

Annual Report 2011



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Representing the European animal health industry

IFAH-Europe (International Federation for Animal Health-Europe) is the federation representing manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It represents both corporate members and national animal health associations in Europe.

These associations comprise local, small and medium-sized enterprises (SMEs) and international companies. IFAH-Europe's membership covers 95% of the European market for veterinary products.

Our mission

IFAH-Europe's mission is to promote a predictable, harmonised, science-based marketplace for the provision of innovative, quality, animal health products that contribute to the supply of safe, healthy food and to high standards of health and welfare for animals and people.

As a responsible industry, we want to ensure that our stakeholders understand the work we do and the broad range of benefits we provide for society at large. To achieve this, as the voice of the European animal health industry, we encourage constructive dialogue with governments, public policy makers, legislators, regulators, non-governmental organisations, the veterinary profession, the food chain, consumers and other stakeholders.

A message from IFAH-Europe's Chairman and Managing Director



Whilst 2010 was a year of data gathering in terms of the revision of the veterinary and medicated feed legislation, 2011 has been a year of communication. It started with a very well attended European Pet Night in the neighbourhood of the European Parliament.

From an events perspective European Pet Night was a great success. We had a record attendance at this showcase event highlighting how pets change the lives of people across Europe. Special guests – the Essex and Lincolnshire Fire and Rescue Teams - presented the incredibly valuable work their rescue dogs do in disaster areas such as Haiti and Pakistan, where the dogs were deployed and saved many lives. Neil Woodmansey from the Lincolnshire Fire and Rescue Team spoke on behalf of teams from Belgium, France, Germany and the UK.

Our June conference was opened by Commissioner Dalli who stated that we have an opportunity to make veterinary legislation more efficient, to stimulate innovation and to bring more products to market. Speaking

on behalf of DG SANCO, Patricia Brunko identified increasing veterinary medicine availability, reducing administrative burden and completing the single market as the three most important elements to be addressed in the veterinary legislative review. Similar consensus was reached at a stakeholder conference in September where medicine availability was highlighted as the key goal.

The FEFAC conference in June provided a good opportunity for stakeholders to exchange views with Commission representatives stressing the need to ensure a single market for medicated feed by harmonising the currently divergent rules across the EU. Concerning carry-over in follow-on feed, we look forward to the Commission requesting EFSA to set tolerances in feed, as done for coccidiostats.

The debate on antimicrobials continued in 2011 and the European Parliament (EP) Committee on Agriculture and Rural Development initiated a resolution that was adopted in May. This was a relatively balanced resolution calling for a definition of the appropriate use of antimicrobials prophylactically (in a preventative manner). The EP Committee on Environment, Public Health and Food Safety initiated a separate resolution which was adopted in October. In contrast, this resolution opposed prophylactic use. These conflicting views need to be resolved by following the guidance of the May resolution as it is important for a veterinarian to retain the right to preventatively administer an antibiotic to an animal in certain situations, such as after a difficult birth. Animal welfare is the key consideration here.

The eagerly awaited Commission strategy on antimicrobials was announced on 17 November and proved to be a balanced text highlighting the key issues to be addressed and concluding with 12 action points. The need for innovation in the veterinary sector was noted as a topic to be investigated. We believe innovation is vital – the job was not done when Alexander Fleming discovered penicillin. Research efforts should be intensified to find new antimicrobials as well as innovative ways to tackle bacterial infections. Given the diversity of species in the veterinary sector, advances that could otherwise go undiscovered may be of great relevance to human medicine. However, the negative comments in relation to cephalosporins are misplaced and based on flawed analysis. We look forward to working with the Commission and other stakeholders in responding to the action points.

The concept of launching a Target Pathogen Monitoring Programme (TPMP) concerning the sensitivity of veterinary pathogens to antimicrobials may emerge from Action n° 10 in the Communication from the Commission. This would be a welcome development. We also continue to support the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) initiative – again in line with Action n° 10 – and we have initiated studies into the relevance of resistance in animals to our ability to treat disease in people. We wish to provide evidence on the risk involved as we believe it to be very low.

We have also been active in EPRUMA and the next important task is to initiate a long-term communications plan with both vets and farmers to reinforce Responsible Use in daily practice – this includes bio-security, good nutrition and housing, herd health plans and vaccination programmes to reduce the risk of disease occurring. We are convinced that Responsible Use coupled with transparency at the use phase will address the concerns of most parties interested in the antimicrobial debate. We will advance the transparency initiative in 2012.

In terms of project-based work, DISCONTTOOLS aims to identify research priorities in the most important animal diseases. From the all important 'One Health' perspective, our work on zoonoses is tangible evidence of the value of animal health research in terms of protecting human health. If we can confine zoonoses to animals or even eradicate a disease in animals, this represents a tremendous benefit to human health.

As Chairman and Managing Director, we wish to thank all those who have contributed to our work. Again, a really big thank you to those who contribute to the DISCONTTOOLS work. We wish to thank our companies and trade associations who contribute to our various committees in pursuit of our goals. A special thank you to our enthusiastic secretariat for their commitment to the work of IFAH-Europe.

A final thanks and farewell goes to our 2007-2011 Chairman Jochen Wieda, whose leadership over the past four years has been highly valued.

At the end of 2012, we will enter the regulatory phase – in both the veterinary and medicated feed legislative areas. 'Availability' is our guiding key word. We look forward to working with all stakeholders to ensure that we have safe, high quality and effective veterinary medicines available across the EU to benefit both food and companion animals as well as public health while ensuring a safe, secure and sustainable food supply.

A message from David Mackay, European Medicines Agency



David Mackay
Head of Veterinary Medicines
and Product Data Management



The European Medicines Agency and its Committee for Medicinal Products for Veterinary Use (CVMP) place great emphasis on transparent and constructive stakeholder engagement. With IFAH-Europe being one of the major veterinary stakeholders, many areas and opportunities for exchange of information between the Agency and IFAH-Europe during the process of regulation of veterinary medicines have been established. These occur both on a regular basis through channels such as annual info days and through the active engagement of IFAH-Europe's experts in workshops, focus groups and other specialist forums. Along with those of other specialist groups, the Agency values the input from IFAH-Europe during the consultation process on the development of guidelines, where it is particularly helpful to receive a considered and consolidated position from a large segment of the animal health industry at key stages of the process.

