

ANNUAL REPORT 2008





TABLE OF CONTENTS

About IFAH-Europe	4
A message from IFAH-Europe's Chairman and Managing Director	6
ACTIVITIES AND ACHIEVEMENTS IN 2008	8
Regulatory affairs	10
Food chain	12
Communications: sharing our commitment and our values.	14
Antimicrobials: preserving a valuable resource.	16
Pooling resources to beat disease threats.	18
New vaccines, the key to combating bluetongue.	20
FUTURE CHALLENGES	22
Regulatory affairs	23
Food chain	24
Communications	25
The European animal health industry in profile	26
Animal health market by region.	26
IFAH-Europe structure	27
Corporate Members	29
National Member Associations	29
Glossary of acronyms	31



ABOUT IFAH-EUROPE

IFAH-Europe is the federation representing manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It acts on behalf of both corporate members and national associations across the European Union. In turn, these associations represent local, regional and international companies. IFAH-Europe's membership covers 90% of the European market for veterinary products.

IFAH-Europe's mission

IFAH-Europe's mission is to promote a predictable, harmonised, science-based and innovative market-place for the provision of quality animal medicines, vaccines and other animal health products, thereby contributing 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 wide range of benefits we provide for society at large. To achieve this, IFAH-Europe, as the voice of the European animal health industry, encourages 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



Jochen Wieda
Chairman of the IFAH-Europe Council

The spike in food prices during the year ended a very long period – at least 30 years - since the developed world had to concern itself about food availability. This culminated in the FAO Summit becoming a Food Security Summit in June 2008 where leader after leader from across the world recognised the need to increase food production especially as we recognise that 932 million of the global population of 6.7 billion go hungry every day.

This crisis has resulted in a pragmatic approach being taken to increasing food production. The need to use fertiliser, good quality seeds and to protect crops and animals against disease is well recognised. Each year, the OIE estimate that we lose 30% of animal production to disease. As we look into the future, the statistics are stark. We need to increase food production by 100% by 2050 to feed the then global population of over 9 billion. Whilst the FAO estimate that 20% of this extra production may come from additional land being used for agriculture, 80% will have to come from increased production on existing land.

This is a challenge and the animal health industry will play its part. We can strive to fill part of the gap by controlling the diseases that currently reduce production by 30%. At the FAO Summit, we presented the work of the European Technology Platform for Global Animal Health (ETPGAH) the objective of which is to focus research funding towards filling the most important gaps in our ability to control the most damaging diseases. We advocated, and received good support for, the idea of rolling out this concept at a global level. We continue to pursue this objective.

Emerging from the work of the ETPGAH is another DG Research-funded initiative called DISCONTTOOLS. The purpose of DISCONTTOOLS is to put in place an objective methodology for prioritising diseases and reaching agreement on the most important gaps. Working Groups were established and started their work during 2008 to good effect. Their work will culminate in the development of a prioritisation model that will be available on an interactive public website.

A most welcome development during 2008 was the creation of the EMIDA ERA-Net (Emerging and Major Infectious Diseases of Livestock). The ETPGAH Action Plan called for the creation of the ERA-Net and it made great progress during 2008. Nineteen countries, controlling annual research budgets of €270 million, are members of the initiative. The excellent collaboration between the ETPGAH and EMIDA will ensure that research funding is targeted in an efficient manner and the cross border collaboration being developed is truly inspirational. We look forward to major breakthroughs from EMIDA in terms of controlling some of our most difficult diseases.

Bluetongue continued its expansion across Europe but the industry enabled farmers to counter this threat by providing very effective vaccines. The result was the protection of cattle and sheep against the ravages of the disease where vaccination was deployed on time. Many regions of Europe organised mass vaccination campaigns over the winter months and this should greatly reduce the impact of the disease in 2009. It remains to be seen whether eradication can be achieved in the future.

The Slovenian and French Presidencies of Council are to be thanked for ensuring that the review of the Maximum Residue Limit (MRL) legislation was almost complete by the end of 2008. Various complex issues arose and good solutions were found. The legislation will improve medicine availability and will make the system more efficient.

Dwelling on the word efficiency, all parties concerned made substantial progress in moving towards a review of the main veterinary legislation with a united focus on efficiency. At our conference in June 2008, we welcomed the call from the representative of the Heads of Medicines Agencies (HMA) for greater efficiency in the context of the Lisbon Agenda and Better Regulation. The HMA spokesperson advocated the creation of a true single market bringing benefits for animal health, public health, innovation and competitiveness. During the French Presidency, a very successful conference was held at which the industry stressed its focus on what is branded as the “1-1-1 Concept” - 1 dossier, 1 assessment and 1 decision. This concept was widely welcomed and, along with data protection, will be our major focus as the review of the legislation commences in 2010.

A major milestone was reached in the life of EPRUMA (European Platform for the Responsible Use of Medicines in Animals) with the publication of its best practice framework for the use of antimicrobials. This is a collaborative initiative between COPA/COGECA, EISA, FEFAC, FESASS, FVE and IFAH-Europe. Our focus is now to ensure that the framework is communicated

widely and ensures responsible use of antimicrobials. As a means of initiating this communication, the publication was launched during Veterinary Week organised by DG Sanco and the FVE. Various events were held during the week and subsequently across Europe. The emphasis was on bio-security at borders and farms, not only as a means of preventing disease, but also as a way to communicate the ongoing Animal Health Strategy aimed at protecting animals against disease.

