

IFAH
annual report
2013

**Overcoming barriers to animal
disease prevention and control,
a critical step towards One Health**



Contributing to
economic growth,
food security,
sustainability and
public health



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About us

The International Federation for Animal Health (IFAH) is the global representative body of companies engaged in research, development, manufacturing and commercialisation of veterinary medicines, vaccines and other animal health products in both developed and developing countries across the five continents.

IFAH represents both animal health companies (10) and national/regional animal health associations (28). These associations comprise both local small and medium-sized enterprises and international companies. Overall, these companies represent approximately 80% of the global market for animal health products.

IFAH is led by Executive Director Carel du Marchie Sarvaas¹ and headed up by President Jeff Simmons, President of Elanco.

IFAH is an international non-profit organisation registered under Belgian law based in Brussels, Belgium.

Why does IFAH exist?

- Foster a greater understanding of animal health;
- Promote a predictable, science-based regulatory environment that facilitates the supply of innovative, quality products into a competitive market place. These products contribute to the supply of safe, healthy food, and to high standards of health and welfare for animals and people.

What does IFAH do?

- Act as a unified global industry voice in dialogue with major international bodies (OIE, FAO, WHO, Codex Alimentarius, etc.), governments, animal health stakeholders, food industry partners and consumers.
- Encourage and assist the development of predictable science-based regulatory processes and standards where authorisation and approval to market medicines is firmly rooted in a thorough risk-benefit analysis.
- Promote international harmonisation of testing requirements for animal health products to facilitate the availability and delivery of new and innovative products worldwide.
- Act as a source of information on the benefits of animal health products for animal health and welfare, food and safety, and public health.
- Actively promote the value of research-based medicines developed to the highest standards and authorised according to the regulatory criteria of quality, safety and efficacy.
- Ensure the availability of all classes of veterinary medicines to the benefit of animal health and welfare, and promote their responsible use.
- Provide expertise on emerging diseases and fulfil its role as part of the solution to control these diseases in animals.

¹ Joined IFAH in March 2014, succeeding Acting Executive Director, Mike McGowan

A message from IFAH's President and Acting Executive Director

Welcome to IFAH's Annual Report for 2013. Here you can read about some of our key activities from the past year and learn more about IFAH's work both globally and across our member regions.

The rapid increase in human population and prosperity have resulted in unprecedented demand for livestock products and seen the rise of globe-spanning food supply chains. With greater wealth and social evolution, more people have added pets to their families, offering both companionship and assistance to people.

The combination of these socio-economic developments with the emergence of new disease risk as a consequence of man and animals living in closer proximity has created a global environment with a substantial need to secure the health of both animals and people.

IFAH has taken these challenges and turned them into opportunities to enhance awareness of the One Health concept, which encourages greater cooperation among stakeholders. Promoting further investment in both innovation and education, IFAH highlights the vital role that research into developing new technologies will play in overcoming the hurdles of existing and emerging public health issues. Innovations in animal health go hand-in-hand with a global approach to product development, authorisation and supply,

and are indispensable to minimising risks to animal and human health, ensuring food remains abundant, safe, affordable and sustainable, and encouraging long-term economic growth.

Disease control and food security will continue to be of particular importance to IFAH as they become increasingly relevant to communities around the world. By 2050 the global population is projected to grow to approximately 9 billion people, but with only a small percentage of land available to produce the required extra food, 70% of the necessary increase in food production has to come from innovation and technology, along with increased farming efficiency. The animal health industry has a positive story to tell in this respect. How global agriculture will maintain and indeed optimise productivity with fewer resources is intrinsically linked to innovative solutions for animal health, and that is what we do best.

The year 2013 has been rich in activities with two important additions to highlight: First, we are pleased to report the expanding reach of the federation as we welcomed a new member, the Indian Federation for Animal Health Companies (INFAH). Also, we welcome Carel du Marchie Sarvaas as the new Executive Director of IFAH and wish him every success in enhancing the federation's leadership.

Disease control and food security will continue to be of particular importance to IFAH as they become increasingly relevant to communities around the world

We, as President and Acting Executive Director, can only stress the importance of the federation in highlighting the work of the animal health industry and the value of healthy animals to society. IFAH will continue to work with industry stakeholders, governments, NGOs and the general public throughout this year and beyond to foster a greater understanding of animal health and promote a predictable, science-based regulatory environment that facilitates the supply of innovative, quality products into a competitive market place.



JEFF SIMMONS
PRESIDENT



MIKE MCGOWAN
ACTING EXECUTIVE DIRECTOR

Overcoming barriers to animal disease prevention and control



According to the FAO report 'World Livestock 2013: Changing Disease Landscapes', over 70% of new diseases emerging in humans over recent decades are of animal origin and are, in part, directly related to the increasing demand for animal protein. With today's ever expanding population, the need for the development of new veterinary medicines is imperative not only for safeguarding against disease transmission, but also to ward off the staggering burden of disease outbreaks which affect food security, peoples' livelihoods, and in some cases the entire economy of a country.

While animal disease outbreaks are not a new phenomenon, modern trends have dramatically increased the risks associated with outbreaks and the likelihood of further epidemics will grow. Animal health products will play an increasingly central role in effective disease prevention and control. While government, industry and regulators around the world have already taken important steps to ensure that veterinary medicines can be delivered quickly and effectively when needed, many challenges still remain.

Key barriers to research and development, the availability of medicines for veterinarians and animal keepers, their appropriate use, and the deployment of new innovative products need to be addressed to withstand this changing disease landscape. With this in mind, IFAH commissioned global analysis and advisory firm, Oxford Analytica, who were supported by a group of independent experts in animal health, to examine the barriers that currently hinder the effective control of animal disease.



Need for harmonised and streamlined regulation

Illustrated through telling case studies on avian influenza, bluetongue, West Nile fever, classical swine fever, equine influenza and the use of antibiotics, key findings of the report outlined the main constraints related to research and development, bringing veterinary medicines to market and the use of those medicines. Looking at the administrative processes involved with licensing veterinary medicines, the report concludes that the current regulations governing licensing are overly burdensome and that legislative frameworks across regions are divergent. This absence of globally streamlined approval processes causes major delays to marketing authorisations and increases costs.