The animal health sector within Europe faces a unique opportunity over the next few years with the legislation on veterinary medicines, medicated feed and animal health all being the subject of review at the same time. Whilst contributing directly only in the area of veterinary medicines, the European Medicines Agency is conscious of the inter-relationship between all three areas of legislation and the impact that all three have on stakeholders such as IFAH-Europe. For this reason, the Agency often works to facilitate the dialogue that is necessary between a complex web of international, national, public, private and professional stakeholders to implement measures in the field of regulating veterinary medicine. The Agency strives in all cases to put the principles of 'better regulation' into practice. A good illustration of this is the approach that has been taken by the Agency to collecting data on the sales of veterinary antimicrobials as part of the ESVAC Project (European Surveillance of Veterinary Antimicrobial Consumption). From the outset, the Agency established a stakeholder coordination group in which IFAH-Europe plays a leading role, together with the other suppliers of antimicrobials to the EU market. The sales data on which this project currently depends originate from industry. IFAH-Europe's support in facilitating data submission, and in promoting understanding of the project among its members, has been a great help and a good example of constructive cooperation.

The European Medicines Agency and its stakeholders face a number of unprecedented opportunities and challenges during 2012. In terms of opportunities, the recently completed impact assessment of the legislative framework for veterinary medicines carried out on behalf of the European Commission highlighted the issues that currently exist in terms of an overall problem with availability of veterinary medicines, poor functioning of the internal market and a high administrative burden for industry relative to the return on investment. The

review of the legislation currently being finalised by the Commission therefore represents a unique opportunity to create a streamlined regulatory system that recognises the particular needs of the veterinary sector. Looking further forward, the Agency and IFAH-Europe share the vision of a European Union where innovation in the field of veterinary medicines is fostered in line with the objectives of the Europe 2020 Strategy. However, the Agency is not just looking forward to a better future, we are active today in a number of areas such as scientific advice, regulatory support, international cooperation, and specific help to innovation to facilitate access to the market for new veterinary products.

David Mackay

Head of Veterinary Medicines and Product Data Management

David qualified as a veterinary surgeon and worked in general veterinary practice before embarking on a career as a research scientist in exotic viral diseases of livestock, specialising in Foot-and-Mouth Disease, ultimately in the position of the Head of the Pirbright Laboratory of the Institute for Animal Health in the United Kingdom. He subsequently moved into the regulatory area, assuming the posts of Head of Immunologicals and then Director of Licensing at the Veterinary Medicines Directorate in the UK. David now works at the European Medicines Agency in London as the Head of Veterinary Medicines and Product Data Management. During his career, he has published widely on epizootic diseases of livestock and on regulatory issues, particularly in relation to immunological veterinary medicinal products.

David is a member of the Royal College of Veterinary Surgeons, the Association of Veterinary Teachers and Research Workers and is an honorary professor of the Royal Veterinary College of the University of London.





On the brink of major changes, thanks to another year of solid progress

IFAH-Europe focuses its resources on 3 strategic areas: **REGULATORY AFFAIRS**
FOOD CHAIN
COMMUNICATIONS

Some of our key activities and achievements in 2011, and our future goals in each of these priority areas are reviewed in the following pages. During 2011, IFAH-Europe experienced changes in two of its key committees and welcomed a new Chairman. We review the year and look forward to the next, together with existing, outgoing and new Chairs.

Acting today, shaping tomorrow

Eye to eye with Erik De Ridder, Elanco, Chair of IFAH-Europe's Technical and Regulatory Committee.

What progress has been made in the veterinary medicines review this year?

Erik De Ridder (EDR): Solid progress has been made. It has been a year of continued dialogue with all stakeholders. Notably, discussions have become more open than in previous years. During 2011, the European Commission continued the public consultation phase of the veterinary medicines review. The data that IFAH-Europe released last year for the impact assessment, has proved to be invaluable. IFAH-Europe has contributed even more through ongoing discussions and key events in 2011, such as our annual conference in June, the first public debate on issues regarding the new legislation. The Commission also organised a stakeholder meeting at the end of September that brought together key groups, including IFAH-Europe, to discuss the way forward. There is, however, much work still to be done to fully align viewpoints and move forward with a solid set of proposals.

How can reform of the European legislation improve access to veterinary medicines across Europe?

EDR: The reform could have a fundamental impact on improving the access to veterinary medicines in Europe. It offers the opportunity to bring benefits for all - animals, farmers, animal owners, veterinarians, animal health professionals, national and international authorities, the pharmaceutical industry and Europe's people. The complexity of the current system has created a heavy administrative burden, increased development costs, as well as development times and drastically hinders access and innovation. Centralised, simplified procedures with adequate data protection and a clear system to integrate existing products would improve efficiency and deliver savings that would keep the costs of veterinary medicines down and allow more research and innovation.

When are these changes likely to happen?

EDR: The European Commission plans to release its draft legislation towards the end of 2012. It must then be reviewed by various European institutions before it can be finalised - a process that could take one and a half to two years before the legislation is adopted. Following this, the new regulations must then be fully transposed in each Member State of the EU - a process that also takes time to implement.



Erik DE RIDDER
Elanco,
Chair of IFAH-Europe's
Technical and Regulatory
Committee



If the legislative review were an animal....

"It would be 'Fluffy' - the giant, three-headed guard dog in J.K. Rowling's book, 'Harry Potter and the Philosopher's Stone'. Just like 'Fluffy', the legislative review is larger than one realises at first! It is the guardian of something of great significance, positioned at the labyrinth's entrance. It initially seems fierce and difficult to work with, but there are safe pathways through the complex array of challenges. The 'three heads' of the legislative review could be interpreted as hope, fear and the courage needed to tackle it."

Erik de Ridder

IFAH-Europe hopes that the new legislation is announced as soon as possible. This would bring benefits to everyone faster and allow alignment and progression of other important developments in the regulation of veterinary medicines occurring globally.

We also hope that the proposals will take the legal format of a Regulation, rather than a new Directive. Both are adequate legal structures to drive reform, but a Regulation – being directly applicable - would enable the new system to be put into place faster.

How has IFAH-Europe been involved in the process?

