



# ANNUAL REPORT 2009



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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 across the region. These associations comprise local businesses, small and medium-sized enterprises (SMEs) 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 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, 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

Having launched the "1-1-1 Concept" in 2008, preparation for the revision of the veterinary legislation was a major theme in 2009. The 1-1-1 Concept became our major platform for communicating our views on the revision of the veterinary Directive which featured strongly at our conference in June. Simply put, we have the vision of a true single market where we submit one dossier, which is subjected to one assessment leading to one decision on the marketing authorisation - the 1-1-1 Concept.



Declan O'Brien

We foresee one licensing procedure in the future available to all products. It may be appreciated that this represents tremendous simplification which would increase medicines availability across the EU. In addition, if a product has been licensed according to the Directive, it should be available across the EU - a single market! The animals can be moved, the food can be moved, why not the medicines? After all, a cow is a cow whether in Finland or Greece!

Whilst Bluetongue caused us great concern in 2008, the impact of the disease in 2009 was much less damaging. We believe that vaccination made a tremendous difference and allowed us, collectively, to get on top of this disease. However, we should maintain our guard in case this disease flares up again in the future. Linked to this, we were very pleased with the developments in the area of determining future needs for antigen, diagnostic and vaccine banks. We were happy to contribute to a work package under the Animal Health Strategy where the future disease threats were debated and where a detailed paper analysing the threats and making recommendations for antigen, diagnostic and vaccine banks were discussed. We expect this paper to make good progress in 2010, for the advancement of plans to put the appropriate banks in place and for the authorities to be best equipped to face future disease challenges - including different strains of Bluetongue.



Jochen Wieda

The use of antibiotics continued to be a topic of considerable discussion in 2009. We were and are very supportive of an initiative by the European Medicines Agency (EMA) to launch a system for gathering data on volume use across the EU. Whilst various systems exist to gather such data, the initiative of the EMA will ensure standardisation of data collection at the Member State level, facilitating the creation of an overall EU picture. Such information is important to monitor use over time and to place all parties in a position of good information concerning trends with the possibility to influence use as may be necessary over time.

The DISCONTTOOLS project (prioritisation of diseases for research purposes) continued its development during 2009. 50 diseases are within its scope and Expert Groups were established to assist in generating stakeholder agreement on the priority research needs in terms of developing control tools such as diagnostics and/or vaccines and/or pharmaceuticals. This work will continue into 2010 when we expect to be in a position to publish the results on the DISCONTTOOLS website. This work should lead to the more rapid development of critical tools enabling us to control diseases more effectively.

We wish to thank all those who have contributed their time so generously to the DISCONTTOOLS project. We clearly all share the same view: it is in the public interest to reduce the disease burden in animals.

We wish to thank our member companies and trade associations who contributed so much to achieving our goals. We also wish to thank the secretariat for their enthusiastic commitment to the work of IFAH-Europe. As ever, we look forward to a busy year in 2010 where we finish our work on some topics, continue our work on others and engage with new opportunities and challenges in accordance with our strategic priorities.

**Jochen Wieda**  
Chairman of the IFAH-Europe Council

**Declan O'Brien**  
Managing Director, IFAH-Europe

# A MESSAGE

from John Dalli,  
European Commissioner for  
Health and Consumer Policy



*John Dalli*

Having served as a government minister for over 20 years in his native Malta, Europe's new Commissioner for Health and Consumer Policy brings a wealth of experience to a portfolio that has been broadened to include responsibility for human pharmaceuticals and veterinary medicinal products.

Before taking office as Commissioner for Health and Consumer Policy I made a pledge to put patients and consumers first. The health and wellbeing of European citizens will be at the forefront of all that I do during the next five years.

Many events in recent years have underlined the interdependent nature of human and animal health. For that reason I am pleased to take on a portfolio that now covers all sides of the health equation.

The health of Europe's patients and consumers also depends on the availability of affordable and safe food. Where animal produce is concerned, this means livestock must be reared and kept healthy with the best farming practices and also through the responsible administration of veterinary medicinal products that prevent and control disease, whenever appropriate. Those products must be the subject of rigorous scientific scrutiny.

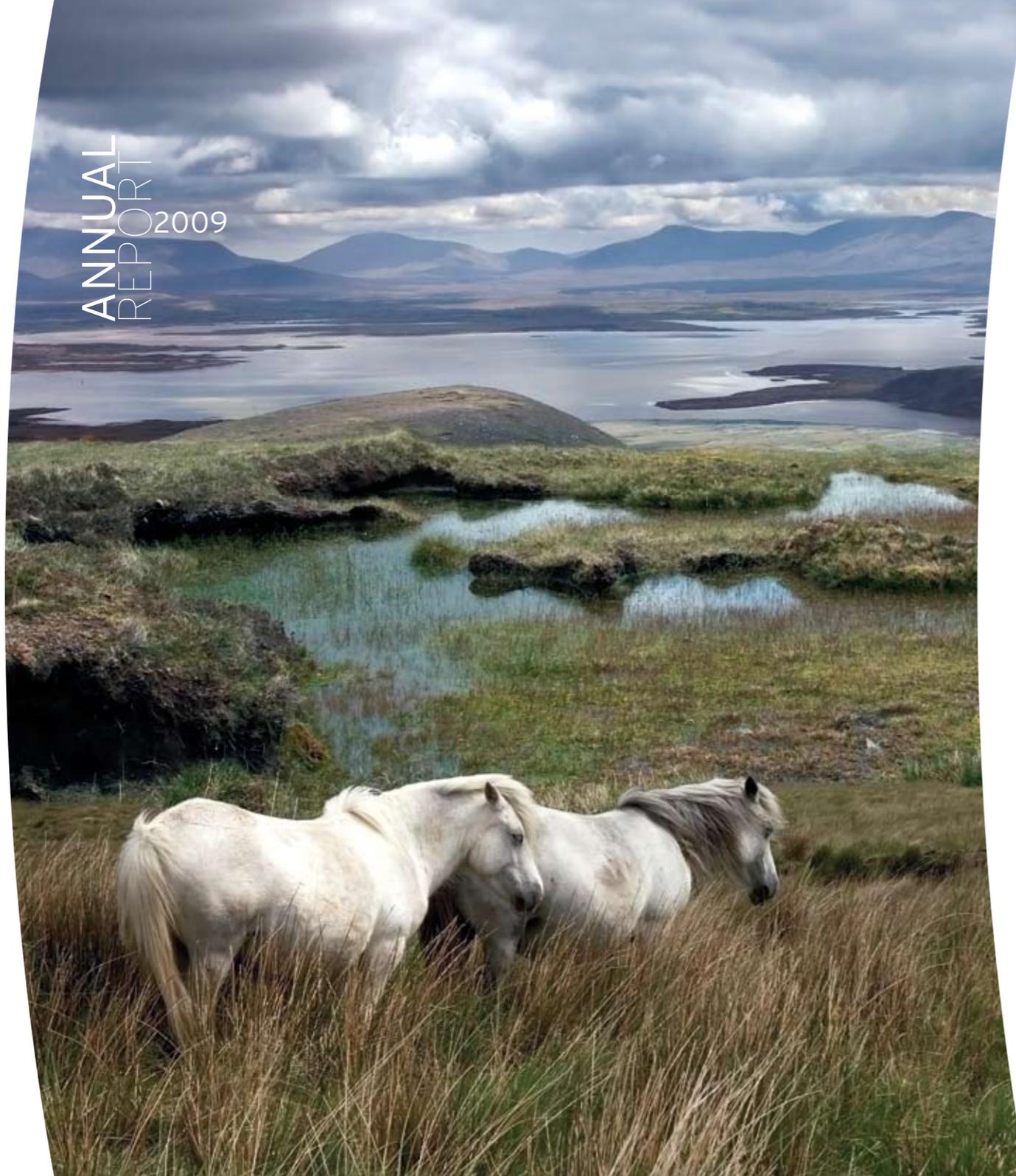
I am a firm believer in the value of innovation, which holds the key to improve the health and wellbeing of patients, consumers and animals alike. The opportunities it offers must be balanced against the risks it may present but sound scientific information and advice must form the basis of the decisions we make where new technologies are concerned.

