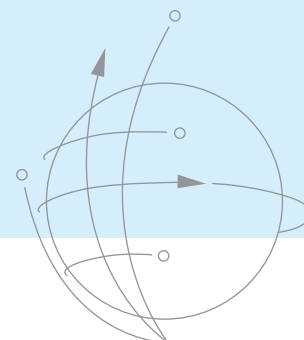
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ACRONYMS



ACVM	Agricultural Compounds and Veterinary Medicines Group of the New Zealand Food Safety Authority
ADUFA	United States Animal Drug User Fee Act
AER	Adverse Event Report
AI	Avian Influenza
ANZCCART	Australia/New Zealand Council for the Care of Animals in Research and Teaching
API	Active Pharmaceutical Ingredient
APVMA	Australian Pesticides and Veterinary Medicines Authority
BEUC	The European Consumers' Organisation
CEESA	European Animal Health Study Centre
CEJA	European Council of Young Farmers
COPA- COGECA	Committee of Agricultural Organisations in the EU - General Confederation of Agricultural Co-operatives in the EU
CVM	United States Center for Veterinary Medicine
CVMP	EMA Committee for Veterinary Medicinal Products
DAFF	Australian Department of Agriculture, Fisheries and Forestry
DG SANCO	European Commission Directorate General Health and Consumer Protection
EAFN	European Agri-Food Network
EFSA	European Food Safety Authority
EISA	European Initiative for Sustainable Development in Agriculture
EMA	European Medicines Agency
EPRUMA	European Platform for the Responsible Use of Medicines in Animals
ETPGAH	European Technology Platform for Global Animal Health
EU	European Union
EWG	Expert Working Group
FAIRad	Forum for Animal Health Industry Regulation of Advertising

FAO	Food and Agriculture Organisation of the United Nations
FDA	United States Food and Drug Administration
FMD	Foot-and-Mouth Disease
FVE	Federation of Veterinarians of Europe
GACT	IFAH Global Antimicrobial Core Team
GMP	Good Manufacturing Practice
HSNO	Hazardous Substances and New Organisms
IAFN	International Agri-Food Network
JECFA	Joint Expert Committee on Food Additives
MRL	Maximum Residue Limit
MRP	Mutual Recognition Procedures
NGO	Non-Governmental Organisation
OCABR	Official Control Authority Batch Release
OIE	World Organisation for Animal Health
SAGAM	CVMP Special Advisory Group on Antimicrobials
SPC	Summary of Product Characteristics
US	United States of America
VDD	Health Canada's Veterinary Drugs Directorate
VETCAST	Veterinary Committee on Antimicrobial Susceptibility Testing
VICH	Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMRFG	Veterinary Mutual Recognition Facilitation Group
WHO	World Health Organisation
WTO	World Trade Organisation

IFAH thanks the following for having provided pictures for this report: Elanco Animal Health, Meril Ltd, Pfizer Animal Health Group and Virbac SA.



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April 2006