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The International Federation for Animal Health (IFAH) is a global body representing companies engaged in the research, development, manufacture and commercialisation of animal health products across five continents.

Members of IFAH and affiliated national/regional associations account together for approximately 80% of animal health product sales worldwide*.

**OUR MISSION**

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

To fulfil its mission, IFAH will:

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

**STRATEGIC PRIORITIES**

**Leadership**

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

**Value**

Increase awareness of the animal health industry’s value to society, building trust and acceptance among fellow food chain stakeholders and the public.

**Regulation**

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

* Detailed information on the size and structure of the animal health industry is available on IFAH’s website (www.ifahsec.org).
Alongside distinguished global organisations that include the OIE, WVA, FAO, WHO and UNESCO, IFAH is proud to support the veterinary profession as it celebrates World Veterinary Year in 2011. The occasion marks the 250th anniversary of a profession born when, in 1761, the world’s first veterinary school – at Lyon in France – opened its doors.

The Lyon school’s visionary founder, Claude Bourgelat, also pioneered the use of veterinary science to improve our understanding of human health. How appropriate, then, that we should acknowledge his achievements in a year that sees delegates from around the world gather at the first One Health Congress in Melbourne (Australia) to address disease risks posed by interactions between animals, humans and the environment.

If Bourgelat’s lessons had been forgotten, then the emergence of new zoonotic infections has provided a chastening reminder of the need for an integrated approach to the fight against disease. Recent developments have also highlighted the value of animal health products to the veterinary profession and animal owners. These are not just valuable tools for the protection of animal health – they are an increasingly vital means of safeguarding human health, and will play a crucial role in the struggle to feed a rapidly growing global population.

In the process, veterinary medicines will contribute significantly to the attainment of UN Millennium Development Goals adopted by world leaders a decade ago. They will help to alleviate hunger by improving animal health and the availability of animal protein, and to tackle poverty in developing countries where livestock represent such a vital source of income. Agriculture-driven economic development in poorer parts of the world will have a beneficial impact on a number of other Millennium Development Goals.

Driving home these fundamental messages is vital if we are to promote a broader understanding of our industry’s value to society. In so doing, we aim to secure improvements in the regulatory framework governing our member companies, which, unless we get the balance right, has the potential to compromise the availability of some veterinary medicines and stifle the development of new products.
Our goal is the establishment of proportionate rules that balance the concerns of society and the requirements of a small but highly innovative industry.

While we are calling on regulators to streamline their procedures, we are also working hard to maximise the efficiency and impact of our own activities. By adopting new approaches we aim to keep members informed and up-to-date on the activities of IFAH’s core teams and working groups, their goals and their achievements. We are also working to broaden the reach and appeal of IFAH in emerging markets.

Our Value Team has laid the platform for a dynamic and proactive approach to the communication of key IFAH messages. By benchmarking stakeholder and consumer attitudes, we have also gained important insights into their priorities where animal health issues are concerned. The challenge now is to build on that platform, delivering key messages in a way that will secure broader recognition of the role played by our industry, and of the need for efficient, proportionate regulation of its products.

That process has already begun, with IFAH enjoying strong representation at the One Health Congress and taking centre-stage as co-host of the second Global Animal Health Conference in London during March.

Looking ahead, I am confident that the effort and commitment shown by IFAH members, the individuals who staff our core teams and working groups, and our dedicated secretariat, will continue to pay dividends. I thank all of those who have contributed to the federation’s recent success, and look forward to working with you in 2011.

Animal health products are an increasingly vital means of safeguarding human health, and will play a crucial role in the struggle to feed a rapidly growing global population.
To describe the atmosphere at the July 2010 meeting of the Codex Alimentarius Commission (CAC) as ‘volcanic’ may be stretching a point. The tone of discussions was certainly lively, however, and helped to clear the air – which was apt in a year that saw the Icelandic ash cloud forcing IFAH to reschedule its General Assembly.

The CAC session was among a series of Codex meetings I attended in 2010, and in many ways was the most heartening. For while the Commission again failed to adopt MRLs for ractopamine, the ensuing debate on this and other controversial topics prompted action that could eventually resolve some of the problems that have hindered Codex progress in recent years. An informal ‘friends of the chair’ group has been established, and will present a proposed resolution to the impasse at the next meeting of the Commission. I am pleased to report that IFAH will be involved directly in those discussions.

The Commission’s Committee on General Principles (CCGP) had set the ball rolling in April when, with attendance affected by the ash cloud, it set up an electronic working group that will develop mechanisms to resolve final Codex standards where non-scientific factors have prevented agreement to date. The CCGP also recommended a reassessment of existing approaches to risk analysis used by Codex committees – a proposal that was adopted by the CAC at its July session.

A similar determination to address procedural issues was evident when the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) met two months later. Again, IFAH played a leading role, tabling proposed solutions to a number of procedural problems that have affected the work of the committee. The year also saw a positive outcome to the fourth and final meeting of the Codex Task Force on Antimicrobial Resistance.
Elsewhere, the fourth VICH Conference yielded equally promising results, with the initiative committing to a global outreach programme that will encourage the uptake and implementation of harmonised regulatory guidelines on a truly international scale.

Alongside fellow IFAH members I was proud to represent our industry in meetings with a range of other major stakeholders – including the OIE, FAO and WHO – during the year.

I am particularly excited by the opportunities that the federation’s new approach to stakeholder engagement and communications will offer in these discussions. Having mapped out new approaches during 2010, we will put them into practice over the coming year, raising the profile of the animal health industry and demonstrating its true value to society.

