



ANNUAL REPORT 2010



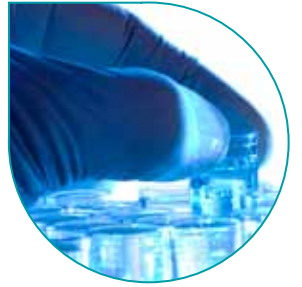


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REPRESENTING THE EUROPEAN ANIMAL HEALTH INDUSTRY

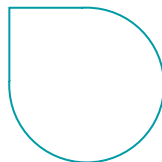
IFAH-Europe (International Federation for Animal Health-Europe) is the federation representing manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It represents both corporate members and national animal health associations in Europe. These associations comprise both local, small and medium-sized enterprises (SMEs) and international companies. IFAH-Europe's membership covers 90% 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

Providing data, inspiring change

Preparing for the revision of the legislation in the animal health area continued to be a major theme throughout our work in 2010. Promoting the “1-1-1 Concept” (1 dossier, 1 assessment, 1 decision), building awareness of the need to stimulate innovation via data protection (towards securing 10 years data protection for each species) and contributing to discussions concerning the revision of the medicated feed legislation were all important activities in the past year.

2010 was a year of data gathering. The Commission was busy with the development of their Impact Assessments for both the revision of the veterinary medicines Directive and medicated feed legislation. IFAH-Europe was pleased to contribute considerable data as a means of ensuring the availability of the best information base, allowing all parties the opportunity to choose the most informed future policy options. Concerning the veterinary medicines Directive, we assembled our own ‘Impact Assessment Data Package’, providing important facts and figures concerning the current impact of legislation on the industry. We wish to thank all those who contributed to this data compilation, allowing us to establish very important benchmarks for the industry.

Concerning data protection, we continued to highlight the need to provide sufficient protection to allow decisions to be taken to develop existing medicines for use in additional species. Whilst some data protection exists, it is, in reality, inadequate. Appropriate data protection will help to alleviate the medicine availability issue and we will continue to stress the need for action as the legislation is revised.

The development of antimicrobial policy advanced during 2010. The Commission held a public consultation early in the year and was engaged in a dialogue with the United States (US) authorities as the year progressed. IFAH-Europe's Policy Working Group (WG) took the lead in developing our policy direction. This took the form of gauging the wants and needs of all major stakeholders, exploring connections between stakeholders, analysing the ‘proposals for action’ from various stakeholders that were being suggested and then trying to come up with proposals that would best fit the needs of all parties. This has been a very constructive approach to a complex issue. It is clear that Responsible Use, compliance with label conditions,



Declan O'Brien
Managing Director,
IFAH-Europe

Jochen Wieda
Chairman of the
IFAH-Europe Council

being aware of the sensitivity of the bacteria being targeted, having a range of antimicrobials available and stimulating innovation are all important. Our work will continue in this area in 2011 and we look forward to contributing substantially to policy development as we progress through the year.

As part of the antimicrobial strategy, EPRUMA met with European Commissioner for Health and Consumer Policy, John Dalli, and issued a press release, in which, the Commissioner welcomed the EPRUMA initiative which brings together all relevant stakeholders to pursue Responsible Use - an essential component of public health that fits well with the "Animals + Humans = One Health"[®] initiative of the European Commission. EPRUMA launched its website during 2010 at www.epruma.eu and we look forward to the possibility of working jointly with the Commission in communicating the EPRUMA concept in pursuit of our common goal to maintain the long-term efficacy of veterinary medicines, including antimicrobials.

The DISCONTTOOLS project (prioritisation of diseases for research purposes) moved from a phase of setting up expert groups in 2009, to the completion and reporting of work done by many of these groups. At the end of 2010, 25 out of the 51 expert groups had completed their work. The DISCONTTOOLS board approved the publication of data on the website (www.discontools.eu) and this work is ongoing. In 2011, the expert groups will complete their work and we look forward to some very interesting feedback from the public, allowing us to further refine our priorities for research. In turn, this will enable the more rapid development of new or improved diagnostics, vaccines or pharmaceuticals and facilitate more effective control of animal diseases.

IFAH-Europe was pleased to organise and host, in conjunction with the World Organisation for Animal Health (OIE), the International Cooperation on Harmonisation of Technical Requirements for Registration of New Veterinary Products (VICH) 4 conference in June, in Paris. This was a major international event and the 4th conference in VICH's 15-year history. OIE member countries were specifically invited to come and learn about VICH and government officials attended from 30 countries.

As Chairman and Managing Director, we wish to thank all those who have contributed to our work. A big 'thank you' to the third party experts who contribute to the DISCONTTOOLS work and to the EPRUMA partners for their input to the platform – it is greatly appreciated. We wish to thank our member companies who helped us to develop our 'Impact Assessment Data Package' - a really valuable source of information. Thanks also to the companies and trade associations who contribute to our various committees in pursuit of our goals. Special thanks goes to our enthusiastic secretariat for their dedication to progressing the work of IFAH-Europe.

2011 promises to be a busy year as we continue our preparations for regulatory reform and as we pursue our other key objectives. 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 the benefit of the health and welfare of all animals, and to public health.

Jochen Wieda
Chairman, IFAH-Europe Council

Declan O'Brien
Managing Director, IFAH-Europe

A Message from Paola Testori Coggi, Director-General for Health and Consumers (DG SANCO), European Commission

Keeping animal health at the top of Europe's agenda

DG SANCO strives to help make Europe's citizens healthier and more confident and animals play an integral role in achieving that.

