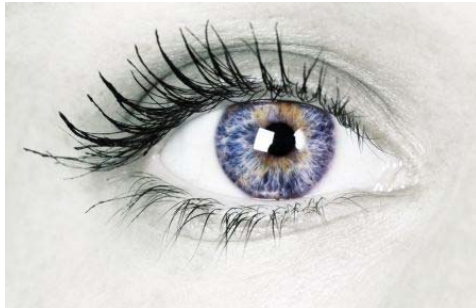


The 2010 review - 1 vision:



1 final step



to 1 market?



PROGRAMME

08.00 **Registration**

09.00 **Opening session**

Introduction and welcome

Jochen Wieda, IFAH-Europe Chairman

The Community Animal Health Strategy and the future animal health regulation

*Androulla Vassiliou, European Health Commissioner
Rolf Eriksson, Swedish State Secretary for Agriculture*

09.30 **Session I: Objectives of the review in 2010**

Chair: Jiri Bures, Czech Republic (HMA Presidency)

Stakeholders' view: Why we need a single market; why we need improved availability

Avril Doyle MEP

DG Enterprise's considerations for a review of the veterinary medicines legislation*

Martin Terberger, European Commission DG Enterprise

Questions and answers

Coffee break (10.30)

11.00 **Session II: Possible solutions**

Chair: Consuelo Rubio, Deputy Director General Spanish Medicines Agency

The HMA Task Force reflection paper on opportunities for the review

Patrick Dehaumont, Chair of the Heads of Medicine Agencies' Task Force

The animal health industry's proposals towards the review

Neil Craven, IFAH-Europe

12.00 **Panel discussion****

Lunch (12.30)

13.30 **4 parallel workshops around the HMA reflection and the IFAH-Europe 1-1-1 concept**

1. How to achieve the objectives of a true single market for veterinary medicines?
2. How do we achieve 1 assessment & 1 decision?
3. How do we stimulate Innovation?
4. What measures do we need to take to improve access to veterinary medicines?

Coffee break (15.30)

16.00 **Closing session**

Chair: Jochen Wieda, IFAH-Europe Chairman

Presentation of conclusions and recommendations

Rapporteurs of workshops

Closing words

Declan O'Brien, IFAH-Europe Managing Director

17.15 **Cocktails**

* including COM declaration

** speakers from sessions I & II plus other invited opinion leaders

OPENING SESSION

Jochen Wieda opening the conference

Biography

Jochen Wieda serves on the IFAH Europe Council as Chairman since 2008.

He joined the animal health industry in 1985, after 2 years in a large animal veterinary practice. He started in clinical development and then established a project-management system within Hoechst Animal Health. Following the merger with Roussel Uclaf he became globally responsible for regulatory affairs and compliance.

From 2001 to 2002 he managed the pharma R&D-site of Intervet in Germany. Subsequently, Dr. Wieda was Global R&D Director for pharmaceuticals with Intervet International in Boxmeer, The Netherlands, for 5 years.

Recently he became a member of the Management Team of R&D Pharmaceuticals with Intervet/Schering Plough Animal Health.

A German citizen, Dr. Wieda studied veterinary sciences at the Free University of Berlin.

Philip Tod (on behalf of Androulla Vassiliou) speaking on:

The Community Animal Health Strategy and the future animal health regulation

Philip Tod

Biography

Philip Tod is a member of the Cabinet of European Commissioner for Health, Androulla Vassiliou, since April 2008. He is responsible for animal health and welfare, as well as enterprise and industry, internal market and justice and home affairs.

Previously he was the spokesman on Health and Consumer Protection, European Commission (from November 2004) until being appointed to the cabinet of Commissioner Markos Kyprianou in November 2007, having been previously worked as the leader's spokesman and Head of the Press Office of the European Liberal Democrat and Reform Group (ELDR) in the European Parliament between 2002 and 2004.

He was a policy adviser for the Economic and Monetary Affairs Committee of the European Parliament (2000-2002) and a consultant with Hill and Knowlton (1997-2000).

A British and French citizen, he has a MA in European Political and Administrative Studies at the College of Europe, Bruges (1996) and BSc (ECON) on Government at the London School of Economics and Political Science (1995).

