



Report of the
EMA/IFAH/DIA
Global Animal Health Conference

London, 15-16 November 2007



EMEA/IFAH/DIA Global Animal Health Conference

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I. About the conference

Programme co-chairs

Peter Jones, Executive Director, IFAH

David Mackay, Head of Unit, Veterinary Medicines and Inspections, EMEA, EU

Scientific panel

Christianne Bruschke, Chargée de Mission, OIE

Rick Hill, Director, Center for Veterinary Biologics, USDA, APHIS, United States of America

Peter Holdsworth, Chief Executive Officer, Animal Health Alliance Ltd., Australia

Catherine A. Knupp, Vice President, Pfizer Veterinary Medicine R&D, USA

Quintin McKellar, Principal, Royal Veterinary College, United Kingdom

Brian Perry, formerly Team Leader, Animal Health and Food Safety, International Livestock Research Institute, Kenya

Stephen F. Sundlof, Director of Center for Veterinary Medicines, FDA, United States of America

Peter W. Wells, Global Head of R&D, Novartis Animal Health, Switzerland

Key topics

- Positive environment for veterinary medicines
- Innovation in animal health
- Partnerships: Are they the answer?

Objectives

- Promote a dialogue among key stakeholders in global health in the field of veterinary medicines.
- Identify opportunities for creating a positive environment for veterinary medicines and their greater availability.
- Encourage further industry, academia and regulatory interactions to facilitate greater availability of medicines.
- Highlight areas of unmet medical need related to emerging and existing infectious diseases
- Increase awareness of advances in the research of new therapies and technologies and explore ways to accelerate their progress to market.

II. Executive summary

A meeting on global animal health was co-organised by IFAH and EMEA and run by DIA at the EMEA premises in London 14-15 November 2007. The meeting was attended by a wide range of stakeholders in the area of animal health, principally representatives of the animal health industry, regulators, academia and other research organisations. The agenda covered many of the most important issues affecting the availability and future development of medicines for animals worldwide.

The joint organisers drew the following main conclusions from the meeting:

- The animal health industry faces an ongoing challenge in terms of long term sustainability. The cost of bringing a new product to market in many cases continues to rise at a faster rate than the expected return and when this occurs such an imbalance acts as a disincentive to innovation. When developing new requirements, regulatory agencies need to ensure that these are appropriate for the particular nature and constraints of the animal health industry rather than merely transposing across requirements from the human sector, where the drivers are often very different.
- The challenges faced by both regulators and industry are global in nature with relatively minor regional variations. Due to the small size of the industry and the bodies that regulate it, there is much benefit to be gained from tackling common issues at a global level. International initiatives to promote a global approach are therefore encouraged, particularly through the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).
- A range of new technologies (e.g. the results of proteomics, transcriptomics, genomics) will result in a range of new products within the next few years. For successful transfer from the research laboratory to the veterinary clinic, regulators will need to have in place the necessary guidance specifically adapted for animal health products and all stakeholders will need to ensure that issues of public acceptance of new technologies are appropriately addressed. Acceptance needs to be based on trust which itself requires education, integrity and effective communication.
- The availability of medicines in less developed countries is constrained by factors distinct from those that apply in more developed regions. An effective regulatory system is a prerequisite to ensure that the market in these countries is attractive to the animal health industry which will start to invest in less developed regions as animal husbandry progresses from subsistence-based to commodity-based.

- Establishing effective partnerships between industry, academia, international animal health organisation and regulators is the single most effective step that can be taken to accelerate the progress to market of innovative products for animal health. The European Technology Platform for Global Animal Health represents a useful model of how these stakeholders can be brought together effectively.
- Limiting the development of antimicrobial resistance due to the use of antimicrobials in animals is one of the greatest challenges currently facing stakeholders in animal health. It is essential that the approach adopted takes into account all uses of antimicrobials in both man and animals and that the benefits of such use are fully considered when deciding on appropriate risk management measures.
- The effective use and continued development of animal medicines should form a key component of any national, international, regional or global animal health strategy and those bodies responsible for drawing up and implementing such strategies should ensure that all relevant stakeholders are involved.

III. Opening

■ Welcome

Thomas Lönngren, Executive Director, EMEA, European Union

Thomas Lönngren welcomed all participants. He emphasised that the conference provided the opportunity to link both developed and developing countries given the wide breadth of world regions represented.

He reminded the audience of the objectives of the conference and announced that a summary report would be prepared in due course.

■ Opening remarks

Rick Hill, Director, Center for Veterinary Biologics, USDA, APHIS, United States of America (Chairperson)

Peter Jones, Executive Director, IFAH (Co-chair)

Rick Hill, the session chair, thanked Dr. Lönngren and said that it was an honour for him to work on the scientific panel of the conference. He praised the high quality of the programme.

Peter Jones, co-chair, expressed his gratitude to the EMEA for providing the facilities for the conference, to DIA for the support in facilitating the conference and to the scientific panel for putting the programme together.

■ Strategic influences and considerations for successful development on new medicines

George Gunn, President, IFAH

George Gunn welcomed all participants to what he considered a truly global conference with delegates from all over the world.

He said that the importance of strategic consideration for the research and development portfolio is best demonstrated by the fact that the availability of medicines - and importantly the lack of new ones - today is largely due to strategic considerations made 5 to 10 years ago. He expressed hopes that the discussions about the future regulatory framework during the conference will become evident in a broad range of innovative products in 5 to 10 years from now.