The chance to meet and strengthen ties with IFAH member associations is always rewarding, so I relished my visits to AHI in the US, JVPA in Japan, SAAHA in South Africa, INFAVET in Mexico and SINDAN in Brazil, as well as discussions with the Korean association (KAHPA), which took part in a meeting of the IFAH Antimicrobials Working Group during the year.

Without exception I was made extremely welcome, often was given the opportunity to meet important representatives from national governments and regulators, and was briefed expertly on issues affecting our industry at national level.

Our national association and corporate members are the lifeblood of the federation, so we were pleased to welcome Lohmann Animal Health and the Thai Animal Health Products Association (AHPA) into the IFAH fold. I look forward to meeting with them, and to working alongside them in future.

Finally, I offer my heartfelt thanks to all those who helped to make 2010 such a positive year for IFAH. Your dedication is, and will remain, the key to our success.
Increasing awareness of the animal health industry’s value to society is a key goal for IFAH.

By building trust in and acceptance of its products, the federation aims to encourage the creation of a commercial and regulatory environment capable of sustaining an innovative, science-based industry. In a bid to achieve that goal, it has begun to pursue a more proactive approach to engagement with fellow stakeholders and, through them, the public.

It is an approach that acknowledges the media-driven nature of modern society. Television, newspapers and, increasingly, the internet, are powerful forces, capable of shaping public opinion. And since it is consumers who ultimately set the political agenda, it follows that the media now has the potential to affect policies pursued by those who govern the regulatory framework within which the industry operates.

The arrival of 24-hour news channels and global electronic communications also means media-driven issues can move at unprecedented speed. A rapid, effective response to such events is vital, and the establishment of new issue management procedures has greatly improved IFAH’s ability to provide accurate, informative information to stakeholders at short notice.

These were tested during the outbreak of H1N1 influenza which dominated headlines in 2009, when an industry position statement and a factual Q&A document were made available on the federation’s website just days after the story broke.

Coincidentally, the outbreak also highlighted the ease with which misconceptions surrounding animal health issues can spread. For while the pathogen involved was a strain of the human influenza A virus – and despite the fact that it was not apparent in pigs during the initial outbreak – it was rapidly dubbed ‘swine flu’ by many in the media. Among other things, this prompted unnecessary concern among consumers regarding its implications for food safety.

CONSUMER PERCEPTIONS

To help guide its approach, IFAH commissioned a major study designed to benchmark opinions within the industry, among stakeholders and the public on a range of animal health issues. Delivered in 2010, the results are helping the federation build a clear picture of consumer concerns. They also provide a valuable insight into the way existing opinions have been shaped, and the depth of knowledge on which they are based.

“2010 was a landmark year for the IFAH Value Team. We have laid the foundations for a more proactive approach to communication with our stakeholders.”

MARGARET MAY CHAIR, IFAH VALUE TEAM
The arrival of 24-hour news channels and global electronic communications also means media-driven issues can move at unprecedented speed.
At consumer level, the study involved the participation of citizens from eight countries across four continents in discussion groups. Most cited food safety as their overriding concern, while zoonoses, new technologies and the regulation of animal health products were high on their list of priority issues. With specific regard to the use of veterinary medicines, the level at which they are administered to food animals and perceived shortcomings in the testing of new technologies were cited as major issues of concern.

Virtually all participants felt they were more aware of animal health issues today than they had been ten or even five years ago, reflecting widespread media coverage of issues such as BSE and avian influenza. Acknowledging the ‘sensationalist’ nature of some media output, many expressed a desire for more information on the industry, but believed a trusted source of such information was lacking.

“Authorised veterinary medicines, used in a responsible, sustainable manner, are vital to the health of animals and people across the world.”

TJEERD JORNA \ PRESIDENT, WORLD VETERINARY ASSOCIATION
While awareness of animal health may have risen, the survey results show that consumers are still poorly informed about the sector in general, and about the animal health industry in particular. Questioned about avian influenza vaccines, for example, many were not aware that such products existed. Some also expressed concern that animal health products were being tested after they had reached the market – clearly unaware of the rigorous checks a new product must undergo before receiving a marketing authorisation, and of the role post-marketing surveillance schemes play in the protection of both human and animal health.

VALUE TEAM
Armed with this battery of information, IFAH has begun to address key issues raised by stakeholders and consumers in the course of the survey. Spearheading those efforts is the federation’s Value Team (VT), which is leading IFAH’s push to emerge as a trusted, agenda-setting player in the animal health sector. Along the way, it aims to dispel some of the myths and misunderstandings that have clouded the public’s perception of the industry, and demonstrate its commitment to basic goals that are shared by all stakeholders in animal health.

As part of that push, a new strap-line – ‘Healthy Animals, Healthier World’ – has been added to the federation’s logo, underlining the interconnected nature of animal health, human health and the global environment. Improvements to the IFAH website are also planned, offering a broader range of information on issues of concern to stakeholders and consumers alike.

The federation will also begin to disseminate its core messages more widely, strengthening its resources where communication with the media is concerned and pursuing dialogue with a broader range of stakeholders. With the federation co-hosting a Global Animal Health Conference and planning active participation at a range of other major events during the year, 2011 will see those efforts begin to gather real momentum.

KEY DEVELOPMENTS IN 2010
- A major study benchmarking industry, stakeholder and consumer concerns is delivered, providing IFAH with valuable information that will help to shape the federation’s approach to communications.
- Key issues highlighted by the study are used to map plans to engage effectively with a broad range of stakeholders through 2011 and beyond.
- The federation’s range of communication tools is expanded, and plans are made to provide more information to stakeholders through the IFAH website.
- A new strap-line, ‘Healthy Animals, Healthier World’, is added to the federation’s logo, highlighting the animal health industry’s positive contribution to society.
Statistics tell us that, for every $40 the world spends on human medicines, it devotes just $1 to animal health products.