IFAH-EUROPE CONFERENCE
COMMUNITY ANIMAL HEALTH STRATEGY AND
THE FUTURE ANIMAL HEALTH REGULATION
25 June 2009

SPEECH

President, Minister, Ladies and Gentlemen,

I would like to begin by conveying the sincere apologies of Commissioner Androulla Vassiliou for not being able to address you today due to institutional commitments. As the member of her cabinet responsible for animal health and welfare, Commissioner Vassiliou asked me to thank IFAH Europe for the invitation to address this conference, and deliver her speech on the Community animal health strategy and the future animal health law.

This event is a good opportunity to share and explore recent developments in this important area.

It is also an opportune moment to raise some of the Commission's future ambitions as regards the broad issue of animal health, and especially its regulatory aspects in Europe.

As many of you will know, the Commission published a Communication on a new Animal Health Strategy in 2007 with the overarching theme of "Prevention is better than cure."

This was followed in September 2008 by the adoption of an Action Plan implementing the Strategy, with 31 actions grouped under the four pillars of the Strategy:

1. Prioritisation of EU intervention
2. A modern EU animal health framework
3. Improving prevention and crisis preparedness
4. Science, Innovation and Research

We should, of course, first recognise that our previous animal health policy served its purpose well.

Over the decades harmonised Community animal health measures and systems for disease surveillance, diagnosis and control have progressively replaced many national regulations.

In fact we have achieved a fully harmonised legal framework ensuring a single European market for live animals and animal products.

The current measures have made a crucial contribution towards eliminating certain diseases or keeping them under control.

They have enabled the farming community and other stakeholders to remain competitive as well as ensuring the safety of animal products.

This is clearly an area where the added-value of the Community has been proven time after time.

But despite this success, we were aware that there could be room for improvement, and we listened carefully to suggestions from stakeholders to that effect – notably during an external evaluation in 2006. This was an essential precursor leading to the birth of our new Strategy.

Our emphasis has now shifted towards a more proactive approach, especially on the prevention of the occurrence of animal diseases and the reduction of their impact.

Ongoing actions under the Strategy are numerous and diverse. Commissioner Vassiliou is well aware that IFAH Europe is an active member in several of our steering groups and she truly appreciates your efforts to contribute to all four pillars.

Under the first pillar work is ongoing within the framework of the European Technology Platform for Global Animal Health to develop a disease database; to identify gaps regarding available information and tools to deal with animal diseases; and to direct research activities towards those gaps that are considered as a priority.

Under the second pillar, on the animal health framework, one of the actions aims for the current complex legal structure to be replaced by a simpler framework.

Our veterinary *acquis communautaire* is a vast body of legal texts – some 60 basic acts with the principles of intra-Community trade, disease eradication and so forth, supplemented by some 400 Commission acts for the implementing rules.

The expected outcome of the ongoing work is a single, clearer Animal Health Law. This will form one of the main instruments to implement the new Animal Health Strategy.

And in addition to simplification, it will also address some other fundamental issues. For example:

- responsibilities of the main actors such as animal keepers, operators, competent authorities;
- disease prevention and biosecurity;
- links between animal health policy to, and coherence with, other relevant Community policies;
- flexibility to adapt to new circumstances and account for new developments based on scientific facts;
- keeping the animal health legislation up to date with the evolution of relevant technology.

As you are well aware, however, Commissioner Vassiliou's sphere of responsibility within the Commission does not encompass the area of authorisation and registration of veterinary medicines.

That falls under the enterprise and industry portfolio of Vice-President Guenter Verheugen, and I understand that officials from his services will cover that subject in detail later on today.

But, of course, the availability and innovative development of veterinary medicines, including vaccines and diagnostic tools, is clearly of major importance to Community animal health policy.

The availability (or lack of it) of suitable products or technology to deal with certain situations already forms part of the considerations to determine specific intervention priorities.

In that sense we have already scored some notable successes in recent years – such as the reduction of the number of rabies and classical swine fever cases in Europe.

Another prominent example is bluetongue where vaccination is an important tool for its control.

Some Member States have recently embarked upon large scale vaccination programmes, and the trend of the disease now seems to have taken a favourable turn.