2008 was a busy and productive year. We would particularly like to thank Brian Clark who retired from his position as the Chairman of IFAH-Europe for health-related reasons. Brian has been an inspiration to all of us since IFAH-Europe was launched in 2005. We wish Brian well in his retirement and look forward to maintaining our friendship.

We wish to thank our secretariat for their enthusiastic commitment to the work of IFAH-Europe. We also wish to thank our member companies and trade associations who contributed so much to achieving our goals.

Jochen Wieda
Chairman of the IFAH-Europe Council

Declan O'Brien
Managing Director of IFAH-Europe



Declan O'Brien
Managing Director of IFAH-Europe

A black and white cow stands in a field of tall green grass. The cow is looking towards the camera. The background is a clear blue sky. The image is framed by a white border with a wavy, organic shape on the right side.

ACTIVITIES AND ACHIEVEMENTS IN 2008

IFAH-Europe focuses
its resources on three
strategic areas:

- › REGULATORY AFFAIRS
- › FOOD CHAIN ISSUES
- › COMMUNICATIONS

Key activities and achievements in each of these three fields during 2008
are reviewed in the following pages.

► REGULATORY AFFAIRS

A predictable, proportionate and efficient regulatory framework is a prerequisite for the long-term success of our industry. Confident that their products will be judged in a timely fashion by science-based criteria, companies will continue to invest and innovate. Those investments will drive the development of new and improved products to protect the health and welfare of animals, guard against threats to human health and contribute to the supply of safe, healthy food.

The existing regulatory framework is far removed from the vision of a 'single European market' crystallised by EU policymakers in the original goals of the EU. Addressing the inefficiencies and inconsistencies in the current framework is a challenging task, but one that IFAH-Europe has pursued in determined fashion. At the same time, the federation has continued to press for a change of approach to the regulation of veterinary medicines. Those efforts have now begun to bear fruit, and we are optimistic that significant improvements can be delivered in coming years.



“The intention of new legislation was not to compromise but rather to enhance the availability of veterinary medicinal products in the EU which continues to be a problem for many veterinary practitioners.

Avril Doyle, MEP (Irl, EPP-ED),
on the review of the MRL legislation

Regulatory reform and the “1-1-1 Concept”

The Heads of Medicines Agencies (HMA) has established a task force to advise on potential improvements to current rules governing animal health products. IFAH-Europe submitted its reform proposals to the task force during 2008. At their heart is a call for improved support for innovation and the creation of a true single market for veterinary medicines in the EU - a goal laid down by Member States many years ago, but one that has never been properly achieved. The federation's proposals envisage improved protection for innovation and the establishment of a “1-1-1 Concept”, under which a single dossier describing the quality, safety and efficacy of a product would be subjected to a single scientific evaluation, resulting in a single decision on marketing authorisation. By cutting out existing duplication of resources, this would generate substantial savings in terms of both time and money for regulators and the industry alike. Saving time means a quicker response to animal health challenges and therefore a substantial benefit in terms of animal welfare.

The principles of the “1-1-1 Concept” received widespread support. The goal now is to agree how this could be achieved in time for more detailed proposals to be considered during the European Commission's review of the existing regulatory framework in 2010.

Dialogue with authorities

The key to recent progress has been IFAH-Europe's focus on engaging in constructive dialogue with the European authorities and policy makers. Regulators and legislators were among the delegates who attended the federation's 2008 annual conference, which addressed Animal Health Solutions for the Future. In many ways, this provided the catalyst for positive developments witnessed later in the year. Chief among these was a conference organised by the French Food Safety Agency (AFSSA), at which IFAH-Europe was invited to expand on its suggestions for reform, and where the stakeholders present broadly agreed to the proposals of the federation. Elsewhere, fruitful discussions were also a feature of the joint “info-day” organised by the federation and the European Medicines Agency (EMA), which looked at balancing the benefits and risks of veterinary medicines.

Improved residue regulation

Further welcome news came towards the end of 2008, when EU Member States supported a revised regulation governing the establishment of maximum residue limits (MRLs) for veterinary medicines in foodstuffs of animal origin. Drawn up by the European Commission, this will address product availability issues, and will encourage innovation. Residues of coccidiostats in non-target animal feed will also be controlled via reference to residue limits in future,

after regulators agreed to dispense with a “zero tolerance” approach that had long been an issue for animal feed compounders in the EU.

Regulatory efficiency

IFAH-Europe surveys members on a regular basis, identifying areas in which the efficiency of existing regulatory procedures can be improved. These form the basis of discussions with regulators. In 2008, dialogue focused on the development of improved packaging and labelling requirements and the introduction of electronic submission procedures. The federation is also involved in a pilot project designed to improve the efficiency of pharmacovigilance procedures which represent a large burden for both the industry and regulators. The first step towards broader improvements involves the adoption of a synchronised approach to the submission and assessment of safety reports for products on the European market. Regulators have also adopted a more flexible approach to requests for variations to existing marketing authorisations. This will encourage the industry to pursue improvements to established products.

Data requirements

The federation contributed to discussions on a range of new and revised guidelines outlining data requirements for veterinary products. Its input helped to secure key revisions to guidelines on environmental risk assessment and user safety, a draft guideline on approaches to risk-benefit assessment, and data requirements for bluetongue vaccines.

Harmonising EU data requirements with those in other major geographical markets is the goal of VICH - a joint initiative being pursued by the industry

and regulators from Europe, the US and Japan. An IFAH-Europe delegation contributed to discussions at the 21st meeting of the VICH steering committee, hosted by the OIE at its Paris headquarters in July. Harmonised target-animal safety guidelines for pharmaceutical and biological products were signed off by the committee for implementation in the three participating regions by July 2009. Considerable progress was also noted in the finalisation of a set of pharmacovigilance guidelines, and the drafting of four guidelines on metabolism and residue kinetics studies.