The Commission has embarked on a review of existing legislation governing veterinary medicines. Our aim is the creation of a regulatory framework that safeguards the health of consumers and the environment and that enables the efficient development and authorisation of veterinary medicinal products, thus providing veterinarians access to more and better medicines. This activity is also in line with our Better Regulation initiative where we wish to remove unnecessary administrative burdens. In the review the possibilities of an adapted system (built on the specificities of the animal health system) will be explored.

Promoting innovation is also central to the new EU Animal Health Strategy, under which the creation of public-private partnerships such as the European Technology Platform for Global Animal Health will help make best use of the knowledge and expertise required to deliver new and improved products. The 7th Research Framework Programme, which runs parallel to the Animal Health Strategy, will be an important tool to support collaborative research into animal health issues.

Constructive dialogue and co-operation are essential to the success of any initiative involving a broad range of stakeholders. IFAH-Europe is a valued partner for the Commission in this respect, and I look forward to working with you towards our shared objectives: protecting and promoting the health of consumers and animals across Europe.

**John Dalli**  
May 2010



# ACTIVITIES, achievements and future goals

IFAH-Europe focuses its resources  
on three strategic areas:

- FOOD CHAIN
- REGULATORY AFFAIRS
- COMMUNICATIONS

Our activities, achievements and future goals in each of these three areas are reviewed in the following pages.

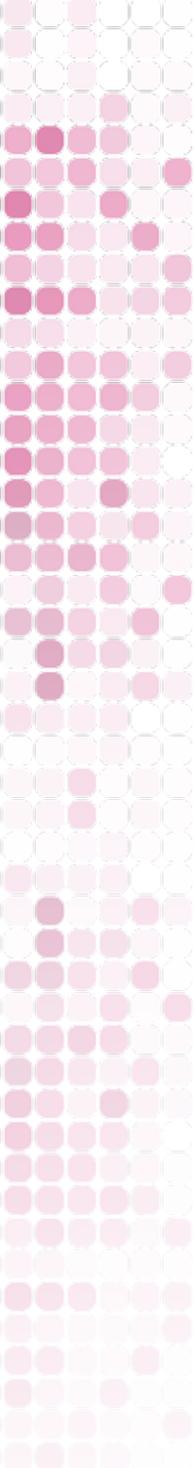


# FOOD CHAIN

Healthy animals  
feed the world

Animal health products are essential to the health and welfare of food-producing animals. By protecting them from disease and enabling the effective treatment of sick animals, they help to ensure the availability of safe, quality food for consumers across Europe and beyond.

By keeping livestock healthy, animal health products benefit public health, preventing the spread of infections that can affect humans as well as animals. By minimising the financial impact of disease, they also support an efficient, sustainable livestock production sector that provides jobs for nine million European farmers. IFAH-Europe works alongside partners in the food chain to ensure that its products are used responsibly, maximising their benefits to both producers and consumers.



## Supporting sustainable food production

IFAH-Europe underlined its support for sustainable approaches to food production in 2009 when, alongside eight other organisations, it became a founder member of the European Food Sustainable Consumption and Production Round Table.

Bringing together all links in the food chain - from farmers and their suppliers, through agricultural traders to food and drink producers and packaging organisations - this unique coalition is co-chaired by the European Commission, and enjoys the support of both the UN's Environment Programme (UNEP) and the European Environment Agency (EEA). Its initial aim is to establish scientifically reliable environmental assessment methods for food and drink products.

The round table, which is encouraging applications for membership by organisations representing consumers and the environment, will also promote improved communication along the food chain, enabling consumers to make fully-informed choices. Membership has already grown rapidly, with 23 organisations represented by the end of 2009.

## The food security challenge

IFAH-Europe will bring together European opinion leaders, decision-makers and food-chain stakeholders at its annual conference in 2010, which will highlight the role played by animal health in our efforts to feed a growing global population. Delegates will be invited to discuss the food security challenge, strategies for the optimal use of resources in food production, and its impact on the environment.

The event will provide an opportunity for the federation to highlight the role played by animal health products in safeguarding the health and welfare of production animals, and the inextricable links that exist between animal health, public health and food safety. The need for an efficient regulatory system - enforcing strict safety and quality standards whilst ensuring the continued availability of safe and effective medicines - will also be discussed, alongside the importance of responsible use and best-practice initiatives.

## Responsible use of animal medicines

IFAH-Europe is joining forces with partner organisations to ensure that animal health products are used responsibly. This not only protects animals, consumers and the environment, but also ensures the current and future efficacy of these valuable tools.



The federation is a founding member of the European Platform for the Responsible Use of Medicines in Animals (EPRUMA), which provides a forum for discussion between manufacturers and those who administer the products. The EPRUMA platform has produced a growing range of tools designed to foster a greater understanding of animal health products, and to ensure that they are used in accordance with best practice.

EPRUMA continues to attract interest from a growing range of partners. Existing members, meanwhile, are determined to introduce the EPRUMA initiative to new audiences. To that end, a dedicated website for the platform is being developed, and will go online in 2010. Best practice guidelines for the use of antimicrobials in food-producing animals, published in 2008, are also being translated into a growing range of languages, rendering them accessible to vets and farmers across Europe.

### The partners of the European Platform for the Responsible Use of Medicines in Animals (EPRUMA) are:

- COPA-COGECA: European Farmers and Agri-Cooperatives (<http://www.copa-cogeca.eu>)
- EISA: European Initiative for Sustainable Development in Agriculture (<http://www.sustainable-agriculture.org>)
- FECAVA: Federation of European Companion Animal Veterinary Associations (<http://www.fecava.org>)
- FEFAC: European Feed Manufacturers' Federation (<http://www.fefac.org>)
- FESASS: European Federation for Animal Health and Sanitary Security ([http://www.adt.de/fesass\\_en.html](http://www.adt.de/fesass_en.html))
- FVE: Federation of Veterinarians of Europe (<http://www.fve.org>)
- IFAH-Europe: International Federation for Animal Health-Europe (<http://www.ifaheurope.org>)

## Commitment to electronic data recording



*Datamatrix code on the packaging of an Italian veterinary medicine*

IFAH-Europe member companies have been at the forefront of an industry-led initiative that has involved the introduction of bar codes on product packaging. This enables the electronic capture of data including batch numbers and product expiry dates at all stages of the distribution chain.

Almost 90% of products being manufactured for use in Europe now carry these bar codes. That figure will rise rapidly towards 100% as stocks previously in the distribution chain are used up. The initiative will facilitate distributors, retailers, veterinary surgeons and farmers in complying with record-keeping requirements.

The 2D barcodes introduced by manufacturers use the data-matrix identification standard, which allows the verification of product details with a single scan. The initiative, which has been praised by both regulators and distribution-chain partners, has also been monitored with interest by other industrial sectors - including European pharmaceutical manufacturers, which began piloting a similar system in 2009.