EDR: We have been integral to the whole process. IFAH-Europe sees the improvement of the veterinary medicine regulation as a key priority in animal health. We have established a dedicated team to work on developed and proposed solutions, such as the 1-1-1 concept towards improving marketing authorisation and collected extensive data to quantify the issues. Through meetings and conferences with all the stakeholders involved, we have delivered consistent messages about the urgency, necessity and potential benefits of reform, proposed solutions and presented key data, so that everyone can make an informed choice.

IFAH-Europe was a driving force in organising a workshop between industry experts and regulatory authorities towards rationalising packaging and labelling requirements for veterinary medicines. This issue has been identified as a specific contributor to the high administrative burden and as a hurdle to making products available in the smaller markets.

Apart from the review of the veterinary medicines legislation, what are the other major activities within the world of European regulatory affairs?

EDR: Our commitment to a broad range of regulatory issues is helping to shape a landscape of improvements that will benefit so many. Providing input to the European Commission's new proposals and reviews of legislation on medicated feed, antimicrobials and pharmacovigilance have been other important priorities for IFAH-Europe's Technical and Regulatory Committee this year.

During 2011, the Commission held public consultations towards the review of the medicated feed legislation that have contributed significantly towards shaping revised proposals. The Commission also published its five year strategic plan on antimicrobials in November. These incorporate our input, and are welcomed



by IFAH-Europe as a step in the right direction for tackling rising threats from antimicrobial resistance and promoting Responsible Use of veterinary medicines.

IFAH-Europe continues to contribute to the development of many technical guidelines, commenting on drafts produced by authorities and helping to ensure their effective implementation through our working groups focused on pharmacovigilance, e-presentations, anti-infectives and biologicals.

We also participate in a global project for the International Cooperation on the Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH). The project, which has been running for 15 years, has already developed 49 harmonised guidelines. This year, our focus was on guidelines for pharmacovigilance, bioequivalence, acute reference dose, target animal batch safety testing, mycoplasma testing, extraneous agent testing, and also revised quality guidelines. Our work on existing guidelines and the addition of new important guidelines such as bioequivalence, could have a major impact on development costs, helping to support innovation. The VICH project is expanding to provide a basis for wider international harmonisation. IFAH-Europe's work is helping to promote adoption of new global standards.

Certainty in legislation is critical to enable investment and innovation, and since diseases continue to evolve, we must innovate to ensure we can control them in the future. Innovation is particularly important, to ensure the future availability and efficacy of antimicrobials to protect the health and welfare of all animals, farm animals as well as companion animals.

We are pleased with the recognition by the European Commission of the value in monitoring pathogens – this information will be very useful for all stakeholders in the future, and we welcome the proposal to introduce this concept in new legislation.

Overall, IFAH-Europe, through EPRUMA, is deeply committed to and actively involved in advocating Responsible Use of all veterinary medicines, including antibiotics, and supports monitoring resistance and the collection of usage data. The future must be guided by the phrase, "As little as possible, as much as necessary."

The veterinary medicines regulatory review: the big debate

A Commission proposal for revised legislation governing the authorisation of veterinary medicines across Europe is on its way in 2012. The animal health industry has lobbied for years for better regulation of veterinary medicines to improve their availability across Europe, reduce the costs of administration and ensure that innovation is supported and not thwarted. IFAH-Europe's 2011 annual conference provided a platform for the first public debate on the future legislation.

IFAH-Europe has led the campaign to improve veterinary medicine regulation and has developed and proposed solutions, such as the 1-1-1 Concept, towards improving marketing authorisation. In response to industry concerns, the European Commission launched a fundamental review of current legislation and carried out wide-ranging consultations during 2010. IFAH-Europe contributed extensive and relevant data to help all stakeholders choose the best policy options.

Key stakeholders in animal and public health met at IFAH-Europe's annual conference in Brussels on 16 June 2011 to discuss what future legislation might include. All agreed that simplification is needed and consensus was reached on a number of essential steps towards formulating new regulations.

The European Institutions' vision of the future

At the conference, John Dalli, European Commissioner for Health and Consumer Policy, welcomed the opportunity for a fundamental rethink of the whole veterinary medicine system as the chance to remould the model, with health as the cornerstone of the new legislation. Acknowledging the clear and unanimous input provided by all major stakeholders, he promised an all-embracing review that also includes a revision of the medicated feed legislation and will address antimicrobial resistance with concrete proposals for further coordinated actions.

A key objective will be to reduce the administrative and regulatory burden. Commission research estimates that the administrative burden for the current system of regulation of veterinary medicines will top €538 million in the coming years. This represents 13% of the annual turnover of the animal health sector in Europe. By reducing the regulatory and administrative burden of the current system, and the time and money involved in currently bringing products to market, manufacturers would be encouraged to invest more heavily in the research and development of new products. A broader range of products would be registered for more conditions and they could be made available to veterinarians and animal owners across the EU.

Representatives from Europe's key veterinary medicines and pharmaceutical agencies, such as the Committee for Medicinal Products for Veterinary Use (CVMP) of the European Medicines Agency (EMA), the Pharmaceuticals Unit at the European Commission's Directorate General Health and Consumers (DG SANCO) and the Heads of Medicines Agencies (HMA), also participated in the debate. They outlined their vision of the future for veterinary medicine and antimicrobial legislation.

Discussions developed around the outcome of the Commission's public consultation held in 2010, which showed that most respondents support major change. The changes called for include: increased data protection, with emphasis on extra provisions for medicines for certain minor species, adoption of centralised procedures, clearer and simpler labelling and packaging, improved support for innovation and the development of new diagnostics, therapies and devices.



The European stakeholders' views Farmers at the frontline

Gwyn Jones, National Union of Farmers (UK) / COPA-COGECA, joined the debate on behalf of the 1-1-1 Alliance. He urged for a wide-reaching review and highlighted the need to make new and innovative animal health products available to the livestock keeper to tackle mounting global threats to animal health.

Farmers experience many problems in availability of veterinary medicines. For minor species only a few veterinary medicines are available and in some Member States and for some species (such as bees), there are no authorised medicines available at all. Sheep farmers in the United Kingdom experienced immense difficulties early in 2011 when a vaccine used against orf in sheep was temporarily not available because there was no licensed alternative in the UK.

Better legislation would help farmers treat their animals with more efficiency, deliver savings that would keep the costs of veterinary medicines down and allow more research and innovation to benefit animals, farmers and consumers. With the risk of animal disease outbreaks spreading globally due to climate change and increased international trade and tourism, livestock keepers are our frontline allies in the fight against disease. They need to be adequately prepared and receive clear guidelines on using veterinary medicines.

