

IFAH-Europe conference



The Animal Health Industry – An essential partner for Global Health

PROCEEDINGS

Wednesday 28 June 2006
Crowne Plaza Brussels-Europa Hotel

IFAH-Europe

International Federation for Animal Health - Europe

a non-profit international organisation established under Belgian law (AISBL/IIVZW)

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Introduction

IFAH-Europe was very pleased with the success of its annual conference "*The Animal Health industry - an essential partner for Global Health*", an all day event which took place on Wednesday 28 June 2006 at the Crowne Plaza Brussels-Europa hotel in the EU quarter of Brussels. The conference was very well attended with **over 130 participants** from the animal health industry, the EU institutions, national regulatory agencies, international organisations, agricultural sector organisations, the veterinary profession, academia and the media.

The conference was opened by European Commissioner for Health & Consumer Protection **Markos Kyprianou**. The four main sessions of the conference featured speakers and chairs from the EU institutions (EMEA, EFSA, European Commission, European Parliament), international organisations (FAO, OIE), the animal health industry, NGOs (vétérinaires sans frontières) and academia. The conference covered a wide range of topics related to innovation in the animal health industry including the need for efficient regulatory systems, the work of the European Technology Platform for Global Animal Health (ETPGAH), the importance of animal disease control in developing countries, stakeholder cooperation in the food chain, the Community Animal Health Policy (CAHP), and the need to continue to develop innovative medicines to treat and prevent animal diseases including zoonotic diseases.

Opening Session

IFAH-Europe Chairman Brian Clark opens the conference

IFAH-Europe chairman from Virbac **Mr Brian Clark** opened the conference, welcoming participants and noting the diverse representation present from industry to regulators, academia, international organisations and NGOs. He then emphasised the key points that IFAH-Europe would like to bring to the fore at the conference, namely: the benefits the animal health industry brings to society, its pro-active role as a partner towards other stakeholders, and the increasing global dimension of animal health. Examples of the global nature of animal health are only too evident with the current situation of avian influenza.



Mr Brian Clark opens the conference

Stakeholder relationships should change. They need to move from a confrontational style - each party taking its own position and then winning/losing in a zero sum game - to one of collaboration, where a "how do we solve this problem?" approach becomes a win-win situation. A good example of this climate of collaboration is the European Platform for Responsible Use of Medicines in Animals (EPRUMA).

The problem facing the animal health industry today is not one of stakeholder confrontation, but a lack of awareness among political decision makers about the importance of animal health. All stakeholders and institutions active in animal health should have one major aim in

the coming years: to raise awareness of the importance of animal health among political decision makers at the national, regional and international level, concluded Mr Clark.

Commissioner Kyprianou recognises the success of animal health



*Commissioner Kyprianou
addresses the packed
audience*

In his speech **European Commissioner for Health and Consumer Protection Mr Markos Kyprianou** acknowledged the resourcefulness of the animal health industry and the success of the Community Animal Health Policy (CAHP) in recent years, as demonstrated by the control of BSE. The innovative spirit of the animal health industry needs to be harnessed, the Commissioner said, in order to help strengthen the EU response to major animal diseases like foot-and-mouth disease and avian influenza.

He then reported on the recent evaluation of the CAHP in preparation for a new strategy for 2007-2013, which should be unveiled next year. The evaluation had raised many valid points including simplification of legislation and innovation gaps such as weaknesses in industry-university links and lack of medicines for some species and/or medical conditions.

The Commissioner concluded by saying that the future animal health policy should have clear objectives and be coherent with other policies in order to be able to improve disease surveillance and diagnostics, build animal health capacity, ensure the availability of veterinary medicines and vaccines, and address the social and economic concerns of animal disease.

Session 1: A successful history of innovation – a formula for future challenges

Chair of the session, **Dr Horst Schnellhardt** MEP and member of the EP Committee on the Environment, Public Health & Food Safety began by commenting on the international dimension in which the animal health sector now finds itself. He also expressed satisfaction at hearing Commissioner Kyprianou confirm the need for a more coherent comprehensive future Community Animal Health Policy (CAHP).