## Food safety



IFAH-Europe continued to build on its relationship with the European Food Safety Authority (EFSA) through 2009, playing an active role in its stakeholder consultation platform. In its 2009-13 strategic plan, the authority confirmed its desire to play a broader role in the provision of advice on animal health and welfare issues. As a key player in these fields, IFAH-Europe looks forward to liaising closely with EFSA. Accordingly, the federation will continue to press for full-member status on the authority's stakeholder consultation platform.

# ANTIBIOTICS

key to a healthy,  
well-fed world

Antimicrobials will play a key role in maintaining animal health, public health and the production of safe, quality protein to feed a growing global population. So let's make sure we preserve this valuable resource.

Whilst vaccines have transformed animal health for both livestock and pets - like human populations - animals are still prone to a range of infections that require therapeutic intervention.

Antibiotics are a key therapeutic tool for veterinary surgeons. Without them, sick animals would continue to suffer, and infections would spread through a herd of flock. Public health would also be put at risk, with zoonotic infections transferred from animals to humans, while losses from disease would affect both the economic viability of livestock farming and the production of safe, healthy animal protein.

With the global population set to exceed nine billion by the middle of this century, the FAO has calculated that food protein

production will have to increase by 70% over the next 40 years to meet demand. Meat production alone will need to rise by 200 million tonnes. At a global level, animal diseases currently reduce livestock output by 20%. Clearly, we can ill afford an increase in that figure, and must make every effort to ensure that it declines.

As a research-driven sector, the animal health industry continues to deliver novel products that will help to reduce the incidence and impact of infectious disease. It is vital that we also make the most of existing resources, including antibiotics, however. To that end, IFAH-Europe has been working alongside vets and farmers to ensure that its products are used responsibly.

*“As little as possible; as much as necessary”* is the message at the heart of a Best Practice Framework for the use of antimicrobials in food-producing animals, which was developed by the federation and fellow stakeholders working together through the European Platform for the Responsible Use of Medicines in Animals (EPRUMA). The document underlines the need for good animal husbandry practices, including health management, biosecurity and vaccination - all of which limit the need for therapeutic intervention. Where problems do emerge, veterinary surgeons must use their professional expertise and clinical experience to advise on the choice of antimicrobial to be used.

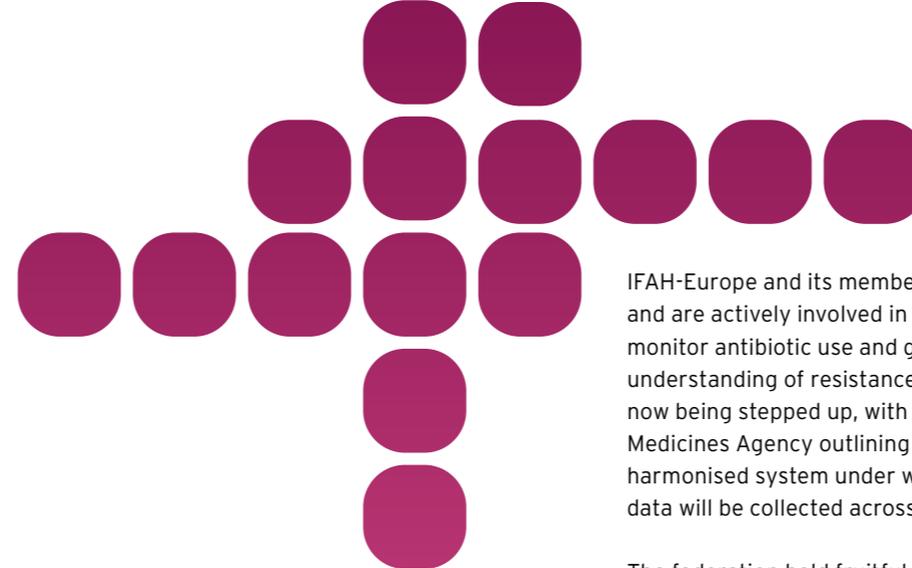
Resistance is a natural process, which is set in train from the moment an antibiotic is first administered. Indiscriminate use would encourage the development of resistant microbial populations which could ultimately limit the efficacy of a product. So it is a testament to the good practice of Europe’s vets and farmers that many antibiotics used for more than half a century remain highly effective today.

Resistance has emerged as a threat to the efficacy of some antibiotics used widely in human medicine, however. This has prompted efforts to clamp down on indiscriminate prescribing by physicians,

but has also triggered a global debate on antibiotic resistance and how best to preserve the efficacy of other key products. In the course of that debate, some have claimed that the use of antibiotics in animals has contributed to problems encountered in the human health sector.

We still have much to learn about antibiotic resistance - including the extent of current problems, factors that have contributed to the emergence of resistance and the exact mechanisms involved in the process. As a result, the debate has been conducted largely in the absence of hard scientific facts or on the basis of evidence that has subsequently proved to be erroneous. This has led in some quarters to calls for a complete ban on the use of certain antibiotics in animals.

Thanks largely to the responsible approach of the World Organisation for Animal Health (OIE), such precipitous action has been avoided. Instead, attention has turned to the job of gathering concrete data on levels of antibiotic use, the way in which individual products are used, the extent to which resistance exists, and the factors that have contributed to the emergence of resistant bacteria.



IFAH-Europe and its members support - and are actively involved in - efforts to monitor antibiotic use and gain a fuller understanding of resistance. These are now being stepped up, with the European Medicines Agency outlining plans for a harmonised system under which volume data will be collected across the EU.