He said that the industry represented at this conference is dedicated to further advance animal health to address society's needs making its contribution to animal welfare and public and consumer health. He felt confident that industry

and other stakeholders will be able to jointly launch a trend in finding ways as to how such an objective can best be achieved.

Dr. Gunn continued by saying that the time and cost to bring a new veterinary medicine to the market, coupled with the characteristics of the fragmented market for veterinary medicines, was having a negative effect on innovation.

He expressed concern about what industry considers to be the overburdening regulatory environment for veterinary medicines and the slow market growth, and said he looked forward to making the conference a platform to make this environment better for the animal health sector as a whole. He emphasised the need to simplify regulations bearing in mind the particular nature and needs of animal health in general. He called on stakeholders across all sectors and at global level to work together in order to shape an environment for innovation that benefits all parties.

He concluded that a paradigm shift was necessary to best fulfill the mission of advancing animal health and protecting public and consumer health and that the animal health sector needs to be recognised for its own merits and needs.

IV. Positive environment for veterinary medicines

Chairperson: **Rick Hill**, Director, Center for Veterinary Biologics, USDA, APHIS, United States of America

Co-chair: **Peter Jones**, Executive Director, IFAH

This session looked at the impact of the regulatory environment and whether or not it creates an incentive for developing new veterinary medicines. It was covered by six distinguished speakers representing the three main regions, Europe, US and Japan.

■ **Global benchmarking survey of regulation of veterinary medicines** **Richard Meads**, Director, Business Decisions Ltd., United Kingdom

Richard Meads opened the session presenting the conclusions of the IFAH 2006-07 benchmarking survey. This study looked at the relation between competitiveness and the business environment, including the regulatory framework, in five geographic areas: Australia, Canada, Europe, Japan and the United States of America.

He highlighted the impact of the lengthy development times, costs and risks which can affect the innovation cycle, which means that products need to be on the market for 10 to 15 years before any return on investment can be ensured. Competitiveness can be divided into short and long term, the first being driven by exploiting the potential of existing products, the latter by innovation in new product development. In both cases, regulatory uncertainty creates an inappropriate environment and leads to reluctance by companies to invest.

While stressing the decline in social acceptance of risk in Europe, which is becoming a global trend, he concluded by emphasising the major role that regulators play in setting the right environment that will ensure risk acceptance.

■ **Better regulation of veterinary medicines in the EU** **Martin Terberger**, Head of Pharmaceuticals Unit, DG Enterprise and Industry, European Commission, European Union

Martin Terberger presented the EU perspectives for the future. He started by highlighting what characterises the EU animal health business, i.e. a fragmented market in comparison to the US and the fact that the market for companion-animal products is developing better than the one for food-producing animals.

He described the setting up of the European Medicines Agency (EMA) in 1993 as a major positive development in ensuring a science-based environment. The EU aim is to guarantee protection of public and animal health and eventually achieve a single market, while ensuring innovation, medicines availability and competitiveness.

Dr. Terberger presented the EU 'Better Regulation' agenda with examples of the 'Maximum Residue Limits' (MRLs) and 'Variations' Regulations reviews, which are both in progress. The MRL legislative review is under discussion at the European Parliament, while the Variations Regulation is under public consultation. The latter especially aims at simplifying the Variations procedures by primarily making the system more predictable.

He concluded that the EU activities are taking place in alignment with the global agenda e.g. MRL review in the context of Codex activities. He emphasised the commitment of the European Commission and its agencies to the 'Better Regulation' agenda as a way of easing the regulatory burden for the animal health industry without compromising on safeguarding human and animal health.

■ Opportunities for better regulation

Jim Riviere, Distinguished Professor, North Carolina State College of Veterinary Medicines, United States of America

Jim Riviere looked at the impact of 21st century biology on existing regulatory systems. He stressed the need for a global common data package that could eventually lead to the adoption of the common technical document, which is already in use for human medicinal products in some countries.

He went on to alert the audience to six transforming science-based technologies, namely: computers, microfluidics, nanotechnology, high-throughput screening, controlled and targeted drug delivery and pharmacogenomics, as well as the combination of these.

Such technologies are currently already being used in development and the regulatory environment must be ready in 15 to 20 years to accept products arising from their use. He highlighted the reduced cost of developing companion animal drugs and the emergence of life-style drugs for these animals, with increased profit margin.

Professor Riviere concluded that the global regulatory environment must therefore prepare for evolving science and emerging diseases and must consider the importance of putting in place a global pharmacovigilance system.

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The second half of the session focused on international harmonisation and three speakers from the United States, Japan and the United Kingdom shared their perspectives on international harmonisation in relation to the global regulatory environment.

■ **Has VICH facilitated medicines availability globally?**

Stephen F. Sundlof, Director of Center for Veterinary Medicine, FDA, United States of America

Stephen Sundlof provided the background to international harmonisation efforts under the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

Dr. Sundlof indicated that, while the benefits are difficult to measure and are to some extent unknown, the overall consensus is that VICH efforts have increased global trade and the availability of veterinary medicinal products.

Commitments by industry and regulators towards VICH harmonisation over the past 10 years have led to the adoption and implementation of over 40 guidelines across the 3 regions. He stressed the challenge in reaching agreement in the pharmacovigilance area.

He continued saying that the VICH process, though slow and costly, is definitely worth the effort. Speaking for regulatory officials, Dr. Sundlof concluded that in the US there is commitment to continuing the process as long as industry values its achievements.