› FOOD CHAIN

Strengthening links with fellow stakeholders along the food chain is helping to promote a broader understanding of the vital role played by our industry, and of the goals that we share with many of these groups.

IFAH-Europe has spearheaded a number of multiple-stakeholder alliances, and is regarded increasingly as a valued partner in the food chain. The federation continued to strengthen and broaden its links with other stakeholders during 2008.



Responsible antimicrobial use: EPRUMA

Working alongside organisations representing the region's veterinarians, feed industry and farmers, and with input from the European Initiative for Sustainable Development in Agriculture (EISA), IFAH-Europe produced a best-practice framework for the use of antimicrobials in food-producing animals. Part of the EPRUMA initiative, which champions the responsible use of veterinary medicines, the document contains guidance designed to promote best practice and so minimise antimicrobial resistance. It was launched during the EU's Veterinary Week in November 2008, and received widespread praise from a range of food chain partners.

Vaccination policy

The disastrous impact of epidemics witnessed earlier this decade has prompted a significant shift in attitudes towards vaccination, which is now seen as an integral part of disease control strategies in the EU. Community funds have been made available to finance Member State vaccination programmes designed to combat bluetongue, which has emerged as a major new threat to the health and welfare of ruminants in the region.

IFAH-Europe liaised closely with EU institutions on the approval and timely provision of bluetongue vaccines developed by the federation's member companies. These had a major impact in several Member States during 2008, but supply issues emerged after some countries failed to place orders for vaccines at a sufficiently early stage. In a bid to avoid a repeat of such problems, IFAH-Europe drew up a vaccine fact sheet, which highlights the complex nature of vaccine development, registration and manufacture. The document stresses the

need for coherent, well-planned approaches to vaccination programmes, and for the involvement of all stakeholders in those plans.

Food safety

The federation continued to build on its relationship with the European Food Safety Authority (EFSA), playing an active role in its stakeholder consultation platform and participating in technical consultations held by the authority on antimicrobial products.

The EFSA's strategic plan 2009-2013, which was unveiled at the latest stakeholder consultation meeting, confirms the importance of animal health and welfare within its remit. It also reveals a desire on the part of the authority to play a role in the conduct of risk-assessment exercises in these fields. Proper consultation with the animal health industry on these topics is clearly vital. Accordingly, IFAH-Europe seeks to obtain full-membership status on the EFSA stakeholder platform.

Stakeholder relations

The federation engaged in constructive dialogue with a broad range of other stakeholders during the year. It contributed to the activities of groups representing farmers (COPA/COGECA and FESASS) and veterinary surgeons (FVE) across Europe, and was involved closely in debates that took place in forums such as the European Agri-Food Network (EAFN) and the European Initiative for Sustainable Development in Agriculture (EISA).

Sustainable consumption

Since the end of 2008, IFAH-Europe has announced its involvement as a founding member of a broad new coalition established to promote environmental sus-

tainability in Europe, the European Food Sustainable Consumption and Production (SCP) Round Table. The federation will work alongside groups representing farmers, the food, feed, packaging and retail sectors, the World Wildlife Fund and institutional partners. Involvement in this new initiative will provide IFAH-Europe with a great opportunity to help shape sustainability policies for Europe.



IFAH-Europe is a member of the European Food Sustainable Consumption and Production Round Table



“We cannot be complacent as the changes taking place in the food safety environment will present significant challenges to all of us. In the same way as food travels, so do disease vectors, and animal and plant diseases are now regularly reported in parts of Europe that hitherto were regarded as free from those diseases.

Jordi SERRATOSA,
European Food Safety Authority,
at the 2008 IFAH-Europe Annual
Conference

► COMMUNICATIONS: SHARING OUR COMMITMENT AND OUR VALUES

Effective communication has helped to raise awareness of the vital role played by our industry, and to position the federation as a reliable, trusted source of information on a broad range of animal health issues. As ever, progress towards the achievement of key goals reported during 2008 owed much to the success of our communications strategy.

Animal health – solutions for the future

Around 150 delegates, including representatives of the FAO, OIE and EU institutions, attended our 2008 conference, which has become a key date in the European animal health calendar. Participants agreed on the need for a coordinated, collaborative approach to the development of policies spanning animal health and welfare, food safety and disease control.

The conference also marked an important step towards the revision of rules governing veterinary medicines in Europe. Patrick Dehaumont, Director of the French Agency for Veterinary Medicinal Products (ANMV - AFSSA), told delegates it was time to address necessary improvements in the existing regulatory framework so as to foster innovation and improve the availability of animal medicines. At a subsequent conference hosted by the French agency, IFAH-Europe was invited to table its proposals for change. These received a positive response from regulators, and now look set to help shape major regulatory reforms.