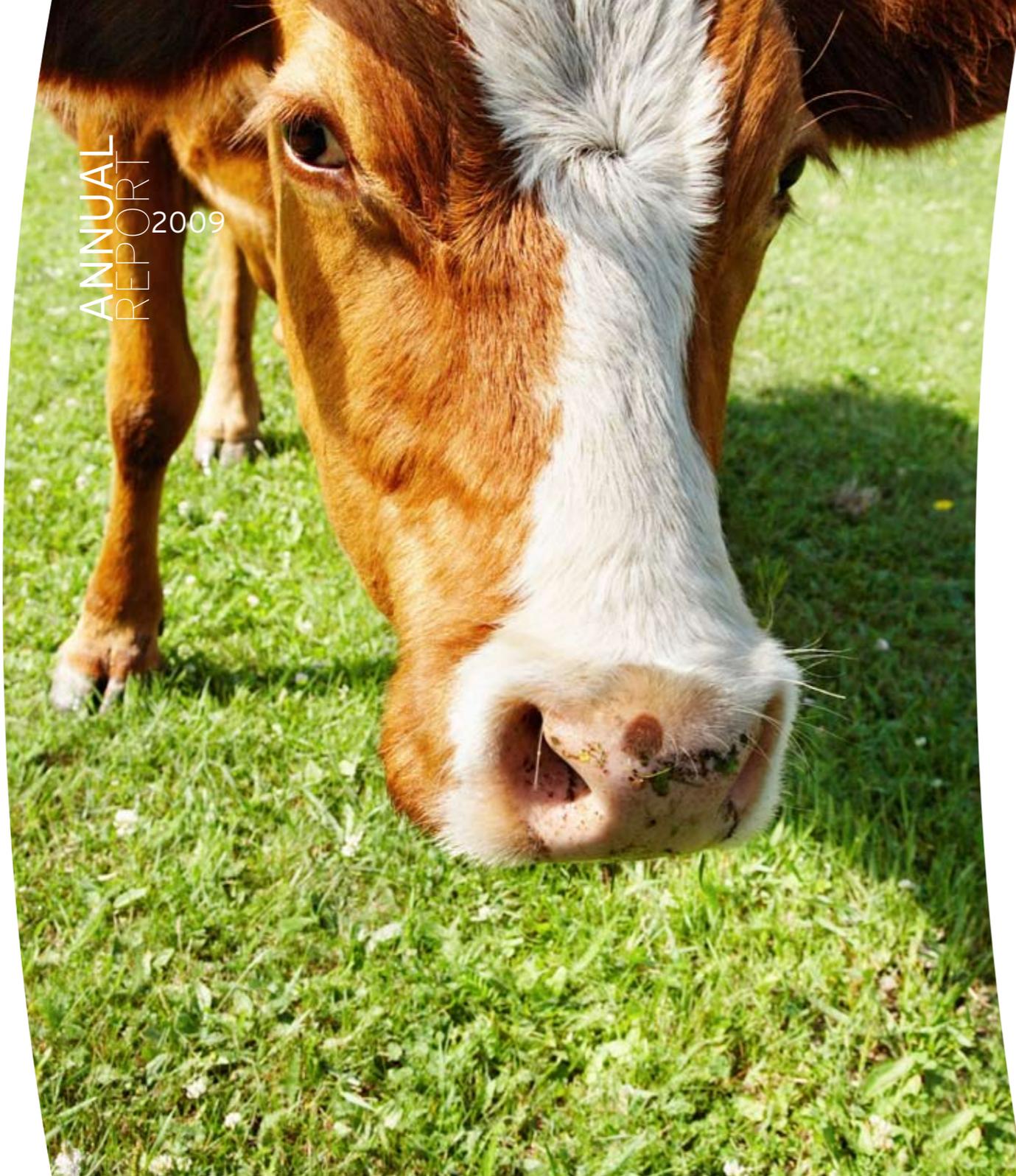
The federation held fruitful discussions with the European Medicines Agency (EMA) at a meeting on antibiotic volume collection and surveillance systems in November 2009. As the EMA and other European agencies prepare to establish more robust data-collection schemes, IFAH-Europe has submitted its own review of existing programmes. The document highlights discrepancies between existing systems, and the need to agree on a harmonised approach to surveys.

Only when data can be compared directly, and when key definitions have been agreed, will it be possible to interpret information accurately and implement sound, science-based strategies to combat resistance. A full understanding of the factors that influence usage trends over time and between individual countries is also essential. Changes in volume may be affected by a range of factors, including disease patterns, animal numbers, climate, and

prescribing trends - all of which must be factored into the interpretation of survey results.

IFAH-Europe is an enthusiastic supporter of moves to generate more and better data about antibiotics. From a practical viewpoint, harmonised data will enable the federation and its member companies to provide more feedback to vets and farmers. Importantly, the availability of comprehensive, comparable data will also provide the platform for a more informed debate on the resistance issue.

More will also be learnt about the contribution of antibiotics to animal health and welfare, public health and food safety. Broader recognition of their role will help to create a more certain environment for manufacturers. This will give them the confidence to invest in the development of new antibiotics, further enhancing the range of therapeutic tools available to those charged with the protection of animal health and welfare.



# STEALING A MARCH

## on major disease threats

A unique initiative being co-ordinated by IFAH-Europe promises to deliver new tools to combat the growing threat posed by infectious disease.

The disastrous foot-and-mouth disease (FMD) outbreak that hit the UK in 2001 has triggered a fundamental change in EU approaches to disease control. The epidemic, which also affected several other member states, led to the slaughter of 10 million cattle and sheep across Europe, and cost the UK economy alone an estimated £8 billion.

Studies undertaken in the aftermath of the 2001 outbreak confirmed that a preventative approach would have been more advantageous - not just economically, but also in terms of animal welfare. More recent research by the World Organisation for Animal Health (OIE) reached similar conclusions, while the change of approach in Europe was underlined when the EU's new animal health strategy, which runs from 2007 to 2013, was published under the heading: "Prevention is Better Than Cure."

Disease poses a threat not only to the health and welfare of animals, but also to human health and food production. The OIE has estimated that disease reduces global livestock output by 20%, for example, while research shows that 60% of emerging infectious diseases can affect humans as well as animals.

Effective diagnostics, vaccines and pharmaceuticals play a vital role in the prevention and control of these infections. With new diseases emerging, and established infections spreading into new areas, staying one step ahead of the threat they pose is a growing challenge. But 2010 marks the halfway point for a unique four-year project that could pave the way for new, more efficient and effective approaches to the development of products to combat major disease threats.

# The DISCONTTOOLS initiative



Co-ordinated by IFAH-Europe, the DISease CONTROL TOOLS (DISCONTTOOLS) initiative is a programme that pools expert knowledge from the public and private sectors across

Europe and beyond. It has identified 50 diseases that pose particular threats. These will be 'scored' according to the magnitude of the danger they present. Gaps in our knowledge of and ability to control individual diseases will also be identified, so that research efforts can be channelled into the development of new or improved diagnostics, vaccines and pharmaceutical treatments.

Co-ordinating several hundred international experts and harnessing their diverse skills effectively is a challenge in itself, but significant progress has already been achieved. Expert teams for each disease have been established, and work in early 2010 should pave the way for the appearance of fully-scored information for around a dozen of these on the DISCONTTOOLS website during the second half of 2010.

That information will be freely available, helping to point not only scientists but also those holding the animal health research purse-strings towards areas of particular need. Importantly, the interactive nature of the DISCONTTOOLS database will also allow experts from around the globe to exchange information on major animal diseases.

## A predictive, proactive approach

The federation is proud of the speed with which its member companies have reacted to the recent emergence of new threats to both animal populations and public health in Europe. A prominent example is the spread of new bluetongue virus strains, which briefly threatened to wreak havoc in the region's sheep production sector. Less than two years after bluetongue began its rapid northerly spread, vaccines targeting those strains had been developed, tested and made available to farmers across the region.

But as more new diseases emerge, and as established pathogens spread into previously unaffected areas, IFAH-Europe believes the time has come for a change of approach where disease control strategies are concerned. A predictive, proactive approach is the only way to counter the risk posed by established, emerging and future disease threats. And while predicting future developments poses a major challenge, it is one that must be taken on, since to take no action would be to invite failure.

