

# Annual Report

2012



Europe  
**IFAH**  
Representing the European  
Animal Health Industry

## Table of contents

Representing the European Animal Health Industry . . . . .	2
Our Mission . . . . .	2
A Message from IFAH-Europe's Chairman and Managing Director . . . . .	3-4
Harmonisation Towards a Single Market . . . . .	5-6
Year at a Glance . . . . .	7-10
The European Animal Health Industry in Profile . . . . .	11



# Representing the European Animal Health Industry

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

## Our Mission

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

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



## A Message from IFAH-Europe's Chairman and Managing Director

### The provision of **SAFE, SECURE and SUSTAINABLE** food into the future.

**Declan O'Brien**  
Managing Director  
**Alejandro Bernal**  
Chairman

Our June conference focused on the provision of safe, secure and sustainable food into the future. The statistics of a growing global population requiring more food are well known – the challenge is significant and increases in commodity prices in 2012 highlight the fact that we cannot defer action. As the animal health industry, we are directly involved in this challenge and remain clearly focused on where we can add value: eliminating or reducing the burden of disease in animals. Diseases in animals are estimated by the World Organisation for Animal Health (OIE) to reduce food production from animals by 20%. Increasing production by 20% would be ideal but may be difficult to achieve. We should nevertheless aspire to reaching that target.

As discussed at our conference, it is a given that food must be safe. However, sustainably producing enough food to secure our food supply will necessitate the collaboration of all stakeholders. The challenge can be summed up in three simple numbers: 50-100-70. By 2050 we need to increase production by 100% and 70% of this increase will have to come from technological advances. The latter number arises from the fact that we cannot exploit more land across the globe. We therefore need to produce more from the land currently in production.

Whilst this is a significant task, our conference concluded that we can substantially increase production across many parts of the globe – including in Europe – as the difference between the most and least efficient producers in terms of both food security and sustainability is still considerable.

Just a few facts: Comparing 1944 to today, milk production requires 65% less water, 90% less land, produces 76% less manure and the carbon footprint has been reduced by 63%. The goal is to continue this trend.

In terms of addressing future food security by aggressively attacking the 20% loss of production from animal diseases, the DISCONTTOOLS project identifies the most important gaps in the most important diseases and aims to focus research funding towards these gaps. Via our collaboration with a network of countries in Europe ([www.ANIHWA.eu](http://www.ANIHWA.eu)) and on a global level ([www.STAR-IDAZ.net](http://www.STAR-IDAZ.net)), we are encouraging this focus across funders of research around the globe.

As an industry, we are deeply involved in the debate surrounding the use of antibiotics. We have a very clear vision: antibiotics must be used responsibly and in order to ensure Responsible Use, we must have

“ Since 1944, milk production requires 65% less water, 90% less land, produces 76% less manure and the carbon footprint has reduced by 63%. The goal is to continue this trend. ”

transparency at the use phase. To help promote Responsible Use, we are involved in the stakeholder-driven initiative, EPRUMA ([www.epruma.eu](http://www.epruma.eu)). We are encouraged by the European Commission Communication from November 2011 where the first action point speaks about strengthening the promotion of the appropriate use of antibiotics. We continue to urge the Commission to consider using EPRUMA as a vehicle for this communication, especially with veterinarians and farmers.

Transparency at the use phase is achieved through the provision of electronic data by the prescribing veterinarian. Data on use at the farm level will ensure that the intensity of use is transparent and if it is not in line with best practice in the region, support should be provided to ensure future use is in accordance with expected norms. This combination of Responsible Use and transparency can help ensure that misuse does not occur in the veterinary sector.

IFAH-Europe supports the principle of data collection as a means of informing decision-making, especially as regards antibiotic usage. We therefore welcomed the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report issued by the European Medicines Agency (EMA) which provides volume data by animal body mass on antibiotic use across the European Union. ESVAC is a useful initiative but we remain convinced that the data will greatly increase in value when the figures are broken down by species and when they account for different dose rates. Informed estimates should be provided in the absence of definitive data.

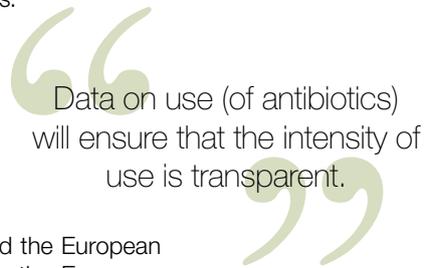
As a means of informing the debate on antibiotics, we released the first of our studies commissioned to look at the relevance of antibiotic use in the veterinary sector in terms of an impact on human therapy. The conclusion includes the following: 'A number of risk assessments have been carried out and all consistently show little evidence that antibiotic use in food animals gives rise to resistance that subsequently prejudices antibiotic use in treatment of human disease.\*' The study tries to bring balance to the debate but in no way detracts from the need to use antibiotics in the veterinary sector in a responsible manner.