L-R: Dr Jan Vaarten, Interpreter, Dr Horst Schnellhardt MEP, Dr Paul van Aarle, Dr Christianne Bruschke

A track record of animal health innovation

Dr Paul van Aarle from **Intervet** gave an overview of the animal health industry in recent years highlighting success and pointing out challenges. Industry consolidation has come about in order to pool resources for innovative R&D, which is a positive development. The centralised (EMA) procedure for registering medicines had not had the desired effect on innovation, as most registrations had not been for new medicines but for product variations, in other words “defensive” rather than innovative R&D. Real growth in the industry was only 2.9% between 1995 and 2005, which must further be broken down into volume growth and growth because of currency fluctuations. Taking this background into account, the industry does not currently have a level of growth that demonstrates innovation.

However, the industry has an excellent history of innovation, with recent success including new vaccine technologies such as marker vaccines and vector vaccines. There are vaccines against scourges like foot-and-mouth disease and salmonellosis. Enabling factors for industry include basic research, which is often driven less by the needs of society and more by the interests of researchers, and applied research, which needs an effective regulatory framework to support it. Regulation can often be creative in inventing frameworks for new technologies, but not for taking unnecessary requirements away.

The global need for new medicines

Dr Christianne Bruschke from the **OIE** (World Organisation for Animal Health) presented the OIE and its mission to improve animal health worldwide by being the international standard setting body and providing support for the control of animal diseases. Dr Bruschke highlighted the difference in consumption of meat, eggs and milk between developed and developing countries in order to show how the need for increased livestock production in developing countries, which will require solid animal health services. Good livestock medicines adapted to the needs of developing countries will be essential to guarantee the

safety of food of animal origin. The veterinary vaccine market is as big as the human vaccine market, but far more diverse and some vaccines are not available in developing countries. In addition, a vaccine is unlikely to be developed if it cannot be sold in Europe/North America.

In order to plug the gap, particularly for developing countries, public-private-partnerships between industrialised countries and developing countries are one way forward. Networks of animal health stakeholders can work together to stimulate innovation and to build robust regulatory processes where they do not exist.

The Veterinarian's toolbox 2015

Dr Jan Vaarten, Executive Director of **FVE** (Federation of the Veterinarians of Europe) began his speech by approving of the "global health" focus of the conference. Veterinary medicines, he said, are valuable tools as they contribute both to animal health and welfare, and public health in general.

However, particularly for food producing animals, there is such strong price competition that some innovative medicines are too expensive to combine with low cost production systems. It is therefore necessary to move from concentrating on price to focusing on value. Pressure to reduce the use of veterinary medicines in food producing animals will increase, leading to more emphasis on disease prevention and disease monitoring. When it comes to diseases with a large public interest (as per OIE criteria) development of products cannot be left to the market alone; public commitment is needed.

Although there is a single market for food products and for veterinarians (through professional mobility), there is a fragmented market for veterinary medicines, especially those for minor use/minor species (MUMS). So the vet can move, but not his tools. Automatic recognition of marketing authorisations for veterinary medicines should be the rule instead of the exception.

In Dr Vaarten's vision, the veterinarian's toolbox 2015 would contain:

- A comprehensive range of products;
- New and better diagnostic tools;
- Preventative medicines such as vaccines;
- User friendly products;
- Good product information.

Session 1 Conclusions

A more competitive Europe is the right answer to a more globalised competitive world. The right regulatory environment for economic growth in the EU could be achieved through three main drivers:

1. Further opening of markets;
2. Fostering innovation through better regulation (removing bottlenecks that hamper the development of new veterinary medicines), favourable legal framework for investment and increased national government and EU (e.g. FP7) funding;
3. Pursuing balanced sustainable development.

Session 2: The benefits of innovation in the Animal Health Industry

The chair **Dr Manuel Hallen** from the **European Commission's DG Research** opened the session indicating that he strongly supported the previous session's plea for the FP7 to increase the focus on basic research and enhance the funding available for animal health. New technologies such as genomics and other advances in immunology would enable emerging diseases, campylobacteriosis, salmonellosis and other new zoonoses such as avian influenza to be tackled. He indicated further that the EU has supported the launch of 7 Platforms in areas of life sciences; these Platforms met last March to agree on a common strategy.