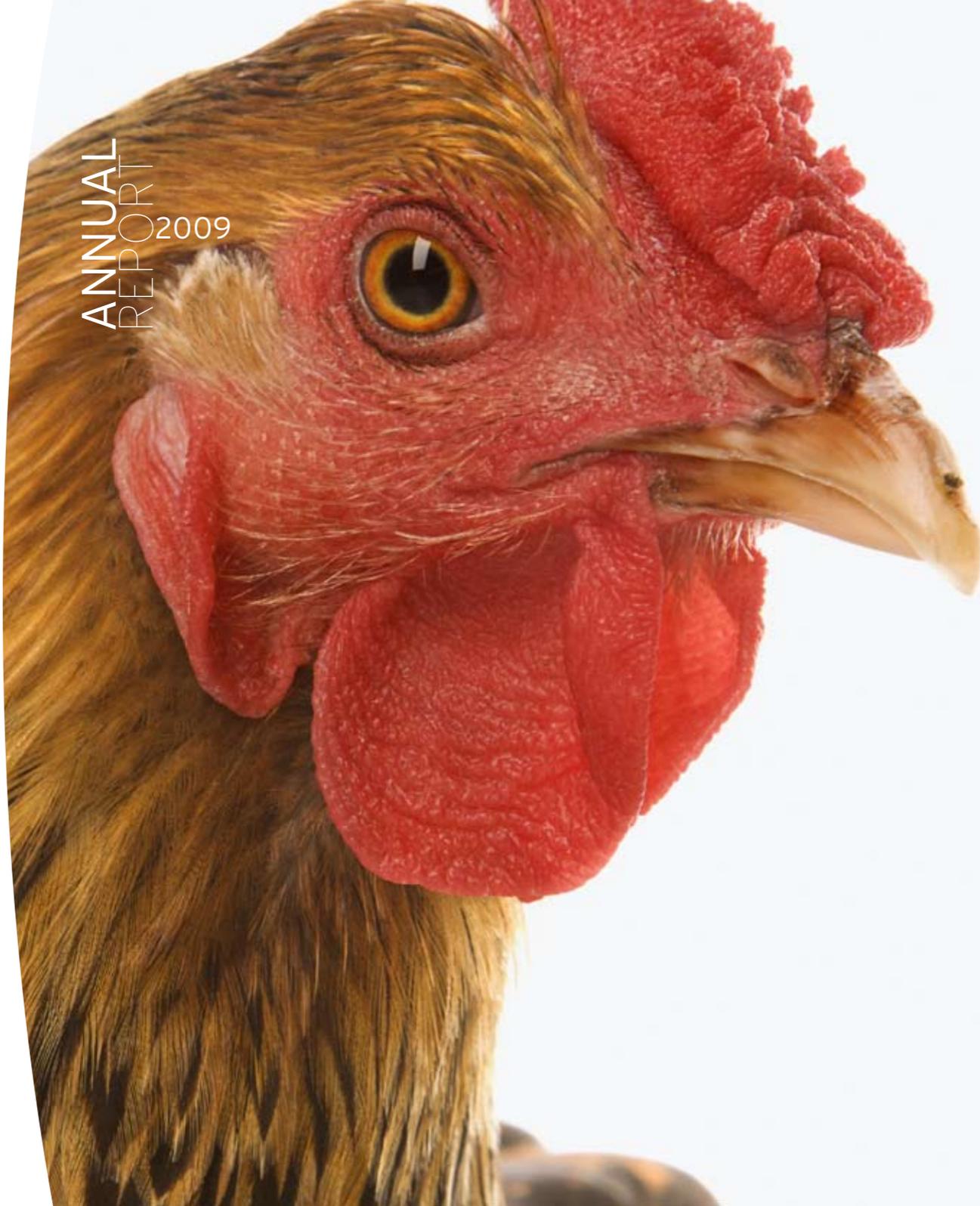
DISCONTTOOLS teams met with representatives from a range of research-driven industries in December last year to discuss the best ways to unlock innovation. The meeting was a valuable exercise, which confirmed the need to build on what has been achieved to date.

African horse sickness (AHS) is among the diseases deemed most likely to follow in bluetongue's path. And with infection resulting in close to 100% mortality, it has the potential to devastate Europe's equine populations. Not surprisingly, AHS is among the 50 DISCONTTOOLS targets, for while vaccines against the disease are available elsewhere, more work will be required to develop products suitable for use in Europe.

Funding for the initiative, which was secured under the EU's 7<sup>th</sup> Research Framework, currently covers the period to 2012, but must be extended if we are to reap the full rewards of the huge effort that has gone into the venture. IFAH-Europe is also keen to make sure EU authorities recognise the need for private companies to generate an economic return on investments in the development of products for the prevention and control of potential disease threats.

Tenders for the supply of "medicine banks" containing antigens and vaccines against FMD and some other key diseases already provide manufacturers with

the necessary economic return on their investment in those products. And the federation is encouraged by the European Commission's decision to review its medicine bank needs in light of the latest information on current and emerging disease threats in the region. This process needs to be repeated on a regular basis to ensure we are prepared for the most imminent threats. Of course, the best outcome would be that we never have to use those banks because the threat never materialises. But being prepared will bring tremendous benefits for animal health and welfare, human health and the European economy.



# REGULATORY AFFAIRS

Efficient regulation  
for an optimal market

IFAH-Europe has campaigned tirelessly for the establishment of a predictable, proportionate and efficient regulatory framework governing veterinary medicines in the EU. Its efforts have been instrumental in securing welcome reforms over the past decade, and further progress was achieved in several key areas during 2009.

Nevertheless, the existing regulatory framework remains incapable of delivering the 'single European market' that was envisaged by the EU's founding fathers, and that was a declared aim of the first harmonised veterinary legislation ratified more than a quarter of a century ago. Accordingly, while it continues to address a range of other regulatory issues, IFAH-Europe has launched a final push for the creation of a true single market for veterinary medicines in the EU.

## The 2010 regulatory review

Responding to issues raised by both regulators and manufacturers, the European Commission will undertake a fundamental review of the regulatory framework governing veterinary medicines in the EU during 2010. Proposed improvements to existing legislation will be tabled by the Commission in 2011.

IFAH-Europe supports the creation of a system under which a single dossier, subjected to a single assessment, would result in a single, unified decision on the registration of all products in the 27 EU member countries (the "1-1-1 Concept"). It is an approach that has won widespread support - as evidenced by the content of a 'reflection paper' released by the heads of Europe's national medicines agencies (HMA) in 2009.

The federation confirmed its support for most ideas contained in the HMA document, but stressed the importance of simplifying regulatory procedures. It also highlighted the need to stimulate innovation by providing adequate protection for data submitted in support of original products.

Before it issues concrete proposals for change, the Commission must carry out a comprehensive impact assessment. IFAH-Europe is working to transform its "1-1-1 Concept" into detailed proposals for a practical registration system, which will be contained in its submission to the Commission.



## Data requirements

Through its team of technical experts, IFAH-Europe is involved closely in discussions on the development and implementation of guidelines and monographs outlining data requirements for veterinary medicines in the EU. The federation provided input on no less than 50 official documents released for public consultation in 2009.

Among the most significant developments was the publication of a revised framework for data requirements that has been annexed to legislation governing the marketing authorisation of veterinary medicines. Elsewhere, a dedicated bioequivalence working group represented the industry in discussions with regulators on this key issue. Guidance aimed at controlling the development of antibiotic resistance was another focus of activity during the year, while the federation contributed to the transposition of the new 'Variations' rules into detailed guidelines.

IFAH-Europe was also involved in a public consultation on the European Medicines Agency's transparency policy, while the federation's experts contributed to revised guidance on rules outlining the pharmacovigilance obligations of both the industry and the authorities. IFAH-Europe was also a major contributor to a European Commission impact assessment designed to map future approaches to the regulation of medicated feed products. The efforts of the federation's In-Feed Working Group should rule out the introduction of unnecessarily restrictive regulations in this field.

## Efficient regulation

IFAH-Europe continues to work with the authorities on a range of other projects designed to improve the efficiency of European regulatory systems. These include the introduction of electronic submission procedures, and the adoption of improved packaging and labelling requirements. Increases in the efficiency of pharmacovigilance systems are also being pursued through the establishment of a synchronised approach to the submission and assessment of post-marketing surveillance (PMS) reports.