Our citizens depend on animals for their food, for companionship, assistance and many leisure activities and so their health is intertwined with ours. Animal health is therefore a fundamental element of 4 of the 5 pillars of our activities - consumers - health - food - and animals. By working to improve the health and welfare of animals, we are helping to improve the lives of people all across the EU.

One of our top priorities is to ensure food safety and availability. 'From farm to fork' is our approach, which provides the legislation and monitoring to create the highest standards of food safety, animal health and welfare across Europe, whilst supporting thriving, sustainable agriculture. We have carried out many activities to advance this during the past year. Our 2010 EU Vet Week, for example, was focused on improving identification and traceability in the food chain.

The event, which was held in Brussels, in June, comprised meetings and conferences to help raise awareness amongst farmers and consumers of key European veterinary issues connected with identification and traceability in food production. The issues covered included zoonoses, disease prevention and control, food safety and quality, consumer confidence, animal welfare, preventing fraud, genetic improvement, trade, livestock farming, distribution management efficiency, and crisis management.

During 2010, the European Commission agreed to finance a network of European Union reference laboratories in the animal health and food safety area. These laboratories act as reference points for the Commission and Member States and are essential elements in the EU policy to ensure a high level of animal health and food safety throughout the European Union.

The Commission also continued its ongoing work to fight key diseases. It has made progress towards the eradication of Brucellosis, Tuberculosis, Bovine Spongiform Encephalopathy (BSE) and Rabies. The



Paola Testori Coggi was appointed to her current post in April 2010. Originally a biologist, with a masters degree in ecotoxicology from the University of Milan in Italy, she also received an honorary degree in veterinary medicine from the University of Cluj, in Romania. Paola joined the European Commission in 1983. With a wealth of experience in public health, the environment, the food chain, research and animal health and welfare, she has made a major contribution to the development of many EU policies in food safety, R&D and consumer health over the last 17 years.

Animal Health and Animal Welfare on
DG SANCO's website:

http://ec.europa.eu/food/animal/index_en.htm



Animals + Humans = One health

control of Salmonella and Avian Influenza and the monitoring of Transmissible Spongiform Encephalopathy (TSE) and Bluetongue are also priorities.

New legislation on veterinary medicines is in the pipeline following the extensive review of the veterinary medicines Directive carried out during 2010. IFAH-Europe has provided invaluable input into this review. We aim to create a regulatory framework that safeguards the health of consumers and the environment, which enables the efficient development of veterinary medicines. This in turn should ensure veterinarians across the EU have access to more medicines.

This is a crucial time for animal welfare. The Commission has started its work to launch a new European strategy for animal welfare that will define the EU initiatives in this area for the next 5 years. In October 2010, we held our first international conference on animal welfare education, entitled 'Everyone is responsible'. The conference was designed to provide information to citizens about educational tools and programmes on animal welfare and raise awareness about how important it is to educate Europe's consumers, farmers, professional animal carriers, handlers, slaughterhouse operators, retailers, and other stakeholders on how animals should be treated.

Achieving the best results for the people of Europe depends upon continued collaboration with a wide range of stakeholders. IFAH-Europe has proved, yet again this year, that it is a valued, long-term partner in our work to improve the health and welfare of animals and the lives of people both in and outside the EU.

Paola Testori Coggi

Director-General for Health and Consumers, European Commission



LOOKING BACK, WE'RE MOVING AHEAD!

IFAH-Europe focuses its resources on 3 strategic areas:

- REGULATORY AFFAIRS
- FOOD CHAIN
- COMMUNICATIONS

Read our "EYE TO EYE" interviews to find out how our committees in charge of those areas reflect on 2010, and 2011.

EYE TO EYE

Erik DE RIDDER

- ▲ Belgian
- ▲ Chair of the Technical and Regulatory Committee
- ▲ European Regulatory Affairs Director, Elanco Animal Health
- ▲ Based in Brussels, Belgium



Erik, you have a long-term involvement with the European regulatory affairs for veterinary medicines. Is Europe an important market for veterinary medicines?

Erik: It certainly is! While just a small percentage of all pharmaceutical sales are for animals, the animal health industry has a huge impact on the lives of animals and people all over the world. It is responsible for the production and distribution of a broad range of products to prevent, diagnose, treat or cure diseases, in animals kept for production or as our companions. Animal health is a \$18.6 billion industry globally and the European Union (EU) is the world's second largest market for animal health products. Our industry provides 50,000 jobs in the region and has a substantial impact on other industries, like agriculture, to which it contributes to the viability of the EU's nine million farmers. Europe has, however, some of the most complex market and regulatory systems in the world.

What makes Europe's regulatory system different from other regions of the world?

Erik: Well, the EU has one of the most stringent regulatory systems in the world for veterinary medicines. And yet, it contains many

unnecessary hurdles. The main difference comes because the EU consists of 27 different Member States, each of which has its own government regulatory agency for veterinary medicines. Our market is effectively managed by 27 national agencies in addition to several bodies at European level, including the European Medicines Agency (EMA), its Committee for Medicinal Products for Veterinary Use (CVMP) and the European Food Safety Authority (EFSA). Good regulatory decisions are based on sound science, which is, of course, continually evolving. Having so many bodies involved in regulation can aid in progressing science at a rapid pace. We can share best practice from one country with another more easily. However, EU legislation is currently implemented differently in many of the countries creating differences in the availability of products. On the positive side, the Commission is also open to reviewing and revising this process. In 2010, this process was initiated, so we have the opportunity to upgrade this legislation in the next few years.