Key drivers for innovation

IFAH President and President of Pfizer Animal Health Mr Pedro Lichtinger began his presentation with two key messages:



Mr Pedro Lichtinger
IFAH President

1. The Animal Health industry is currently facing tremendous opportunities because science is progressing and brings growth, business and benefit to society. In this environment the Animal Health industry needs a predictable science based regulatory environment.
2. There is a growing demand for a supply of safe wholesome food. Animals have therefore to be healthy and for this they need veterinary medicines. Consequently the industry must bring new products to the market.

Most innovation is however directed to companion animals because the registration process is long and lacks predictability for food producing animals. In Companion Animals, the increase in geriatric diseases for example, demands specific products for ageing pets.

It is important to note that many products for food producing animals are old and the development of resistance is undermining their efficacy; this means that there is an opportunity for new products. The animal health industry thoroughly supports the prudent use of products, but surveys have shown that in 50% of the cases treatments of farm animals are not completed. Furthermore, the resistance to parasiticides is increasing because of ageing products. There is therefore a potential for innovation and new products.

For avian influenza, huge resources have been made available in human health, but only very limited funds have been directed to research at the source of avian influenza, namely the birds, although there is certainly an opportunity for innovation at their level.

In conclusion, the animal health industry is convinced of the current opportunities and has increased its research budgets over the past years. Innovation is a key driver for industry, but the industry needs a business predictable science-based regulatory environment and the recognition of the importance of animals for the production of safe and wholesome food.

A global strategic research agenda for animal health

Professor Jim Scudamore from **Liverpool University** spoke on the European Technology Platform for Global Animal Health, presenting in particular the recently released Strategic Research Agenda (SRA).

The European Technological Platform for Global Animal Health (ETPGAH - <http://www.ifaheurope.org/EUPlatform/Platform.htm>) views animal diseases as a global problem. Animal migration, poverty, and livestock diseases in developing countries are generating worldwide risks. There is therefore a need for the proper tools to be made available using the best technologies to resolve European and global problems. The Stakeholders of the ETPGAH comprise the entire veterinary field from academia and research to the product manufacturers. A Vision Document was produced in August 2005 followed by thorough discussions in 3 Expert Working Groups, which have identified six themes for further consideration detailed in the Strategic Research Agenda (SRA) published in May 2006.

The next phase of the Platform's activities is to ensure the implementation of the SRA's recommendations. The actions required to meet the aims laid down in the six themes need to be determined. Strong collaboration between all stakeholders is critical to the success of the Platform. In Europe funding is currently available from the EU Institutions, from National research programmes and from public/private research partnerships. A proper coordination is essential to avoid unproductive duplication.

In conclusion, the ETPGAH has now reached the phase of the "who and how", requiring the involvement of all stakeholders. An Action Plan will be elaborated, including a proper gap analysis, funding will be identified, and responsibilities will be determined. Once the ETPGAH has adopted its Action Plan, the Platform will monitor progress and review its aims at regular intervals.

The importance of disease control in developing countries

Dr Joseph Domenech Chief Veterinary Officer of the **FAO** focused his presentation on the importance of supporting animal disease control in developing countries. Dr Domenech explained that in the developing world the expected increase in consumption will enhance the trade in meat and milk. The spread of animal diseases may therefore pose major problems in relation to food safety and human health. The interactions between animal health and global issues are very complex depending on factors such as land use, climate, and movement of animal populations. It is therefore essential to set up an efficient global warning system for early and rapid detection of disease. Many information sources exist such as veterinary services information or the OIE early warning system.

International cooperation between FAO, OIE, the EU and national veterinary services exists already and enables exchange of knowledge, understanding, surveillance and warning information in order to facilitate the definition of research and tools that are needed. One of the tools is new vaccines that will enable the differentiation of vaccinated and non-vaccinated animals. There are still issues to work on, for example rinderpest, which should be totally eradicated by 2010, and the role of wild birds as a reservoir of avian influenza, which is still unsure and needs to be defined.