Spreading industry messages

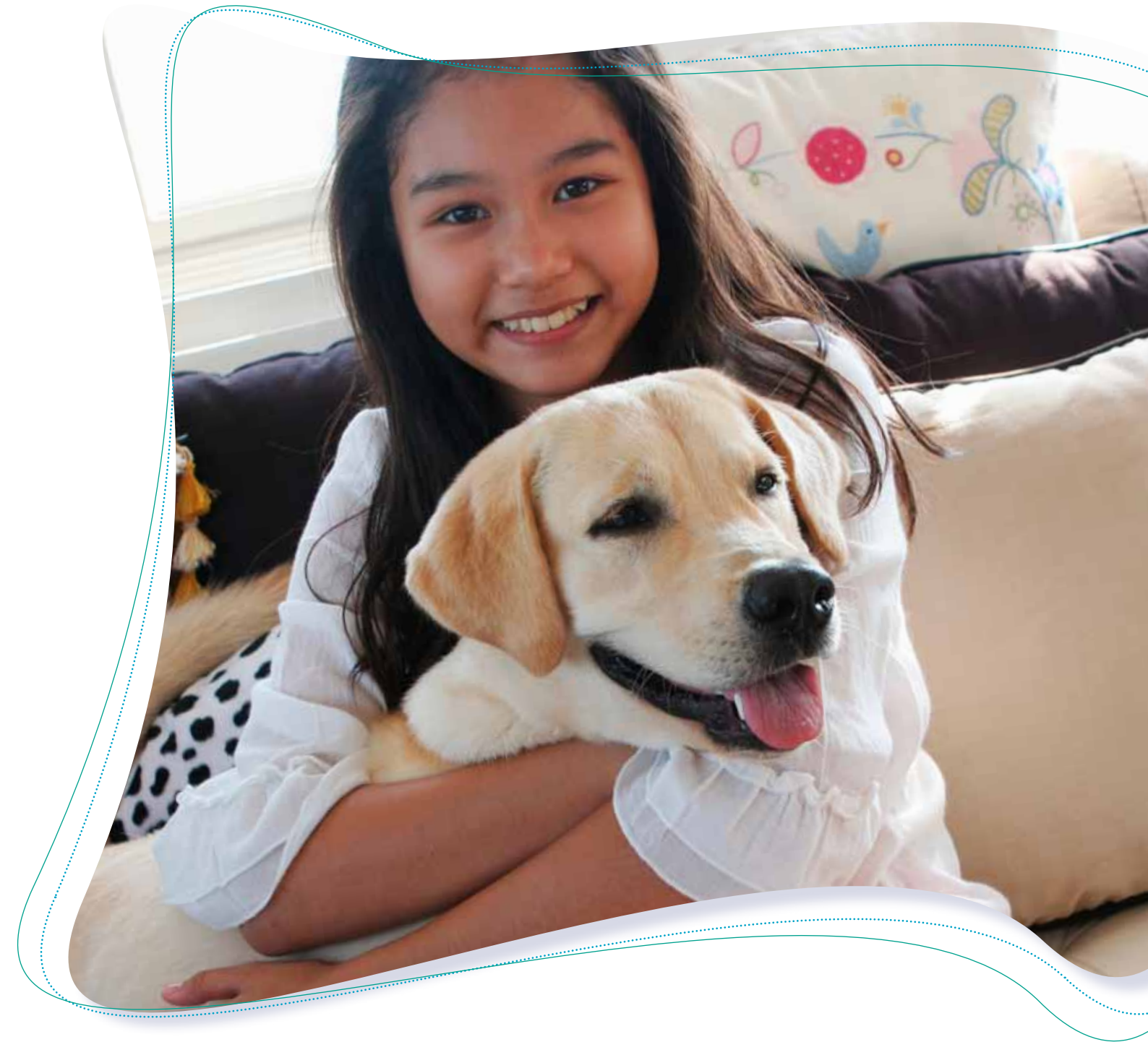
IFAH-Europe representatives addressed a broad range of other conferences throughout the year, including events hosted by the FAO, the OIE and the European Commission. At the FAO's global summit on food security, the collaborative approach to animal health research being spearheaded by the federation through

the European Technology Platform for Global Animal Health (ETPGAH) received widespread support. Elsewhere, the European Commission's conference on bluetongue afforded an opportunity to stress the importance of well-planned, proactive approaches to vaccination in the Member States.

New communication tools

The federation has developed a range of electronic communication tools, including a dedicated website, extranet facilities for members and online newsletters. These offer both internal and external audiences regular updates on developments within IFAH-Europe and on the broader European animal health stage. Improvements introduced during 2008 will offer users a broader range of interactive options, and will simplify internal and external communications.

Our range of print-based communication tools was also expanded during the year, which saw the publication of a new vaccines fact sheet and a Facts & Figures booklet. The former highlights the complex nature of vaccine development and production, underlining the need for stakeholders to plan vaccination strategies in advance. The latter provides readers with a detailed profile of the European animal health industry, including information on research spending, employment levels, the size of the regional market for animal health products and the regulatory framework within which companies work.



Antimicrobials: preserving a valuable resource

“AS LITTLE AS POSSIBLE, AS MUCH AS NECESSARY”. IFAH-EUROPE IS A COMMITTED ADVOCATE OF RESPONSIBLE ANTIMICROBIAL USE. WORKING WITH A RANGE OF FELLOW STAKEHOLDERS, IT HAS DRAWN UP GUIDELINES THAT WILL FOSTER RESPONSIBLE USE OF THESE VALUABLE PRODUCTS, HELPING TO PRESERVE THEIR ROLE IN THE PROTECTION OF ANIMAL HEALTH, ANIMAL WELFARE AND THE PRODUCTION OF SAFE, HIGH QUALITY FOOD.

Accepting the Nobel Prize in 1945 for his discovery of penicillin 17 years earlier, Alexander Fleming cautioned against indiscriminate use of antimicrobials, as this could lead to the development of resistant bacteria. By the time Fleming was honoured, antimicrobials had already begun to transform medical practice. Their impact on veterinary medicine was similarly dramatic, and they remain hugely important to the health and welfare of pets and livestock. They have also played a key role in the development of efficient farming systems able to meet a rapidly growing demand for supplies of safe, high quality food. Resistance, though, has emerged as a threat to the efficacy of some antimicrobials, just as Fleming feared.