And yet that modest investment supports an industry which plays a crucial role in safeguarding the health not only of animals, but also of our planet’s rapidly-growing human population. The new strap-line accompanying IFAH’s logo – “Healthy Animals, Healthier World” – highlights the fundamental link between animal and human health, and the breadth of the industry’s contribution, which transcends notional distinctions between the two sectors. It also signals a new determination to ensure that the true value of that contribution is understood and acknowledged more widely.

There is no better illustration of the link between animal and human health than smallpox. One of the most deadly infections in human history, it became the first virus to be wiped from our planet when scientists declared its successful eradication in 1979 – almost 200 years after Edward Jenner pioneered experimental inoculation against the disease.

Jenner’s work was based on the observation that milkmaids exposed to cowpox – a mild relative of the deadly smallpox virus prevalent in cattle – were immune to infection. It paved the way for the development of vaccines that now protect humans and animals from a range of potentially fatal diseases.

In 2010, Rinderpest became the second viral disease to be eradicated, following a concerted global vaccination campaign. Killing over 80% of infected cattle, it had devastated affected communities down the years, decimating milk and meat production and depriving farmers of draught animals used to plough the land. Dr John Anderson, former head of the FAO’s Rinderpest reference laboratory, described its eradication as “the biggest achievement of veterinary history.”

Animal health products are playing an equally important role in the fight against many other diseases, including zoonotic infections. Huge strides are being made towards the effective control – and perhaps eventually the global eradication – of rabies, thanks to the availability of safe, affordable and effective animal vaccines. Highly effective vaccines have also been developed to protect horses against West Nile virus. These have laid the foundations for the development of a human vaccine offering protection against an infection that is fatal in one out of every 30 cases.

Almost two-thirds of the 1,500 infectious diseases known to affect people can be transmitted between animals and humans, while three out of every four emerging infections have come to us courtesy of contact with animals. These sobering statistics mean dependable veterinary medicines are no indulgent luxury – rather, they are a critical necessity to prevent life-threatening disease in humans as well as animals.

“IfAH’s strength lies in its global reach. Co-operating with its national member associations is vital at a time when diseases spread at jet speed.”

ANDREAS BUEHLMANN CHAIR, IFAH LEADERSHIP TEAM
Almost two-thirds of the 1,500 infectious diseases known to affect people can be transmitted between animals and humans.

Those inclined to doubt the magnitude of such a statement need look no further than the success of recent global efforts to halt the spread of the H5N1 avian influenza strain. Regarded by some experts less than a decade ago as a pandemic threat with the potential to kill up to 150 million people, it is now a manageable, isolated infection that accounts for only a handful of deaths per year. That transformation has been attributed to a combination of human medical preparedness, vaccine development and the establishment of effective surveillance and containment programmes. Together, these have checked much of the disease’s potential spread, and have eliminated the virus in many previously affected countries.

Success in the animal health sector, it seems, breeds anonymity, with ‘bird flu’ fading from the global consciousness as rapidly as the doom-laden headlines that dominated the media just a few years ago. In similar fashion, other ground-breaking developments in the treatment and protection of both companion animals and livestock have either been forgotten or are now taken for granted. Thus, as dog owners, we are more likely to grumble at the cost of vaccinations than to wonder at the ability of a product to protect our pet against diseases such as parvovirus, which was once such a widespread canine killer.

And while we regard chicken as an affordable source of protein, how many of us stop to consider what it might cost if coccidiosis still ravaged producer margins, as it did until the development of effective disease control products in the 1950s and 1960s.

Animal health products have transformed our ability to safeguard the health and welfare of animals over the past 60 years, but they must do so again if we are to feed a global population that is forecast to reach 9 billion by the middle of this century. The FAO believes global output of animal protein must double within the next 40 years if food production is to keep pace with rising demand. And it says almost three-quarters of the required increase will have to be achieved through improvements in efficiency, delivered via the adoption of new and existing agricultural technologies.

IFAH is already working alongside the FAO and other global stakeholders to improve the availability of effective, affordable animal health products in developing countries. At the same time, the federation’s members continue to invest in the development of new and improved products that will safeguard animal and human health, and that will help farmers rise to the global food production challenge.

“Disease is a constant threat to animal production, a barrier to trade and to the alleviation of poverty in developing countries. Access to quality veterinary medicines for all livestock producers is crucial.”

BERNARD VALLAT | DIRECTOR GENERAL, OIE
Efforts to harmonise regulations governing animal health products around the world took a major step forward in 2010, with the launch of a global outreach initiative by the VICH project.

Established in 1996, VICH (the International Co-operation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) is a trilateral initiative involving regulators and the industry in the US, the EU and Japan. By pooling expertise and resources, the project has established and implemented a series of harmonised guidelines governing the regulation of veterinary medicines in these three markets.

Canada, Australia and New Zealand already participate in the initiative at observer level, but providing a platform for broader, truly global harmonisation has always been among VICH’s long-term objectives. Efforts to achieve that goal will now be stepped up after the VICH Steering Committee identified global outreach as a priority in its strategy for the period to 2015, which was agreed when it met in Paris last June.

**Benefits and Challenges**

Harmonised regulatory standards offer potentially huge benefits for a broad range of animal health stakeholders. Some of these are already apparent in VICH member countries, where they have helped to limit the costs and time expended by regulators and the industry alike on the registration of veterinary medicines.