Animal health industry unanimous

Erik de Ridder, Chair of IFAH-Europe's Technical and Regulatory Committee, and Rick Clayton, IFAH-Europe's Technical Director, outlined the industry's vision of the future. It is clear and specific. IFAH-Europe is calling for significantly improved data protection to stimulate increased investment in new veterinary medicines, including 20 years for minor species, and to simplify procedures for obtaining marketing authorisation. To improve efficiency, make good use of

limited resources, and remove duplication, decisions should be made by one central committee with a single procedure to follow with submissions made by Member State authorities based on one dossier (in English), one scientific assessment and one European marketing authorisation.

While the details of the new European legislation will be announced in 2012, the conference reached consensus on a number of important elements:

To stimulate innovation. It was agreed that data protection must be significantly improved. New legislation should maintain the current eight years data protection plus two years market protection (8 + 2) for the first product, with additional provision for each species and each additional indication. Medicines for minor species should receive maximum data protection. It was agreed that existing products modified with major innovation, should receive additional provision.

To simplify procedures. There was unanimous support at the conference to simplify regulatory procedures, avoid duplicate scientific assessments and create a single EU market for veterinary medicines. Conference participants agreed that improved training and quality control systems would help improve the new system. The majority agreed that decisions need to be taken at EU level, with Member States inherently involved in the decision-making process and that assessment of veterinary medicines should not be duplicated and should be made by multinational assessment teams.

To integrate existing products. The conference agreed that existing products should be introduced into the new system in an administrative way wherever possible, by harmonising a product's summary of its characteristics.

All stakeholders eagerly anticipate the results of the regulatory review and anticipate far-reaching yet balanced solutions that bring a win-win-win, situation for regulators, stakeholders and animal welfare. The 1-1-1 Alliance of industry, veterinarians and farmers hopes that the opportunities for 'win-win-win' will become 'won-won-won' in the near future.

Strengthening links in the food chain

Eye to eye with Dieter Schillinger, Merial, and Peter Oostenbach, MSD Animal Health, Chairs of IFAH-Europe's Food Chain Committee.

Food chain means working from farm to fork. How does IFAH-Europe work with food supply chain stakeholders?

Dieter Schillinger (DS): The animal health industry is small in size, but large in impact. It not only directly influences animal health and welfare, but also has implications for public health, including food safety and supply.

There are many stakeholders in the food supply chain. To achieve the best possible results, it is essential that we all work closely together, agree on the same targets, base actions on science and facts, and not on emotional responses. All stakeholders also need to communicate openly and transparently with consumers and citizens. The standard of food safety and health has never been as high as it is today, but there is always room for improvement. The future of food safety relies on effective disease control strategies that optimise the use of safe and effective vaccination programmes. By working together, we can ensure this.

IFAH-Europe cooperates with authorities, politicians, non-governmental organisations and members of the private sector directly and through appropriate platforms. Important stakeholders include the European Commission's Directorate General Health and Consumers (DG SANCO), the European Food Safety Authority (EFSA), where IFAH-Europe is so far (unfortunately) only an observer at the stakeholder platform, and the European Food Sustainable Consumption and Production (SCP) Roundtable. Working together with partnerships, such as the European Platform for the Responsible Use of Medicines in Animals (EPRUMA) further strengthens our voice on specific issues.

Prevention and control of diseases in food animals is at the heart of IFAH-Europe's goal. What are some of the success stories?

DS: Our view is holistic. Effective prevention and control of diseases inherently incorporates Responsible Use of animal medicines as a vital part of the animal health equation, alongside good practices in animal health surveillance, disease monitoring and bio-security.

Achievements in controlling diseases, such as porcine circovirus (PCV), are largely due to effective vaccination programmes. For example, in the 1990s, PCV type 2 caused extensive problems in the pig industry, accounting for up to 30% mortality in piglets.



Dieter
SCHILLINGER
Merial



Peter
OOSTENBACH
MSD Animal Health

Dieter Schillinger held the Chair of IFAH-Europe's Food Chain Committee until September 2011.

Peter Oostenbach took over the chair of IFAH-Europe's Food Chain Committee from Dieter Schillinger, in September 2011.



If vaccination were an animal...

"It would be a hedgehog. A hedgehog with its spines reminds me of a collection of antibodies that direct their antigen-binding sites outwards, like the hedgehog does. To protect itself from predators, the hedgehog rolls itself into a tight ball causing all of its spines to point outwards. Just as the spines protect the hedgehog from predators, antibodies, triggered by vaccination, are used by the immune system to identify and neutralise microbes, such as bacteria and viruses."

Dieter Schillinger

Effective vaccines were developed and launched in 2006, which has reduced the impact of this virus to zero. The outbreak of bluetongue (a viral disease that affects ruminants, such as sheep, cattle and goats) in northern Europe in 2006/2007, is another example of how vaccination with effective products has achieved major results in bringing the disease under control. Today many countries are, once again, classified as bluetongue-free.

These results have been possible through effective collaboration of all stakeholders, including authorities, veterinarians, farmers and the animal health industry.

Scientists expect that new animal diseases will hit Europe in the near future.

What diseases are these?

DS: New animal diseases (emerging diseases), as well as existing ones on the increase (re-emerging diseases), are shaping the future of the animal health industry. Diseases, such as foot and mouth, avian influenza, bluetongue, African swine fever, African horse sickness, Rift Valley fever and West Nile fever are a growing, or ongoing threat in Europe and beyond.

Animal health is building a stronger position on the 'One Health' platform. The need to protect against animal pathogens in order to protect human health is higher than ever. It is estimated that 60% of known infectious diseases are zoonotic in nature. We face mounting challenges in guaranteeing food security for our growing global population and we need to ensure the availability and effective use of innovative animal health solutions in the future. Culling programmes to control disease are no longer acceptable and, thanks to technological advances, options in disease control are broadening.

Is the animal health industry looking at this issue?

DS: Yes. IFAH-Europe is leading developments to ensure that the animal health industry adopts a more forward-looking approach to disease control. We are aiming to build our industry's foresight and develop successful partnerships and appropriate tools to combat future disease threats. By working together with all those involved in animal production, animal health and associated authorities, there is no reason why we shouldn't develop an effective disease control strategy. An effective system should harness the potential of new technology and the benefits of effective vaccines and vaccination programmes. We are not yet fully prepared for this, but we hope to see huge developments in this field in the coming years.