How does regulation affect animal health products? Is it a friend or foe?

Erik: Currently, it is both a help and a hindrance. Europe is a science-led environment. Just like medicines for human use, the safety, efficacy and quality of new veterinary medicines must be proven scientifically before the product is approved for introduc-

tion to the market by national and European authorities. For medicines intended for use in food-producing animals, additional tests must be carried out to define that food produced by the treated animal is safe for human consumption.

The purpose of regulation is to protect people, animals and the environment. However, systems of regulation must be efficiently and effectively implemented. The current EU marketing authorisation procedures for veterinary medicines are overly complex and costly and require revision. They have had a major impact on the animal health industry. Because of the growing regulatory burden, companies struggle to justify the significant investment required to develop and introduce a new veterinary product. This has contributed significantly to a decline in new products being developed.

What is the impact of the regulatory changes already made?

Erik: EU legislation is being reviewed for the second time in a decade. Following the last review in 2004, significant improvements were introduced, which have helped to stave off a major medicines availability crisis in Europe, but the regulatory framework governing veterinary products remains deficient in several key areas. The complexity of the system has created a heavy administrative burden and has significantly increased the cost of doing business in Europe. Prod-

My favourite animal

"Definitely Beau, my chocolate labrador. The labrador is the ultimate family dog. It represents everything that is positive about owning a pet – great companionship, reliability and a constant source of inspiration and education - for us and also for our children. As our own chocolate labrador becomes older, I am reminded how fragile health can be. I realise, first hand, just how important it is to have innovative solutions available in veterinary medicine, as well as the human health industry."



MY CHOCOLATE LABRADOR



EU legislation is being reviewed for the second time in a decade. (...) Manufacturers now spend more than a third of their research budgets generating data required simply to maintain (...) established products.

E. De Ridder,
Chair of the IFAH-Europe
Technical and Regulatory
Committee

uct development costs have increased drastically and the time needed to bring new medicines to market has risen by almost five years. At the same time the, data protection needed to make veterinary medicines product development viable has become inadequate. This has stifled innovation and has stopped new products from getting to the market. The regulatory problems also extend to existing medicines. Manufacturers now spend more than a third of their research budgets generating data required simply to maintain approvals for established products that have already proved their safety, quality and efficacy.

What is the role of a European federation like IFAH-Europe in optimising the regulatory framework?

Erik: We play an essential role. Through IFAH-Europe, the animal health industry can become integrally involved in shaping the regulatory environment. The stakeholders in the regulatory system should make a significant contribution to the debate and provide constant feedback on how to improve the framework. This is done most easily through an industry association, like IFAH-Europe, who can provide one voice for the numerous stakeholder involved and can engage in an open dialogue with legislators. We have contributed significantly towards the European Commission's 2010 review of our regulatory system. We share our expertise

with authorities, provide feedback on how it works in practice and propose solutions to overcome some of the shortfalls of the system. We have proposed the 1-1-1 Concept and made other suggestions for regulatory improvements.

IFAH-Europe's team of experts work together with its members and the authorities on a range of projects designed to improve the broader efficiency of the regulatory system. As well as working to create changes in the legislation on marketing authorisation for veterinary medicines, we have played an integral role in the introduction of electronic submission procedures, the adoption of improved packaging and labeling systems and enhancing the efficiency of pharmacovigilance systems through the establishment of a synchronised approach to the submission and assessment of post-marketing surveillance (PMS) reports.

2011, a critical year for improving regulation

TOWARDS A SINGLE EUROPEAN MARKET FOR VETERINARY MEDICINES

Developing better regulation for veterinary medicines has been at the top of the animal health agenda for many years. In response to issues raised by regulators and manufacturers, the European Commission carried out a fundamental review of the legislation surrounding veterinary medicines in the EU during 2010. This review included considering the provisions of the veterinary medicines Directive and medicated feed legislation. The results and the subsequent reforms proposed will be announced in 2011.

IFAH-Europe finalised and submitted an extensive Impact Assessment (IA) during 2010. It assembled critical data, highlighted facts and figures outlining the current impact of legislation on the industry, and stressed the importance of simplifying regulatory procedures. This has been a key task for the federation for the majority of the year.

Diseases don't recognise geographical boundaries, but in Europe, where you are can determine which medicines are available to treat our animals. A farmer routinely vaccinating sheep in one EU country, for example, might be prescribed a certain product, while a fellow sheep farmer in a neighbouring country might not have the same option. Veterinarians prescribing these medicines are bound by national and EU legislation that currently dictates that whilst animals (and their diseases) are able to move freely within the EU, the veterinary medicines required to maintain their health are not.

The problem

Just like human medicines, medicines for animals have to undergo market authorisation processes to ensure that they are safe, effective and of consistent quality. Companies developing new veterinary medicines must submit scientific data on the new potential product demonstrating its safety, quality and efficacy in a 'dossier', which is then reviewed by an independent scientific committee that works on behalf of a national government agency. For products intended for use in food-producing animals, additional tests must be carried out to define when food produced by the treated animal is safe for human consumption. It sounds like a straightforward process, however, in reality, it's quite complicated.