The adoption of harmonised scientific guidance has reduced barriers to trade between participating countries and has removed many unnecessary or duplicate requirements. It has also enabled a decline in levels of animal testing required to support the registration of new products. Finally, by helping to ensure timely access to safe, effective medicines, it has benefited pet owners, livestock producers and the health of their animals.

Expanding its reach beyond current participants will present the VICH project with some tough challenges. Not least of these is the limited nature of both existing regulatory frameworks and resources available to administer them in some developing countries. VICH is keen to avoid the systematic imposition of guidelines that would be impossible to implement in these regions. Instead, it will focus on communicating how VICH works and encouraging the establishment of basic regulatory controls in developing countries. It will also support mutual recognition of marketing authorisations and regional cooperation. In future, existing guidelines may be adapted to meet conditions in new regions, while new guidelines may be developed to meet their needs. Accordingly, much of the debate at VICH’s 4th public conference, which took place in Paris last June, focused on the identification of needs and expectations in non-member countries.

The World Organisation for Animal Health (OIE), which is a long-standing associate member of VICH, is set to play a pivotal role, channelling information about the project to its member countries. The organisation is already working to improve the availability of safe, effective veterinary medicines in developing regions. Since good governance is a prerequisite to achieving that goal, strengthening the capacity and capabilities of regulatory authorities in developing markets is high on the OIE’s agenda. And since harmonised guidelines can only be implemented...
effectively where a basic regulatory framework exists, goals being pursued by the OIE and the VICH outreach programme dovetail perfectly. By working together, the two organisations could ultimately have a major impact on the availability of quality medicines for use by animal owners and livestock producers throughout the world.

LESSONS FROM CODEX
The scale of the challenge posed by global harmonisation initiatives is highlighted by issues surrounding the Codex Alimentarius Commission (CAC). Established almost 50 years ago by the FAO and WHO, the CAC develops guidelines designed to protect the health of consumers and ensure fair trade in food products around the world. These have been adopted by many smaller countries which lack the resources required to generate their own national standards.

Like the VICH initiative, science lies at the heart of Codex activities. The complexity of the issues with which it deals has increased enormously since its establishment in the 1960s, however. Exacerbated by divergent approaches to the calculation and management of perceived risks to consumer health, this has seen the commission struggle to obtain a consensus on expert scientific advice, delaying the establishment of Codex-approved maximum residue limits (MRLs) for veterinary medicines in food animal produce.

The lengthy nature of Codex procedures is a complicating factor, since MRLs have invariably been established in some member countries before Codex guidance is debated in detail. With members already committed to divergent national stances, the adoption of Codex MRLs on some substances has been rendered impossible. Having witnessed these developments, manufacturers have become increasingly reluctant to invest in the submission of data to expert committees responsible for the establishment of proposed Codex

“Codex is the recognised international standard-bearer for safe, fair trade of food. Setting international standards for veterinary medicine residues is one of its most important functions.”

DAVID CORLEY \ PRESIDENT, SSAFE

“The Codex process remains the best way to protect consumer health and harmonise global standards, encouraging fair trade in safe food.”

KAREN HULEBAK \ CHAIR, CODEX ALIMENTARIUS COMMISSION
MRLs. With fewer new veterinary medicines in development, and the adoption of final MRLs for others being delayed so badly, progress achieved by Codex in this field has almost ground to a halt.

Proposed MRLs for ractopamine have been awaiting final adoption by the CAC since 2008. Additional data backing up existing expert advice was presented when the Commission met in July 2010, but after hours of discussion it failed once again to secure the agreement of its members on the issue. In a bid to break the deadlock, a ‘friends of the chair’ group has now been set up, tasked with the development of possible solutions to the impasse. IFAH will be involved directly in those discussions, which could finally see the matter settled when the Commission meets again in 2011.

Signs of progress were also evident at the 19th session of the Commission’s Committee on Residues of Veterinary Drugs in Food, which convened a month later. Taking a lead from new committee chair Dr Steven Vaughan, who is clearly determined to address existing problems, delegates agreed to adopt more flexible approaches – including the establishment of electronic working groups – in a bid to speed up procedures. IFAH and its member companies played a key role, agreeing to cooperate with regulatory authorities on the compilation of a dossier for the evaluation of ampicillin. The federation also tabled potential solutions to other problems, including more flexible approaches to Codex assessments of new medicines. These would enable Codex MRLs to be established at an earlier stage, and would involve the extrapolation of existing MRLs to related species.

**Harmonised regulatory standards offer potentially huge benefits for a broad range of animal health stakeholders.**
“In their current form, the draft guidelines drawn up by the Codex Task Force on Antimicrobial Resistance constitute a transparent process that will strengthen the adoption of a risk analysis framework in Codex member states.”

OLIVIER ESPEISSE \ CHAIR, IFAH ANTIMICROBIALS WORKING GROUP

The Codex year ended on a similarly positive note, when the Commission’s Ad-Hoc Intergovernmental Task Force on Antimicrobial Resistance finalised proposed guidance on the assessment of potential risks to human health associated with the use of antibiotics in veterinary medicine. IFAH has been an active contributor to the development of the guidelines, and is satisfied that, if adopted by the CAC in their current form, they will provide a valuable, science-based tool for use by Codex member countries. In turn, this will foster the adoption of proportionate approaches to antimicrobial regulation, safeguarding human health whilst maintaining access for veterinary surgeons and their clients to safe, effective products that play such a key role in protecting the health and welfare of animals.