To encourage the move towards paperless electronic submissions, the EU's electronic submission guideline was updated in 2009, and work on e-application forms began. Elsewhere, a pilot project involving the synchronised submission and assessment of PMS reports has been extended, and will involve more participants.



# Regulatory harmonisation

Many of IFAH-Europe's corporate members are global businesses, and the federation is an active partner in moves to harmonise technical standards governing veterinary medicines at international as well as regional level. These are being pursued under the VICH initiative, which involves regulators and manufacturers from Europe, the USA and Japan.

Canada, Australia and New Zealand are already observers of the tri-partite initiative, but those involved are keen to reach a broader geographical audience. IFAH-Europe is contributing to the development of a VICH Outreach plan, which will outline the objectives, scope and achievements of the programme to non-member countries.

The federation supported the adoption of new VICH topics in the areas of bioequivalence, target animal batch safety testing and rabies vaccine potency testing. Its role as a key VICH partner will be underlined in 2010, when it hosts the initiative's fourth international public conference, to be held at the OIE's Paris headquarters in June 2010.



# A VISION FOR THE FUTURE

of veterinary medicines regulation

EU legislation governing veterinary medicines is under review for the second time in a decade, with the European Commission due to table proposals for further reform in 2011. What's wrong with the existing system - and how might current problems be tackled?

As another damp Irish spring approaches, veterinary surgeons will be advising dairy farmers to make sure their herds are protected against the parasites that thrive on the country's lush green pastures.

But consider this: while purchasing a parasite control for use in his milking cows will pose no problems for a farmer in County Tyrone, his neighbour across the border in Donegal may struggle to buy a product licensed to do the job. For while Tyrone is part of the United Kingdom, Donegal is part of the Irish Republic. And though the cows that graze those adjacent pastures - and the milk they produce - can move freely between EU member states, the veterinary medicines required to keep them healthy cannot.

Farmed in such close proximity, animals on the two holdings will encounter similar challenges to their health. The two neighbours may well call the same vet when expert intervention is required. And yet there will be times when that practitioner may prescribe a medicine to treat a problem on one farm, but would be breaking the law if he prescribed the same product for identical use on the other.

More than half a century after the Treaty of Rome laid the foundations for the free movement of people, goods, services and capital across Europe, a single market for veterinary medicines has still to be created. The situation faced by neighbouring dairy farmers and their vets in Ireland is replicated across borders between many of the EU's 27 member states, with respect to many products and in a range of species. And while efforts have been made to address some of the worst anomalies, the availability of veterinary medicines continues to vary markedly across the region.

# Identifying the problems

## *So what has gone wrong - and how can current problems be addressed?*

Europe's animal health industry has struggled increasingly to cope with the demands of catch-all standards that have been applied to both human and veterinary medicines. The two sectors do share a number of fundamental similarities, but existing legislation ignores major differences in terms of product requirements, the conditions under which they are used and - crucially - the respective resources of the human and veterinary medicine industries.

The global market for human medicines is worth 40-times more than its veterinary counterpart, while there is a 30-fold difference between the research budgets of the market leaders in the respective sectors. And yet, to take just one of many examples, existing regulations demand that livestock pre-mixes must meet the same levels of purity as human medicines. This means products consumed by pigs from a feeding trough must comply with the same purity standards as medicines administered to patients by intravenous injection in a hospital or clinic.

The growing regulatory burden has had a major impact on the animal health industry. Since the early 1990s, product development costs have rocketed by 150%, while the time taken to bring new veterinary medicines to market has risen by almost five years. Manufacturers now spend more than a quarter of their entire research budgets generating data required simply to maintain approvals for established products that have already proved their safety, quality and efficacy.

The cost of supporting some minor products has become prohibitive, while it no longer makes financial sense for manufacturers to pursue the approval of new medicines in all European markets, or for all indications. The result has been a steady decline in the availability of products in some of the region's smaller markets, while the number of medicines approved for use in minor species, or for the treatment of rarely encountered diseases, has dwindled.

A decade ago, the problem had reached such levels that Europe stood on the threshold of a veterinary medicines availability crisis. Hasty action by regulators has helped to stave off a looming disaster for the region's equine population, while legislation has been

amended on a broader basis to encourage the development of so-called "minor use and minor species" (MUMS) products. New rules allowing vets to prescribe "off-label" alternatives where no suitably approved product is available have also been introduced.

Recent changes may have helped to stave off a major medicines availability crisis, but the regulatory framework governing veterinary products remains deficient in several key areas. Those shortcomings have been acknowledged by the European Commission, which has pledged to review existing legislation again in 2010, and to table reform proposals in 2011. Its aim is to deliver a more efficient, proportionate regulatory system, capable of safeguarding animal health, public health and food safety without stifling innovation.

The 2010 review represents a unique opportunity for Europe's policymakers and regulators to create, at long last, a single market for animal health products in the 27 EU member states. IFAH-Europe has urged them to grasp that opportunity, and has presented a set of detailed proposals which it believes would help to deliver that goal.





# Seeking solutions

The federation's vision - dubbed the "1-1-1 Concept" - is a system 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 throughout the EU.

This is no headline-grabbing call for the delivery of the impracticable. For behind the slogan lies a raft of fully-researched proposals which, if the political will to implement them exists, could transform the future of animal health in Europe.

By reducing the time and money required to bring products to market, the proposals would encourage manufacturers to invest more heavily in the research and development of novel products. Free from previously prohibitive regulatory burdens, those products would be registered for the treatment of more conditions in a broader range of species, and would be available to vets and animal owners throughout the EU.

The 1-1-1 Concept has won widespread endorsement among European policymakers and regulators. IFAH-Europe is under no illusions about the scale of the task involved in piloting such changes, however.

Nor does it expect instant results. But if policymakers and member-state governments are prepared at last to grasp the reform nettle, 2010 could be the year in which the foundations for the long-term future of an innovative, sustainable European animal health industry are finally secured.

## THE 1-1-1 CONCEPT

### From vision to reality

1

#### DOSSIER

Applicants would submit a single dossier - written in English and including all necessary data in support of a marketing authorisation - to a co-ordinating body. No additional data requirements would be imposed by regulators at national level.

1

#### SCIENTIFIC ASSESSMENT

Dossiers would be subjected to a single review under a procedure combining the best aspects of the existing centralised and decentralised systems. Each dossier would be assigned by the co-ordinating body to a project manager and scientific assessment team. National agencies would remain the backbone of the system, enjoying representation on the central co-ordinating body and providing resources for project management, dossier reviews and pharmacovigilance.

1

#### DECISION ON MARKETING AUTHORISATION

Scientific assessments would result in a single decision on requests for marketing authorisation (MA) of a veterinary product. That decision would be valid in all EU member states. A two-stage fee structure would prevent cost acting as a barrier to requests for marketing authorisation. Applicants would pay a set fee for the scientific assessment of their dossier, payable to the central co-ordinating body. A second fee - essentially for market access - would be payable to individual member states when the product was placed on the market in a particular country.



# COMMUNICATIONS

## Animal health at the heart of society

Veterinary products are crucial not only to the preservation of animal health and welfare, but also - and increasingly - to the protection of human health and our ability to feed a rapidly-expanding global population.

Securing broader recognition of the role our industry plays in society is vital if we are to achieve our other key goals. IFAH-Europe is working hard to strengthen its existing relationships with regulators, policymakers and food chain partners. It is also forging links with a growing range of fellow stakeholders, spreading key messages about the importance of animal health products.