The European Technology Platform for Global Animal Health (ETPGAH - www.etpgah.eu), a stakeholder-led initiative chaired by IFAH-Europe, is an example of how we are working





in partnership on diseases prediction. The platform is currently developing a database to analyse gaps in our ability to control diseases and improve coordination of research on vaccine development. The DISCONTTOOLS project (prioritisation of diseases for research purposes) acts as a platform for prioritisation of animal diseases, so that research efforts can be effectively focused towards developing improved and newer tools to control diseases. It aims to identify the gaps in current knowledge for each priority disease, determine the status of current control tools and to ensure that existing and new technologies are used to maximum effect. There is also close cooperation with research organisations outside Europe to ensure the global aspects.

Why is food safety so high on the European agenda when EU safety standards are already so stringent?

Peter Oostenbach (PO): Food safety's priority position on the EU agenda is not derived from underperformance on safety standards. In fact, the opposite is true. The vast majority of food products available in Europe not only meet rigorous EU standards, but exceed them. However, occasional food safety incidents fuel consumer concerns and trigger widespread media attention, which is often then perceived by European citizens as confirmation of their worries.

Examples of food safety-related incidents that have generated considerable media attention include bovine spongiform encephalopathy (BSE) and dioxin. Food safety is high on the European agenda, because the European Commission aims to minimise the risk that incidents like these reoccur, especially as the movement of food products from outside and within Europe is substantial. Food and food safety are natural, basic human interests. Food safety is often linked to sustainable production, animal welfare, and traceability and these three aspects are increasingly important components in European consumers' choice.

In 2010, the European Food Safety Authority (EFSA) commissioned a survey to measure how consumers' views on food-related risks have evolved over the past five years (Euro barometer 354). The survey shows that most EU residents associate food and eating with pleasure, such as selecting fresh and tasty foods (58%) and enjoyment of meals with friends and family (54%). Food safety (37%) is less commonly associated with food and eating. However, concern regarding food as a potential health hazard has increased slightly (3%) since 2005.



If vaccination were an animal...

"It would be a sheep. Sheep are excellent 'multipurpose' animals. They adapt to almost any geographical situation and most climates, with individual breeds matched to almost any specific conditions. Vaccination mirrors this. Sheep produce a range of products - wool, meat and milk and can deliver the whole combination in an efficient way, and often under harsh conditions. Vaccination also delivers on a broad combination of aspects: from animal health and welfare to public health, food safety, efficiency and sustainability of production."

Peter Oostenbach



Antimicrobials in veterinary medicine are also high on the European Commission's agenda. What were the key initiatives in 2011 and what is IFAH-Europe doing about them?

PO: Four initiatives were important in 2011: Two European Parliament Motions for a Resolution on antimicrobial resistance issued in June and October 2011, the European Commission's five-year Strategy on Antimicrobials, which was announced in November 2011 and the EU Antibiotic Awareness Day, which occurs annually in November. IFAH-Europe has been working hard throughout the year to bring more science into the debate on the use of antimicrobials in animal health care and promoting Responsible Use of antimicrobials to safeguard their future efficacy and availability to relevant stakeholders in the food production chain via EPRUMA - the European Platform for the Responsible Use of Medicines for Animals (www.epruma.eu). The experts of several IFAH-Europe committees and working groups were involved, often reacting on short notice. Our contribution has been appreciated and has helped ensure a balanced result.

IFAH-Europe's other priorities within this framework have been to proactively support the development of two specific projects. One to measure the effectiveness of antimicrobials - the Target Pathogen Monitoring Programme (TPMP) – and another to investigate antimicrobial resistance (AMR) – the AMR transfer study.

What will be on IFAH-Europe's Food Chain Committee agenda for 2012?

PO: In 2012, we will continue our dialogue with key stakeholders including the European institutions, and we will continue to be active in partnerships, such as EPRUMA and the European Food Sustainable Consumption and Production (SCP) Roundtable. There is still a great deal to explain and communicate concerning the impact of animal health on society as a whole and the contribution the industry makes.

In addition, our annual conference in 2012 will focus on the food chain and will address the animal health industry's contribution to the production and availability of safe food. Within the industry, it is often taken for granted that our products contribute to food safety. However, the perception in society nowadays is often challenging. To make our contribution more visible, we are preparing a robust programme and will invite a wide range of stakeholders to be part of the debate.

Taking the right measures: promoting Responsible Use of animal medicines

'As little as possible, as much as necessary' is **EPRUMA's** motto. It is essential that all animal health products are used responsibly to protect animal and human health, optimise food safety and ensure effectiveness of veterinary medicines, for the present and future. Thanks to another year of effective communications with our partners, this message is being spread across Europe.

Throughout 2011, **EPRUMA** intensified dialogue with Europe's veterinarians, farmers, manufacturers of animal medicines, feed manufacturers, professionals working in animal health, sanitary security and sustainable agriculture, and pharmacists.

In May, **EPRUMA** provided feedback on the Heads of Medicines Agencies' (veterinary) Action Plan on antimicrobial issues. In June, the **EPRUMA** partners



IFAH-Europe is a founding member of the European Platform for the Responsible Use of Medicines in Animals (**EPRUMA**) – a multi-stakeholder initiative linking best practice with animal health and public health. Its aim is to promote Responsible Use of medicines in animals in Europe. **EPRUMA** advocates a holistic approach to disease prevention and control by combining bio-security measures, good housing, appropriate nutrition and regular monitoring of animal health and welfare. It supports the use of tailored herd health plans specific to individual farms to best treat disease and the use of vaccines, as well as the use of medicines according to the instructions.



presented their initiative to the European Commission's Animal Health Advisory Committee. The initiative was positively received and there is already evidence that Responsible Use is more and more at the core of the European Commission's communications.

The platform also continued the development of its communications strategic plan and toolkit. It was present at many high-level events, such as the World Conference on Veterinary Education and EU Vet Week in May, the International Conference on the Responsible Use of Antibiotics in Animals in November and the Federation of Veterinarians of Europe (FVE) conference also in November, entitled 'Antibiotics, a true one health issue', which coincided with the 2011 European Antibiotic Awareness Day.