Currently, many pharmaceutical companies produce bluetongue vaccines for various EU Member States – some in large enough quantities to supply sufficient doses for mass vaccination.

Of course, such measures can only be maintained – especially in view of the significant costs involved – where there are clear beneficial outcomes.

Therefore Commissioner's Vassiliou's services are paying very close attention to the Bluetongue situation. The aim for the coming years is to review the policy, including the regulatory framework for the control of the disease and also the Community financial contribution towards fighting against it.

Animal health and welfare issues are, of course, of major concern to European citizens. These concerns stem not only from food safety issues but also the economic costs that animal disease outbreaks can trigger, as well as animal welfare issues – for example, the mass slaughter of animals to control certain disease outbreaks.

Therefore we also need to recognise that for certain emergency vaccination programs, should the need arise, the availability of immunological products which have yet to be authorised for marketing, can still be important.

In this area the flexibility in the current legislation for veterinary medicines remains an important point to consider.

Under the third and fourth pillar of the Action Plan – and truly in the spirit of "Prevention is better than cure" – collaborative work is ongoing among the Commission, Member States and stakeholders to define the necessary and appropriate antigen and vaccine banks for the Community, in case of emergencies.

On a broader scale, we will also reflect on the policy choices to be made and the legislative environment necessary for the most beneficial use of authorised vaccines.

Commissioner Vassiliou is confident that all these efforts will ultimately result in a suitable framework at Community level for veterinary authorities and animal keepers to choose the most appropriate control methods, should diseases occur, and also provide more incentives to manufacturers to develop new medicines and diagnostic tools.

As regards another important area, that of antimicrobials, you will also be aware of concerns about the increase of antimicrobial resistance.

This poses a challenge to human medicine, in view of an increasing public health risk due to resistant zoonotic pathogens transmitted from animals to humans, as well as for animal health.

The use of antibiotics in veterinary medicine may play a role in the selection of these resistant pathogens, but of course, the possible causes are far more complex than just this aspect.

Therefore, Commissioner Vassiliou's services together with those of Commissioner Verheugen, have asked the relevant European agencies –EMEA, EFSA and ECDC – to prepare a scientific report summarising the available scientific information on antimicrobial resistance.

This report should also cover the various sources such as the use of antibiotics in human and veterinary medicine, and also other possible sources such as the use of biocides. The report will be used to identify the need, priority and constraints of possible additional control measures.

Additionally, on 18 November (the second European Antibiotic Awareness Day) a report will be published summarising the ongoing initiatives at European level to manage antimicrobial resistance, covering all its aspects.

The report will be prepared by officials dealing with public health, zoonoses and animal health and will constitute a response to the Council Conclusions on Antimicrobial resistance of June 2008, which called for closer collaboration between all sectors involved.

This report should also form the basis to start reflections on possible additional control measures together with the European Parliament, the Council and stakeholders. When the time comes, Commissioner Vassiliou would welcome your participation in and contributions to these reflections.

Mrs Vassiliou asked me to conclude by reiterating that by acting in isolation the Commission could not hope to fulfil its ambitions.

Effective partnerships at all levels are needed in order to achieve a truly integrated and successful approach.

Under the umbrella of our Strategy, we are implementing all of our actions in a spirit of partnership and communication with key partners, among them the stakeholders.

Indeed, one innovation of the Strategy is the Animal Health Advisory Committee, which has already been operational since early 2008, and which includes representatives from industry, non governmental organisations across the animal health sector and from consumers, and governments.

The Committee held its 5th meeting 10 days ago. It follows the Strategy's progress and advises the Commission on the best means of delivering agreed outcomes.

Commissioner Vassiliou is delighted to note that IFAH is a very active member of that Committee, and she warmly welcomes this forum today, which also brings together key partners in the animal health arena.

We need this innovative and cooperative spirit – plus a capacity and willingness to learn from each other to find the best means to achieve our common goals.

Commissioner Vassiliou hopes that today's conference will contribute to the development of better diagnostics, vaccines and medicines to treat all species and conditions (even where some of these may represent today only a small market sector) – to the benefit of the entire animal health sector.

On behalf of Commissioner Vassiliou, let me thank you for your attention and wish you well for the rest of your conference.