The current procedures for obtaining marketing authorisation of veterinary medicines in Europe are highly complex and costly to administer and there are many inconsistencies at national and European level. Inequalities between availability of products in different countries and areas within the EU are significant. A product that is widely used in one country might not be available at all in another. And three times more new products were introduced to the national markets in France, the Netherlands and the UK, than in the Baltic countries, and approximately 15 times more than in Malta.





Increased research and development costs

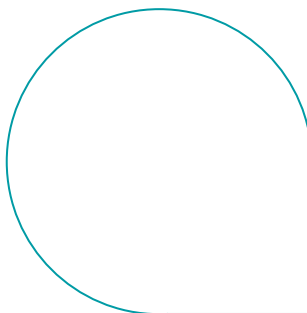
Bringing a new veterinary product to the market requires significant investment. The costs and time needed for new product development in Europe have increased significantly in parallel with the complex regulatory and administrative burdens. Even keeping existing products on the market now involves supplying additional scientific proof that they are still safe and effective.

It takes between 5 and 11 years to develop a new product and launch it. Marketing authorisation alone can take up to 3 years. And the costs total around €150 million. Manufacturers face the added complication of limited data protection. It is therefore becoming increasingly difficult for companies to obtain an acceptable return on their investment. This in turn leads to a decline in research and development and consequently a decline in new products being developed. The animal health sector still invests approximately €400 million in research and development per year towards new products, as well as retaining and upgrading existing ones. It receives no government support for research and, unlike the human health industry, does not benefit from national reimbursement schemes. This means that the entire cost of animal health products must be paid by the animals' owners. Farmers operate in a tight business environment and do not purchase products unless the cost-benefit relationship is clearly demonstrated.

Fewer new products

The current complex legislative framework deprives farmers, veterinarians and pet owners of the latest potential new technologies. Limited availability of new products has already become a problem in disease management in some common species, such as sheep and horses. And it severely limits the medicinal options available for less common species, such as goats and bees and the treatment of less common diseases.

It is not uncommon for veterinarians to resort to treating a disease in one species using a medicine which is intended for use in another animal (or sometimes even humans) as the medicine for that particular species is not available. Known as 'the cascade', this practice has been allowed in the EU to safeguard animal welfare in the absence of the necessary medicines. Regulatory complications could also be contributing to veterinary problems of the future. Diseases can evolve over time, as does our knowledge about them - what may be a minor disease issue today, might just present a major threat tomorrow.



Potential impact on human health

The insufficient availability of veterinary medicines also has negative implications for human health. By not adequately controlling animal diseases, we risk human exposure to zoonoses (infectious diseases shared between humans and animals). Over 1,451 pathogens are known to affect humans - 61% of them are zoonotic in nature. New pathogens can arrive very quickly (e.g. Avian Influenza). It is important that in a crisis situation, legislation allows veterinary medicines to be developed and authorised rapidly so that we can respond to new challenges.

Economy and environment

Veterinary medicines are important to the agricultural economy and the environment. Safe food comes from healthy animals. Animals suffering diseases require more feed and the food they produce often cannot be sold for human consumption. Without veterinary medicines, animal protein would become scarcer and more expensive, while farming would become less sustainable and would require greater areas of land and more animals to deliver the same quantity of food. Our population is growing and with the global demand for animal protein predicted to double by 2050, efficient and sustainable farming is vital.

Change on the horizon

In recent years, IFAH-Europe has promoted its 1-1-1 Concept – a proposed system for all veterinary medicines in Europe, under which, a single application for authorisation to market a product would be subjected to a single regulatory review, resulting in a single decision that would be applicable to all Members States. 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 innovative new products. A broader range of products would be registered for more conditions and they would be available to veterinarians and animal owners right across the EU. The 1-1-1 Concept has received widespread support from industry, farmers, veterinarians and policymakers.

We eagerly anticipate the results of the regulatory review.

View our webpage on efficient regulation on www.ifaheurope.org

And our explanatory leaflet on the 1-1-1 Concept:
www.ifaheurope.org/files/ifah/documentslive/41/2181_111leaflet.pdf



EYE TO EYE



Dieter SCHILLINGER

German ▶
 Chair of the Food Chain Committee ▶
 Head of Public Affairs Europe, ▶
 Middle East, Africa, Meril ▶
 Based in Lyon, France ▶

*Safe food comes
 from healthy animals*

The food chain doesn't immediately spring to mind when thinking about animal health. Is it a very important aspect of the profession?

Dieter: Safe food comes from healthy animals. Animal health makes a vital, but often underestimated, contribution to the production of food. Our industry helps to ensure that there is a plentiful supply of safe, good quality food for Europe's citizens through the veterinary medicines we develop and market. The World Organisation for Animal Health (OIE) estimates that food production globally is reduced by 20% by diseases in farmed animals. Animal health products are of vital importance to fight diseases in animals and prevent this figure from becoming higher. Without veterinary medicines, farming would become less sustainable and require greater land areas to deliver the same quantity of food.

Maintaining animal health is not just a fundamental issue today. We face a food crisis globally. As our population grows, demand for animal protein is expected to double by 2050. The only way to meet this enormous increase in demand is by improving the quantity and quality of livestock, its health,

welfare and production, towards which, veterinary medicines and vaccines are essential tools.