At the third Global Animal Health Conference held in the US in October 2013 stakeholders agreed that harmonising regulatory requirements would help to reduce both cost and development times allowing faster, more efficient approval of urgently-needed treatments for diseases. In turn, supporting the adoption of appropriate, harmonised requirements in emerging markets, which may lack the resources required to generate their own national standards, would be an important step towards ensuring that high quality animal health products are available at the point of need.

Fostering regulatory harmonisation, empowering veterinarians, developing public-private partnerships and promoting cooperation are vital to ensuring an efficient response to and control of disease outbreaks

VICH, the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products, has made good progress in improving coordination and cooperation, having developed more than 50 international guidelines to ensure the quality, efficacy and safety of veterinary medicines, and, where feasible, to reduce the number of animal tests and associated costs.

Stronger disease surveillance and control

It is clear that surveillance at all levels of the animal production chain is necessary to anticipate the emergence of new zoonoses, but the report finds this area lacking, with existing surveillance systems tending to be passive or reactive. The constantly changing nature of virus strains also hinders vaccine development and the lack of veterinary experts available to carry out diagnostic controls creates inefficiencies in responding to an outbreak.

In order to mitigate the risks associated with animal disease, more robust surveillance and control measures need to be put in place, particularly in parts of the developing world where veterinary services and infrastructure remain limited and under-resourced. Where pathogens are variable, surveillance is also critical to allow early detection and the rapid development of effective vaccines. As pathogens evolve and mutate, the likelihood of further

serious epidemics will grow. This will not only impact animal health, but human health, given that 75% of emerging animal diseases are zoonotic.

Rather worryingly, if these epidemics are likely to grow, the white paper finds that there are many logistical problems with the distribution and availability of veterinary medicines even after the licence has been approved. Lack of government support in some countries and deficient veterinary capacity on the ground, as well as infrastructure often leads to incorrect, inconsistent and irresponsible use of veterinary medicines. Empowering veterinary services, strengthening governance, improving local knowledge and infrastructure especially in developing countries is a first vital step to ensuring effective response to disease outbreaks.

Market access: a precondition to sustained animal health research

With this prospect of emerging diseases it is normal to expect that the animal health industry is researching new medicines, yet the white paper highlights that the high costs involved with developing new medicines are a major barrier to research and development. The barriers are not just cost-related however. Consumer attitudes can also impact development and use.



‘The systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of relevant information through the binding notification to the OIE is necessary to anticipate the emergence of new zoonoses so that action can be taken.’

BERNARD VALLAT
DIRECTOR GENERAL, WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

'Changes in land use and marketing systems respond to the growing demand of food have led to increased threats to health and environmental resilience. Sound governance at local and global levels to reduce these pressures is needed.'

BERHE TEKOLA

DIRECTOR, ANIMAL PRODUCTION AND HEALTH DIVISION,
FOOD AND AGRICULTURE ORGANISATION (FAO)



There is growing concern that public opinion on new technologies, which are often based on misguided information, could hinder future research. The industry is increasingly developing new technologies to make animal medicines safer and more effective in combatting emerging and re-emerging diseases. However, many scientists and industry experts now believe that politics, rather than science, might drive some regulatory measures, which may undermine the development and introduction of much-needed novel vaccines and biopharmaceuticals.

Along these same lines, current attitudes toward the use of antibiotics in animals have meant that animal medicines start to face competition with human medicine. The emergence of antibiotic resistance, which is a natural biological phenomenon but is amplified by the inappropriate use of antibiotics in both human and veterinary medicine, has seen many international organisations promoting the monitoring of antibiotic use in animals as a prerequisite for ensuring sound public health. Whilst resistance is a serious and growing problem in contemporary medicine, the risks are

often misunderstood and sometimes used as a rationale for the introduction of unnecessarily strict legislation on the use of antibiotics in animals. Correct and responsible use of antibiotics considerably reduces the likelihood of resistance development and can be vital in combating emerging diseases.



Barriers to disease control



Emerging and re-emerging animal diseases can have serious consequences for animal and human health. Modern trends of globalisation, human development and climate change have dramatically increased the risks associated with outbreaks.

\$200bn

Estimated cost of emerging animal disease outbreaks in the last decade

75%

Proportion of animal diseases that can be transmitted to humans and vice versa

\$200m

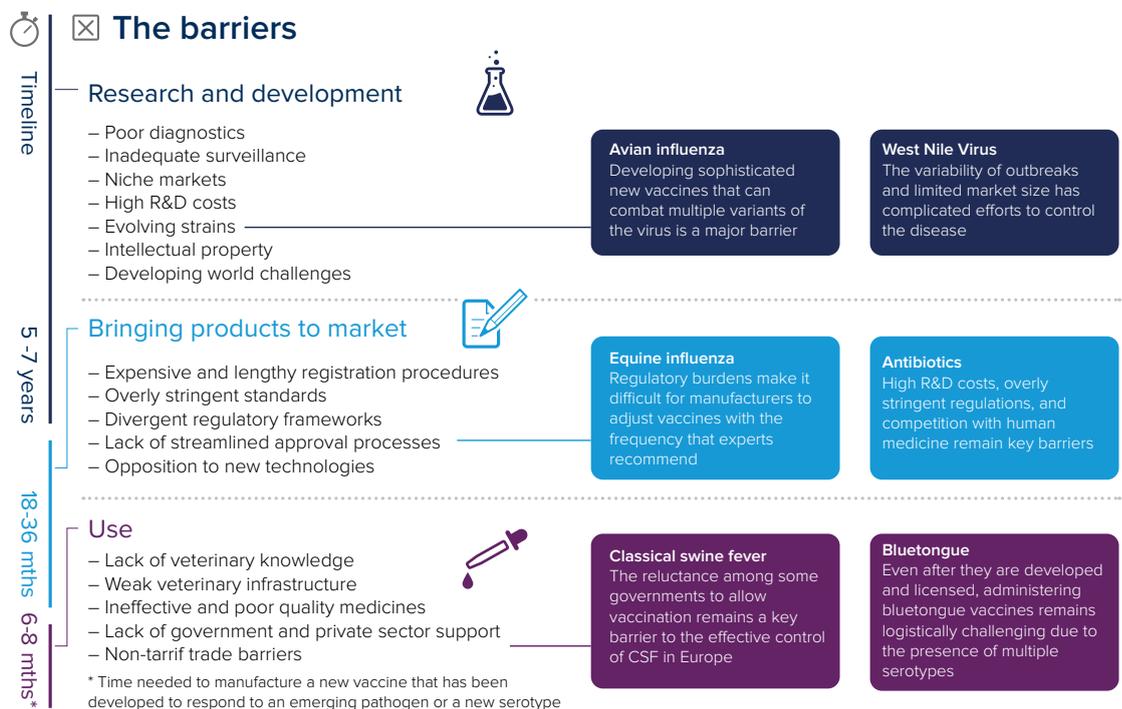
Potential cost needed to develop a major new animal medicine