International communication, information and strategy are key to many solutions. FAO coordinates with WHO and OIE, with a common FAO-OIE crisis management centre and the key role of national CVOs in the chain of command of crisis management. Regional surveillance networks need support from the politicians in order to set up rapid and efficient responses to disease outbreaks.

In conclusion, there is a global threat in all regions from highly contagious diseases that do not respect borders. Efficient surveillance including early detection, early warning and immediate response must be based on a global solidarity to protect animal and human health.

Animal health is essential for human welfare

Dr Nimaya Mogga from **Vétérinaires sans frontières** Sudan explained that in developing countries, pastoralists and agropastoralists depend completely on their livestock for their survival. Governments do not however generally encourage their seasonal mobility, which has led to a marginalisation of these populations.

The pastoral communities have an essential social function and proper training of animal owners, something which is vital where professional veterinary services are lacking, requires respecting this social structure. The development of appropriate therapeutic products by the animal health industry, such as thermostable vaccines (which end the difficult problem of a proper cold chain in remote areas) or simple and adapted field diagnostic kits also require a social acceptance of these important tools by the pastoral communities. Agreements need to be reached before the new tools are used.

Innovation can have huge positive impacts and may enable the eradication of diseases, a good example being rinderpest which is now almost eradicated from Sudan thanks to a thermostable vaccine.

In conclusion, there is urgent need for appropriate vaccines and pharmaceuticals that are easy to use by less trained people, in order to tackle other diseases for which formal government policies are often non-existent.

Session 2 Conclusions

Stimulating innovation is vital in order to achieve the research and development challenges that currently need to be met. In the developed world the need is greatest in the area of medicines for food producing animals, whereas in the developing world, it is vital to develop not only medicines for conditions without existing treatments, but also to develop technology that will allow medicines to be adapted for use in challenging conditions. The work of the ETPGAH is one step in the right direction and its global approach and wide range of stakeholders is a positive development.



L-R: Mr Pedro Lichtinger, Prof Jim Scudamore, Dr Manuel Hallen, Dr Joseph Domenech & Dr Nimaya Mogga

Session 3: A new alliance for improving Animal Health

Mr Hermanus Versteijlen Director from the **European Commission's DG Agriculture** introduced the session in his role as chair, expressing the view that new partnerships and alliances require a redefinition of policy priorities.

European Platform for the Responsible Use of Medicines in Animals



Mr Neil Cutler presents
EPRUMA

Mr Neil Cutler of the **National Farmers Union (UK)** speaking for COPA-COGECA presented the European Platform for the Responsible Use of Medicines in Animals (EPRUMA) as a solid example of a new stakeholder alliance in the food chain. EPRUMA is an alliance of farmers, veterinarians and the animal health industry.

A similar platform (RUMA) had already been successfully established in the UK. The original driver behind RUMA was to promote the managed withdrawal of antimicrobials used as digestive enhancers in feed. Special guidelines were developed for responsible use of antimicrobials. These RUMA guidelines are now accepted as standards for farm assurance schemes in the UK. This cooperation created a new stakeholder model for farm health planning within a new government strategy for animal health and welfare.

EPRUMA began with a presentation of RUMA to the EAFN (European Agri-Food Network) in spring 2005. The founding members of EPRUMA - FVE, IFAH-Europe and COPA-COGECA - have produced a mission statement which recognises "*the importance of promoting animal health, animal welfare and public health by the responsible use of medicines in animals*" and aims to do this using a "*coordinated and integrated approach involving all stakeholders*". Good progress has been made in the year since it was founded.

EPRUMA is currently identifying issues of public concern related to medicines and will focus on developing best practice guidelines, initially for antimicrobial use. In general it will be important to communicate the need for veterinary medicines to the public. In particular, consumer acceptance of produce from vaccinated food producing animals is one area that may need to be tackled.

The IFAH-Europe Food Chain Committee hopes that EPRUMA will prove to be as valuable across Europe as RUMA has proven to be in the UK.

The animal health industry looks to new models of cooperation

Mr Jean Louis Hunault, Secretary General of **SIMV** (French animal health association) and chair of the IFAH-Europe Food Chain Committee described the new models of cooperation in which the animal health industry is now involved.