The Europe Report from the 2011 Global Benchmarking Survey on the Animal Health Industry highlights the need for regulatory reform: 2013 will be very important as we pursue the goals of medicines availability, the operation of the single market and a reduction in administrative burden. We look forward to working with all stakeholders as we pursue these goals.

In reaching out to a wider audience, our European Pet Night once again provided a forum to showcase the benefits of animals to society. It was most impressive to see Medical Detection Dogs in action and to see how animals help people on a daily basis to avoid health crises by alerting the person to an impending attack, such as with diabetes, through odour detection even before the person is aware of any problem. We look forward to continuing the promotion of the tremendous value of animals to society with our partners through European Pet Night.

As Chairman and Managing Director, we wish to thank all those who have contributed to our work especially our companies and trade associations who participate in our various committees in pursuit of our goals. A special thank you also to our enthusiastic secretariat for their commitment to the work of IFAH-Europe.

As ever, we look forward to working with all stakeholders to ensure that we have safe, high quality and effective veterinary medicines available across Europe to benefit both food and companion animals as well as public health while ensuring a safe, secure and sustainable food supply.



Data on use (of antibiotics) will ensure that the intensity of use is transparent.

\*Evaluating The Transfer of Resistance in *Campylobacter*, Report by Professor Peter Silley for IFAH-Europe

## The legislative review: HIGH HOPES for 2013

The animal health industry in Europe is facing a unique opportunity at this time with the legislation on veterinary medicines, medicated feed and animal health all currently subject to review. IFAH-Europe sees the improvement of the veterinary medicine legislation as a major priority for animal health and has been a key player in providing knowledge and expertise in the run up to the legislative review with the hope of forging a streamlined regulatory system that will stimulate innovation and bring more products to market.

The European Commission's public consultation held in 2010 showed that most respondents support major changes, including increased data protection, adoption of centralised procedures, clearer and simpler labelling and packaging and improved support for innovation as well as the development of new diagnostics, therapies and devices. The assessment of the legislative framework for veterinary medicines carried out by consultants on behalf of the European Commission highlighted the issues that currently exist in terms of an overall problem with availability of veterinary medicines, poor functioning of the internal market and a high administrative burden in relation to the turnover of the sector.

These findings were echoed in the [Europe Report from the 2011 Global Benchmarking Survey on the Animal Health Industry](#) published in September 2012. Participants reported that the complexity of the current European legal framework has created a large administrative burden, increased development costs and times, and drastically hinders both market access and innovation. Although survey results ranked the European Medicines Agency and its Committee for Medicinal Products for Veterinary Use best in the world for regulatory quality, the costs of product maintenance and insufficient data protection along with ever-increasing demands for data on environmental impacts and on pharmacovigilance have led some companies to question investment in Europe.



With this in mind the legislative reform could have a fundamental impact not only on improving access to veterinary medicines but also on making Europe more attractive for continued investment. IFAH-Europe's vision is of a Europe where innovation in the field of veterinary medicines is fostered in line with the objectives of the Europe 2020 Strategy for growth. With both public and animal health as the cornerstone of the new legislation, IFAH-Europe encourages industry and policymakers to work together to build an appropriate framework based on scientific evidence for developing innovative solutions. A harmonised approach through a true single EU market with reduced administrative burden via the 1-1-1 Concept (1 dossier, 1 assessment leading to 1 marketing authorisation valid across the EU) is a potential solution to ensuring the competitiveness of the animal health industry in Europe.

There is still some work to be done to truly make veterinary legislation more efficient and to that end IFAH-Europe has spent much of 2012 actively promoting the 1-1-1 Concept to national veterinary agencies and authorities. The 1-1-1 Concept aims to enhance efficiency, improve the use of limited resources and remove duplication. It intends to do so with a submission based on one dossier (in English) being made to a committee of Member State authorities leading to a single scientific assessment and a single decision.

With the medicated feed directive, the objective is to ensure the pan-European availability of medicated feed as an administration route. Appropriate requirements on production facilities need to be in place along with specialist inspection services facilitating the safe and economic production of medicated feed. The current issue of divergent rules across the EU needs to be resolved.