7-10 years

Time required to develop a major new animal medicine, from R&D to end use

25%

Average increase in cost to register new animal health products between 2006 and 2011





'Addressing health risks at the human-animal-ecosystem interface requires strong partnerships. It is important to bring the One-Health concept across to future health professionals. Closer collaboration between veterinary schools and medical schools will foster a broader view on One-Health issues.'

FAOUZI KECHRID
PRESIDENT, WORLD VETERINARY ASSOCIATION (WVA)

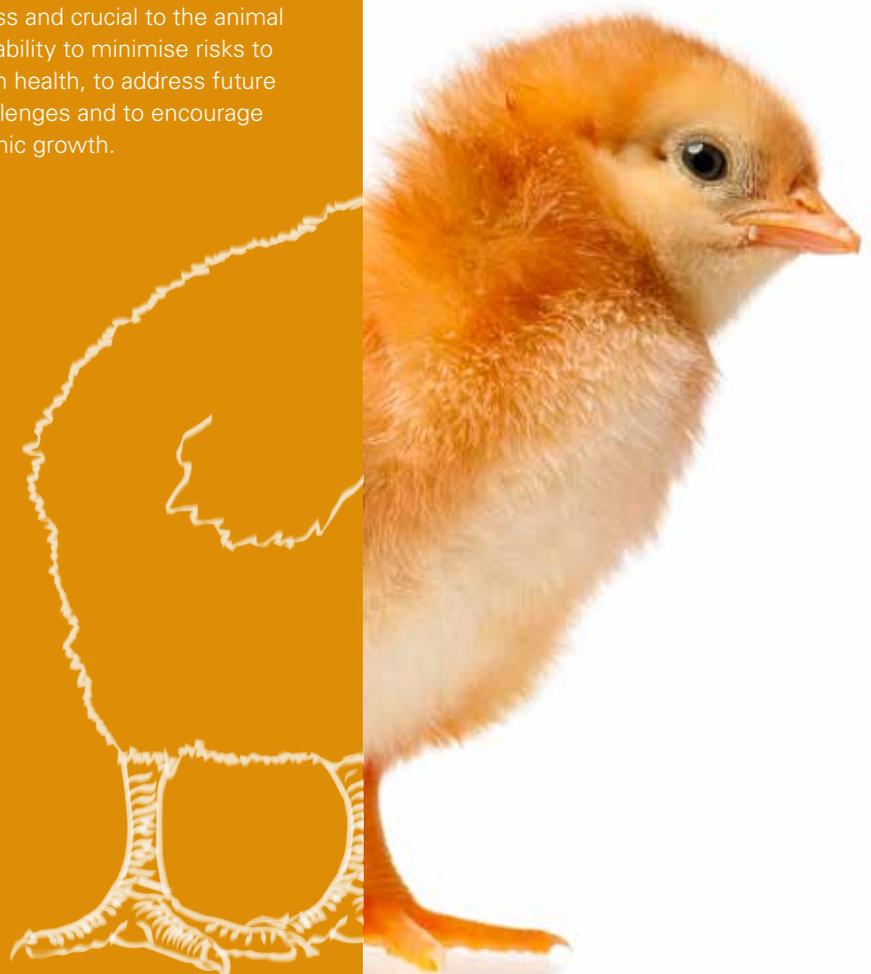
Call for stakeholder cooperation and a One-Health approach

One of the main reasons behind the commissioning of the white paper was to initiate wider collaborative discussions with international stakeholders on what future efforts would be required to overcome barriers that limit our ability to control emerging and re-emerging diseases. In terms of One Health and ensuring the responsible use of antibiotics in both animal and human medicine, it is clear that there is a need for increased interaction and communication between animal and human health sectors to strengthen surveillance schemes and best utilise resources to ensure their efficacy into the future. Fostering regulatory harmonisation, empowering veterinarians, developing public-private partnerships and promoting cooperation are vital to ensuring an efficient response to and control of disease outbreaks. A truly harmonised science-based regulatory environment will help maximise the development of much-needed animal health products. More uniform standards and processes are crucial to ensure response preparedness and availability of veterinary medicines in a timely and effective way.

Improved understanding of developing markets and more capable veterinary services at country level will support the development of regionally applicable vaccines that will be more effective in a national context. Some of the barriers that hinder the delivery of animal medicines

to developing countries can be overcome via the creation of regional vaccine banks. These not only create incentives for national veterinary services to work together and harmonise their control measures, but they also provide a cost-effective way to rapidly distribute vaccines to the outbreak area.