So, the animal health industry makes a significant contribution to society by supporting food supply and public health, although its role remains discrete.

Dieter: We are a very important, but small partner in the long and broad food supply chain that also includes the animal feed industry, farmers, food processors, retailers, and consumers. However, our success helps to ensure that consumers have access to quality food in sufficient quantity, while guaranteeing their safety health-wise. Besides direct food safety, animal health plays an even broader role in protecting public health. Remember that 61% of known pathogenic diseases are zoonotic in nature.

Major disease outbreaks in the past that have threatened the safety of our food and disrupted its production have highlighted the fundamental importance of the relationship between animal health and food safety. They have also consolidated support for the One Health concept – a worldwide strategy for integrating disciplines in all aspects of health care for animals, humans and the environment.

Most consumers, however, are simply unaware of the amount of work, research and dedication that goes into producing their food. We tend to take it for granted that it is now possible

to drink milk without the risk of catching Tuberculosis and that we can eat eggs and meat that are Salmonella-free.

As well as contributing to our health and safety, the animal health industry helps bring significant economic benefits. In Europe, animal health products contribute to support the livelihood of our farmers – a working community that constitutes nine million jobs. In developing countries, where people are even more directly reliant on their food-producing animals for survival and their livelihoods, animal health products are invaluable.

Is Europe a world leader in food safety?

Dieter: Yes, it is the world leader in food safety. The European Commission's Directorate General for Health and Consumers (SANCO) has a comprehensive food safety strategy. It takes an integrated approach – 'from farm to fork' - to not only ensure food safety, but to safeguard animal health and welfare, and plant health. The strategy ensures that food is traceable so that safety can be checked as it moves from production through to consumption, even if this means crossing internal EU borders. Animal health and welfare standards must be met, not just on the farm, but also during transport. These standards apply to food produced inside the EU and to food imports. The strategy has 3 core elements – rigorous legislation on the safety of food and animal feed; solid, scientifically-based

My favourite animal

"I am particularly impressed by camels. They are one of the species that fascinated me most when I first became a veterinarian and I have spent several years studying these physiologically remarkable animals in Kenya, Africa. The camel forms the heart of village life in Africa. They provide a major contribution to food, transportation, construction and clothing for villagers. Even their colour reminds us of the beauty of the desert."



THE CAMEL

Europe's model of food production and safety is globally unique. We can help to inspire and guide other regions towards improving their standards for the benefit of public health.

D. Schillinger, Chair of the IFAH-Europe Food Chain Committee



advice, upon which, decisions are formulated; and enforcement and control. The legislation is comprehensive – covering animal feed as well as our food, and extending to food and veterinary hygiene. It applies the same high standards across the EU.

When there are outbreaks of animal diseases, the EU acts quickly to contain them. There is also a rapid alert system to avoid exposing consumers to the risk of food poisoning. This system also spots whether foodstuffs contain banned substances or excessive amounts of other substances, such as residues of veterinary medicines in meat. When a threat is spotted, alerts go out across the EU and necessary action is taken.

Science forms the basis of the food safety strategy in Europe. An independent agency based in Parma in Italy, the European Food Safety Agency (EFSA), provides advice when legislation is being drafted and when policymakers are dealing with a food safety scare and the European Medicines Agency (EMA) monitors the safety of medicines through a pharmacovigilance network. DG Health and Consumers (SANCO), EFSA and EMA work in partnership to ensure our high standards of animal health and food safety. IFAH-Europe works closely together with each of these partners in contributing to the health of our animals and citizens.

Does it also have a role to play outside its borders?

Dieter: Definitely. Europe's model of food production and safety is globally unique. We can help to inspire and guide other regions towards improving their standards for the benefit of public health by acting as a role model. We need to globally promote the added value of its model of food safety, animal health and animal welfare.

Are there any other bodies that are important in ensuring food safety in Europe?

Dieter: The European Platform for the Responsible Use of Medicines in Animals (EPRUMA) is a particularly important, multi-stakeholder initiative, which provides a forum for discussion between manufacturers and those who administer their medicines. IFAH-Europe is a founding member of EPRUMA. This organisation is an excellent platform for promoting understanding of good agriculture practices including responsible use of animal health products and has made great progress since it was established in 2005. It 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 also 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.

Feeding minds, protecting livestock and fighting hunger

FOOD SECURITY - THE GREAT CHALLENGE

The world's population is growing rapidly. It is predicted to top nine billion by the year 2050. It goes without saying that this will put an extreme demand on the world's food supply, which is already stretched. More than one billion people in the world already do not have enough to eat. To meet our food demands of the future, we need to double global food production over the next 39 years. Keeping our animals healthy has never been more important.



IFAH-Europe devoted its 2010 annual conference to exploring the role of animal health in the global food challenge we face. The event held in June in Brussels, Belgium, helped examine the integral link between global food security and improving animal health and urged Europe's decision makers to put in place better policies to address this challenge. The federation believes that there is an urgent need for realistic measures to be established to address this challenge and that the animal health industry can play a critical role in this, together with the World Organisation for Animal Health (OIE), the Institutions of the European Union, the United Nations Food and Agriculture Organisation (FAO), and partners within the food chain.

Healthy animals produce more

Protein derived from animals, such as meat, eggs, milk or along with protein derived from poultry and fish, is a valuable part of the global diet. As the world's population continues to grow, and more and more households in emerging economies join the world's middle class, the demand for animal protein is expected to double over the next 39 years.