In addition, EPRUMA published an even wider range of materials in 2011. A new video on the role of the animal health industry regarding the Responsible Use of veterinary medicines was launched in October and is available on the platform's You Tube channel, which already features a clip on Farmers and Responsible Use. Ten language versions of the document outlining EPRUMA's best practice framework on antimicrobials in food-producing animals are now available on the organisation's website. Looking ahead towards next year, additional language versions and new videos will be added to the website and a special poster on the role and benefits of EPRUMA is under development.

MEMBERS OF EPRUMA IN 2011

www.epruma.eu

www.youtube.com/user/eprumacom

COPA-COGECA - European Farmers and Agri-Cooperatives

www.copa-cogeca.eu

EISA - European Initiative for Sustainable Development in Agriculture

www.sustainable-agriculture.org

FECAVA - Federation of European Companion Animal Veterinary Associations

www.fecava.org

FEFAC - European Feed Manufacturers' Federation

www.fefac.org

FESASS - European Federation for Animal Health and Sanitary Security

www.fesass.eu

FVE - Federation of Veterinarians of Europe

www.fve.org

IFAH-Europe - International Federation for Animal Health-Europe

www.ifaheurope.org

PGEU - Pharmaceutical Group of the European Union

www.pgeu.eu



Communicating with conviction

Eye to eye with Alison Glennon, NOAH, and Sabine Schueller, MSD Animal Health, Chairs of IFAH-Europe's Communications Committee.

How important are companion animals to the animal health industry in Europe?

Alison Glennon (AG): They are vitally important. Europeans depend on animals for their food, for companionship, assistance and many leisure activities. Around 70 million homes in Europe have companion animals, or pets, accounting for 64 million cats, 60 million dogs and 39 million cage birds. Our pets live most closely with us in our homes, and so their health is more evident and intertwined with our own. Approximately 41% of all animal health products are used in companion animals. This figure has increased substantially in the past years as the population of companion animals increases, as we learn even more about them and their health, and as technology and investment in developing new companion animal health products increases.

Why should we as European citizens care about companion animals? What benefits do they bring to our daily lives?

AG: Pets are important family members. They bring joy to their owners, provide emotional support, reduce stress and loneliness and increase social contact. They can help children learn to be responsible and develop a sense of caring. Dog-owners in particular are generally more physically active, tending to the needs of their pet for exercise. This in turn, helps them stay healthy, and contributes towards lowering blood pressure and cholesterol levels, for example. Companion animal ownership can be therapeutic in human health, helping in recovery after surgery or treatment, creating positive effects on quality of life in health centres, helping with social rehabilitation and reducing the need for medication in mental health. Companion animals are involved in many sporting activities, such as equestrian sports, racing and agility competitions. Trained assistance dogs help physically and mentally-impaired people gain more freedom and independence. Rescue dogs are trained to perform a number of highly specialised tasks, like searching for survivors and victims during disasters, saving thousands of lives every year. Dogs and horses are also important in transportation and the work of the police, fire brigade, armed forces and other public services. Dogs are trained in all kinds of detection work, sniffing out anything from explosives to cancer to rare plant and animal species in nature conservation work (e.g www.workingdogsforconservation.org). Pets definitely benefit society in a variety of ways and play an important role, beyond mere companionship.

**Alison
GLENNON**
NOAH



**Sabine
SCHUELLER**
MSD Animal Health



Alison Glennon held the Chair of IFAH-Europe's Communications Committee until September 2011.

Sabine Schueller took over the chair of the IFAH-Europe Communications Committee from Alison Glennon in September 2011.



If IFAH-Europe were an animal...

"It would be a colony of ants. Ants display true social behaviour. They work together to build communities and each individual has a different role in contributing towards the good of the community. As a colony of individuals, they can achieve great things. This mirrors the way that IFAH-Europe operates. Ants also play an important role in maintaining the balance of nature - another parallel to IFAH-Europe's role in the animal health industry."

Alison Glennon

How does IFAH-Europe work on promoting this awareness of the importance of companion animals among its stakeholders and the general public?

AG: Companion animal health issues are a special focus in IFAH-Europe's communications work. We work throughout the year to promote and advance companion animal health with all relevant stakeholders, but one particular event that places it firmly in the European spotlight is IFAH-Europe's European Pet Night. In February 2011, the event brought together more people than ever before from European institutions, the animal health industry, companion animal organisations, pet owners and the media to celebrate the contribution companion animals make to our lives. The event showcased the role of rescue dogs through a presentation given by the UK's Lincolnshire and Essex Fire and Rescue Dogs.



European Pet Night
February 2011

How does the industry contribute to the health of companion animals in particular?

AG: The animal health industry places companion animal health firmly within the concept of 'One Health'- that human, animal and environmental health is interlinked and intertwined. With such a strong role in society, our pets have to be healthy. An important part of pet ownership is taking measures to prevent and treat disease effectively when necessary and the animal health industry has developed a wide range of products to support this. Many of the greatest innovations in the animal health industry are for companion animals. As well as vaccines and medicines to prevent disease, many animal health products have been developed specifically for companion animals with conditions that can be exacerbated by lifestyle, such as diabetes and obesity.

What is the link between companion animals and the other activities of IFAH-Europe?

Sabine Schueller (SS): As Alison indicates, our communication about companion animals epitomises our entire approach to animal health. They are an important part of society and their health is intertwined with ours. IFAH-Europe's objective is to communicate the importance of having healthy and happy animals, regardless of whether they are pets or livestock or other animals.



If IFAH-Europe were an animal...

"It would be a combination of a horse and an elephant. It's difficult to find one animal that 'fits the bill', but this unusual mixture combines the agility and speed of the horse and the strong memory, strength and power of the elephant. These are the key qualities of IFAH-Europe that are combined in one effective organisation to represent the voice of the animal health industry."

Sabine Schueller



Companion animals help to illustrate the many issues that are important for animal health as a whole. Some of the issues affecting companion animals also affect food-producing animals, for example, the availability of veterinary medicines and ensuring innovation and nurturing the development of new products by reducing the burden of regulatory procedures for all types of veterinary medicines. The EU can contribute to this by developing legislation that improves the way we deal with all animal health products and by adopting the 1-1-1 concept. The upcoming veterinary medicines review will be an important opportunity to ensure that all animals, including companion animals, can receive the rapid and effective treatment that they deserve.