End

Word count:1602

Rolf Eriksson speaking on:

The Community Animal Health Strategy and the future animal health regulation

Rolf Eriksson

Biography

Rolf Eriksson is State Secretary with the Swedish Ministry of Agriculture, a position he holds since 2006. His areas of responsibility include agriculture, fisheries, livestock protection, food matters, rural development, research and education in land-based industries and forestry, among other.

Previously, he worked at the Brussels office of the Federation of Swedish farmers for 6 years, first as an expert and then as head of the office.

Formerly, he served at the Swedish Ministry of Agriculture as Press Secretary and Political Advisor.

Mr. Eriksson was Political Secretary at the Centre Party Secretariat of the Swedish Parliament between 1988 and 1991. He is also a past-member of the EU Committee of the Royal Swedish Academy of Agriculture and Forestry.

A Swedish national, he studied economics at the Stockholm University. He has a Master of Science in Agriculture from the Swedish University of Agricultural Sciences in Uppsala.

Abstract

Sweden welcomes the Commission's work to launch a new Animal Health Strategy where "Prevention is better than cure".

There is an increasing interest in animal welfare, which in itself is a reason to prevent diseases in animals. Furthermore, there is an economic interest in improving health and welfare of animals, as animal diseases cause economic losses to producers which in the end are paid by consumers. Animal diseases can also be a threat to human health.

Large herds of domestic animals provide an excellent ground for the spreading of various disease agents. Diseases that can spread between animals and humans are, however, not the only risk. Use of antibiotics for treatment of animals may lead to resistance problems that impact human health.

To improve animal health EU-wide the concept of biosecurity needs to be broadened to include all aspects of farming and trading. An in-depth analysis is needed to ascertain what measures and incentives are necessary to prevent unnecessary spreading of diseases within the EU.

Public acceptance and confidence in animal production depends on how well we succeed in our future policies in the animal health area. One factor for success in improving animal health is that sales statistics and data on antibiotic resistance are readily available in all countries.

The funding of veterinary measures, both at national level and EU-level, is an important factor in achieving results. Priority should be given to developing systems that will provide incentives at all levels to reduce the risks of animal health threats.

Sweden intends during its presidency to cooperate closely with the Commission and other stakeholders in bringing the work with the Animal Health Strategy forward.

**SESSION 1:
OBJECTIVES OF THE REVIEW IN 2010**

Jiří Bureš chairing session 1 on:

Objectives of the review in 2010

Biography

Jiří Bureš is Deputy Director - Head of the Marketing Authorisation Department – at the Institute for State Control of Veterinary Biologicals and Medicines in Brno (Czech Republic), a position he holds since 2007. Previously, he was Pharmacovigilance assessor.

Mr. Bureš started his professional career as field veterinarian. He then joined the State Agricultural and Food Inspection Department as analyst in the field of food hygiene inspections, before moving to the Institute for State Control of Veterinary Biologicals and Medicines.

Mr. Bureš is a member of the European Medicines Agency's Committee for Veterinary Medicinal Products. He is also on the European Commission's Standing Committee on Veterinary Medicinal Products. Additionally, he is a member of the Chamber of Veterinary Surgeons of the Czech Republic.

A Czech citizen, Mr. Bureš studied veterinary sciences at the Veterinary College in Brno.

Avril Doyle speaking on:

Stakeholders' view: Why we need a single market; why we need improved availability

Biography

Avril Doyle has been an elected public representative since 1974 and is currently a member of the European Parliament; she represents Fine Gael for Ireland East and is a member for the European People's Party and European Democrats Group.

She sits at the Committee on the Environment, Public Health and Food Safety and formerly at the Agriculture Committee as a Substitute Member.

As an Honorary Member of the British Veterinary Association and Former President of the Irish Equestrian Federation, she has always been very interested in animal health. In 2001, she was Rapporteur on the Communication on the availability of animal medicinal products and in 2008 she was appointed Rapporteur on the MRLs Regulation establishing residue limits of pharmacologically active substances in foodstuffs of animal origin.

At the European Parliament she also serves other committees, including the one on Fisheries, the Temporary Committee on Climate Change and the Committee on Industry, Research and Energy.