"Animal health: helping to feed a growing population" conference, Brussels, June 2010. Proceedings and presentations available at www.ifaheurope.org under Media Room / Events / 2010

www.ifaheurope.org



However, we are struggling to even feed our current population. One in every six people in the world is malnourished, chronic hunger is more widespread than at any time over the last 40 years and is on the rise, according to the FAO. Today, 1.02 billion people do not have enough to eat, 907 million of these live in the developing world.

The OIE estimates that global production from farms is reduced by 20% due to diseases in animals. Animal health products are of vital importance to fight diseases in animals and prevent this figure from becoming higher. With nearly 700 million of the world's poorest people relying on farming livestock directly for their survival, improvements in animal health could have a significant positive impact on communities, protecting their food sources and securing income.

Without veterinary medicines, farming is less sustainable and requires greater land areas to deliver the same quantity of food. It is estimated that if we didn't have veterinary medicines at all in Europe, we would need 89% more cattle, 54% more pigs, 25% more poultry and 25% more sheep.

Developing countries need additional support

The developing world has a greater burden of infectious diseases. Africa has the world's heaviest occurrence of infectious and protozoan diseases. Of the 15 major emerging diseases, 12 are present in Africa. Due to their limited access to products and services, 25% of livestock keepers' animals die each year from diseases that could be controlled through therapy or vaccination.

It is extremely important that the global community helps developing countries to strengthen their veterinary services and laboratory capacity, to enable them to improve prevention, early detection and control of diseases. Improving the health of livestock here requires high quality veterinary medicines and innovative technologies.

Protecting global public health

As well as reducing available animal protein and causing suffering in animals, there is a more direct threat to global public health from animal disease.

With man and animal living in ever closer proximity, infections are passing more frequently from animals to humans and vice versa. 75% of emerging human infections (diseases that have recently been recognised or have shown a significant increase over the last 20 years, in a specific place or amongst a specific population) originate from animals. They include

Ebola, Severe Acute Respiratory Syndrome (SARS) and Avian Influenza. Once present in human populations, the rapid flow of commodities and people across the world enables these pathogens to spread quicker than ever before.

Tackling animal health in one part of the world has a global effect on protecting human health. Preventive veterinary medicine and the widespread use and development of vaccines will play an increasingly important role globally.

Supporting innovation is key

If we look at the impact of animal diseases in the world, it is easy to see that we need technology and tools to lessen the impact of them. The European animal health industry is an important part of the solution and has a great deal to offer. However, we also need the right framework to allow innovation to thrive so that we can target diseases worldwide that cause the worst production losses.

While IFAH-Europe is helping to drive the debate towards viable solutions, European leaders have a responsibility to create an environment stimulating the research and development of new medicines.

This is vital to protect both animal health and public health through the food chain, thereby safeguarding food production.



From left to right:
Declan O'Brien, IFAH-Europe Managing Director,
George Alagiah, British journalist and
Jeff Simmons, CEO Elanco Animal Health at the
IFAH-Europe conference on food security.

Without veterinary medicines, farming is less sustainable and requires greater land areas to deliver the same quantity of food.

EYE TO EYE

Alison GLENNON

- ▲ British
- ▲ Chair of the IFAH-Europe Communications Committee
- ▲ Communications Manager, National Office for Animal Health, London, United Kingdom
- ▲ www.noah.co.uk



Alison, you have been in the driving seat of the IFAH-Europe Communications Committee since 2008. How important is good communications for a European federation like IFAH-Europe?

Alison: It is vital. Our organisation has become bigger than ever before and is still growing. Clear and effective communication is essential for finding consensus between our members and act as the unified voice of the industry. It is undoubtedly an ongoing challenge. We must maintain a strong and vivid link with our members across Europe and relevant European institutions. Overall, we must deliver the message to all stakeholders that animal health is an all-encompassing issue for society and a part of the One Health concept - a worldwide strategy for integrating disciplines in all aspects of health care for animals, humans and the environment. Research and innovation, animal welfare, human health, agriculture, the environment, sustainability of the food chain and food safety are all interrelated issues.

Would you say that animal health is playing an increasing role in society?

Alison: Without a shadow of a doubt! Animal health itself is a growing concern and understanding of it is only increas-

ing. IFAH-Europe has already achieved much in improving the awareness of animal health in society and helped towards integrating it better into the many other disciplines. We are establishing excellent, two way communications – listening to people carefully as well as informing them. This is our essence. All our communications activities are geared towards creating greater visibility and understanding of our involvement in the daily lives of European citizens.

Was 2010 a particularly important year for IFAH-Europe's Communications?

Alison: Yes. During 2010, we introduced and implemented a new communications strategy. This was developed with a strengthened commitment to help the public understand the true role that animal health plays in society. We aim to break down barriers by adopting an open and approachable attitude and encouraging two-way conversation with all our stakeholders and citizens.

Last year, we also continued to broaden our activities in partnership with other organisations. Through partnership we can work together with organisations like EPRUMA (The European Platform for the Responsible Use of Medicines in Animals) towards common goals and achieve results more quickly and efficiently.