How do you see the role of communications in the future?

SS: It is increasingly important for industry to communicate to the general public and decision-makers that healthy animals mean healthy people and to continue to emphasise the role that animals play in our daily lives whether they are companion animals or livestock. There still is a lot of misunderstanding and our communications work will continue to address this. We will also continue to incorporate new technology and communication tools in our work. Alongside this, our existing methods of communication, such as meetings, cooperation with various platforms, like DISCONTTOOLS, ETPGAH, EPRUMA, and conferences and events, like European Pet Night, will continue and will be strengthened wherever possible, to further engage with all stakeholders. As the complexity of IFAH-Europe's communications work increases, we will need to ensure that we deliver the right message with the right medium to the right audience and that we engage a wider range of skills in this area of our work, drawing on an ever-growing communication resource pool and broadening range of communication staff.

Staying ahead of the game: mapping the animal disease landscape

IFAH-Europe is leading developments to ensure that the animal health industry adopts a more forward-looking approach to disease control. Disease landscapes change over time. New animal diseases (emerging diseases), as well as existing ones on the increase (re-emerging), influence the future of the animal health industry. By enhancing our industry's foresight and through developing successful partnerships with all those involved in animal production, animal health and associated authorities, we will be able to create even more effective disease control strategies. These will enable society to harness the potential of new technology in the best possible way and optimise our vaccines and vaccination programmes.

DISCONTTOOLS (Disease Control Tools) is an ongoing, EU-funded project, led by IFAH-Europe. It has three important objectives. Firstly, to develop a system that will identify disease priorities and enable focus in research efforts, so that we can deliver new or improved diagnostics, vaccines or pharmaceuticals. This will help to improve our ability to effectively control animal diseases – a key priority in meeting the challenges of the future. The methodology of the DISCONTTOOLS project has been agreed with stakeholders and an animal disease reference database has been built. Secondly, the aim is to identify gaps in our disease knowledge, where additional research is needed. Thirdly, the DISCONTTOOLS project is designed to explore how new technologies can be identified and deployed more efficiently and effectively in animal health research.

The project was launched in 2008, originating from the Action Plan of the European Technology Platform for Global Animal Health (ETPGAH). It incorporates input from a wide range of stakeholders, including representatives from universities, research institutes, chief veterinary

officers, farmers, veterinarians, the diagnostics industry, the animal health industry, Heads of Medicines Agencies (HMA), the European Medicines Agency (EMA) and the World Organisation of Animal Health (OIE). A structure for implementation of the project was established comprising a total of 52 expert groups to explore 52 key diseases. The findings of the expert groups feed into an evaluation system for all stakeholders to analyse in greater detail.

By the end of 2011, 43 of the 52 expert groups (83%) had completed their work enabling publication of even more important data on the DISCONTTOOLS website (www.discontools.eu). In 2012, the remainder of the work of the expert groups will be completed and published, opening the field to further feedback from the public, which will add further insights into the disease landscape.

Much has been learned with the DISCONTTOOLS project in 2011. New challenges have emerged and have been successfully tackled. It has truly evolved into a 'living tool' that will allow all involved in protecting animal health to refine priorities for research. This will in turn, enable the more rapid development of new or improved diagnostics, vaccines, or pharmaceuticals and facilitate more effective control of animal diseases. Thanks to the continued commitment and dedicated input of all the stakeholders involved, we are moving the platform forward at a rapid pace.



The European animal health industry in profile

The animal health industry is a highly regulated, science-driven sector focused on the provision of products that preserve the health and welfare of animals, protect human health and help to ensure the provision of safe, affordable and high quality food.

IFAH-Europe member companies invest over €400 million in research and development every year. The industry provides around 50,000 full-time jobs in Europe.

ANIMAL HEALTH PRODUCTS

	Subtotals in €	Total values in €	%
Vaccines		1,143,813,324	26.34
Antimicrobials		831,124,030	19.14
Injectable forms:	446,079,372		
Oral forms:	385,044,658		
Parasiticides		1,191,878,718	27.45
Endoparasiticides:	445,551,095		
Ectoparasiticides (ears excluded)	633,522,060		
Endectocides:	112,805,563		
Topical products (skin ecto excluded)		292,186,421	6.73
Other products		883,216,464	20.34
TOTAL		4,342,218,956	100

GLOBAL ANIMAL HEALTH MARKET BY REGION



Countries covered include AT, BE, CH, CZ, DE, DK, ES, FR, UK, GR, HU, IE, IT, NL, PL, PT, SK.

Source: 12 IFAH-Europe and CEESA member companies. 20% added for non-participating companies. CEESA stands for European Animal Health Study Centre www.ceesa.be

IFAH-Europe's structure

IFAH-Europe is led by a ten-member Council comprising representatives from member companies and national industry associations. Headed by IFAH-Europe Chairman, Alejandro Bernal (Pfizer Inc. Animal Health), the Council is the federation's decision-making body.

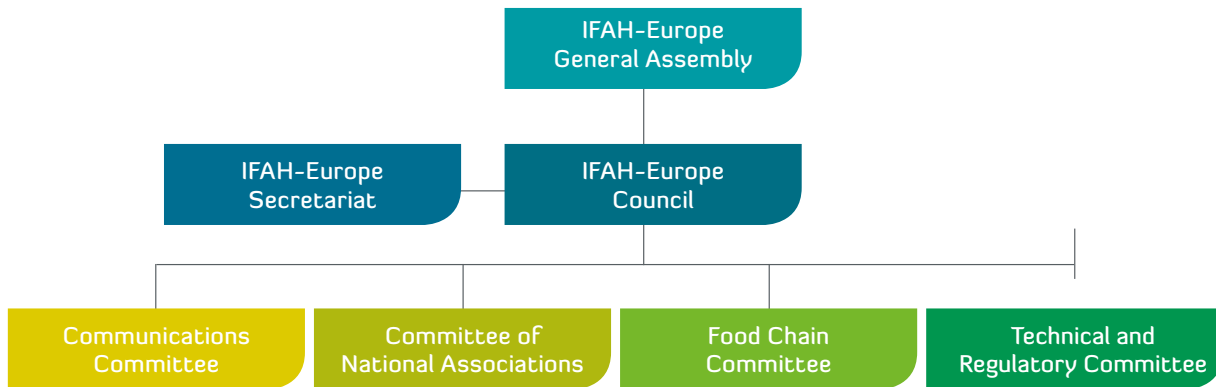
The General Assembly consists of full members and is responsible for:

- Ratification of accounts and approval of the budget;
- Approval of an annual programme of activities;
- Appointment and discharge of the members of the Council for having performed their duties;
- Amendments to the Articles of Association.