According to the Commission work programme, the proposed revised legislation for both the veterinary directive and the medicated feed directive should enter co-decision in the second quarter of 2013. Time-wise, this appears to be a feasible target as the work on both impact assessments is well advanced and extensive consultation of stakeholders has taken place. We look forward to the Commission keeping a focus on medicines availability, the functioning of the single market and a reduction of the administrative burden. Each and every proposal needs to 'tick the box' on each of these three criteria, otherwise we are not moving towards our stated goal.

As the co-decision procedure unfolds, the Member States and the European Parliament, as well as other stakeholders, should keep these objectives clearly in mind when proposing or advocating changes to the text proposed by the Commission. At the end of the day, we wish to see safe, high quality and effective medicines available across the EU which have come through an efficient licensing system. This is to the benefit of animal health, animal welfare and public health.

## The Year at a Glance

IFAH-Europe firmly believes that progress is made when legitimate interests of different partners combine to further a common goal. The issues facing both human and animal health are significant but surmountable provided we are able to collaborate, share knowledge, identify gaps and prioritise issues to be tackled to further develop our capacity to control diseases. IFAH-Europe regularly works alongside authorities and other stakeholders in order to achieve this common goal. These next few pages highlight just some of our activities from 2012.

### WORKSHOP

IFAH-Europe and the Committee for Mutual Recognition and Decentralised procedures (veterinary) organise a **joint packaging workshop** at the European Medicines Agency co-chaired by IFAH-Europe's Technical Director Rick Clayton and Deputy Head of the Czech National Veterinary Authority Jiri Büres.

### Eliminate zoonotic threats

IFAH-Europe presents ETPGAH and DISCONTTOOLS and promotes public-private partnerships at Davos One Health Summit to eliminate zoonotic threats to people by preventing or controlling diseases in animals.

[www.etpgah.eu](http://www.etpgah.eu)

**ETPGAH**  
EUROPEAN TECHNOLOGY  
PLATFORM FOR  
GLOBAL ANIMAL HEALTH

22/2



### European Pet Night

Hosted by MEPs Horst Schnellhardt and Iratxe García-Pérez, European Pet Night 2012 features Medical Detection Dogs who give a live demonstration of their cancer detecting abilities.

[www.ifaheurope.org](http://www.ifaheurope.org)



### CONFERENCE

14/3

'Rational thinking, science-based decision-making and Responsible Use of antibiotics by all is key to curb antimicrobial resistance' is IFAH-Europe's message at the conference on "**Combating Antimicrobial Resistance - Time for Joint Action**" taking place in Copenhagen, Denmark, under the Danish Presidency.

[www.eu2012.dk](http://www.eu2012.dk)

## The Latest Developments

**The Latest Developments in Scientific Review, Legislation and Marketing Developments**, theme of the 2012 EMA and IFAH-Europe Info Day at EMA in London. Another record attendance.

[www.ema.europa.eu](http://www.ema.europa.eu)

# Q2



## Responsible use of medicines in animals: What does it mean?

EPRUMA publishes a poster highlighting the role of veterinarians, farmers, pet owners and pharmacists in ensuring Responsible Use.

[www.epruma.eu](http://www.epruma.eu)

13/6

## Viruses on the Move

IFAH-Europe presents DISCONTTOOLS at EPIZONE Conference in Brighton, UK.

[www.epizone-eu.net](http://www.epizone-eu.net)



26/6

## VICH Outreach Forum

IFAH-Europe hosts the 27th VICH Steering Committee and the first ever **VICH Outreach Forum** in Brussels which brought together 7 countries - Argentina, China, Mexico, Morocco, Russia, South Africa, and Ukraine – with the existing VICH countries (USA, EU, Japan) and observers (Canada and Australia/ New Zealand) to discuss how they wish to interact with VICH members.

[www.vichsec.org](http://www.vichsec.org)



### NEW LEAFLET

promoting responsible pet ownership, highlighting a number of ways in which companion animals are good for us and suggesting various ways in which pet owners can be good to their animals.

## Healthy animals for a safe, secure and sustainable food supply

theme of IFAH-Europe's 2012 conference featuring keynote speaker Catherine Geslain-Lanéelle from EFSA.

In line with the conference IFAH-Europe publishes four disease fact sheets:

- Bluetongue
- Circovirus
- Foot and mouth disease
- Salmonella

21/6



# 1/7

## EFSA

IFAH-Europe becomes a full member of the EFSA Stakeholder Consultative Platform

[www.efsa.europa.eu](http://www.efsa.europa.eu)



# Q3

## PUBLICATIONS

Publication of the Europe Report from the **2011 Global Benchmarking Survey on the Animal Health Industry**. Examining the interactions between industry and regulatory systems, the outcome of this survey provides an invaluable wealth of information to support informed policy decisions in the continual search for best regulatory practice.