■ **VICH – harmonised guidelines: What impact at country level?**

Tomoaki Shimazaki, Chairperson of VICH BQMEWG, Ministry of Agriculture, Forestry and Fisheries, Japan

Tomoaki Shimazaki provided an example of the practical application of VICH guidelines in this region. He highlighted the challenges that regulatory authorities face in incorporating VICH guidelines into existing regulatory frameworks. The implementation of 18 Guidelines in 2003 was highlighted as a significant accomplishment and commitment to the VICH objectives.

Dr. Shimazaki indicated that, while the harmonisation of technical requirements has been the initial focus of VICH expert working groups, a shift to common guidelines that will allow registration simultaneously will be critical to long-term success of harmonisation efforts.

■ Regional harmonisation through mutual recognition

Steven Dean, Chief Executive Officer, Veterinary Medicines Directorate, United Kingdom

Steve Dean emphasised the importance and advantages of harmonisation efforts in the EU. His presentation outlined the complexities associated with the different aspects of harmonised processes, e.g. methods, standards, measures, surveillance, communications, enforcement, along with the cultural aspects of 27 EU Member States working together.

He indicated that there were several key factors that were essential to ensure the success of harmonisation in the EU. These included: a common language and a sound communication strategy; a regulatory network that supports harmonisation; transparency and increasing the use of the world wide web to share information; and an ongoing dialogue among all stakeholders.

Professor Dean also highlighted the challenges that remain: legal issues; availability of veterinary medicinal products; ensuring that regulatory frameworks are open and adaptable to change; and telematics improvements that are critical to an efficient use of resources. The possibility of a harmonised approach through mutual recognition in other parts of the world was also discussed.

■ Creating the positive environment – breakout sessions

This session comprised 3 parallel sessions, which each discussed the topic of creating a positive environment for animal health in a given geographic area. Each group was tasked to consider the questions below and to propose what actions should be taken by stakeholders.

This section summarises the answers that each group provided.

Breakout session 1: EU, USA and Canada

Leader: **Ian Alexander**, Acting Director General, Veterinary Drugs Directorate, Health Canada, Canada

1. Main disincentives and impediments to investment and innovation in the EU, USA and Canada

- Over-emphasis on safety versus clinical benefit (for example in US);
- Intellectual property limits;
- Unpredictability in requirements (legislation, guidelines), for example, requirements related to ecotoxicity risk assessment, MRLs (EU) and positive lists;
- 'Pull' for innovation needed by regulators, producers, and veterinarians;

- Controversial products (antimicrobial growth promoters and feed additives);
- No return of investment for minor uses/ minor species products;
- Reluctance to pursue registration in small markets, for example, ;
- Phytosanitary requirements at regional level can be a disincentive.

2. Main factors responsible for the loss of existing products from the market in the EU, USA and Canada

- Defensive costs of older products: data not protected; human standards applied; horse treated as a food-producing animal (EU);
- generic products dominating innovative ones;
- Political interventions (EU).

3. Ways to strike balance between availability issues and consumers' safety concerns (real and perceived)

- Communication: early and public directed (particularly on innovation);
- Acceptance of inherent risk in regulatory decision-making.

Breakout session 2: Australia, Japan and Asia Pacific

Leader: **Martin Holmes**, Program Manager Veterinary Medicines, APVMA, Australia

Dr. Holmes indicated that China, which is the country producing about 50% of animal health products in the region, was unfortunately not represented in the meeting.

1. Main disincentives and impediments to investment and innovation in Australia, Japan and Asia Pacific

The principle disincentive and impediment is a low return on investment, because of the following factors:

Disincentives and impediments	Actions to resolve
Low degree of regulatory harmonisation.	VICH and OIE could be vehicles to improve regulatory harmonisation. IFAH is trying to involve those countries in the VICH process.
The region has a large range of government systems throughout many countries	Industry and regulatory authorities have no capacity to influence this. However, all countries have farmers, consumers and other stakeholders who have an interest in removing impediments to the ready availability of high quality, safe and effective veterinary medicinal products. The re-launch of the International Technical Consultation on Veterinary Drug Registration (ITCVDR) could be a step forward.

Disincentives and impediments	Actions to resolve
Some of the regulatory authorities have low flexibility. If regulatory authorities require local studies there may be only limited availability of contract researchers.	<p>There must be more dialogue with regulatory authorities, especially with respect to the capacity to undertake studies which comply with good laboratory practice.</p> <p>IFAH has a role in Japan to discover the reasons for regulatory inflexibility.</p>
Intellectual property protection varies across the region.	Action is difficult; in some countries cultural factors make it difficult for regulatory authorities to improve intellectual property protection.

2. Main factors responsible for the loss existing products from the market in Australia, Japan and Asia Pacific

- Cancellation of the registration of a product in Europe/USA can lead to loss of availability of the product in Australia, Japan and Asia Pacific:
 - If the cancellation is due to regulatory action, other regulatory authorities in Australia, Japan and Asia Pacific may take similar action.
 - If the cancellation is voluntary, no free sale certificate will be available, leading to loss of market access.

It is usually impossible to defend very old chemicals where there is an inadequate database from the past and no current source of funding to undertake contemporary studies.

- Retrospective application of new guidelines makes it very difficult to defend old/existing products.
- Lack of harmonisation of MRLs in Asia Pacific: MRLs are set but the level of residue detection in some countries, leading to zero-tolerance of residues in some animal health products and to inconsistencies in withdrawal periods.
- Inadequate data protection in some countries.
- Local interpretation of guidelines may differ from the mainstream.