In fact, microbiologists understood from an early stage that the development of resistance was inevitable, and that the process sets in

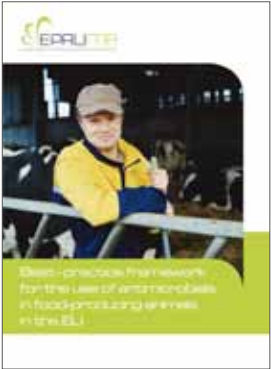
from the moment an antimicrobial is first administered. So it is vital that we use these medicines responsibly. IFAH-Europe and its members have always encouraged the judicious use of antimicrobials in veterinary medicine. Now, working alongside a range of fellow stakeholders, it has gone a step further, drawing up a best-practice framework for the use of antimicrobials in food-producing animals. The document, produced by the European Platform for the Responsible Use of Medicines in Animals (EPRUMA), aims to help maintain the efficacy of veterinary antimicrobials by providing detailed advice on when, how, and under what circumstances they should be administered. The key principle guiding antimicrobial use should be “as little as possible, as much as necessary,” the framework says. Starting on the farm, it encourages good ani-

mal husbandry practices, including health management, biosecurity and vaccination - all of which limit the need for antimicrobial use. Where problems do emerge, it is the role of the veterinarians - using their professional expertise and clinical experience - to advise on the choice of antimicrobial. The animal health industry has brought a number of new antimicrobials to market in recent years, strengthening the therapeutic armoury available to veterinarians and improving the choices available to the profession. Where it is practical to do so, vets should make full use of those choices, ‘rotating’ antimicrobials in order to limit opportunities for the emergence of resistant bacteria, the document says. Record-keeping is mandatory for both farmers and veterinary surgeons in the EU. Historical information, including sensitivity data generated by laboratory testing,

may be very valuable for those planning future treatments. The sensitivity of bacteria to antimicrobials is also monitored closely by regulators, while IFAH-Europe member companies survey the performance of their products on a constant basis. These pharmacovigilance studies show that the vast majority of antimicrobials - some of which have now been used for around 60 years - remain highly efficacious. Adhering to the EPRUMA best-practice framework will help to ensure that they continue to play a key role in veterinary medicine.

EPRUMA and the Best Practice Framework

IFAH-Europe is a founding member of EPRUMA - the European Platform for the Responsible Use of Medicines in Animals. Established in 2005, the platform is a multi-stakeholder initiative comprising representatives of the animal health industry, veterinarians, farmers and feed manufacturers at European level. The European Initiative for Sustainable Development in Agriculture (EISA) is also a member. EPRUMA's best-practice framework for the use of antimicrobials in food-producing animals was drawn up with input from all stakeholders. It lays down core concepts which will foster a coordinated, integrated approach to responsible antimicrobial use across the EU. By doing so, it will contribute to the continued effectiveness of antimicrobials.



Pooling resources to beat disease threats

IFAH-EUROPE IS SPEARHEADING A UNIQUE, MULTIPLE STAKEHOLDER INITIATIVE DESIGNED TO COMBAT THE GROWING CHALLENGE POSED BY INFECTIOUS DISEASES. AND THE FEDERATION IS KEEN TO SEE ITS REGIONAL VISION GO GLOBAL.



"If ever a case demonstrated the need for greater public-private partnership, this is it," IFAH-Europe Managing Director Declan O'Brien told delegates at the European Commission's conference on bluetongue. Forward planning, better preparation and truly coordinated action are essential if we are to deal effectively with the threat posed by new diseases, he said. Rift Valley fever, African swine fever and African horse sickness are among the serious infections that could emulate bluetongue, spreading far beyond their historical boundaries as climate change, environmental pressures and global trade flows affect their distribution, incidence and virulence. Recognising the need for action, IFAH-Europe cofounded and now chairs a unique initiative set up to encourage and accelerate the development of tools to control major animal diseases. The European Technology Platform for Global Animal Health (ETPGAH) aims to identify potential threats, and to combat them by harnessing public and private sector research resources more effectively.

Emanating from the ETPGAH is a four-year project that got underway in 2008, with active support and funding - to the tune of € 1 million - from the European Commission. Known as Disease Control Tools (DISCONTTOOLS), it will identify gaps in the range of products available to treat and control individual pathogens, and will prioritise areas in which research is required. By providing all stakeholders with access to a continuous flow of information on key diseases and research activity, it will also encourage the development of a more coordinated, efficient approach to work in the sector.

Five elements crucial to the success of the DISCONTTOOLS project have been identified. Work on these got under way at meetings held in October 2008, which were attended by participants representing NGOs, European institutions, academia, the veterinary profession and farmers, as well as the animal health industry. Action plans for 2009 were also agreed at the meetings, which represented a highly constructive start for the project.

The ETPGAH continues to attract widespread support - not only at European level, but also on the global stage. A call by IFAH-Europe for the creation of a global version of the initiative was received positively by delegates at the FAO's 2008 global summit on world food security.

"Trans-boundary" diseases were identified by the summit as one of four key obstacles to raising global food output, which experts believe

must increase by 50% in the next 20 years to keep pace with demand. Alongside the OIE, the WHO and the World Bank, the FAO has drawn up plans to address the risks posed by infectious diseases. Encouraging broader collaboration between key stakeholders is among their key objectives. The ETPGAH was identified as a potential partner in a strategic framework document published recently by these four highly influential bodies.