As an active participant in VICH, Codex and other major global initiatives, IFAH is a staunch advocate of harmonised approaches to the regulation of veterinary medicines. Achieving international agreement on common standards may be difficult, but the potential rewards for all stakeholders make this a challenge that simply cannot be ducked.

KEY DEVELOPMENTS IN 2010

- As secretariat to the initiative, IFAH plays a key role in the development by VICH of a global outreach strategy that will see harmonised standards governing the regulation of animal health products adopted more widely.
- IFAH pledges to work with Codex representatives and officials to address concerns surrounding Codex procedures, tabling a series of proposed solutions to current problems. The federation is invited to participate in a ‘friends of the chair’ group, set up to thrash out a compromise where the establishment of Codex MRLs for ractopamine is concerned.
- Co-ordinated by its Antimicrobials Working Group, active participation by IFAH helps to ensure balanced, science-based debate on antimicrobial resistance at key meetings of Codex and the OIE. The need for responsible use of these valuable resources – in human as well as veterinary medicine – is the federation’s core message to fellow stakeholders.
REGULATORY ‘BEST PRACTICE’ WILL UNLOCK THE ANIMAL HEALTH INDUSTRY’S TRUE POTENTIAL

While real growth in the market for their products has averaged little more than 1% a year over the past decade, IFAH’s member companies continue to plough a double-digit share of their revenues back into the research and development of new or improved products and technologies.

For a small industry with such a strong commitment to innovation, the ability to make best use of limited resources is clearly imperative.

Historically, the regulatory framework governing the industry has inflated its operating costs, and has hindered the path to market for some of its products. Product development costs incurred by the industry have risen by 150% since the 1990s. Over the same period, the average time taken to bring a new veterinary medicine to market has increased by almost five years, while companies are now spending over a quarter of their entire R&D budgets on defensive research required simply to maintain approvals for existing products.

While it is possible to quantify the impact of poorly framed, inconsistent or unnecessary regulations on the industry, gauging their effect on owners and the health of their animals is more difficult. What cannot be disputed, however, is the fact that inconsistent approaches to regulation have denied farmers in some countries access to safe, highly effective products that are available to producers in other markets. Access to products for use in companion animals has also been compromised in some regions.

Supported by dedicated, issue-specific working groups, the federation’s Regulatory Strategy Team (RST) is at the forefront of IFAH’s drive for more effective regulation of the animal health industry. High on the team’s current agenda is the preparation of a survey that will benchmark the effectiveness of regulatory frameworks in the EU, the US, Japan, Canada and Australia.

Results of the study, which will be conducted by an independent provider during the first half of this year, will be shared with the relevant authorities, providing a platform for dialogue on key issues and the development of solutions to outstanding problems. This is the latest in a series of benchmarking surveys undertaken by IFAH, with previous studies having paved the way for important regulatory reforms.

“With food prices rising, the availability of safe, effective and affordable veterinary medicines for use in food animals is vital, so we must find a way to overcome the challenges faced by Codex.”

MIKE MCGOWAN \ CHAIR, IFAH REGULATORY STRATEGY TEAM
**IFAH is making its own contribution to improvements in the availability of safe, effective animal health products, and to the ability of authorities to trace their distribution.**
The beneficial impact of those changes is already evident, and further positive developments are anticipated in the wake of the 2011 survey.

Like a consistent, proportionate regulatory framework, adequate protection of intellectual property is essential if innovative corporations are to reap a fair reward for the risks associated with investment in the research and development of new products. In addition to patents, this should include protection for original data submitted in support of product approvals. Explicit laws providing defined periods of data exclusivity are well established in most developed markets, but are either inadequate or non-existent in a number of other countries. An IFAH working group set up to address this issue has surveyed the situation in markets across the globe, and will spearhead a push for the implementation of adequate data protection where it is not currently available.

While it continues to press for action by regulators and law makers, IFAH is making its own contribution to improvements in the availability of safe, effective animal health products, and to the ability of authorities to trace their distribution – from the site of manufacture right through to the end-user. This has seen the federation’s member companies introduce Datamatrix bar codes on all of their product packaging, enabling the electronic capture of data on batch numbers and product expiry dates at all stages of the distribution chain. The initiative is already helping distributors, retailers, veterinary surgeons and farmers across Europe to comply with record-keeping requirements, while plans to roll the scheme out in other regions are now being discussed.

“Facilitating mutual recognition and harmonisation of veterinary medicines regulation in Africa is a mutual interest shared by IFAH and GALVmed. The aim is to improve access to veterinary medicines in communities that depend on livestock for their livelihood.”

BAPTISTE DUNGU SENIOR DIRECTOR R&D, GALVmed
**Regional Activities: Europe**

**Regulatory Affairs**

*Regulatory reform*
Preparation for the European Commission’s review of the legislative framework governing veterinary medicines in the EU continued to dominate IFAH-Europe’s regulatory activities. The federation is calling for a system under which a single dossier, subjected to a single assessment, would result in a single, unified decision on the registration of all products in the 27 EU member countries (the ‘1-1-1’ concept). Its proposals have won widespread backing from other stakeholders, and have stimulated strong interest from national regulatory authorities.

As part of its submission to the Commission’s open consultation, IFAH-Europe developed a detailed impact assessment data package, quantifying the effect of current legislation on the animal health industry and highlighting areas where reforms are required. Key messages contained in the package – particularly the high administrative burden imposed by regulatory and pharmacovigilance procedures – were openly shared with the press. Major issues, including the simplification of procedures and the need to stimulate more innovation, will be debated in depth with a range of stakeholders at IFAH-Europe’s annual conference in 2011.