Participants identified the re-launch of the International Technical Consultation on Veterinary Drug Registration (ITCVDR) as a possible action to resolve the problem.

3. Ways to strike balance between availability issues and consumers' safety concerns (real and perceived)

- The question should be on the assessment of benefit versus risk, rather than risk versus benefit.
- Communication between governments, citizens and the animal health industry is a big issue. Industry must be proactive, not reactive, in relation to the regulatory requirements for the registration of animal health products.
- Europe's focus in risk versus benefit is a negative influence on other countries.
- Industry should seek to stop the drift of the precautionary principle in a disproportionate manner on topics such as antimicrobial resistance.

Breakout session 3: Enhancing medicines availability in developing countries

Leader: **Brian Perry**, formerly Team Leader, Animal Health and Food Safety, International Livestock Research Institute, Kenya

Dr. Perry noted that there was no representative working for developing countries in the discussion group.

Why should veterinary pharmaceutical companies care for livestock keeping in developing countries?

- Given the economic challenges in developing new products, particularly for diseases in developing countries, there is a growing interest in products for diseases in a wider geographical area.
- There is a huge growth in the demand for livestock products in developing countries, especially in East and South Asia. There is the feeling that in many developing countries there is the capacity to pay.
- There was a concern regarding the fact that pharmaceutical companies have to provide very high quality products and that for ethical reasons companies have to provide information on any adverse reaction.
- Many existing products are either not used or misused by poor livestock farmers. There is the opportunity for the animal health industry to work with regulators to improve the regulatory side and work with the end-users.

Participants mentioned a possible role for IFAH in working with governments especially for livestock. However, it was pointed out that industry does not have the capacity to run educational programmes in developing countries.

What are the demands for veterinary medicinal products in developing countries?

Participants agreed that the major problem was in the supply chain.

How to ensure that product registration is efficient?

Attendees felt that some models coming from EU enlargement countries could be used in developing countries to educate regulators. It was also mentioned that national governments often do not make good vaccines producers and that public/private partnerships are often more effective.

V. Innovation in animal health

Chairperson: **Peter W. Wells**, Global Head of Research and Development, Novartis Animal Health

Co-chair: **David Mackay**, Head of Unit, Veterinary Medicines and Inspections, EMEA, European Union

■ **New trends in veterinary medicine: What's in the research pipeline**

Catherine A. Knupp, Vice President, Pfizer Veterinary Medicines R&D

Catherine Knupp opened her presentation by saying that the research pipeline can be stimulated by certain enabling factors, such as global market trends and demands, the development of more cost-effective technologies, and the demand being driven by the human-animal bond. On the other hand, research can be impeded by increasing development costs, changes in risk perception, and economic realities.

Research can contribute to several areas, not only therapy and prophylaxis, but also to drug delivery, manufacturing efficiency, and improvements to quality, safety, efficacy, and environmental safety.

Current trends in animal health R&D are towards lifestyle drugs and oncology therapies for companion animals, improving livestock production efficiency, and improving the genetic stock of livestock. Dr. Knupp added that current trends are directed towards supporting the developments of new technologies such as biotherapeutics, nanotechnologies, transgenic plant bioexpression products and novel adjuvants.

Dr. Knupp concluded that such trends are fuelled by the increasing longevity of companion animals, and the increasing demand for affordable animal protein derived from food animals.

■ **Emerging technologies in the development of veterinary medicines**

Cyril Gay, National Program Leader, Animal Health, USDA, United States of America

Cyril Gay identified three key areas that will greatly impact animal health research and the discovery of new veterinary medicines in the next 10-15 years: sequencing of whole genomes, new genomic tools, and RNA-based technologies.

He pointed out that following a slow start after the birth of the 'Genome Age' in the 1980's, it 'arrived' in the '2000's' when genome selection became possible. The interest in comparative genomics by the human health community and the investment in the 'Avian and Cow Genome Projects' are

delivering new research tools that are fundamentally changing scientific approaches to animal health research.

Dr. Gay explained that genomics are relevant to the development of veterinary medicines as it is a starting point for understanding the molecular basis of certain diseases, leading to the identification of which genes are involved, how genes are regulated, and what proteins are expressed. Facilitating this is the emergence of new research tools, particularly genetic markers, transcript profiling, proteomic tools, and RNA-based technologies.

Micro RNA has recently been discovered as playing an important role in controlling gene expression in several biological processes, including cancer and immune response.

Dr. Gay concluded with 4 overarching topics for reflection:

1. Quantitative population genetic studies to identify markers of health trails.
2. Functional genomics of host-pathogen interactions.
3. Translating genomics information into tools for controlling diseases.
4. Integrating stakeholders support to advance animal genomics in animal health.

He re-inforced the message that academic - government - industry partnerships will be essential to tackle these issues.

■ Collaboration between research – academia and industry and the challenge of technology transfer
Quintin McKellar, Principal, Royal Veterinary College, United Kingdom

Quintin McKellar reviewed the evolution of the higher education system in the UK, from its roots in Oxford and Cambridge as a provider of “persons to serve in church and state”, through to the mid-1900’s when universities became bastions of learned professions and defenders of cultural values, pure research and free thinking.

Since the 1960’s universities have evolved into catalysts for growth of national GDP. This has been made possible by changes in funding and the recognition of the importance of intellectual property protection. More recently they have become models for the successful exploitation of research, such as licensing, spin-out companies (backed by venture capital) and joint ventures.