## Conference highlights consensus on regulatory reform



IFAH-Europe's 2009 annual conference brought key opinion leaders together to discuss proposals for a review of the regulatory framework

governing veterinary products in the EU. Attended by over 130 delegates, the event was notable for the broad consensus it drew from regulators, senior European Commission officials, MEPs and member state governments. And widespread support was expressed for IFAH-Europe's vision (the "1-1-1 Concept") of a system under which a single dossier, subjected to a single assessment, would result in a single, unified decision on the registration of all products in the 27 EU member countries.

MEP Avril Doyle said the EU had a responsibility to ensure that its legislation did not act as a disincentive to the development of veterinary medicines, which she said were critical to protect the health and welfare of animals, and to preserve public health throughout the food chain. European Commissioner for Health Androulla Vassiliou said current, complex legal structures should be replaced by a simpler framework as part of broader efforts to reduce the impact

of animal disease. *"The availability and development of innovative veterinary medicines...is clearly of major importance to the Community animal health policy,"* she said.

The conference could not have been more timely, coming shortly after the heads of Europe's veterinary medicines agencies (HMAv) published a draft 'reflection paper' on regulatory reform. HMAv representative Patrick Dehaumont said they had agreed *"A global vision for veterinary medicines legislation that will provide the greatest range of authorised products available in all member states, safeguard food production, and be responsive to new animal health disease threats."* The proposals would help towards the realisation of a single European market, in keeping with the spirit of the Lisbon agenda, he said.

Determined to build on the momentum achieved at the conference, IFAH-Europe continues to communicate key messages on the need for reform. The federation has been busy collating data to back up its proposals for change, which will be presented to the Commission during an impact assessment of draft reforms.

## "We care" about companion animals

european pet night  
we care

The European Pet Night, organised jointly by IFAH-Europe and around a dozen partners, continues to go from strength to strength. The event has rapidly become a key date in the diaries of those with the interests of companion animals at heart, drawing bigger crowds to the European Parliament building every year. It has helped to highlight the contribution animals make to our society, and the responsibility we have to look after their health and welfare. It has also provided an opportunity for delegates to remind Europe's decision-makers not only that animal and public health are inextricably bound, but also that pets represent a sector of considerable economic importance.

Across Europe, 62 million households keep at least one pet. Half of all the region's veterinary surgeons are engaged in companion animal practice. Vets and animal owners have access to a growing range of sophisticated products with which to prevent and treat diseases that threaten the health of pets. Over 40% of all animal health products by value are now sold for use in companion animals. Policy-makers and regulators have a duty to ensure that legislation does not stifle investment in new and improved companion animal health products, and that practitioners and owners in all EU member states are able to access veterinary medicines freely.

European Pet Night gathered further momentum at its fifth renewal in February 2010, when MEPs Caroline Lucas and Horst Schnellhardt hosted the event. Following in the footsteps of Neil Parish and Paulo Casaca, their involvement underlines the broad nature of support for animal welfare within the parliament

### The European Pet Night platform includes:

- ADEu - Assistance Dogs Europe,
- Belgian Police dog support unit,
- Cancer and bio-detection dogs,
- European Commission Directorate-General for Health and Consumers (DG SANCO),
- The Eurogroup for Animals,
- FCI - Fédération Cynologique Internationale,
- FEDIAF - European Pet Food Industry Federation,
- FRDI - Federation of riding for the disabled international,
- FVE - Federation of Veterinarians of Europe,
- IFAH-Europe - International Federation for Animal Health-Europe,
- IAHAIO - International Association of Human-Animal Interaction Organisations.

## The drive to reduce animal testing



IFAH-Europe's commitment to animal welfare is underlined by the federation's participation in the European Partnership on Alternative Approaches to Animal Testing (EPAA). This unique collaboration, involving representatives from seven industrial sectors, seeks to remove wherever possible the need to conduct tests on animals in order to generate the necessary data to satisfy regulatory requirements.

The EPAA supports the implementation of the "3Rs" concept - refining, reducing and replacing animal testing. At the partnership's 2009 annual conference, delegates addressed a range of new initiatives, including "weight of evidence" approaches to product testing. Where available data is judged to provide a suitable basis for risk/benefit analyses, these avoid the unnecessary repetition of animal tests. Members also held a meeting in the European Parliament, providing an update and overview of the EPAA's achievements to new MEPs not familiar with the initiative. By spreading its core messages more widely, the partnership aims to generate broader political dialogue, encouraging a more flexible approach to testing requirements in future.



# MORE than just friends

Companion animals are already an integral part of our society, but we are still learning about the true extent of the benefits they bring. Just like us, they need medicines to keep them healthy. IFAH-Europe is committed to providing those medicines.



*"He's my true friend, my angel, my knight in shining armour,"* says Karen Ruddlesden, administering an affectionate tickle to the tummy of Coco, the 20-month-old Chocolate Labrador who has transformed her life.

Karen has Addison's disease, a condition that means her body does not produce enough steroid hormones. When her cortisol levels drop dangerously low she suffers an Addison's crisis. Impossible to predict, these episodes are always serious, and can be fatal if not treated quickly.

Before Coco came into her life Karen was too frightened to leave her home, and was being rushed to hospital on a regular basis. But since Coco arrived she has not suffered a single Addison's crisis. For Coco is trained to detect minute changes in Karen's body odour that occur up to half an hour before such an episode. He licks her face to warn her of the danger, and brings her the bag containing medicine that will stave off the attack.

*"Since having Coco I'm not afraid to go out anymore because I've got my little safety blanket,"* Karen says. *"Now I look forward to living every day of my life rather than simply existing."*

## An integral part of our society

Coco was trained by the UK charity, Cancer & Bio-detection Dogs, which works with medical researchers training specialist animals to detect the odour of human diseases. As its name suggests, the organisation's first target was cancer, but it has also trained dogs to alert diabetic owners when their blood sugar is reaching dangerous levels. Now Coco has become its first Addison's disease detection dog, and researchers believe similar approaches could prove valuable in the detection and control of many other serious conditions.

While medical alert animals are a relatively recent development, dogs have long been more than simply "man's best friend". Their amazing sense of smell has been used to locate disaster victims, while their loyalty and obedience has made them invaluable guides for thousands of blind or deaf owners.

We have also begun to realise how great the therapeutic effects of interaction with animals can be. Research has shown how their companionship aids the recovery of patients following major surgery, while we now know that contact with "therapy" animals can have a profoundly positive impact on the severely disabled.

Animal ownership has other day-to-day benefits for the 62 million households across Europe that are home to one or more pets. They provide companionship for those living alone. They encourage us to take more physical exercise (research has shown that dog owners have lower-than-average blood pressure and cholesterol levels). And they help children learn valuable lessons about responsibility and caring. In short, animals are an integral, highly valuable part of our society.

## Companion animals need medicines too

Responsible owners make sure their pets lead happy and healthy lives. The animal health industry plays a key role in ensuring they can do so, providing safe, effective vaccines that protect dogs, cats and a range of other companion animals from a growing range of potentially damaging infections. These include serious diseases like rabies, which is a danger to public as well as animal health, but which has been eradicated across much of Europe thanks to concerted vaccination campaigns.

Animals still get sick, however, and a sick animal, like a sick person, needs treatment. Here again, the range and complexity of medicines available to vets and animal owners continues to grow, spanning not only anti-infectives, parasite controls, reproductive

aids and metabolic medicines, but also novel treatments for chronic conditions such as osteoarthritis, cardiovascular disease and even cancer.