Ms. Doyle's previous political appointments include that of Minister of State at the Department of Finance and Environment and at the Department of the Irish Prime Minister, Finance and Transport, Energy and Communications. Previously, she was a member of the Wexford County Council and became the first Mayor of Wexford in 1976.

An Irish national, Ms. Doyle studied biochemistry at the University College Dublin.

Abstract

As a society, we must ask ourselves how much control do we want - How much regulation do we need in the area of veterinary medicines? Should this regulation occur at the Member State level, at EU level or even on a global scale and in the case of the latter, what are the effects/consequences on global trade?

The current system of authorisation and registration of Veterinary Medicines is overregulated and not in line with the principle of the Internal Market. We need to quantum leap to a more efficient system based on mutual recognition between Member States. Ideally, Licences should be issued across the EU and not through separate regulatory authorities in 27 Member States. Less bureaucracy would benefit consumers, vets and farmers across the EU and with this in mind, the EU must act swiftly to improve the current system for the benefit of all.

Martin Terberger speaking on:

DG Enterprise's considerations for a review of the veterinary medicines legislation

Biography

Martin Terberger is Head of Unit F1 (pharmaceuticals) in the European Commission's Directorate General Enterprise and Industry, a post he was appointed to in 2005.

Dr. Terberger first joined the European Commission in 1995 as a detached national expert in DG Agriculture. From 1998-1999, he was Assistant to the Director General of DG SANCO, before becoming Head of Unit in DG Administration.

Dr. Terberger worked as a veterinarian for 5 years. In 1990 he joined the German Ministry of Agriculture where he served until moving to the European Commission in 1995.

A German citizen, Dr. Terberger studied veterinarian sciences at Justus Liebig University Giessen and the Free University of Berlin.

IFAH-Europe conference 25 June 2009, Brussels

Review of veterinary medicines legislation

Martin Terberger and Mario Nagtzaam
Unit F2 „Pharmaceuticals“
Directorate-General Enterprise and Industry
European Commission



Key initiatives of the last four years

- New Regulation on Maximum Residue Limits
- New Annex I
- New Variations Regulation



However, criticism persists

- Limited availability of medicines
- Lack of innovation
- High administrative burden
- Limited benefits of the Common Market

Mandate, declaration by the Commission in the context of co-decision procedure on MRLs

"The Commission is aware of concerns expressed by citizens, veterinarians, Member States and the animal health industry..., the Commission will present in 2010 an assessment of the problems in the application of the veterinary medicinal products directive with a view to making, where appropriate, legal proposals".

I. Questions brought up by interested parties

1. Are the relevant differences between the human and veterinary sector adequately reflected in legislation?
2. Is there a need to develop mechanisms that address the specific needs and characteristics of the veterinary sector?
3. Would there be a risk that such mechanisms influence the legal environment for human medicinal products?
4. What would the possibilities to provide incentives, in particular for small markets (MS, minor species, minor uses), for
 - the development of new veterinary medicinal products
 - the scope of existing medicinal products to be extended?

III. Questions brought up by interested parties

5. Is it required to have a better framework for the treatment of animals in the absence of authorised products?
6. Can the legal framework reply adequately to new veterinary medical needs?

IV. Questions brought up by interested parties

7. What would be the impact of simplifying, harmonizing and/or streamlining marketing authorisation procedures for medicines?
8. What would be the potential of simplifying the data requirements for authorisation, for pharmacovigilance, for packaging and labelling, and for the distribution chain?

Process

1. In 2009-2010 Impact Assessment
2. Subsequently, where appropriate, legal proposals

Key analytical steps in Impact Assessment

- Defining the scope
- Identifying the problems
- Define the objectives
- Develop main policy options
- Analyse the impacts of the options (Standard Cost Model)
- Compare the options

General objectives

- To enhance public health and animal health, and to increase availability of veterinary medicinal products
- To improve functioning of the internal market
- To decrease administrative burden

Public consultation

- **Not** necessarily to outline possible detailed legal amendments
- Basis for discussion on key items where possible improvements of the legislative framework have been identified

Next steps

- Defining problems, objectives and main options
- Concluding contract with consultant
- Setting-up Impact Assessment Steering Group
- Launching public consultation document

SESSION II: POSSIBLE SOLUTIONS

Patrick Dehaumont speaking on:

The HMA Task Force reflection paper on opportunities for the review

Biography

Patrick Dehaumont is the Director of the French Agency for Veterinary Medicinal Products (AFSSA-ANMV). He is also Director of the Collaborating Centre for Veterinary Medicinal Products of the World Organisation for Animal Health (OIE).