Professor McKellar said that universities can ‘add value’ to research via both intellectual resource (e.g. unique animal-model) and also physical resources (specialised equipment). He added that, however, the academic institution must adopt professional procedures to ensure contract outcomes are delivered on time and on budget, and to appropriate standards (GLP).

He added that respect of confidentiality is sometimes an issue. In return, the academic institution requires appropriate financial reward and enhancement of its international reputation.

Professor McKellar concluded that academic institutions must confer equal importance to the commercial research as to teaching and blue-sky research.

■ **Managing consumer perceptions of risk and benefit**

Arnout Fischer, Professor, Food Safety and Consumer Behaviour,
University of Wageningen, The Netherlands

Arnout Fisher said that an understanding of the psychology of public risk perception is an essential pre-requisite to managing consumer perceptions of risk and benefit. Following that the key elements in managing public perception are good risk communication, transparency and trust in the risk management process (and risk manager).

Public risk perception is usually based on emotional, subjective and heuristic judgements, and is influenced by a broad range of issues. While expert risk assessment is formalised and delimited, it is nevertheless also based on human judgement, subjective arguments and heuristics.

Prof. Fischer identified the quantity and quality of media attention as the main barrier to good risk communication. He added that only experts believe that media attention causes *unnecessary worry* among consumers.

He continued on the role of trust, which implies honesty, care and competence. Trust is critical to public acceptance of risk management and a pre-condition for successful communication. He acknowledged that trust is easily lost and difficult to regain. Risk managers and risk communicators activities must be consistent to build trust (the actions must match the words).

He emphasised that full transparency and public consultation will be necessary in attempts to restore trust, and that the outcome of the consultation must be respected.

Prof. Fischer concluded saying that trust is an important precondition for communication. The public has a very broad view on animal health issues, which is not limited to risk to human health. Public opinion also considers ethical, environmental and animal welfare aspects of risk management decisions.

■ **Parasite control in livestock: Are we in control?**

Peter Willadsen, Chief Scientist, CSIRO Livestock Industry, Australia

Peter Willadsen said that twenty years ago 'control' may have been defined as close to 100% elimination of parasites. More recent and realistic definitions talk about reducing parasite impact to acceptable limits in a sustainable way.

Control can be lost by over-dependence on medicines, such as antiparasitics, particularly when other technologies, such as vaccines and genetics, are not applicable. Good control is also dependent on political support and acceptance by farmers of new technology. Loss of control can be minimised by good management practices to control resistance development, and by investment in the development of new antiparasitic molecules.

A successful parasite control system requires effective technology (an efficient drug or vaccine and a practical (simple) programme) supported by a suitable regulatory framework and sufficient political will. The control programme also needs the full support of the farmers, local administration and local community.

Dr. Willadsen illustrated the problem with case studies in the development of resistance. Acaricide resistance development was one example using Australian and South American experience with control of the cattle tick via different chemical groups. A second example given was the development of resistance of buffalo fly to insecticides and a third the current situation with nematode parasites of sheep.

The importance of effective parasite control is increasing, as new and emerging diseases can present global threats to both livestock and humans from zoonoses. This is caused by increased global movement of people and animals and other factors including global warming.

In Dr. Willadsen's view, future work should focus on research into all aspects of resistance management and into the development of new control technologies and agents. In this, genomics will play an increasing role. Novel technologies such as therapeutic RNAi offer a potential future solution. In conclusion, he said that we have not lost control of parasites, but we are only in a "holding" position.

■ **What does the animal health community need in terms of new medicines to tackle disease in animals?**

Steve Sloan, CEO GALVmed, United Kingdom

Steve Sloan said that the focus of the Global Alliance for Livestock Veterinary medicines (GALVmed) reflects the Millennium Development Goals – "Protecting livestock – saving human life". It serves the needs of the 600 million poorest livestock keepers in Africa, Asia and South America, and has plans to develop 4-6 new vaccines, treatments and diagnostics by 2015, using the model of partnership building. Although the largest target population for GALVmed is in India, the biggest issues are to be found in sub-Saharan Africa.

He emphasised that these developing countries need products that are appropriate to their conditions, sustainably produced and supplied, trusted, understood and accessible. Such products must be adapted or developed specifically for the region. They must be thermostable, appropriately packaged (pack size), registered, marketed and supported. It may even be necessary to develop commercial networks and a supply chain.

Dr. Sloane concluded that a global focus is necessary, as today's problems in the developing world are tomorrow's headache for us all. He added that all those involved in the animal health industry have it within their power to make a contribution to the plight of the poorest people in developing countries whose very survival depends upon the health and survival of their livestock.

VI. Building alliances to find solutions (parallel sessions)

Theme 1: Antimicrobial resistance: Managing the threat to animal and human health

Chairperson: **Quintin McKellar**, Royal Veterinary College, United Kingdom
Co-chair: **Peter Holdsworth**, Chief Executive Officer, Animal Health Alliance Ltd., Australia

■ Defining lists of critically important antimicrobials Catherine Lambert, Technical Advisor, OIE

Catherine Lambert reviewed the activities of the last 10 years within OIE relating to antimicrobial resistance and referred to international cooperation with FAO, WHO and Codex experts.

Further to 2 joint FAO/WHO/OIE experts consultation meetings (in 2003 and 2004) on non-human antimicrobial usage and antimicrobial resistance, there was a recommendation to develop the concept of "critically important" classes of antimicrobial agents both in human and veterinary medicines.