Closer cooperation between governments, regulators and industry is needed to ensure the development of new and innovative products, promote acceptance of new technologies and to address barriers to animal movement and international trade of animal products. Looking forward, IFAH believes that no single institution can overcome the barriers to animal disease prevention and control, nor can they succeed in combatting the burden of disease outbreaks alone. We are strongly committed to supporting harmonised regulations and further developing partnerships with stakeholders as they are vital to our success and crucial to the animal health industry's ability to minimise risks to animal and human health, to address future food security challenges and to encourage long-term economic growth.



IFAH's achievements in 2013

IFAH and its member companies play an essential role in ensuring availability of quality veterinary medicines for preventing and controlling disease, permitting people to bring pets into the home and supporting a sustainable supply of safe and nutritious food across the globe.

Fostering a favourable regulatory environment

IFAH believes that one way to drive efficiencies to address societal concerns is through global harmonisation of animal health regulations and standards. Fostering a regulatory environment that is innovation-friendly and supports the needs of the animal health industry, the veterinary profession, the farming community, as well as the general public is one of IFAH's main goals.

In early 2013 IFAH successfully negotiated the continued use of thiomersal, which acts as a preservative in vaccines, during the fifth session of the United Nations Environment Programme (UNEP) Intergovernmental Negotiating Committee to prepare a global legally binding treaty on mercury (Minamata Convention). The federation was also happy to congratulate the Codex Alimentarius Commission (CAC), established by the United Nations' Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO), on 50 years of setting global food safety standards. We look forward to continuing to work with the CAC to ensure that standards help protect consumers around the world.

The development of global standards is critically important, especially in countries with limited resources and infrastructure. The ability to adopt scientific and proven standards means, for example, that countries in the developing world can treat potentially disastrous animal diseases quickly and efficiently. To this end, IFAH partners with GALVmed, a charity helping to ensure better accessibility to quality vaccines, medicines and diagnostics for animals in developing countries. 2013 saw the culmination of a project initiated by IFAH, GALVmed and FAO to develop internationally agreed quality standards (monographs) for all available

animal trypanocidal medicines. These monographs are now under review for adoption and publication by the World Organisation for Animal Health (OIE).

Focusing on regulatory convergence and technical regulatory issues, as well as challenges and solutions in developing countries to support food security and sustainability, the third Global Animal Health Conference was a major milestone for IFAH in October 2013. Titled, 'Developing global animal health products to support food security and sustainability', the event was jointly organised with the Drug Information Association (DIA) and provided a platform for the animal health industry, national and regional authorities, and other international delegates to look into the opportunities and barriers for the sector to deliver new solutions across the world and to continue working together to promote global unified standards. The conference report and conclusions are available on www.ifahsec.org.

In terms of global outreach, IFAH continued to actively participate in the work of VICH, the trilateral (EU-Japan-USA) programme established under the auspices of the OIE aimed at harmonising technical requirements for veterinary product registration. Now running since 1996, VICH has been expanding over the years and was delighted to welcome South Africa as an observer in 2013 alongside the current observer countries Australia, Canada and New Zealand. In terms of further expansion, IFAH fully supports the VICH Outreach Forum, an initiative to improve information exchange and raise

awareness of VICH and its guidelines with non-VICH countries/regions. The Outreach Forum comprises a growing number of countries and regional organisations with an interest in establishing a basis for wider international harmonisation of technical requirements.

Providing leadership to increase our voice

In our dealings with external bodies we not only provide leadership for the animal health industry as a whole, but by increasing dialogue with stakeholders we also aim to increase the voice of the industry as a recognised thought leader on all animal health issues. 2013 saw IFAH invited to speak and share experiences on such issues as responsible use of animal health products, monitoring and surveillance, and comprehensive and efficient management of livestock disease risks at high-level events organised by the OIE, the Organisation for Economic Cooperation and Development (OECD) and FAO.

On the occasion of the G8 Summit taking place in June 2013, where antibiotic resistance was one of the many topics on the agenda, IFAH called on leaders of the G8 nations to promote the responsible use of antibiotics both in human and veterinary medicine to ensure their continued availability and efficacy. IFAH had further occasion to reiterate this message following the announcement by the US Food and Drug Administration late 2013 to phase out growth promotion use of medically-important antibiotics.

IFAH used the opportunity of the Global Animal Health Conference to create awareness of innovative solutions and to highlight the vital role that research into developing new technologies will play in meeting the challenges of increasing demand for animal protein brought on by a growing population.



3rd Global Animal Health Conference

Our guiding message – ‘Healthy Animals, Healthier World’ – is both an objective and a responsibility

By creating an understanding about the benefits of animal health products and promoting their responsible use, IFAH aims to underline how crucial animal health products are to safeguarding not only animal but also human health, as well as securing a sustainable food supply.



IFAH white paper on emerging and re-emerging diseases

Promoting our value to society

Another major milestone for IFAH in 2013 was the publication of another white paper, this time focusing on emerging and re-emerging animal diseases and the barriers to control them. Key findings of the paper were discussed with various international stakeholders during a roundtable event at the London Royal Society in November.

‘Influence’ and ‘innovation’ were the key focus points of the discussions with consensus that more stakeholders should be involved in encouraging governments to provide the right environment to allow more innovation in vaccine and medicine development, as well as surveillance to minimise risks to animal and human health, and encourage long-term economic growth.

IFAH hopes that the white paper, which is accompanied by an infographic illustrating the main barriers to control disease, will serve as a launch point for wider collaborative discussions.

IFAH’s members are continuously researching and developing innovative products to address global concerns in terms of animal health, food safety and security, as well as public health. Through sustained dialogue with international stakeholders and by enhancing and expanding awareness of our industry’s value to society, IFAH lays the foundations for future progress. At IFAH, our guiding message – ‘Healthy Animals, Healthier World’ – is both an objective and a responsibility. By ensuring healthy animals we strive to ensure a healthy existence for livestock producers, veterinarians, pet owners and consumers of animal-based food products in all parts of the world.





Regional activities

Europe

Regulatory affairs

IFAH-Europe welcomed the European Commission's proposed EU Regulation referred to as the draft animal health law. The federation supported proposals to monitor the efficacy of antibiotics against certain bacteria that cause disease in animals as these complete the existing monitoring programmes. It also welcomed the proposal's emphasis on education and good collaboration between the European Commission and Members States on the organisation and deployment of antigen, vaccine and reagent banks to allow for preparedness for future disease outbreaks.