Animal health companies need to listen to their customers both directly and indirectly. Currently market guarantees are threatened downstream (after production). Distribution and prescription differ from country to country, but there is a global need for security and confidence in the post marketing phase. Lack of confidence in the post-marketing phase is not an incentive for Animal Health companies to risk R&D investment, particularly for sectors/species which currently lack appropriate medicines.

The future of products depends on their correct use today. Communication is key to this. New models of collaboration are underway in several areas.

1. Industry initiatives:
 - Traceability of products through advanced bar-coding (matrix);
 - Training of sales people;
 - Codes of practice for the ethical promotion and communication of medicines.
2. Technical collaboration:
 - Drawing up standards of good practice;
 - Training for veterinarians;
 - Training for breeders/good farming practices.
3. Economic collaboration:
 - Industry-veterinarian networks/platforms of cooperation;
 - Good compliance for better effectiveness.

EFSA values stakeholder collaboration

Dr Hubert Deluyker from the **European Food Safety Authority (EFSA)** gave a talk on EFSA's stakeholder relations. He began by presenting EFSA's mission as one of building public confidence in the food chain by providing high quality scientific opinions on request of the European Commission, the European Parliament and Member States.

There are two distinct types of EFSA stakeholders:

- Legal stakeholders – with whom EFSA's relations are prescribed in legislation such as the European Commission, the Member States and the European Parliament;
- Civil society stakeholders – with whom EFSA consults through a variety of mechanisms.

The main tasks of EFSA are:

- To provide independent scientific opinions to the Commission, EP and Member States, the development of risk assessment methodologies and identifying emerging risks;
- Scientific and technical assistance to the Commission through collection and analysis of data and commissioning of scientific studies;
- Risk communication.

Following a number of policy developments including the GMO (genetically modified organism) debate, there has been an increasing realisation in EFSA of the need to consult with a wide group of stakeholders. IFAH-Europe is one of those stakeholders. EFSA wants both consumers and stakeholders to have confidence in its work, which it seeks to do by

contributing to the scientific debate while maintaining quality, transparency and independence.

Currently formal stakeholder policy is under development. EFSA wants to consolidate existing stakeholder activities and formalise interaction. The department responsible for this work at EFSA is the department of International and Institutional Relations.

Session 3 Conclusions

All speakers stressed the need for multi-stakeholder collaboration. This collaboration is no longer restricted to simple economic concerns, but now incorporates responsible use of medicines, compliance with treatments, the development of scientific opinions, and ethical codes of communication. Also mentioned by many speakers in the conference was the importance of getting societal acceptance of technology in animal health products. Wide stakeholder collaboration is vital for this.

Session 4: An improved regulatory framework for Animal Health innovation

Dr Martin Terberger, Head of the Pharmaceutical Unit of **DG Enterprise, European Commission**, chaired this session and gave participants encouragement by expressing the willingness of the Commission to work to improve the regulatory framework.

How the EMEA furthers innovation

Dr David Mackay head of the veterinary medicines unit at the **European Medicines Agency (EMA)** highlighted a number of factors by which the EMA tries to help further innovation in animal health.

A key theme of the EMA "Roadmap to 2010" is its stated aim to "*stimulate research and innovation*" and to allow "*timely access to safe and effective innovative medicines*", which links to the Lisbon agenda stated goal of making the EU "*the most competitive and dynamic knowledge based economy in the world*" by 2010. Specific Roadmap objectives include "*more rapid access to medicines*", "*special measures for innovative medicines*" and "*incentives for SMEs*".

Specific measures to encourage innovation include:

- Access to EU scientific advice;
- Sliding scale of fees;
- Regulatory guidance through guidelines, concept papers and reflection papers;
- Special SME unit.

Innovation can be helped by the centralised procedure in a number of ways:

- Single high quality assessment with predictable timetable (210 days) leading to single marketing authorisation valid throughout the 25 EU Member States;
- Access to accelerated procedure (150 days);
- Single point of contact for post authorisation activities.