Building on this recommendation, two lists were developed:

1. The list of (human) critically important agents based on the following criteria:
 - sole therapy or one of few alternatives to treat a serious human disease.
 - antibacterial used to treat diseases caused by organisms that may be transmitted via non-human sources or diseases caused by organisms that may acquire resistance genes from non-human sources.
2. The list of veterinary critically important agents. These are defined as "antimicrobials used for treatment, prevention and control of serious animal infections that may have important consequences on animal health and welfare, public health or important economic consequences and where there are few or no alternatives".

The aim was to help veterinarians in their therapeutic choice, to complement the OIE guideline for responsible and prudent use of antimicrobial agents.

The OIE General Session adopted a refined list in May 2007. This includes three categories of antimicrobials:

- i) Veterinary critically important antimicrobials (criteria 1 and 2) – VCIA: aminoglycosides, cephalosporins, macrolides, penicillins, phenicols, quinolones, sulfonamides, and tetracyclines.
- ii) Veterinary highly important antimicrobials (criteria 1 or 2) – VHIA: rifamycins, fosfomicin, ionophores, lincosamides, pleuromutilins and polypeptides.

iii) Veterinary important antimicrobials (neither criteria 1 or 2) – VIA: bicyclimycin, fusidic acid, novobiocin, orthosomycins, quinoxalines and streptogramins.

Dr. Lambert underscored that the number of antimicrobials considered reflects the complexity of veterinary medicines, the multiplicity of target species and the variety of national or regional needs. She noted that the families of products are mostly the same for humans and animals.

Dr. Lambert concluded that antimicrobial resistance is a global and multidisciplinary issue and that the ongoing cooperation between FAO, WHO, Codex and OIE is essential. Cooperation and communication among stakeholders remains a key issue.

■ **Risk assessment to define the problem and its management: Report from the Codex Intergovernmental Task Force**
Peter Jones, Executive Director, IFAH

Peter Jones provided a report of the Codex Intergovernmental Task Force on antimicrobial resistance, which met in Seoul (Korea) in October 2007.

The objective of the Task Force is to develop science-based risk assessment guidelines based on CODEX risk-analysis principles and standards set up by international organisations such as FAO, WHO and OIE. The scope of the group is food- producing animals only.

Three project working groups were created for further work on:

- Risk Assessment: to be chaired by Canada. The purpose of the group is to support/enable JEMRA and national authorities in assessing potential overall risk to human health associated with presence in food and feed of antimicrobial-resistant organisms.
- Risk Management: to be hosted by the EU and co-chaired by France and Denmark. The objective is to develop appropriate risk management guidance for national authorities to guide the actions that may be necessary following risk profiling and/or risk assessments.
- Risk Profile/Prioritisation: to be chaired by the USA. The intent is to develop guidance on identifying food safety issues related to antimicrobial resistance and on the data needed for risk profiling. Additionally the group will advise on the methodology for setting priorities with respect to risks related to antimicrobial resistance in food-borne micro-organisms.

Dr. Jones concluded by saying that it is expected that the project working groups will complete their work by end of Q2 2008 and that the documents will be submitted to the Codex Commission for approval in July 2008. The Task Force is expected to complete its work by the end of 2010.

■ The industry perspective

Thomas R. Shryock, Senior Microbiology Technical Advisor, Elanco Animal Health

Thomas R. Shryock emphasized that antibiotics help to keep animals healthy and they improve animal welfare. He also underlined the contribution that judicious use of antimicrobials can make to human health by ensuring that healthy animals enter the food chain. There are no alternatives to antibiotics to treat bacterial disease. The use of vaccines is important but there are currently no alternatives to antibiotics to treat bacterial diseases.

He noted that the animal health sector is very proactive in managing the threat of antibiotic resistance in animals and humans by fully implementing risk management actions. For example, the industry has been supportive of national authorities that have instituted risk assessment into their regulatory evaluations, based on the OIE risk analysis procedures and that of the VICH.

Additionally, the animal health industry has been conducting independent risk assessments of specific pathogens and antibiotic uses, undertaking resistance monitoring programmes and supporting responsible use programmes. In every risk management activity, it is important to consider the effect on the availability of medicines and the different groups of antimicrobials.

He finalised his presentation by pointing out that it is important to establish some form of measurement to assess the success of the risk management procedures introduced. He concluded by saying that we need to consider antimicrobial use in people and animals within the context of the "One Medicine" theme. A key component will be partnerships to fully implement risk management to achieve the goal of an appropriate balance between animal health and public health.

■ The veterinarian's viewpoint in managing antimicrobial disease in animals

Mike Apley, Associate Professor, Production Medicine/Clinical Pharmacology, World Veterinary Association

Mike Apley opened his presentation by raising the point that resistance implies unfavourable outcomes. He referred to the challenges associated with addressing the problem of resistance in veterinary medicines, which includes interpretation of susceptibility testing, patient delivery, patient and client considerations, available clinical data, and a gallery of challenging organisms.

He then said that one of the major concerns should be not only to keep antibiotics safe but also to be sure that they continue working well in human and veterinary patients. He highlighted the possibility of direct or indirect transfer between animals and humans (bidirectional potential) and the obligation for all parties to preserve antimicrobial resources to maintain the ability to treat animals.

Dr. Apley mentioned the role of education by making the best science available to every veterinarian. He stressed the importance of developing a clinical database and the need to improve the interpretation of susceptibility testing and to optimise duration of treatment.

He identified the need to define which animals need to be treated and the importance of applying rational treatment regimes. He concluded by saying that we need a good selection of safe and effective antimicrobials; readily available information on optimal use; and continued research to optimise regimes for efficacy and minimise selection for resistant organisms.