My favourite animal

Our partnerships support all areas of animal health. The ETPGAH (European Technology Platform for Global Animal Health) and DISCONTTOOLS (the Disease Control Tools project) are key initiatives which reach researchers and academics to ensure that efforts to find new medicines are optimised across the EU. Continued discussions in the EU Food Sustainable Consumption and Production Round Table, co-chaired by the European Commission and food supply chain partners, has been another very successful platform for all food supply chain members at European level to commit to a more sustainable food-producing system.

"All our communications activities are geared towards creating greater visibility and understanding of our involvement in the daily lives of European citizens"

A. Glennon, Chair of the IFAH-Europe Communications Committee

What does being a member of IFAH-Europe mean to your organisation?

Alison: The National Office of Animal Health (NOAH) in the United Kingdom (UK) is a founding member of IFAH-Europe. It is our voice for critical issues for our industry on a European and global level. There are many issues to face, but with the growing success of IFAH-Europe, we have already made progress. We are committed to supporting IFAH-Europe, 100%.

"Horses are a passion for me. The companionship, affection, beauty and pleasure that they offer are unparalleled. My passion for horses started during my teenage years - I spent every spare moment of my time at the stables. It inspired me to study equine science and subsequently follow a career in animal health. I consider myself very lucky to have had these opportunities and wanted my three children to share the experience of the joy that horses can bring. They have benefited from growing up with Sugar, the elderly Welsh Mountain pony we bought them."



THE HORSE

Getting the message across

PROMOTING RESPONSIBLE USE OF ANIMAL MEDICINES



The veterinary medicines most commonly used generally fall into 3 categories: antibiotics, antimicrobials, antiparasitics and vaccines. It is essential that all these animal health products are used responsibly to protect animal and human health, optimise food safety and ensure effectiveness of the medicines, for the present and future.

'As little as possible, as much as necessary'. Through a year of effective communications with our partners, the message is getting through across Europe.

IFAH-Europe is a founding member of the European Platform for the Responsible Use of Medicines in Animals (EPRUMA) – a multi-stakeholder initiative that provides a forum for discussion between manufacturers and those who administer their medicines. The organisation, which celebrated its fifth anniversary in 2010, is proving highly effective in promoting good agricultural practice and communicating the link between this and responsible use of medicines.

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.

Throughout the year, EPRUMA intensified discussions with European veterinarians, farmers, manufacturers of animal medicines, feed manufacturers, professionals working in animal health, sanitary security and sustainable agriculture, and pharmacists.

The organisation also continued development of its communications strategic plan and toolkit. It was present at many high-level events throughout Europe and published a wider range of materials in 2010, including a new introductory brochure and website, which can be found at www.epruma.eu, many language versions of its antibiotic brochure and a video explaining the farmers' role in ensuring the responsible use of medicines. As part of its antimicrobial strategy, EPRUMA also met with Commissioner Dalli, who endorsed the initiative

European Platform for the Responsible Use of Medicines in Animals:
www.epruma.eu

also on YouTube:
www.youtube.com/user/eprumacom



publically. EPRUMA would like to work with the Commission in communicating the EPRUMA concept as part of the "Animals + Humans =One Health"® approach. EPRUMA attracted even more interest from potential partners over the last year. In 2010, the Pharmaceutical Group of the European Union (PGEU) became a member of the organisation.

MEMBERS OF EPRUMA IN 2010

COPA-COGECA - European Farmers and Agri-Cooperatives

Website: www.copa-cogeca.eu

EISA - European Initiative for Sustainable Development in Agriculture

Website: www.sustainable-agriculture.org

FECAVA - Federation of European Companion Animal Veterinary Associations

Website: www.fecava.org

FEFAC - European Feed Manufacturers' Federation

Website: www.fefac.eu

FESASS - European Federation for Animal Health and Sanitary Security

Website: www.fesass.eu

FVE - Federation of Veterinarians of Europe

Website: www.fve.org

IFAH-Europe - International Federation for Animal Health-Europe

Website: www.ifaheurope.org

PGEU - Pharmaceutical Group of the European Union

Website: www.pgeu.eu



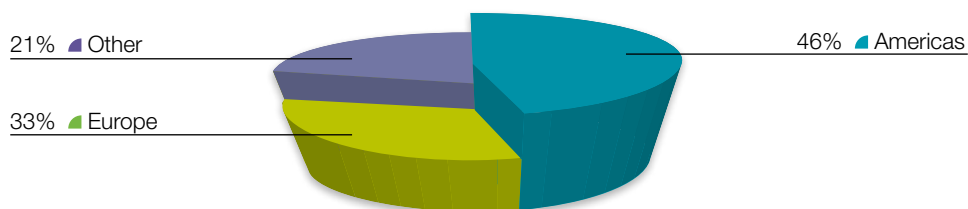
EPRUMA delegation with Commissioner **John Dalli**,
September 2010

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.

GLOBAL ANIMAL HEALTH MARKET BY REGION



© Vetnosis Limited (2010)

ANIMAL HEALTH PRODUCTS	Subtotals	Total values	%
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

Countries covered include AT, BE, CH, CZ, DE, DK, ES, FR, GB, 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, Jochen Wieda, the Council is the federation's decision-making body.