The EMA's engagement with stakeholders includes CVMP interested parties meetings, EMA infodays, Focus group meetings and EMA input to the VICH. The EMA believes that good dialogue between regulators and industry is vital. In this respect, the EMA is also proud of its involvement with the ETPGAH, which includes membership of the Steering Council.

The future Community Animal Health Policy

Dr Bernard van Goethem from the **European Commission's DG Health & Consumer Protection** gave an overview of the review of the CAHP which was currently underway and plans for the future policy. The review comprised an EU wide survey (over 100 respondents), a separate survey of 34 third countries, and interviews with national authorities and stakeholders (including IFAH-Europe).

The review has revealed some weaknesses in the current policy such as lack of coherence, which is a result of the development of the CAHP as a set of interrelated actions rather than a single policy framework. Also identified was a focus on crisis management and the tension between commercial and health related objectives.

Recommendations for the future include a focus on research and development for new tools to prevent, diagnose and treat animal diseases, sharing of costs and responsibilities among operators, incentive oriented approaches and wider promotion of biosecurity. With regard to the research priority, it should be highlighted that the Commission views the ETPGAH with its strategic research agenda (SRA) as an important partner in this area. It must however be remembered that the global objective of the CAHP is to protect human health; animal health is a secondary objective.

The evaluation of the CAHP will be officially presented at the 7 November 2006 conference jointly organised by the Austrian and Finnish presidencies of the EU. The Commission communication on the future EU animal health strategy 2007-2013 is expected in mid 2007.

Steps toward a more efficient regulatory system



Dr Brigitte Boenisch speaks on improving regulation

Dr Brigitte Boenisch of **Merial** and chair of the IFAH-Europe Technical and Regulatory Committee began her speech by outlining what she saw as the characteristics of a good regulatory system. This would be a science based, predictable and proportionate system.

Specifically such a system would:

- Promote the operation of the EU single market;
- Have faster approval times;
- Optimise the use of EU resources;
- Emphasise the risk-benefit balance;
- Have efficient decision making and enforcement.

The recent new pharmaceutical legislation is a start, but there are some drawbacks and the full potential of the legislation is not being exploited. There are, for example, delays in transposing the legislation, differences in interpretation and a lack of mutual recognition. In addition, the veterinary sector suffers from the direct application of "human" concepts to veterinary products.

There is a disconnect between broad EU objectives such as those related to the Lisbon agenda (e.g. less red tape, better regulation) and animal health and welfare, and narrow

regulatory objectives. The question to be asked is how can we close this gap? Communication on the goals of the Lisbon agenda and the role of the regulatory system alone may not be enough. Timely and consistent (harmonised) implementation of legislation and specific consideration of veterinary needs are two steps that can be taken. Early input on new regulation by stakeholders could help. It is also important to apply such concepts at the national level as well as the European level to ensure consistency. The Commission, the EMEA and the HMA (Heads of Medicines Agencies) all have key roles to play.

Session 4 Conclusions

It is important to link broad EU objectives, such as the Lisbon agenda goals, to sector objectives laid down, for example, in the CAHP. Efficient stakeholder collaboration including dialogue between regulators and industry is important. All speakers stressed that incentive oriented approaches were necessary to stimulate innovation.

Closing Session

The animal health priorities of the Finnish Presidency

Mr Veli-Mikko Niemi of the Finnish Agriculture and Fisheries Ministry outlined the animal health priorities of the Finnish EU Presidency (July – December 2006). On the veterinary agenda were the review of the CAHP, proposals on animal welfare and Maximum Residue Limits (MRLs).

Looking at the new CAHP, it was important to look at preventative measures in animal health and the movement of animals. Proposals likely to be released during the Finnish presidency include those on aquaculture, TSEs, MRLs, animal welfare, and broiler protection.

In animal health, prevention and diagnostics were very important. Political support for these comes through the recognition that these activities have public health and economic benefits.

Closing Remarks



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

Mr Declan O'Brien, IFAH-Europe Managing Director thanked the chairs, speakers and audience for their contribution to the conference. He noted that a very wide range of stakeholders had participated in the conference and he looked forward to ongoing constructive collaboration to solve common problems for the benefit of all concerned.