[www.ifaheurope.org](http://www.ifaheurope.org)



# 19/9

## Alliance on Antibiotic Resistance



EPRUMA co-signs the Bavarian Alliance on Antibiotic Resistance (BAKT) consensus paper on the sustainable control of antibiotic resistance in Erlangen, Germany.

[www.epruma.eu](http://www.epruma.eu)

Publication of explanatory leaflet on the EPRUMA initiative regarding the **responsible use of veterinary medicines**.



## 1-1-1 Concept

IFAH-Europe travels across Europe throughout 2012 visiting a total of 21 national competent authorities to promote the 1-1-1 Concept and garner support for a single EU market. Remaining Member States are covered by the national associations.



# Legislation to favour innovation

16/11

## Global Cooperation on the 3Rs

The European Partnership for Alternative Approaches to Animal Testing - a voluntary collaboration between the European Commission, European trade associations and companies from seven industry sectors, including IFAH-Europe for the replacement, reduction and refinement (3Rs) of animal use in regulatory testing - hosts its 8th Annual Conference in Brussels titled 'Global Cooperation on the 3Rs'.

[www.ec.europa.eu/enterprise/epaa](http://www.ec.europa.eu/enterprise/epaa)



The European Partnership  
for Alternative Approaches to Animal Testing



IFAH-Europe chairs session on 'Legislation to Favour Innovation' at **TOPRA 2012 Veterinary Symposium in Dublin, Ireland.**

## CONFERENCE

IFAH-Europe participates in first **CALLISTO Conference** to discuss important conclusions of project cycle no. 1 dedicated to the overview of the current situation and knowledge gaps on companion animals zoonoses.

CALLISTO - Companion Animals multisectorial, interprofessional and Interdisciplinary Strategic Think tank On zoonoses

[www.callistoproject.eu](http://www.callistoproject.eu)



15/11

## Fighting animal diseases

Fighting animal diseases - identifying research priorities, theme of **DISCONTTOOLS conference** focusing on the results of almost five years of effort involving up to 400 scientists from 36 countries and examining the future of the project.

[www.discontools.eu](http://www.discontools.eu)



28/11

IFAH-Europe participates in the Annual meeting with Inspectors at the **European Medicines Agency in London, UK.**



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

[www.ema.europa.eu](http://www.ema.europa.eu)

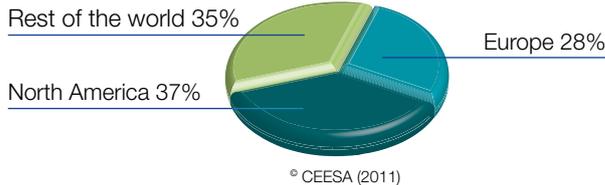


# The European Animal Health Industry in Profile

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.

<b>ANIMAL HEALTH PRODUCTS</b>			
	<b>Subtotals in €</b>	<b>Total values in €</b>	<b>%</b>
Vaccines		1,226,057,192	27.45
Antimicrobials		749,680,339	16.78
Injectable forms	419,025,879		
Oral forms	330,654,459		
Parasiticides		1,298,463,073	29.06
Endoparasiticides	441,156,191		
Ectoparasiticides (ears excluded)	734,910,989		
Endectocides	122,395,894		
Topical products (skin ecto excluded)		315,655,974	7.06
Other products		877,713,017	19.65
<b>Total</b>		<b>4,467,569,956</b>	<b>100</b>



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

Source: 10 IFAH-Europe and CEESA member companies. 20% added for non-participating companies. CEESA stands for European Animal Health Study Centre [www.ceesa.eu](http://www.ceesa.eu)

## IFAH-Europe Overview

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

Policies agreed by the Council are executed by four key operating committees: National Associations, Technical and Regulatory, Food Chain and Communications. These committees are supported by a range of working parties and ad-hoc groups focused on specific issues, and by a permanent Brussels-based secretariat led by IFAH-Europe's Managing Director, Declan O'Brien.

IFAH-Europe is a member of IFAH, the federation representing the animal health industry at a global level.

Find out more about IFAH-Europe, its membership, structure and activities at [www.ifaheurope.org](http://www.ifaheurope.org).



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@ifahaurope.org  
[www.ifahaurope.org](http://www.ifahaurope.org)