Prior to this position, he worked at the French Ministry of Agriculture, where he was responsible for regional veterinary services and in charge of European programmes concerning the enlargement of the European Union.

A French national, Mr. Dehaumont is doctor in veterinary medicine.

Abstract

The new legislation for veterinary medicinal products, last updated in 2004, is now in place. However, even if huge progress has been achieved, practical problems are being encountered during the implementation of the new Directive and Regulation. This was noted by the heads of veterinary medicines agency (HMAv) during internal discussions and also during stakeholders meetings.

In order to address this issue and to contribute to possible improvements, HMAv decided to establish a Task Force Working Group (TFWG) in April 2008, with the mandate to identify the main hindrances and to propose possible improvements for the short, medium and long term.

In order to implement this mandate a group composed of representatives from National Competent Authorities, the European Commission and the EMEA was set up.

After 12 months work, the TFWG presented to HMAv a report as well as a work plan and a list of actions. HMAv endorsed the report during their meeting in Marienbad on 19 May under the Czech Presidency and decided to launch an external consultation on the issue.

This report presents an overall vision, specifies strategic objectives and addresses different aspects of outstanding importance such as availability, generics, the procedures or pharmacovigilance.

It must be underlined that as far as the long term aspects are concerned, the proposals are ultimately ideas to be further discussed in order to help the process of the revision of the legislation. HMAv is willing to contribute to an evolution of the landscape by providing innovative ideas, but also acknowledges that these ideas could only help the process of revision which is, at the end of the day, under the right of initiative of the European Commission.

At the end of the day all our combined efforts will contribute to a better implementation of the “European Single Act”, of the “Better Regulation Principles” and of “the European Sustainable Development Strategy”.

The report is available on the HMA website.

IFAH – EUROPE conference: 1 vision: 1 final step to 1 market?



06/2009 IFAH – Europe conference; BRUSSELS
Patrick Dehaumont

Opportunity for open dialogue



From the IFAH « Talking Cows » to the

*French Agency
« Grazing cow »*



Veterinary medicines , an essential tool for animal and public health



- ✓ **After 3 decades, a mature regulatory system in place with lot of benefits**
- ✓ **However lot of voices raising concerns:**
 - *Users*
 - *Industry*
 - *Regulatory and competent authorities*
 - *The general public*

**... better regulation,
a quite long lasting story!!**

[Copie de IFAH 12 JUne 08.ppt](#)

**IMPROVEMENT OF
VETERINARY LEGISLATION
Report of the HMA TFWG**



06/2009 IFAH – Europe conference; BRUSSELS
Patrick Dehaumont

TFWG on veterinary legislation



Created by HMA in April 2008 on the basis of identification of needs of improvements and following interaction with stakeholders.

Mandate adopted:

*“The work of the group will cover both **short term improvements** aimed at **promoting a harmonised interpretation of existing legislation** to the benefit of the network and for **medium to longer term improvements** in the form of proposals **to amend legislation** at the earliest available opportunity.”*

5

TFWG on veterinary legislation



Task Force members:

Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Spain, United Kingdom, Sweden, European Commission, EMEA,

6

Preliminary statement



- ✓ *Beyond the short term proposals, the report proposes a vision for the future,*
- ✓ *This is food for thoughts, stimulation of the debate, confrontation of ideas*
- ✓ *Contribution to the next review when any, under the initiative of the European Commission*
- ✓ *Implementation of such global vision will probably be a combination of the proposals*

The Task Force Report



Proposal for a global vision:

Key drivers

- a) the need to provide adequate protection for public health
- b) the single European act, the Lisbon Agenda, the better regulation principles, the European sustainable development strategy
- c) improved availability of veterinary medicines
- d) simplification of authorisation requirements to reduce administrative burdens on companies and reduction in the numbers of animals used for testing.

The Global vision:



What should be achieved?