The planned revision of the veterinary medicines Directive and medicated feed legislation was the focus of IFAH-Europe's stakeholder roundtable. The aim of the revision is to ensure a true single market for veterinary medicines and a more efficient regulatory process to improve the availability of medicines, protect animal health and public health, and contribute to a sustainable food supply. Areas of scrutiny include variations, packaging, vaccine batch release, pharmacovigilance and electronic dossier submission.

IFAH-Europe is very supportive of the VICH initiative on international harmonisation as a means of creating global standards for licensing veterinary medicines. As such, it participated in the VICH Steering Committee meeting and the Outreach Forum held in Auckland (New Zealand).

Antibiotics

The use of antibiotics in veterinary medicine continued to be actively discussed in many European fora. IFAH-Europe is committed to protecting both public and animal health alongside the long-term efficacy of existing antibiotics. In 2013 the federation advocated a two-pronged strategy: responsible use and transparency at the use phase to address resistance concerns in a focussed manner.

In line with fellow EPRUMA partners, IFAH-Europe called on the European Commission to support the training of veterinarians, farmers and other operators on the responsible use of veterinary medicines through the EU 'train the trainer' programmes.

Communications

IFAH-Europe launched a revamped website (www.ifaheurope.org) with a fresh design and general information on the animal health sector and featured content on companion and food-producing animals.

Led by IFAH-Europe, European Pet Night featured Belgian NGO APOPO, whose HeroRATS have been detecting landmines and tuberculosis in developing countries, as well as Activ'Dog with their animal-assisted activities for educational, social and therapeutic purposes.

The federation launched the 'We Care' Facebook page promoting responsible pet ownership and highlighting the numerous benefits of pets. Additionally, it carried out a campaign promoting the benefits of pets for the elderly under the motto 'Animals give us daily companionship and support. We care for them' (<https://www.facebook.com/WeCare.petsEurope>).

IFAH-Europe presented its views at important European Commission events such as the conference on the animal, plant and control package, and the conference on the welfare of dogs and cats in the EU, as well as a workshop on antimicrobial resistance.



IFAH-Europe launched its new website



Bart Weetjens (APOPO), MEPs Maria Irigoyen and Horst Schnellhardt, and IFAH-Europe Managing Director, Declan O'Brien, at European Pet Night



IFAH-Europe Chairman, Alejandro Bernal, European Health Commissioner, Tonio Borg, and Managing Director, Declan O'Brien, discussed the revision of the veterinary medicines legislation

North America

AHI (USA), CAHI (Canada), INFARVET (Mexico)

Regulatory affairs

Having identified issues with the illegal veterinary medicine compounding, the US Congress ordered a study on the topic, which will be carried out by the Congressional Research Service. AHI emphasised that medicine compounding from bulk is illegal and asked the US Food and Drug Administration (FDA) to take action against compounders that do not respect the law.

AHI attended a stakeholder forum for the Trans-Atlantic and Investment Partnership set up between the USA and Europe. The forum was intended to seek stakeholders' comments on priorities in terms of trade of products including agricultural commodities.

CAHI provided the animal health industry's recommendations on Health Canada's and the Canadian Food Inspection Agency's (CFIA) joint initiative to modernise the veterinary medicine and feed regulations aiming to ensure that regulation reflects current needs. CAHI advocated that regulation should be risk-based and proportionate in terms of risk/benefit. As part of this initiative, the Veterinary Drugs Directorate (VDD) looked at measures to have a risk-based pre-marketing review programme and ways to optimise oversight of imports and the use of non-authorized veterinary medicines.



CleanFarms unwanted/expired medication collection

On environmental stewardship, CAHI participated in a programme to collect unwanted/expired veterinary medicines and pesticides in over 31 agricultural product retail locations in Ontario. This was coordinated by CleanFarms, a not-for-profit industry stewardship organisation, and supported by the Ontario Government.

Antibiotics

The US FDA published the final guidance 213 and proposed veterinary feed Directive 213 and proposed veterinary feed Directive 213 establishing a three-year timeframe for phasing out growth promotion uses of antibiotics important in human medicine and phasing in veterinary oversight of these products. AHI supported the decision and committed to work with FDA on its implementation.

FDA announced new formats for reporting animal antibiotic sales data in more detailed summaries. AHI commented on these and conveyed its concerns to FDA as some of the proposed summaries could potentially disclose confidential information.



AHI President and CEO Alex Mathews introduces celebrity pets 'Baxter' and 'Aragon' and their trainers during the 2013 Pet Night media briefing on Capitol Hill.

Communications

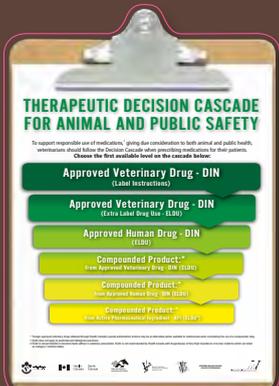
AHI hosted its 17th Annual Pet Night on Capitol Hill with a turnout of over 500 people, including Members of Congress, Hill staff and coalition partners. Attendees lined up to meet Quince, the dog who



plays 'Baxter' in the film 'Anchorman 2', and Aragon, the cat who stars as 'Lord Tubbington' in the hit television show 'Glee'.

AHI sponsored a thought leadership event entitled 'Human-Animal Medicine: Communicating across the Species Divide'. Co-hosted with the American College of Preventive Medicine and the Association of American Veterinary Medical Colleges, the event brought together physicians, veterinarians, policymakers, academics and industry stakeholders for a panel discussion.

CAHI published a poster on the therapeutic decision cascade for distribution to veterinary clinics across the country. This was endorsed by Health Canada, the Canadian Veterinary Medical Association and 5 provincial veterinary licensing bodies. CAHI also renewed efforts to communicate to pet owners the importance of vaccination and post-vaccination symptoms that might be expressed by pets.