Europe's animal health industry remains both innovative and dynamic, ploughing hundreds of millions of euros into the research and development of novel products every year. More than 40% of all animal health products by value are used in companion animals, while many of the projects being researched by IFAH-Europe member companies are focused on the development of new vaccines or medicines for use in pets. The federation and its members are committed to providing products that will help to protect the health and welfare of these animals, which truly are more than just our friends.



## Reaching out to a broader audience: electronic communications

While it continues to build on established relationships, IFAH-Europe aims to forge links with a broader range of stakeholders, increasing awareness of the animal health industry's value to society. Significant progress towards that goal was achieved in 2009 when the federation's new website went online.

The site provides a wealth of information on a range of animal health issues, and encourages interactive stakeholder communication. A regular downloadable newsletter provides external audiences with valuable background on animal health topics. The site also features an RSS feed that alerts readers to the availability of updated information in real time. In a further move to enhance its electronic communications, the federation has established a dedicated YouTube channel providing video highlights of the European Pet Night event and an insight into the huge impact that animals can have on our lives.



[www.ifaheurope.org](http://www.ifaheurope.org)  
[www.youtube.com/europeanpetnight](http://www.youtube.com/europeanpetnight)  
[www.youtube.com/user/ifaheurope](http://www.youtube.com/user/ifaheurope)

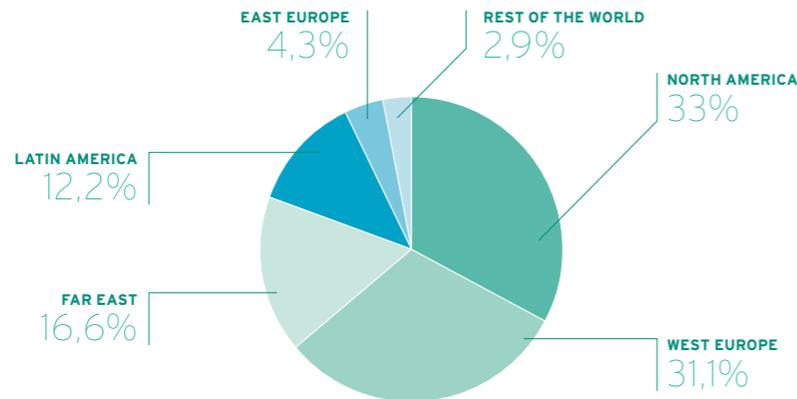
## The European animal health industry in profile

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 Euro 400 million in research and development every year. The industry provides around 50,000 full-time jobs in Europe.

ANIMAL HEALTH PRODUCTS	SUBTOTALS	TOTAL VALUES	%
<b>Vaccines</b>		<b>1.116.869.000,00 €</b>	26,50
<b>Antimicrobials</b>		<b>802.446.000,00 €</b>	19,10
Injectable forms	430.356.000,00 €		
Oral forms	372.090.000,00 €		
<b>Parasiticides</b>		<b>1.168.785.000,00 €</b>	27,70
Endoparasiticides	428.580.000,00 €		
Ectoparasiticides( ears excluded)	609.616.000,00 €		
Endectocides	130.589.000,00 €		
<b>Topical products</b> (skin ecto excluded)		<b>285.519.000,00 €</b>	6,80
<b>Other products</b>		<b>836.848.000,00 €</b>	19,90
<b>TOTAL</b>		<b>4.210.467.000,00 €</b>	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](http://www.ceesa.be)

## GLOBAL ANIMAL HEALTH MARKET BY REGION - Vetnosis Ltd. 2010



## IFAH-Europe, decision-making, membership and secretariat

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.

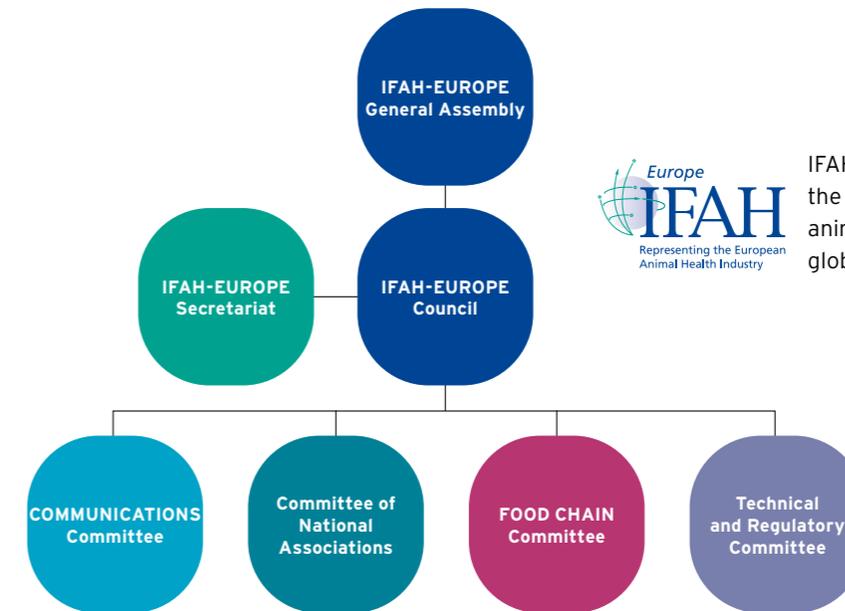
Policies agreed by the Council are executed by four key operating committees:

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

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.

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.

## Membership

### 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 Hunault**  
SIMV (France)

**Jens Kjær** (January to June 2009)  
Boehringer Ingelheim Animal Health GmbH

**Albert Bouria** (July to December 2009)  
Pfizer Inc, Animal Health

**Anne Birgitte Lundholt**  
VIF (Denmark)

**Phil Sketchley**  
NOAH (United Kingdom)

**Wolfgang Trebels**  
Bayer Animal Health GmbH

### 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

### NATIONAL MEMBER ASSOCIATIONS

**Belgium Pharma.be**  
Association Générale de  
l'Industrie du Médicament

**Denmark VIF**  
Veterinærmedicinsk  
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

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**Slovenia SPMA**  
Working Group for Animal Health

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**Sylvie Meillerais**  
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Communications Director

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Communications Manager

**Laurence Leclercq**  
Public Relations Manager

**Pamela Barcellona**  
Senior Secretary

#### Administration and IT

**Linda Moortgat**  
Administration Manager and IT Coordinator

## Glossary of acronyms

<b>COPA-COGECA</b>	Committee of Professional Agricultural Organisations - General Committee for Agricultural Cooperation in the European Union
<b>DG</b>	Directorate-General
<b>DG SANCO</b>	Directorate-General for Health and Consumers (European Commission)
<b>DISCONTTOOLS</b>	Disease Control Tools
<b>EFSA</b>	European Food Safety Authority
<b>EISA</b>	European Initiative for Sustainable Development in Agriculture
<b>EMA</b>	European Medicines Agency
<b>EPAA</b>	European Partnership for Alternative Approaches to Animal Testing
<b>EPRUMA</b>	European Platform for the Responsible Use of Medicines in Animals
<b>ETPGAH</b>	European Technology Platform for Global Animal Health
<b>EU</b>	European Union
<b>FAO</b>	Food and Agriculture Organisation of the United Nations
<b>FVE</b>	Federation of Veterinarians of Europe
<b>HMAv</b>	Heads of Veterinary Medicines Agencies (Europe)
<b>MEP</b>	Member of the European Parliament
<b>VICH</b>	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

# ANNUAL REPORT 2009



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