European legislation governing medicated feed additives is also under review. The federation will endeavour to ensure that this review also fulfils the European Commission’s objectives for Better Regulation. It will also ensure a balanced debate on the importance of medicated feed as an efficient route to control disease at herd or flock level.

*Data protection*
Alongside simplified approval procedures, IFAH-Europe is calling for improved levels of data protection, which were eroded by the last regulatory review, conducted in 2004. More effective data protection is required to stimulate innovation and encourage the development of existing medicines for use in more species. This will help to alleviate medicines availability issues in Europe. The federation is calling for ten years of protection for each data package submitted in order to add another species to a product label.

*Global harmonisation*
In conjunction with the OIE, IFAH-Europe hosted the fourth VICH conference, which took place in Paris during June 2010. With government officials and industry representatives from non-member countries invited to exchange views on the global expansion of the VICH initiative, the event represented a landmark in moves towards the global harmonisation of standards governing animal health products.

**Antimicrobials**

*Policy development*
IFAH-Europe continued to play an active role in the development of European policy on antimicrobials, participating in a public consultation held by the European Commission and addressing the needs
of individual stakeholders in the field. Led by its Policy Working Group, the federation is working on the development of proposals that will best fit the needs of all parties engaged in the debate surrounding veterinary antimicrobial use. It has identified a range of fundamental priorities, including responsible use, compliance with product labelling instructions, awareness of target bacteria sensitivity, the availability of choice for those prescribing antimicrobials, and the development of new antibiotic classes.

**Responsible use of antimicrobials**

Alongside fellow stakeholders in the European Platform for the Responsible Use of Medicines in Animals (EPRUMA), IFAH-Europe worked hard to deliver the alliance’s key messages to a broader audience. The EPRUMA initiative received public endorsement from Europe’s Health and Consumer Policy Commissioner, John Dalli, raising hopes that the alliance can work jointly with the Commission in future, communicating the responsible use concept as part of its One Health approach. A new EPRUMA website (www.epruma.eu) was launched during the year, which also saw the publication of a new brochure outlining the platform’s role and key goals. Discussions with fellow stakeholders on the need for responsible use of antimicrobials were also stepped up, while EPRUMA welcomed a new member in the shape of the Pharmaceutical Group of the European Union (PGEU).
Stakeholder alliances
IFAH-Europe continued to work alongside fellow stakeholders in the pursuit of shared goals, establishing a new alliance with farmers, veterinarians and other industry partners that share common interests where regulatory reform is concerned. Significant progress was also made by existing alliances, including the ETPGAH (European Technology Platform for Global Animal Health) and DISCONTOOLS (Disease Control Tools). These projects involve collaboration between the animal health industry, the broader research community, international organisations and academia, with the aim of developing diagnostics, vaccines and pharmaceuticals for priority diseases.

Addressing the global food challenge
At its annual conference, IFAH-Europe called for the establishment of policies that will enable the animal health industry to work alongside international organisations and food chain partners to combat the global food crisis. Featuring a panel of prestigious speakers, and facilitated by renowned BBC broadcaster George Alagiah, the conference highlighted the scale of current losses caused by animal disease, and the role veterinary medicines and vaccines can play in addressing the global food challenge.

European Pet Night
The profile of the annual European Pet Night event, celebrating the contribution of companion animals to society, has continued to rise. Initiated by IFAH-Europe, the event has gained support from a broad array of institutions and associations that want to highlight this contribution and draw attention to pet-related issues in the European Union.
Efficient, proportionate regulation
In discussions with Canadian regulators, CAHI continued to advocate the establishment of sector-specific regulations governing animal health products. Collaborating with fellow stakeholders including veterinarians and livestock producers, it has also called on regulators to adopt a proportionate, risk-based approach to the management of veterinary medicines.

Dialogue with regulators is already beginning to yield improvements in the effectiveness and efficiency of veterinary drug regulation. Rolling submission review procedures are being applied to biologics under review by regulators in the US, while a similar approach to veterinary pharmaceutical submissions is being piloted. These will ultimately facilitate the availability of new products in Canada at the same time as in the US.

In Mexico, INFAVET continued to work closely with regulators on the development of technical guidelines that will be annexed to a major revision of the country’s Federal Animal Health Law. A number of key industry proposals have been acknowledged in current texts, which are scheduled for adoption in the near future.

Quality standards
In Mexico, INFAVET positions on technical aspects of good manufacturing practice (GMP) standards for veterinary products were acknowledged in final texts approved by the Agriculture Ministry during 2010.

AHI pioneered the establishment of a VICH Bioequivalence Working Group, which will develop harmonised standards for innovative and generic animal medicines in the US, Europe and Japan. These will provide valuable guidance for regulators in other countries as the VICH project is expanded in future.

Stewardship
CAHI is exploring options for a national, industry-run programme to implement best management practices where the removal of unwanted and expired livestock products from farms is concerned. Expansion of the programme to cover companion animal products will be considered in future.

Judicious use
AHI continued to stress the value and importance of antimicrobials to animal health, and the need for responsible use of these products. The association contributed to discussions on proposed changes to the Veterinary Feed Directive, designed to expand veterinary oversight of products used in food animals. It also welcomed publication of FDA draft guidance on the judicious use of medically important antibiotics in food-producing animals.

In Mexico, INFAVET met with government officials to discuss the possible establishment of a body to monitor the use of...
antimicrobials in veterinary medicine. In Canada, CAHI representatives are part of a steering committee organising a meeting on antimicrobial stewardship that will take place in the second half of 2011. The conference will address the multiple approaches required to ensure the long-term sustainability of antimicrobials.