CAHI poster on the therapeutic decision cascade



US Congressman Kurt Schrader, one of only two veterinarians serving in Congress, provides opening remarks for the thought leadership panel 'Human-Animal Medicine: Communicating across the Species Divide'.



South America

ALAVET (Chile),
CAPROVE (Argentina),
SINDAN (Brazil)



Regulatory affairs

SINDAN attended a workshop on the future of the foot-and-mouth disease (FMD) eradication programme organised by the Pan-American Centre for FMD (PANAFTOSA) to define the requirements for setting up a reserve vaccine and antigen bank.

Both CAPROVE and SINDAN participated in the annual assembly of CAMEVET, the Committee of the Americas for the Harmonisation and Control of Veterinary Medicines, held in Panama. Delegates discussed topics linked to the registration and control of veterinary medicines including the adoption of a standard to control inactivated vaccines against infectious bovine rhinotracheitis (IBR), as well as quality control of veterinary medicines in the Americas.

ALAVET participated in the Chilean Ministry of Agriculture's working group on the revision of the regulatory framework for veterinary medicines. The association provided input on topics including the registration of pharmacological and immunological products, and registration renewals.



A SINDAN delegation participated in a meeting of the South American Commission for the fight against FMD (COSALFA), which took place in Panama. The event provided SINDAN with the opportunity to engage with Central American authorities and stakeholders in a strategy to avoid the expansion of FMD to regions with a disease-free status.

Argentina saw progress on the implementation of traceability standards for veterinary medicines, which will first be applied to products containing ketamine, non-hormonal growth promoters and/or estradiol or its salts.

SINDAN participated in the congress of the Brazilian Association of Intellectual Property, held in Rio de Janeiro, which focussed on the situation of data protection in Brazil.

Communications

SINDAN sponsored ENDESA, a major Brazilian event on animal health protection, held in Foz do Iguaçu, which gathered more than 700 delegates from the Brazilian government and authorities from neighbouring countries, as well as other stakeholders. SINDAN gave a presentation on the animal health industry's role in supplying medicines for livestock producers and it had an information stand.

SINDAN participated in the OIE global conference on veterinary education and the role of the veterinary statutory body, which was held in Foz do Iguaçu. With more than 1,000 participants from several countries, the event provided a good opportunity to discuss animal health issues and reinforce SINDAN's worldwide network.



Participants at CAMEVET's 2013 annual assembly

Asia and Africa

AAHA (South East Asia), AHPA (Thailand),
ASOHI (Indonesia), INFAH (India), JVPA
(Japan), KAHPA (Korea), SAAHA (South Africa)

Regulatory affairs

AAHA continued to work with various governments and NGOs such as Asia-Pacific Economic Cooperation (APEC), FAO, OIE and local regulatory bodies on regulatory aspects linked to veterinary medicines.

AHPA provided input to the Thai Food and Drug Administration (FDA) on ways to improve the efficiency of legislation governing veterinary medicines and increase regulatory harmonisation in line with VICH standards.

In Indonesia, ASOHI provided comments to the Agriculture Ministry's proposed regulation on veterinary medicines. It encouraged the national competent authority to assess illegal veterinary medicines including imports and locally-produced products.

ASOHI worked with various national organisations to harmonise the national single window for imports, a procedure aiming to provide a simple and accountable system for all stakeholders.

ASOHI disseminated information published by the national authority both to its members and stakeholders on topics such as Good Manufacturing Practice (GMP) certification for veterinary medicines, ceasing poultry imports from China to Indonesia, and the banning of product registration using the generic name.

The Drug Controller General India (DCGI) issued a notification on the approval of safety and efficacy of fixed dose combinations (FDCs) permitted for manufacture and sale in India without due approval from DCGI. The authority classified all FDCs as new medicines and asked all local licensing authorities to advise all manufacturers to prove safety and efficacy of FDCs before the Central Drug Standard

Control Organisation (CDSCO) within 18 months. Non-compliance could mean withdrawal of permission to manufacture and sale of FDCs. Further to INFAH's input, DCGI issued a new notification announcing the exemption of veterinary products from the review.

The Japanese authorities announced the decision to implement changes in the legislation of veterinary medicines, particularly on the deregulation of diagnostic kits and establishing exceptions for certain clinical studies. Additionally, the Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF) notified an initiative to reduce the requirements of adjuvant disappearance studies for the application of market authorisations for biological products. This initiative should lead to shortening shipping restriction periods.

The Korean Government enforced legislation on veterinary prescription to ensure the responsible use of veterinary medicines in the country. The government also developed complimentary measures to decrease the early economic burden on livestock farms by making a concerted effort to continuously monitor implementation.

SAAHA bolstered cooperation with the South African Department of Agriculture, Forestry and Fisheries (DAFF) on the regulation of veterinary medicines and held quarterly bilateral meetings with them. The association led a revision of the current guidelines and developed new ones to streamline and optimise the national registration of veterinary medicines.

SAAHA was pleased to attend for the first time the VICH Steering Committee and the second Outreach Forum, held in Auckland (New Zealand).

Antibiotics

AAHA hosted a meeting on antimicrobial resistance where association members reviewed and discussed the future challenges of the industry on antimicrobial resistance issues.

AHPA participated in the activities of the Thai National Bureau of Agricultural Commodity and Food Standards (ACFS) Sub-Committee on Antimicrobial Resistance where stakeholders discussed projects such as a database on antibiotic usage and ways to promote the responsible use of antibiotics in veterinary medicine, as well as best practice and control.

AHPA published an animal health directory containing information on legal use of veterinary medicines including antibiotics. The directory was distributed to Thai authorities, veterinarians, farmers and universities, as well as feed mills and animal health companies.

JVPA collected national data on the use of veterinary antibiotics in Japan linking it to impact on food safety and human health. Additionally, JVPA participated in a webinar to promote the responsible use of veterinary medicines including antibiotics.