" A legislative system that:

- will provide the greatest range of authorised veterinary medicinal products for use in each Member State.*
- will help the construction of the single market of veterinary medicinal products, in the spirit of the European Single Act, of the Lisbon Agenda and of the European sustainable development strategy"*

The Global vision:



How to achieve this ?

- " - need to provide authorisation processes that maintain proportionate safeguards for humans, animals and the environment with the least administrative and development costs for companies.*
- need to strengthen cooperation between National Competent Authorities,*
- need to enhance confidence and transparency regarding the public decision making process*
- ...not withstanding the specificities of the veterinary sector": ***Stand alone consideration****

Identification of current concerns and areas for improvement



- Innovation/availability of medicines:

*current situation:

Need of improvement of availability,
existing EU tools to be better used

*issues to be addressed

Data protection, availability, legislative aspects, provisional
authorisation , B/R assessment

Identification of current concerns and areas for improvement



- Generics

*current situation

A multidimensional issue:
Competitiveness , availability , data protection need to be considered

*issues to be addressed

Ecotoxicity issues, possible change of usage pattern due to the
change of the market offer , predictability of the workload for NCAs

Identification of current concerns and areas for improvement



- Pharmacovigilance

*current situation

A simple and efficient system is needed, the risk / benefit approach as a driver for the risk management of the products, administrative burdens need to be overcome, communication and transparency needed to increase the credibility

*issues to be addressed

How to simplify the system,
How to ensure the robustness of the system

Identification of current concerns and areas for improvement



- Simplifications of procedures

*current situation

The system is somehow complex and bureaucratic

*issues to be addressed

How to simplify, how to optimise the use of resources, is there a need for several procedures

Identification of current concerns and areas for improvement



- Others

*current situation

Identification of areas of interest by the task force

*issues to be addressed

Various issues such as parallel import; implementation of the cascade; determination of withdrawal period; harmonisation of reference products; harmonisation of SPCs...

Proposals



- Innovation/availability of medicines:

Protection period, all minor species

Packaging and labelling

Excipients and SPCs

Conditional approval

Proposals



- Generics

Environmental risk assessment
Harmonisation of reference products
Harmonisation of SPCs annually

Proposals



- Pharmacovigilance

Simplification of the legislation
A Pharmacovigilance system in the MA dossier with the development
of the concept of masterfile
Better use of "e-reporting"
EMA proposal "from shall to may provision"

Proposals



- Simplification of procedures

Simplification of the procedures;
Simplification of Applications types;
CVMP role;
Referrals ;
DCP

Proposals



- other areas

International cooperation
Parallel import
Withdrawal period and cascade
Environmental risk assessment
Antimicrobio-Resistance
Withdrawal period calculation and harmonisation

Conclusion



- *All these ideas have been discussed within HMAv and presented to HMAj*
- *HMA decided to launch an external consultation during 2 months*
- *A focus group with stakeholders will be envisaged afterwards as well as the finalization of the draft table of action and workplan*
- *All this will contribute to:*
 - *the preparation of the next HMA strategy (2011/2015)*
 - *the expected initiative of the European Commission regarding the next review to get a "Pan European authorisation system in a true single market "*

The on going Public consultation





- *Report posted on HMA website:*

www.hma.eu

[Heads of Medicines Agencies About HMA.mht](#)

[Heads of Medicines Agencies Veterinary Legislation.mht](#)

- *For comments till 31 August 2009*



**Future challenges are shared
by the actors...**



**Future challenges are shared
by the actors...**

**...common global vision
and goals**

**will help tremendous progress
in a smooth atmosphere,**



Neil Craven speaking on:

The animal health industry's proposals towards the review

Biography

Dr. Neil Craven is Senior Director, Regulatory Affairs and Market Support, Europe/Africa/Middle East with Pfizer Animal Health, a position he holds since 2002. He has had various managerial positions in the animal health industry for over twenty years.

Previously, he worked as a veterinary research officer for the UK Institute of Animal Health.

He is Past-President of the Federation of European Veterinarians in Industry and Research and a member of the Royal College of Veterinary Surgeons. He received a FEDESA award in 2001 for his contribution to the technical activities of the federation and in 1988 he was granted the “green gremlin” award from the UK Green Magazine with regard to his work on environmental impact issues.