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During the panel discussion that followed the presentations participants tackled various aspects of the antimicrobial resistance debate.

It was mentioned that discussions at Codex do not focus on human health aspects.

Animal health industry representatives re-inforced the view that reducing the number of bacteria in animals makes food safer.

A representative from a regulatory body voiced his concern that for the moment it was impossible to define the new risks that would appear if some antimicrobial classes were banned in Europe. He called for an in-depth risk assessment.

As regards formularies, some participants expressed their opposition to this approach. The setting up of a database on the efficacy of each antimicrobial for each disease was suggested as a possible solution. This led to acknowledging the importance of prudent use guidelines, such as those produced by the RUMA (Responsible Use of Medicines in Agriculture) initiative in the United Kingdom. Prudent use guidelines should be aimed at taking into consideration national conditions.

A representative of the veterinary profession stressed that, due to the nature of animals and husbandry, treatment is required; animals cannot be kept and raised in a sterile environment. He felt that the veterinary sector should better explain to the outside world what is done to reduce the use of antimicrobials, when and where possible.

Theme 2: Tackling existing and emerging diseases

Chairperson: **Andy Peters**, Director Translational Research, Royal (Dick) School of Veterinary Studies, United Kingdom

Co-chair: **Declan O'Brien**, Managing Director, IFAH-Europe

■ **Global control of animal diseases,**

Juan Lubroth, Senior Officer, Animal Health Service, FAO (EMPRES)

Juan Lubroth described the FAO mission in relation to the millennium development goals particularly on transboundary diseases. He provided an overview of the various programmes that FAO is involved with concerning the emergency prevention system of global transboundary animal diseases, global warning system such as the emergency prevention system (EMPRES), the global framework for the progressive control of transboundary animal diseases (GF-TADs) and the global early warning system (GLEWS).

He described the global rinderpest eradication programme as an exemplary success story in terms of elimination or virtual eradication of a major animal disease and emphasised the important role of vaccines in that programme.

Dr. Lubroth explained the FAO's work in relation to foot-and-mouth disease and avian influenza in various world regions. The presentation illustrated the reality in some of the countries where FAO is working particularly in relation to poverty, lack of resource, non-existence of facilities, and the deficiencies in terms of training of veterinary staff.

He talked about the constraints in controlling animal diseases. These comprise technical factors linked to knowledge and infrastructure as well as political, economic and social constraints. Additionally, environmental factors and public health play a key role in this field.

In conclusion, he highlighted the importance of prevention and preparedness, improved tools and the need to tackle the disease at source.

■ **Avian influenza – Where do we stand in 2007?**

Christianne Brusckke, Chargée de Mission, OIE

Christianne Brusckke opened her presentation recalling the sequence of events in relation with the avian influenza H5N1 Asian strain (200-2007). She referred to the OIE strategy for control of avian influenza and highlighted the rapid spread of this virus in three continents – Asia, Africa and Europe - and its relatively unpredictable behaviour.

She referred to the importance of minimising the threat in the source animals and explained the lessons learned, such as the fact that early detection and rapid response has prevented the establishment of the disease in most infected

countries. She also mentioned the essential role of strong governance and an efficient national chain of command, among other elements.

Dr. Brusckhe described the main constraints of highly-pathogenic avian influenza (HPAI) control and pointed out the positive trends. For example, mortality of wild birds has strongly decreased, countries are able to detect and resolve outbreaks quicker and the availability of international funds.

She concluded the presentation by talking about future actions needed. Short-term actions in the animal field should be focused to preventing further spread of the diseases amongst poultry. Another stream of short- and medium-term actions should be taken to improve the veterinary services in developing countries in association with public and private partnerships and by identifying key gaps in knowledge and research initiatives.

Longer-term actions comprise: permanent lobbying; permanent follow-up of the veterinary services in developing countries in association with public and private partners; capacity building in the livestock sectors; and research programmes.

Opportunities for stakeholder alliance for future research : The European Technology Platform for Global Animal Health

Jim Scudamore, Professor of Livestock and Veterinary Public Health, University of Liverpool, United Kingdom

Jim Scudamore described the framework for the development of the technology platform. This consists of three stages. Firstly, the development of the vision, then the strategic research agenda and, finally, the action plan. He talked about the rationale behind the ETPGAH in relation to worldwide risks of new and emerging diseases, and their impact in developed and developing countries. The delivery of new or improved control measures involving vaccines, pharmaceuticals and diagnostics were essential for success.

Professor Scudamore went on to explain the main objectives of the platform: to protect Europe from the incursion of epidemic animal diseases and zoonoses, to deal rapidly and effectively with outbreaks, to accelerate the speed to market of innovative products, and to reduce the global incidence of animal disease, thereby indirectly protecting Europe. The platform is unique in that a wide range of stakeholders drawn from regulatory bodies, government bodies, industry, academia, etc. are involved and actively participate in the work of the platform.

The action plan was launched in July 2007 with the vision to facilitate and accelerate the development and distribution of the most effective tools for controlling animal diseases of major importance to Europe and the rest of the world.

The strategic research agenda contains 61 specific recommendations, which fall into 6 themes: prioritisation of disease, gap analysis, fundamental science, enabling factors, regulatory and societal issues as well as global partnerships.

Professor Scudamore said that the platform will henceforth be responsible for monitoring progress and undertaking an annual review of activities. Additionally, the platform will have input into developing research strategies and funding arrangements.