Participants at AHPA conference



INFAH's Managing Committee giving farewell to outgoing President, Dr Asim Banerjee

Communications

ASOHI and key stakeholders actively participated in the Chicken and Egg Festival, an event aimed at promoting the consumption of chicken meat and eggs in Indonesia. The associations organised seminars on 'Poultry Business Prospect 2014', poultry diseases and feed additives. Additionally, ASOHI attended two livestock exhibitions: Indolivestock and ILDEX.

INFAH published its 2012-13 annual report containing articles of social and consumer interest, e.g. how society benefits from the veterinary industry, the changing scenario of the regulatory environment, and the contribution of livestock to the Indian food basket, as well as information on INFAH's various subcommittees. The report is downloadable from www.infah.org.

KAHPA and the Korean Government co-hosted a workshop on veterinary medicines for African countries, held in Korea. Attended by delegates from Ethiopia, Kenya and Uganda, the workshop provided a forum to exchange information and discuss topics such as the registration of veterinary medicines and quality control systems.

KAHPA published the first edition of 'Ani-medi', the first Korean magazine providing latest news on the animal health industry's activities and topics, as well as other relevant information.





Australia and New Zealand Animal Health Alliance* (Australia), Agcarm (New Zealand)

Regulatory affairs

In Australia, the Commonwealth Parliament amended the laws governing the registration of an approval of veterinary chemicals to introduce a system of blanket re-registration and re-approval. The Alliance opposed these reforms as they added to the cost of regulatory compliance for no identifiable benefit for the public or to producers, which resulted in a draft of legislation containing measures to reduce the frequency of registration renewals.

The Alliance provided preliminary comments to the Australian Pesticides and Veterinary Medicines Authority's (APVMA) ongoing revision of the principles applied in the assessment of veterinary medicine residues.

The Alliance actively participated in the governance and activities of AgSafe and AgStewardship Australia through their drumMUSTER and ChemClear programmes to remove and dispose of empty chemical containers and surplus veterinary medicines.

The Alliance also contributed to international harmonisation discussions in the context of the VICH Steering Committee meeting and the Outreach Forum, which were held in Auckland, as well as to Codex Alimentarius.

In New Zealand, Agcarm worked with the national regulators on the revision of legislation to increase data protection for new uses and reformulations of existing veterinary medicines.



Agrecovery processing containers at collections sites for recycling

Agcarm is active in Agrecovery, a levy-based plastic and surplus veterinary medicines recovery scheme. In 2013, industry recommended that the government require all manufacturers to be part of a scheme similar to Agrecovery. The New Zealand government is acting on this recommendation.

Another success was the release of the first ever government report on adverse events involving veterinary medicines, published by the New Zealand Ministry of Primary Industries. The report summarises findings from 179 adverse events from August to October last year. Agcarm members requested the report to encourage adverse event reporting and to identify trends in this area. The end goal is to reduce the number of adverse events.

Antibiotics

The Alliance participated in the development of Australia's national antimicrobial resistance prevention and containment strategy led by the Secretaries of the Commonwealth (national) Departments of Health and Agriculture. The Alliance also attended a colloquium for regulators, scientists and industry representatives on this subject.

The Alliance provided input to the Australian Pesticides and Veterinary Medicines Authority (APVMA) on a report about the quantity of veterinary antibiotics sold in Australia during 2005-2010. Additionally, it engaged in dialogue with government, the scientific community and industry to ensure that the concept of 'best practice' in antibiotic use includes an environmental aspect.



AGCARM presents the undergraduate veterinary medicine scholarship award to Catherine Field

Agcarm participated in the Ministry for Primary Industries (MPI) Antimicrobial Resistance Steering Committee providing a forum for consultation among key New Zealand stakeholders. Agcarm and the organisation representing veterinarians held a workshop on the use of antibiotics in New Zealand.

Stakeholder relations

The Alliance developed best-practice guides for the use of veterinary medicines in companion and food-producing animals.

Agcarm is a driving force behind Wormwise, New Zealand's national internal parasite management strategy, and helped set up a trust to manage the Wormwise initiative.

Agcarm awarded an undergraduate veterinary medicine scholarship. This information was publicised by various New Zealand agricultural and veterinary media.