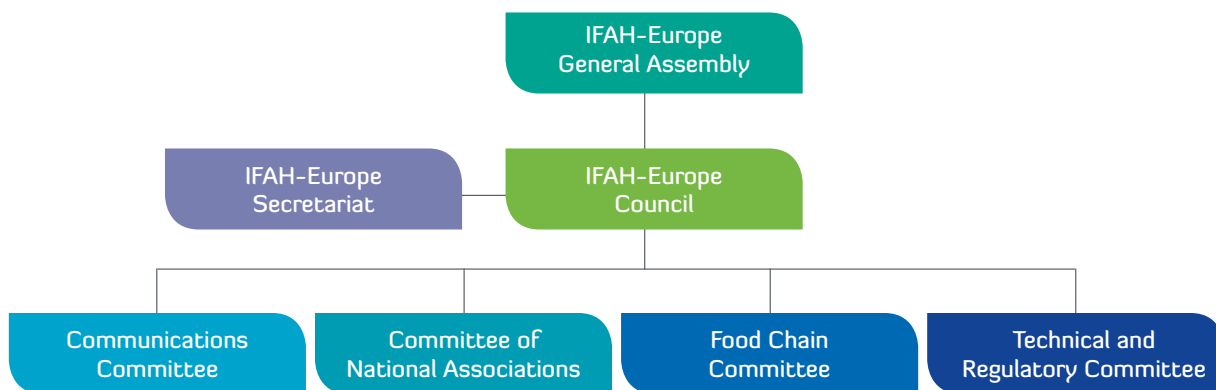
The General Assembly consists of full members and its responsibilities include:

- ▲ The ratification of accounts and approval of the budget;
- ▲ The 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 2010

CHAIR

Jochen Wieda, Intervet/Schering-Plough Animal Health

VICE-CHAIRS

Albert Bourla, Pfizer Inc. Animal Health

Martin Schneidereit, BFT (Germany)

TREASURER

Folkert Kamphuis, Novartis Animal Health Inc.

MEMBERS

Santiago De Andrés, Veterindustria (Spain)

Jean-Louis Hunault, SIMV (France)

Jean-Louis Crosia, Merial Ltd.

Anne Birgitte Lundholt, VIF (Denmark)

Philip Sketchley, NOAH (United Kingdom)

Wolfgang Trebels, Bayer Animal Health GmbH (January to September 2010),

Christian Behm, Bayer Animal Health GmbH (October to December 2010)

CORPORATE MEMBERS

Alpharma Animal Health Division
Bayer Animal Health GmbH
Boehringer Ingelheim Animal Health
Ceva Santé Animale
Elanco Animal Health
Fort Dodge
Huvepharma NV
Intervet/Schering-Plough Animal Health
Janssen Animal Health
Merial Ltd
Novartis Animal Health Inc.
Orion Corporation
Pfizer Inc, Animal Health
Vétoquinol
Virbac SA

IFAH-EUROPE SECRETARIAT

Declan O'Brien, Managing Director

Florentina Pardo, Executive Assistant

TECHNICAL DEPARTMENT

Rick Clayton, Technical Director

Sylvie Meillerais, Technical Project Manager

Yara Antonissen, Technical Assistant

Marie-Hélène Delvaux, Executive Secretary

COMMUNICATIONS DEPARTMENT

Kim Hardie, Communications Director

Myriam Alcain, Communications Manager

Laurence Leclercq, 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
Czech Republic and Slovakia	CSAVPC - Czech and Slovak Association of Veterinary Pharmaceutical Companies
Denmark	VIF - Veterinærmedicinisk Industriforening
Finland	PIF - Pharma Industry Finland
France	SIMV - Syndicat de l'Industrie du Médicament Vétérinaire et Réactif
Germany	BfT - Bundesverband für Tiergesundheit
Greece	HAVEPHARM - Hellenic Association of Distributors, Importers and Manufacturers of Veterinary Pharmaceuticals
Hungary	Hungarian Association of Innovative Veterinary Pharmaceutical Manufacturers' Representatives
Italy	AISA - Associazione Nazionale dell'Industria della Salute Animale
Ireland	APHA - Animal & Plant Health Association
Netherlands	FIDIN - Vereniging van Fabrikanten en Importeurs van Diergeneesmiddelen in Nederland
Norway	LMI - Legemiddelindustriforeningen
Poland	POLPROWET - Polish Association of Veterinary Drug Producers and Importers
Portugal	APIFARMA - Associação Portuguesa da Indústria Farmacêutica
Spain	VETERINDUSTRIA - Asociación Empresarial Española de la Industria de Sanidad y Nutrición Animal
Sweden	LIF - Läkemedelsindustriföreningen
Switzerland	SGCI - Chemie Pharma Schweiz
United Kingdom	NOAH - National Office of Animal Health Ltd

ASSOCIATED MEMBERS

Croatia	VETCRO
Slovenia	SPMA - Working Group for Animal Health

GLOSSARY

BSE	Bovine Spongiform Encephalopathy
CVMP	Committee for Medicinal Products for Veterinary Use (European Medicines Agency)
DG	Directorate-General
DG SANCO	Directorate-General for Health and Consumer Policy (European Commission) ec.europa.eu/dgs/health_consumer
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
FAO	Food and Agriculture Organization of the United Nations www.fao.org
OIE	World Organisation for Animal Health www.oie.int
R&D	Research and Development
IA	Impact Assessment
PMS	Post-Marketing Surveillance
Protozoan disease	Disease caused by organisms classified as protozoa (toxoplasmosis is a protozoan disease)
SARS	Severe Acute Respiratory Syndrome
SMEs	Small and Medium Enterprises
TSE	Transmissible Spongiform Encephalopathy
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products www.vichsec.org





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