The European Technology Platform for Global Animal Health

Chaired by IFAH-Europe, the ETPGAH is a unique, multiple stakeholder initiative set up to encourage and accelerate the development and distribution of effective tools to control major animal diseases. By pooling expertise and resources, it aims to harness public and private sector research funds more effectively, paving the way for improvements in animal health and welfare, human health, food safety and market access.

With support and funding from the European Commission, the ETPGAH has established Disease Control Tools (DISCONTTOOLS), a four-year programme that will identify gaps in existing disease control coverage and prioritise research targets, helping to deliver key goals laid down by the ETPGAH in its action plan.

Included are working groups on:

- Prioritisation of diseases
- Gap analysis for priority diseases
- Technology evaluation

<http://www.ifaheurope.org/EUPlatform/Platform.htm>

New vaccines, the key to combating bluetongue

HOW VACCINES DEVELOPED BY THE ANIMAL HEALTH INDUSTRY HAVE COME TO THE AID OF EUROPE'S FARMERS AND THEIR STOCK IN THE FACE OF A NEW, RAPIDLY-SPREADING DISEASE THREAT.

A viral disease transmitted to ruminants by midges, bluetongue had caused problems for livestock producers in southern Europe for several years but, until 2006, had never been reported north of the Alps. Its subsequent spread across northern Europe has been dramatic, and the virus has ravaged



“Europe is not immune to animal disease and must be prepared. As we move to our adjusted policy, we have to take animal health strategy seriously and find ways of funding crises.

Neil Parish, MEP (UK, EPP-ED), at the 2008 IFAH-Europe annual conference

sheep and cattle populations in a number of EU Member States. In Germany, where more than 20,000 cases were recorded in 2007, mortality rates on affected holdings reached 41% in sheep and 13% in cattle. Animal deaths are the tip of the iceberg where the financial impact of infection is concerned, however. Bluetongue has a residual effect on milk production and fertility rates in surviving animals, while restrictions imposed on livestock movement and trade in areas affected by the disease inflict a huge economic toll. The strain of the virus that has done the damage - serotype 8, or BTV8 - is not the one that has plagued southern EU Member States in recent years. This means vaccines used to combat bluetongue there are of no help. And yet, just a year after the disease reached its peak, the number of new cases being reported in several countries has fallen back sharply, thanks largely to new vaccines developed by the animal health industry. In Germany, for ex-

ample, only 1,000 new bluetongue cases had been reported by the end of August 2008 - compared with a weekly peak of more than 3,000 in 2007. Developing, registering and commercialising a new vaccine typically takes between six and seven years. But less than two years after its emergence in northern Europe, vaccines against BTV8 were available to the region's livestock producers. That is a testament not only to the expertise and hard work of vaccine manufacturers, but also to the efforts of regulators and policy-makers. Recognising the seriousness of the situation, EU scientific experts prioritised the timely review of safety, efficacy and quality data submitted by manufacturers of the new vaccines. The European Commission also played its part, releasing funds sufficient to meet the bulk of costs associated with emergency vaccination programmes carried out in the Member States. The bluetongue story is not one of unmitigated success, however.

Managing the production and supply of vaccines on a regional scale is a major undertaking that requires months of careful planning. But by January 2008, only one country had placed a firm order for BTV8 vaccines. The European Commission urged other Member States to confirm their requirements at an early stage, but indecision on the part of some national authorities left the industry with little time to respond to late requests for vaccine supply. As a result, livestock in parts of the region were exposed to further damaging infection during the summer months. Events in 2008 provided some important lessons. It is essential that we learn from them, establishing clearer, better-planned strategies to combat the disease. For even as we improve our ability to limit the impact of BTV8, the geographical prevalence of other established serotypes is changing, and new strains of the virus are emerging as potential threats to the health and welfare of European livestock.

Countering the Bluetongue Threat

Bluetongue is a viral disease that is transmitted to livestock by biting midges. It is seasonal in nature, reflecting the prevalence of these parasites in warm summer months. Twenty four distinct serotypes of the virus have been identified. The virulence of individual serotypes - and their impact on affected livestock - varies widely.

Insecticides have been used to help combat the threat of infection, while housing livestock in the evenings or early mornings can also reduce levels of exposure. Eradicating midge 'vectors' is impossible, however, and vaccination is widely acknowledged as the best approach to control of the disease. Vaccines not only reduce clinical signs of infection in livestock, but also prevent circulation - and therefore spread - of the virus.

“Extensive vaccination will contain the disease and reduce its prevalence.”

Androulla Vassiliou, European Commissioner for Health.

“I have long been convinced with bluetongue that the only solution for livestock farmers is vaccination.”

Klaas Johan Osinga, COPA-COGECA animal health and welfare working group.



FUTURE CHALLENGES



› REGULATORY AFFAIRS

Developments in the regulatory sphere during the next two years will have a major bearing on future prospects for the European animal health industry. In what promises to be a critical period for the federation and its members, IFAH-Europe will continue to address improvements in the existing regulatory framework, and will expand on its proposals for regulatory reform.

Creating a true single market for veterinary products

Responding to calls for an overhaul of the regulatory framework governing veterinary products in the EU, the European Commission has pledged to undertake a review of existing legislation in 2010. Over the coming year, IFAH-Europe will maintain close dialogue with the regulatory authorities to further develop proposals for reform, highlighting key areas in which improvements are required to support a sustainable, innovative industry.

The federation's overriding goal is the creation of a true single market for animal health products through the implementation of the "1-1-1 Concept" described earlier.