** In February 2014 the Animal Health Alliance became 'Animal Medicines Australia'.*

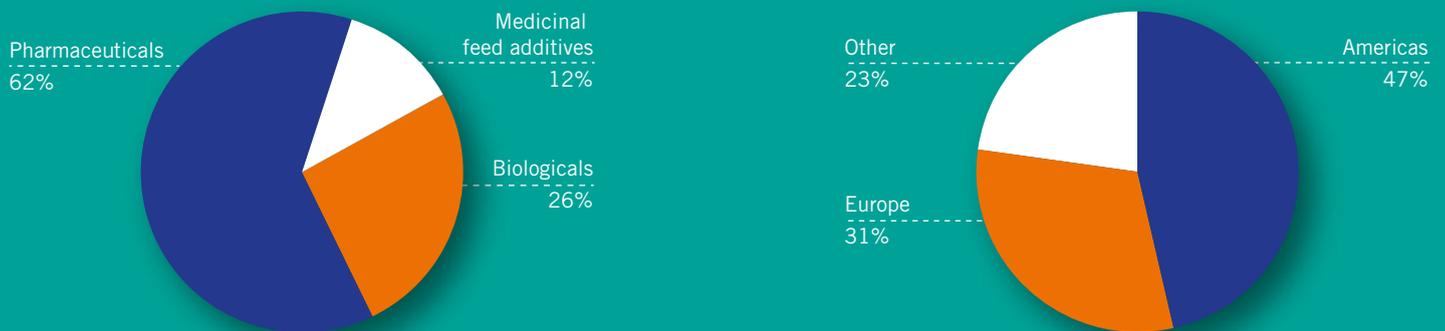
Animal health market report

2013 Animal Health Industry



Source: Vetnosis

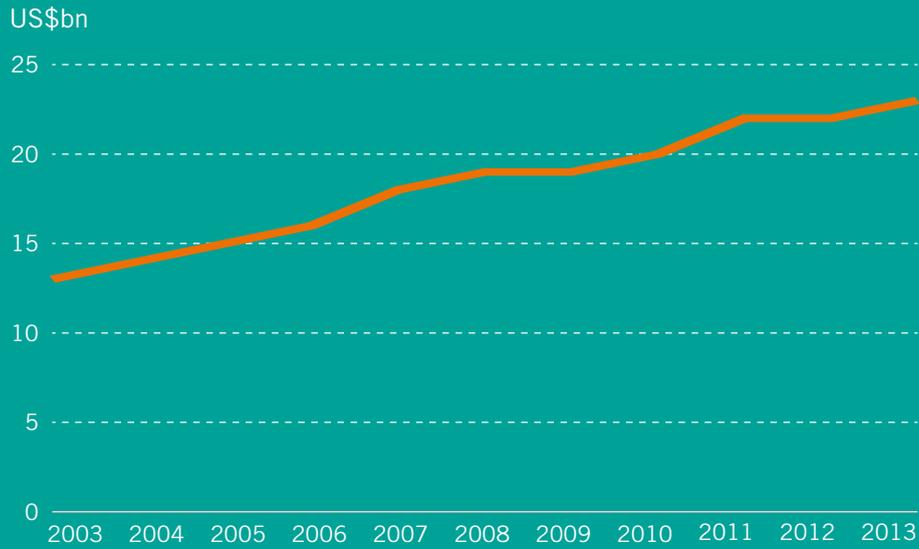
Animal Health Market by Product Group, Region & Species



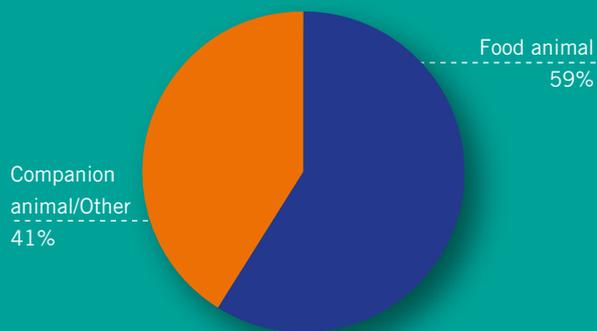
Source: Vetnosis

Global Animal Health Market Evolution

Global Animal Health Market (ex-manufacturer net sales in Nominal US\$ terms)



Source: Vetnosis



Who's who at IFAH

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Elanco

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Communications Director

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CORPORATE MEMBERS

Bayer HealthCare Animal Health Division

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outside the US & Canada)

Lohmann Animal Health

Merial Ltd

Novartis Animal Health

Vétoquinol

Virbac SA

Zoetis

IFAH is led by a 16-strong Board of Directors comprising representatives from member companies and industry associations throughout the world. Headed by IFAH President Jeff Simmons, the Board is the federation's decision-making body. It receives support from a Brussels-based secretariat, national and regional member organisations, and from global teams, task forces and working groups focused on issues identified by IFAH as strategic priorities for the animal health industry.

MEMBER ASSOCIATIONS²

ARGENTINA

CAPROVE – Cámara Argentina de la Industria de Productos Veterinarios

AUSTRALIA

Animal Health Alliance

BELGIUM

Pharma.be – Association Générale de l'Industrie du Médicament / Algemene Vereniging van de Geneesmiddelenindustrie

BRAZIL

SINDAN – Sindicato Nacional da Indústria de Produtos para Saúde Animal

CANADA

CAHI – Canadian Animal Health Institute

CHILE

ALAVET – Asociación de Laboratorios Veterinarios de Chile

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

INDIA

INFHA – Indian Federation of Animal Health Companies

INDONESIA

ASOHI – Asosiasi Obat Hewan Indonesia

IRELAND

APHA – Animal and Plant Health Association

ITALY

AISA – Associazione Nazionale Imprese Salute Animale

JAPAN

JVPA – Japan Veterinary Products Association

KOREA

KAHPA – Korea Animal Health Products Association

MEXICO

INFARVET-CANIFARMA – Industria Farmacéutica Veterinaria

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 Farmacéutica

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 – Läkemedelsindustriföreningens Service

SWITZERLAND

SCIENCEINDUSTRIES - Business Association Chemistry Pharma Biotech

THAILAND

AHPA – Thai Animal Health Products Association

UNITED KINGDOM

NOAH – National Office of Animal Health

UNITED STATES

AHI – Animal Health Institute

² Contact details are available on the IFAH website (www.ifahsec.org)

Acronyms

ACFS	Agricultural Commodity and Food Standard
APEC	Asia-Pacific Economic Cooperation
APVMA	Australian Pesticides and Veterinary Medicines Authority
CAC	Codex Alimentarius Commission
CAMEVET	Committee for the Americas for Veterinary Medicines
CDSCO	Central Drug Standard Control Organisation (India)
CFIA	Canadian Food Inspection Agency
COSALFA	South American Commission for the Fight Against FMD
DAFF	Department of Agriculture, Forestry and Fisheries (South Africa)
DIA	Drug Information Association
EPRUMA	European Platform for the Responsible Use of Medicines in Animals
EU	European Union
FAO	United Nations Food and Agriculture Organisation
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FMD	Foot-and-Mouth Disease
GALVmed	Global Alliance for Livestock Veterinary Medicines
GMP	Good Manufacturing Practice
IBR	Infectious Bovine Rhinotracheitis
JMAFF	Japanese Ministry of Agriculture, Forestry and Fisheries
MPI	Ministry of Primary Industries (New Zealand)
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Development
OIE	World Organisation for Animal Health
PANAFTOSA	Pan-American Centre for FMD
UNEP	United Nations Environment Programme
VDD	Veterinary Drugs Directorate (Canada)
VICH	International Co-operation on Harmonisation of Technical Requirements for Registration of Veterinary Products
WHO	World Health Organisation
WVA	World Veterinary Association



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