**Codex contributions**

AHI was instrumental in the development and presentation of animal health industry positions at meetings of the Codex Alimentarius Commission’s Committee on Veterinary Drug Residues in Food, and the Commission’s Ad-Hoc Intergovernmental Task Force on Antimicrobial Resistance.

**COMMUNICATION**

*Healthy People. Healthy Animals. Healthy Planet*

AHI maintained its campaign to educate policymakers and other stakeholders on the value of animal health products to society. The association hosted forums attended by a range of stakeholders, and expanded its media presence through the launch of a Twitter page. Its award-winning ‘Healthy People. Healthy Animals. Healthy Planet’ communications campaign has heightened the industry’s profile considerably since its launch in 2009.

In Mexico, INFARVET’s annual congress, which was attended by regulators and producer organisations, focused on the animal health industry’s commitment to food safety, highlighting the sector’s contribution not only to animal health and welfare, but also to public health.

CAHI is working with fellow Canadian stakeholders on the organisation of a conference that will focus on the role of livestock agriculture in feeding the world, that will highlight the importance of veterinary medicines to food animals.
REGIONAL ACTIVITIES: SOUTH AND CENTRAL AMERICA
CAPROVE – ARGENTINA, SINDAN – BRAZIL

REGULATORY AFFAIRS

Regional harmonisation
National industry associations from both Argentina and Brazil were active participants at the 16th CAMEVET seminar on the harmonisation of rules governing the registration and control of veterinary medicines in the Americas, held in Colombia during September. Topics on the agenda of the meeting included GMP for ectoparasiticides, stability issues and the registration of biotech-derived vaccines. Future approaches to regional harmonisation under the CAMEVET initiative were also discussed.

Dialogue with regulators
SINDAN welcomed IFAH Executive Director Barbara Freischem, who visited the association and met with Brazilian regulatory officials towards the end of the year. The association plans to step up its dialogue with regulators, offering support for improvements in national legislation governing animal health products.

COMMUNICATION

Raising the industry’s profile
In Argentina, an intensive media relations campaign pursued by CAPROVE helped to raise the industry’s profile, generating widespread coverage of key animal health issues in the written media, on television and radio. The association’s website was also updated, broadening the range of information available to fellow stakeholders and the public on the animal health industry, disease prevention and treatment, and the regulation of animal health products.

SINDAN was the main sponsor of the 2010 Brazilian Veterinary Medicine Congress, raising the profile of the industry at an event where OIE Director General Bernard Vallat delivered a keynote address. The association also lent its support to regional meetings on measures required to eradicate foot and mouth disease in South America.

Stakeholder initiatives
Relations between the industry and fellow animal health stakeholders in
Argentina were strengthened as a result of CAPROVE’s participation in national disease control programmes and livestock productivity initiatives. An industry-sponsored award, recognising achievements in animal health research, management and development was also inaugurated during the year, while the provision of information to the veterinary profession and farmers was stepped up.

SINDAN met with leaders of key livestock producer and agribusiness groups during the visit of IFAH Executive Director Barbara Freischem, discussing a range of topics pertaining to international organisations such as the FAO, OIE and the Pan-American Health Organisation. The association is actively supporting meetings and scientific publications discussing the sustainability of Brazil’s beef cattle production chain, with greenhouse gas emissions the main focus.
REGULATORY AFFAIRS

Efficient regulation
In response to calls by the MAI’s animal health division for the establishment of more efficient authorisation procedures, the time taken to register new veterinary drugs in Israel should begin to decline following the adoption of a fast-track approval process by the country’s Health Ministry. MAI is pressing to achieve similar changes for vaccines which are controlled by the Veterinary Services of the Agriculture Ministry. Guidelines on extra label use and requirements for companion animal products have also been drafted by a joint committee comprising representatives from industry, government and the veterinary profession.

Regulatory standards
In Indonesia, ASOHI maintained its dialogue with the government, which is overhauling regulations governing the manufacture and sale of animal health products. New rules governing feed mills have been introduced, while responsibility for licensing veterinary medicine distributors has been devolved from central government to provincial level. The association sponsored a biotech workshop addressing moves to accelerate registration procedures for biotech products.

Export opportunities for manufacturers in Israel have been boosted following a mutual recognition agreement with the EU covering good manufacturing practice (GMP) certification of plants manufacturing veterinary pharmaceuticals. MAI is pressing for an extension of the accord to cover veterinary vaccines. The implementation of GMP was also high on the agenda in Indonesia, where ASOHI continued to communicate closely with government officials.

Regulatory harmonisation
The Asian Animal Health Association (AAHA) strengthened its links with national associations and regulatory authorities across the Asia-Pacific region. Its status as a communication and
resource point could now see it begin to play a key role in the dissemination of harmonised regulatory guidelines under the VICH global outreach initiative.

In Korea, KAHPA and the national government co-hosted a regional workshop on veterinary medicines. Attended by delegates from seven countries, the event featured presentations and debate on key regulatory issues. One-to-one discussions on specific topics were also held.

COMMUNICATION

Raising the industry’s profile
The animal health division of MAI supported campaigns run by Israeli manufacturers designed to highlight the value of the industry, increasing awareness of its contribution to society.

In Indonesia, ASOHI participated in a range of animal health events, strengthening links with fellow stakeholders in the sector. The association also expanded the range of communication tools at its disposal.
REGULATORY AFFAIRS

Regulatory efficiency
The Animal Health Alliance’s campaign for regulatory reform in Australia began to pay off, with the government acknowledging that improved procedures for the registration of veterinary drugs were required. Some minor changes have already been implemented, while a task force has been established to draw up plans for more fundamental reform. Among the most significant potential changes is one that would see the national agency make more widespread use of foreign data and approvals already granted by regulators in Europe (EMA) and the US (FDA).