Policies agreed by the Council are executed by four key operating committees:

- Communications Committee (ComCom)
- Committee of National Associations (CNA)
- Food Chain Committee (FCC)
- Technical and Regulatory Committee (TRC)

These committees are supported by a range of working parties and ad-hoc groups focused on specific issues, and by a permanent Brussels-based secretariat led by IFAH-Europe's Managing Director, Declan O'Brien.



IFAH-Europe is a member of IFAH, the federation representing the animal health industry at the global level. Find out more about IFAH at www.ifahsec.org



IFAH-Europe Council 2011

Chair

Until June 2011: Jochen Wieda, MSD Animal Health
From June 2011 onwards: Alejandro Bernal, Pfizer Inc. Animal Health

Vice-chairs

Phillip Sketchley, NOAH (United Kingdom)
Christian Behm, Bayer HealthCare Animal Health GmbH

Treasurer

Folkert Kamphuis, Novartis Animal Health Inc

Members

Jean-Louis Crosia, Merial
Santiago De Andrés Juárez, Veterindustria (Spain)
Jean-Louis Hunault, SIMV (France)
Martin Schneidereit, BfT (Germany)
Frederik Schutte, FIDIN (Netherlands)
Hugo Wahnish, MSD Animal Health

Corporate members

Alpharma Animal Health Division, www.alpharma.com
Bayer HealthCare Animal Health Division,
www.animalhealth.bayerhealthcare.com
Boehringer Ingelheim Animal Health,
www.boehringer-ingelheim.com/corporate/products/prod_animal.htm
Ceva Santé Animale, www.ceva.com
Elanco Animal Health, www.elanco.com
HUVEPHARMA NV, www.huvepharma.com
Janssen Animal Health, www.janssenanimalhealth.com
MSD Animal Health (Merck Animal Health in the US & Canada),
www.merck-animal-health.com
Merial, www.merial.com
Novartis Animal Health Inc, www.ah.novartis.com
Orion Corporation, www.orion.fi
Pfizer Inc. Animal Health, www.pfizerah.com
Vétoquinol, www.vetoquinol.com
Virbac SA, www.virbac.com

IFAH-Europe Secretariat

Declan O'Brien, Managing Director
Florentina Pardo, Executive Assistant

Technical department

Rick Clayton, Technical Director
Sylvie Meillerais, Technical Project Manager
David John, Technical Assistant
Marie-Hélène Delvaux, Executive Secretary

Communications Department

Kim Hardie, Communications Director
Myriam Alcaïn, Communications Manager
Clare Carlisle, Public Relations Manager
Pamela Barcellona, Senior Secretary

Administration and IT

Linda Moortgat, Administration Manager and IT Coordinator.

National member associations

Belgium	Pharma.be - Association Générale de l'Industrie du Médicament Algemene Vereniging van de Geneesmiddelenindustrie	www.pharma.be
Czech Republic and Slovakia	CSAPC - Czech and Slovak Association of Veterinary Pharmaceutical Companies	
Denmark	VIF - Veterinærmedicinisk Industriforening	www.vif.dk
Finland	PIF - Pharma Industry Finland	www.pif.fi
France	SIMV - Syndicat de l'Industrie du Médicament Vétérinaire et Réactif	www.simv.org
Germany	Bft - Bundesverband für Tiergesundheit	www.bft-online.de
Greece	Havepharm - Hellenic Association of Distributors, Importers and Manufacturers Of Veterinary Pharmaceuticals	
Hungary	Hungarian Association of Innovative Veterinary Pharmaceutical Manufacturer's Representatives	
Ireland	APHA - Animal & Plant Health Association	www.apha.ie
Italy	AISA - Associazione Nazionale dell'Industria della Salute Animale	http://aisa.federchimica.it
Netherlands	FIDIN - Vereniging van Fabrikanten en Importeurs van Diergeneesmiddelen in Nederland	www.fidin.nl
Norway	LMI - Legemiddelindustriforeningen	www.lmi.no
Poland	POLPROWET - Polish Association of Producers and Importers of Veterinary Medicinal Products –	www.polprowet.pl
Portugal	APIFARMA – Associação Portuguesa da Indústria Farmacêutica –	www.apifarma.pt
Spain	VETERINDUSTRIA - Asociación Empresarial Española de la Sanidad y Nutrición Animal	www.veterindustria.com
Sweden	LIF - Läkemedelsindustriföreningen	www.lif.se
Switzerland	SGCI - Chemie Pharma Schweiz	www.sgci.ch
United Kingdom	NOAH - National Office of Animal Health Ltd	www.noah.co.uk

Associated members

Croatia	VETCRO	www.veterina.hr
Slovenia	SPMA – Working Group for Animal Health	

Glossary

AMR	Antimicrobial resistance
BSE	Bovine Spongiform Encephalopathy
COPA-COGECA	European Farmers and Agri-Cooperatives www.copa-cogeca.be
DG	Directorate General
DG SANCO	European Commission Directorate General for Health and Consumers http://ec.europa.eu/dgs/health_consumer/index_en.htm
DISCONTTOOLS	Disease Control Tools www.discontools.eu
EFSA	European Food Safety Authority www.efsa.europa.eu
EMA	European Medicines Agency www.ema.europa.eu
EPRUMA	European Platform for the Responsible Use of Medicines in Animals www.epruma.eu
ETPGAH	European Technology Platform for Global Animal Health www.etpgah.eu
EU	European Union
FVE	Federation of Veterinarians of Europe www.fve.org
HMAv	Heads of Veterinary Medicines Agencies Europe www.hma.eu
MEP	Member of the European Parliament
OIE	World Organisation for Animal Health www.oie.int
SCP	European Food Sustainable Consumption and Production Roundtable www.food-scp.eu
TPMP	Target Pathogen Monitoring Programme
VICH	International Cooperation on the Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products www.vichsec.org



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