Improving regulatory efficiency

The existing regulatory framework has imposed unnecessary burdens on regulators and the animal health industry alike. Benchmarking studies undertaken by the federation highlight the impact this has had on the ability of the industry to develop new products. Companies have seen inexorable increases in the time and money required to develop new veterinary products, and in the cost of maintaining existing authorisations. By pursuing improvements in the regulatory framework governing the industry, IFAH-Europe's goal is to achieve reductions of 20% in the time it takes to develop veterinary medicines,

the cost of bringing new products to market, and the expense involved in supporting established product approvals.

The federation will also seek to ensure increased efficiencies are delivered from the revised 'variations regulations' and will make proposals for a more efficient and proportionate pharmacovigilance system.

Protecting innovation

If a reformed regulatory framework is to stimulate innovation over the long term, it must offer improved levels of protection for originator products and the data submitted in support of their registration. IFAH-Europe has developed specific proposals in this regard and will continue to advocate its proposals to regulators in the course of 2009.



› FOOD CHAIN

As it seeks to strengthen existing links with fellow stakeholders and forge relationships with new partners along the food chain, IFAH-Europe will focus in particular on issues such as:

- › Food safety
- › The health and welfare of food-producing animals
- › Combating the threat posed by emerging diseases

Responsible use of veterinary medicines

Working alongside its partners in the initiative, IFAH-Europe will encourage compliance with the EPRUMA best-practice framework governing the use of antimicrobials in food-producing animals, which was published in 2008. Participants in the project will also address the development of the best-practice framework governing the use of other veterinary product types.

Shaping European animal health strategy

An action plan for the implementation of the European Commission's EU animal health strategy was published in the second half of 2008. IFAH-Europe will liaise closely with the Commission's Advisory Group on the Food Chain, Plant and Animal Health, and with committees appointed by the group, which will play a key role in delivering policy goals. Science, innovation and research is one of the policy's four strategic pillars. Here, with the support of the EMEA, the Commission aims to improve incentives for manufacturers to develop new animal medicines and diagnostics.

Strengthening relations with the EFSA

The European Food Safety Authority (EFSA) aims to step up its contribution to the improvement of animal health in Europe, and looks set to play a growing role in the provision of advice on health and welfare

issues. As a key player in these fields, IFAH-Europe looks forward to liaising more closely with the authority in future, and has requested full membership status on the EFSA's consultative stakeholder platform initiative.

Forging links with new partners

As a founding member of the European Food Sustainable Consumption and Production Round Table, a new platform set up by the European food chain partners to promote sustainability policies, IFAH-Europe will look to broaden its relationships with fellow stakeholders. The initiative offers an opportunity to help shape the development of practicable, sustainable approaches to food production in Europe. As well as farmers, the new alliance includes bodies representing the food and drink sector, fertilizer manufacturers and the packaging industry.

› COMMUNICATIONS

Effective delivery of our key messages will be crucial in a year during which we will look to build on recent progress - most notably in the regulatory sphere.

The 2010 review

1 vision: 1 final step to 1 market?

IFAH-Europe's 2009 annual conference, which will be held at the Brussels Renaissance Hotel on 25 June, will be devoted to the upcoming review of EU veterinary medicines legislation. The conference will bring together key opinion leaders and decision-makers for a thorough discussion on regulatory reform. Our aim is to play a part in the development of a common vision for the creation of a regulatory framework that will support innovation, encourage competition and deliver a true single market for veterinary medicines in Europe.

Online communication tools

The upgrade and improvement of IFAH-Europe's online communication tools will continue into 2009. Our goal is to unveil the federation's new website towards the middle of the year. The revamp will improve the visibility and image of the federation, and will offer both internal and external users access to a broader range of online materials.

European Pet Night 2010, we care

The European Pet Night hosted by the European Parliament early in 2009 was judged a resounding success by all of those involved. As a result, it has been decided to make the event an annual fixture. This means

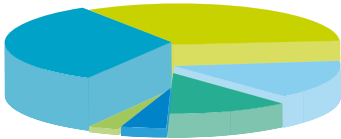
preparations for the 2010 event will begin soon, as we look to build further on an initiative which highlights the strength of the bond that exists between owners and their pets, and the responsibility we have to protect the health and welfare of animals that contribute so much to society.



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 market by region



- North America32,9%
- West Europe32,5%
- Far East15,4%
- Latin America.....11,8%
- East Europe4,6%
- Rest of World2,8%

© Vetnosis Ltd (2009)

CEESA survey of sales statistics (2008 data) - Europe

Animal health products	Subtotals	Total values	%
Vaccines		1.128.569.262,00 €	26,33
Antimicrobials			
➤ Injectable forms	464.696.638,80 €	851.546.692,80 €	19,87
➤ Oral forms	386.850.054,00 €		
Parasiticides			
➤ Endoparasiticides	412.362.739,20 €		
➤ Ectoparasiticides (ears excluded)	621.145.662,00 €		
➤ Endectocides	140.696.196,00 €	1.174.204.597,20 €	27,40
Topical products (skin ecto excluded)		289.922.718,00 €	6,76
Other products		841.495.743,60 €	19,63
Total		4.285.739.013,60 €	100

Countries covered include: AT, BE, CH, CZ, DE, DK, ES, FR, GB, GR, HU, IE, IT, NL, PL, PT, SK.
Source: 14 IFAH-Europe and CEESA Member companies. 20% added for non-participating companies.
CEESA stands for European Animal Health Study Centre.