Positive developments were also reported by Agcarm in New Zealand, where the association has been campaigning for the removal of unnecessary regulations applied to low-risk veterinary medicines under the country’s environmental protection law. Human pharmaceuticals have been exempt from the legislation, intended to regulate hazardous chemicals such as pesticides, for a decade, but it has continued to affect animal health products. Agcarm’s call for low-risk veterinary drugs to be granted a similar exemption has paid off, however. The government is now working with industry representatives on a risk analysis that is expected to pave the way for an exemption in the near future.
MANAGING RESISTANCE

Alliance CEO Dr Peter Holdsworth was part of the Australian delegation to the fourth and final session of the Codex Alimentarius Ad-Hoc Intergovernmental Task Force on Antimicrobial Resistance, held in Muju, South Korea, during October. Advice prepared by the task force, which is scheduled for adoption by the Codex Alimentarius Commission in 2011, will help national authorities frame proportionate, science-based approaches to antimicrobial regulation.

COMMUNICATION

Effective delivery of key messages

The ability to identify and communicate key issues to fellow stakeholders effectively has been the key to recent successes achieved by the Alliance and Agcarm. Having driven home the need for change, both associations are now working directly alongside national authorities on the development of improved regulations.

Having revamped its communication strategy, Agcarm has increased the visibility of the industry, enabling the association and its member companies to engage more effectively with stakeholders. The Alliance has also stepped up its involvement in multi-stakeholder initiatives, with animal welfare among the issues it addressed during the year.
IFAH is led by a 17-strong Board of Directors comprising representatives from member companies and industry associations throughout the world. Headed by IFAH President Eric Marée, the Board is the federation’s decision-making body. It receives support from a Brussels-based secretariat, national and regional member organisations, and from global teams, task forces and working groups focused on issues identified by IFAH as strategic priorities for the animal health industry.

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ARGENTINA \ CAPROVE \ Câmara Argentina de la Industria de Productos Veterinarios

AUSTRALIA \ The Animal Health Alliance (Australia) Ltd

BELGIUM \ Pharma.be \ Association Générale de l’Industrie du Médicament

BRAZIL \ SINDAN \ Sindicato Nacional da Indústria de Produtos para Saúde Animal

CANADA \ CAHI \ Canadian Animal Health Institute

DENMARK \ VIF \ Veterinaermedicinsk Industriforening

EUROPE \ IFAH-Europe \ International Federation for Animal Health-Europe

FRANCE \ SIMV \ Syndicat de l’Industrie du Médicament Vétérinaire et Réactif

GERMANY \ BIT \ Bundesverband für Tiergesundheit

INDONESIA \ ASOHI \ Indonesian Veterinary Drugs Association

IRELAND \ APHA \ Animal & Plant Health Association

ISRAEL \ MAI \ Manufacturers Association of Israel

ITALY \ AISA \ Associazione Nazionale dell’Industria della Salute Animale

JAPAN \ JVPA \ Japan Veterinary Products Association

KOREA \ KAHPA \ Korea Animal Health Products Association

MEXICO \ INFARVET-CANIFARMA \ Industria Farmacéutica Veterinaria

THE NETHERLANDS \ FIDIN \ Vereniging van Fabrikanten en Importeurs van Diergeneesmiddelen in Nederland

NEW ZEALAND \ Agcarm \ New Zealand Association for Animal Health and Crop Protection

PORTUGAL \ APIFARMA \ Associação Portuguesa da Indústria Farmacêutica

SOUTH AFRICA \ SAAHA \ South African Animal Health Association

SOUTH EAST ASIA \ AAHA \ Asian Animal Health Association

SPAIN \ VETERINDUSTRIA \ Asociación Empresarial Española de la Industria de Sanidad y Nutrición Animal

SWEDEN \ LIF \ Läkemedelsindustriföreningen

SWITZERLAND \ SGCI Chemie Pharma Schweiz \ Swiss Society of Chemical Industries

THAILAND \ AHPA \ Thai Animal Health Products Association

UNITED KINGDOM \ NOAH \ National Office of Animal Health

UNITED STATES \ AHI \ Animal Health Institute

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

BSE \ Bovine Spongiform Encephalopathy
CAC \ Codex Alimentarius Commission
CAMEVET \ Committee of the Americas for Veterinary Medicines
CCGP \ Codex Commission’s Committee on General Principles
CCRDVF \ Codex Committee on Residues of Veterinary Drugs in Food
CEO \ Chief Executive Officer
DISCONTOOLS \ DiSease CONtrol TOOLS
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
FAO \ Food and Agriculture Organisation
FDA \ Food and Drug Administration (United States)
GALVmed \ Global Alliance for Livestock Veterinary Medicines
GMP \ Good Manufacturing Practice
MRL \ Maximum Residue Limit
OIE \ World Organisation for Animal Health
PGEU \ Pharmaceutical Group of the European Union
Q&A \ Questions and answers
R&D \ Research and development
RST \ IFAH Regulatory Strategy Team
SSAFE \ Supply of Affordable Food Everywhere
UN \ United Nations
UNESCO \ United Nations Educational, Scientific and Cultural Organisation
US \ United States of America
VICH \ International Co-operation on Harmonisation of Technical Requirements for Registration of Veterinary Products
VT \ IFAH Value Team
WHO \ World Health Organisation
WTO \ World Trade Organisation
WVA \ World Veterinary Association