He also referred to the importance of mirror groups. These are national organisations that operate as a microcosm of the overall European platform to work on the priorities at a national level.

■ **Foot-and-mouth disease: Global roadmap for improved FMD control in endemic settings**

Brian Perry, formerly Team Leader, Animal Health and Food Safety, International Livestock Research Institute, Kenya

Brian Perry opened his presentation by saying that a number of international laboratories are working together to enhance collaboration in the area of FMD control in endemic settings. The activities of this network started with an international workshop held in Agra (India) in December 2006.

The participating organisations identified an ideal FMD vaccine profile and the gaps where the ideal vaccine differed from those currently in use. They identified the strategic approaches to address the gaps - science needs for novel vaccines, the design of vaccines and diagnostics, and the enabling technologies and decision support tools – and the need for a coordinated road map and action plan.

Dr. Perry went on to explain the vision of the programme: a world in which livestock-based livelihoods, enterprises and trade can flourish unimpeded by FMD. The vision is coupled with a mission statement and strategic goals.

The roadmap was launched in April 2007. Dr. Perry is involved in development of tools for the progressive control of FMD in endemic settings as part of a strategic research award pre-proposal submission to the Wellcome Trust.

Dr. Perry referred to challenges linked to running vaccination programmes and to the typology of endemic areas. These vary from countries that are free of FMD but susceptible to the disease where people are trained to run such programmes (e.g. Argentina), to threshold countries with an uneven distribution of trained professionals (e.g. South East Asia), and to self-sustaining countries where there is no capacity to run vaccination programmes because there are other priorities.

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During the discussion session that followed the presentations, participants examined the success story of the elimination of rinderpest and the possibility to extrapolate this to other situations. The discussion revealed that the highly effective rinderpest vaccine used as part of the campaign was a key element of the success. Other critical factors were the availability of a research programme and a global laboratory for rinderpest, a good distribution of the vaccine and the coordination between FAO and OIE through donor support.

Participants felt that the success story linked to the elimination of rinderpest could not be extrapolated to avian influenza. They shared the view that a disease-specific strategy is necessary and that this should be based on current tools and developing new ones, e.g. through private/public partnerships. Attendees acknowledged the importance of contingency measures and keeping fundamental science alive to tackle emerging diseases.

VII. Close

■ Closing keynote address: “Prevention is better than cure” – The global impact of the new EU animal health strategy”

Robert Madelin, Director General of Health and Consumer Protection, European Commission, European Union

Robert Madelin opened his speech saying that the experience of the past years has shown the global nature of animal diseases and the need to reach out to more players and make them part of a single network. The past crises have demonstrated that prevention is better than cure.

He explained the context of the EU Community Animal Health Strategy. The big cataclysm that came with the FMD outbreak in the beginning of the 21st century in the United Kingdom resulted in a shift in fundamental thinking in the veterinary community across the EU to tackle animal diseases. He emphasised that the need to take action was due to both the direct and indirect costs of disease and the suffering linked to the loss of animal lives.

He reviewed the goals of the newly published EU Animal Health Strategy, i.e., a high level of public health and food safety; continuing support of farming and rural economy; improving economic growth, cohesion and competitiveness; and promoting sustainable farming practices and animal welfare.

Mr. Madelin said that the European Commission aims at moving from a reactive approach towards a proactive one (prevention). DG SANCO also wishes to set a single legal framework that should replace the existing interrelated policy actions by converging them as far as possible with recommendations, standards and guidelines of the OIE and Codex. He also mentioned the need to develop efficient cost and responsibility sharing schemes. He explained that diseases would be prioritised in order of impact on health and society, and funds. Public funding would then be allocated accordingly.

He referred to the European Technology Platform for Global Animal Health and welcomed initiatives to enhance international cooperation in relation to zoonotic diseases. He explained that the 7th framework research programme (FP7) and the ETPGAH provide opportunities to advance research in animal health.

He concluded by calling on all players in the EU and at global level to work together to successfully deliver the objectives of the animal health strategy.

■ **Closing words**

Thomas Lönngren, Executive Director, EMEA, European Union

Thomas Lönngren expressed satisfaction that the conference achieved its objectives and highlighted the need to spread the outcome of the conference to the public.

He thanked all participants for their input to the success of the conference and looked forward to a follow-up conference.

VIII. Acronyms

APHIS	United States Department of Agriculture Animal and Plant Health Inspection Service
APVMA	Australian Pesticides and Veterinary Medicines Authority
DG SANCO	European Commission Directorate General Health and Consumer Affairs
DIA	Drug Information Association
EMA	European Medicines Agency
EMPRES	FAO Emergency Prevention System
ETPGAH	European Technology Platform for Global Animal Health
FAO	United Nations Food and Agriculture Organisation
FMD	Foot-and-mouth disease
GF-TADs	Global Framework for the Progressive Control of Transboundary Animal Diseases
GLEWS	FAO Global Early Warning System
GLP	Good laboratory practice
H5N1	Highly-pathogenic avian influenza
IFAH	International Federation for Animal Health
ITCVDR	International Technical Consultation on Veterinary Drug Registration
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
MRL	Maximum residue limit
OIE	World Organisation for Animal Health

R&D	Research and development
RUMA	Responsible Use of Medicines in Agriculture Alliance (United Kingdom)
USDA	United States Department of Agriculture
VCIA	Veterinary critically important antimicrobial
VHIA	Veterinary highly important antimicrobial
VIA	Veterinary important antimicrobial
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organisation