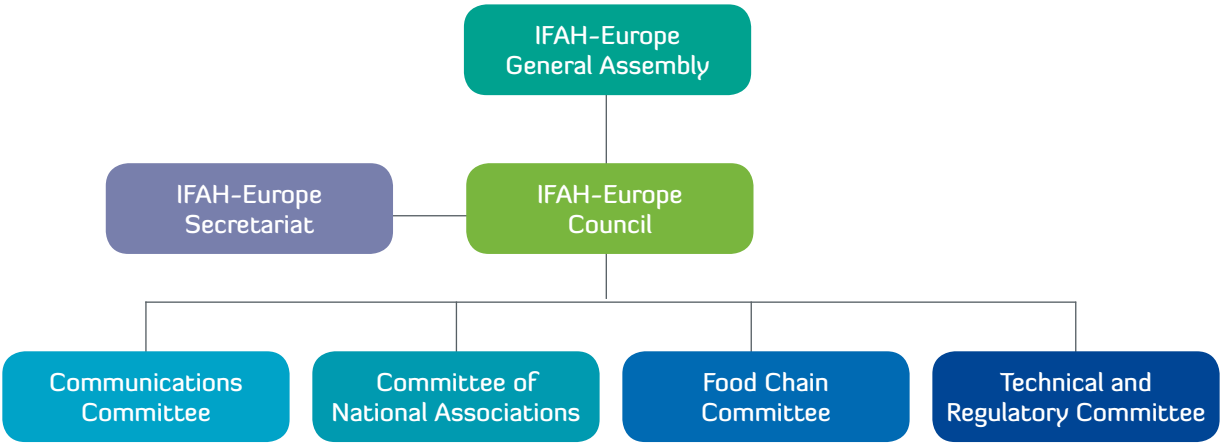
IFAH-EUROPE STRUCTURE

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 is responsible for:
- the ratification of accounts and approval of the budget;
 - the approval of an annual program of activities;
 - appointment and discharge of the members of the Council for having performed their duties;
 - expulsion of members;
 - amendments to the Articles of Association;
 - the dissolution and liquidation of the association.

- Policies agreed by the Council are executed by four key operating committees:
- Technical and Regulatory Committee (TRC)
 - Food Chain Committee (FCC)
 - Committee of National Associations (CNA)
 - Communications Committee (ComCom)

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 Managing Director Declan O'Brien.
IFAH-Europe is a member of IFAH, the federation representing the animal health industry at the global level.



IFAH-Europe Council

CHAIR	Jochen WIEDA, Intervet/Schering-Plough Animal Health
VICE-CHAIRS	Jean-Louis CROSIA, Merial Ltd Martin SCHNEIDEREIT, BfT - Bundesverband für Tiergesundheit (Germany)
TREASURER	Folkert KAMPHUIS, Novartis Animal Health Inc.
MEMBERS	Santiago DE ANDRÉS, VETERINDUSTRIA (Spain) Jean-Louis HUNAUT, SIMV (France) Jens KJÆR, Boehringer Ingelheim Animal Health GmbH Anne Birgitte LUNDHOLT, VIF (Denmark) Philip SKETCHLEY, NOAH (United Kingdom) Wolfgang TREBELS, Bayer Animal Health GmbH

IFAH-Europe Secretariat

Managing Director's office	Declan O'BRIEN, Managing Director Florentina PARDO, Executive Assistant
Technical affairs	Rick CLAYTON, Technical Director Sylvie MEILLERAIS, Technical Project Manager Yara ANTONISSEN, Technical Assistant Marie-Hélène DELVAUX, Executive Secretary
Communications	Kim HARDIE, Communications Director Myriam ALCAIN, Communications Manager Laurence LECLERCQ, External Communications Officer Pamela BARCELLONA, Senior Secretary
Administration and IT	Linda MOORTGAT, Administration Manager and IT Coordinator

Corporate Members

- Alpharma Animal Health Division
- Bayer HealthCare AG, Animal Health Division
- 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
- Vetoquinol
- Virbac SA

National Member Associations

Belgium	Pharma.be Association Générale de l'Industrie du Médicament
Denmark	VIF Veterinaermedicinsk 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
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 OF ACRONYMS

AI	Avian influenza
CAHP	Community Animal Health Policy
COPA-COGECA	European Farmers and Agri-Cooperatives
CVMP	EMA Committee for Medicinal Products for Veterinary Use
DCP	Decentralised Procedure
DG	European Commission Directorate General
DISCONTOLS	Disease Control Tools
EA FN	European Agri-Food Network
EC	European Commission
EFSA	European Food Safety Authority
EISA	European Initiative for Sustainable Development in Agriculture
EMA	European Medicines Agency
EMIDA	Emerging Infectious Diseases of Animals
EP	European Parliament
EPAA	European Partnership for Alternative Approaches to Animal Testing
EPRUMA	European Platform for the Responsible Use of Medicines in Animals
ETPGAH	European Technology Platform for Global Animal Health
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FVE	Federation of Veterinarians of Europe
GL	Guideline
GLOBALGAP	Voluntary certification body representing retailers of agricultural produce
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
IWP	Immunologicals Working Party
MA	Marketing Authorisation
MRL	Maximum Residue Limit
MRP	Mutual Recognition Procedure
MRSA	Methicillin-resistant staphylococcus aureus
NGO	Non-Governmental Organisation
OIE	World Organisation for Animal Health
QWP	Quality Working Party
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organisation

International Federation for Animal Health-Europe AISBL

Rue Defacqz, 1
1000 Brussels
Belgium

T +32 (0)2 543 7560

F +32 (0)2 537 0049

info@ifaeurope.org

www.ifaeurope.org



Mixed Sources

Product group from well-managed
forests and other controlled sources
www.fsc.org Cert no. SGS-COC-004540
© 1996 Forest Stewardship Council