Dr Craven has produced more than forty peer-reviewed papers on therapy and immunology of mastitis, milk production and antimicrobial resistance.

A UK citizen, Dr. Craven was awarded a Ph.D. degree at the University of Reading.

Abstract

In the years following the implementation of the 2004 amendments to the veterinary legislative framework IFAH-Europe conducted 2 regulatory surveys; these recognised many positive improvements to the legislation, and identified several key issues that needed further regulatory reform.

However, in a strategic workshop in 2008 IFAH-Europe realised that its “Proposals for Regulatory Reform” would be insufficient, even when taken all together, to achieve the high level “common goals” of the legislation – the realisation of a true single market in the EU (and the protection of public and animal health) – and the Lisbon agenda for a European competitiveness business and Better Regulation. The 2008 strategic workshop concluded that this could only be achieved through the adoption of a “1-1-1 Concept”, requiring 1 dossier, 1 scientific assessment and 1 decision for marketing authorisation throughout Europe.

Neil Craven will outline these events and the key drivers for change, together with how the high level “common goals” and IFAH-Europe’s strategic objectives interface. He will discuss IFAH-Europe’s priorities for regulatory reform and the 1-1-1 Concept in more detail, particularly the critical important factor of data protection to stimulate investment in innovation in the veterinary sector.

IFAH-Europe proposals for regulatory reform

A single market for
veterinary medicines in Europe by
removing licensing barriers

Neil Craven, IFAH Europe
IFAH-Europe Annual Conference, 25 June 2009



Defining IFAH-Europe's strategic objectives

**1. Benchmarking the
regulatory environment**
2006-7

**2. Surveys of the functioning
of the 2004 legislation**
2006-7

3. Strategic objectives

4. Policy workshops
2007-2008

1. Benchmarking the regulatory environment

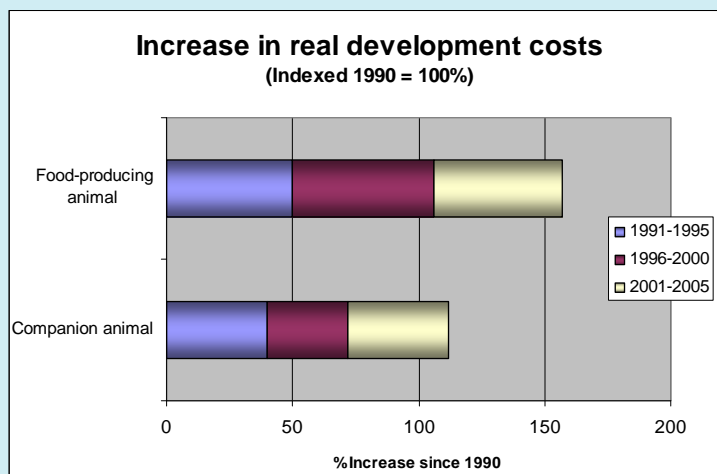
-  **Innovation - the key long-term driver**
 - EU regulation does not stimulate innovation

-  **Time & cost to market - key factors of success**
 - Time & cost determined by EU regulatory framework

-  **High product maintenance costs in Europe**
 - Caused by the EU regulatory environment

-  **Increase in time & cost of product development since 1990**
 - Time has increased by 2-4 years
 - Cost of product development has more than doubled
 - But - data protection period has not changed!


IFAH Benchmarking survey 2006 - Impact of Regulatory Factors on the average cost of new product development in Europe



Source: Business Decisions Limited 'Survey of Animal Health Companies in Europe and the USA' (1997, 2001 and 2006)

- Strategic Decisions and Regulation

- Major strategic decisions taken by companies have been negatively affected by regulations:

 – Fewer breakthrough products launched (57% of companies)



– R&D and production investment shifted away from Europe (86% of companies have switched production)



– Product availability reduced (71% of companies have reduced overall product range; 77% have reduced coverage of species/indications)



– Focus on older technologies (69% focus on existing or older technologies)

2. Functioning of the 2004 legislation

• **Negative impact on innovation**

– Insufficient data protection

• **European Reference Product**

– Positive development for generics

– Creates “un-level playing field” for reference product

• **Post-authorisation responsibilities**

– All MAHs should be treated the same post-authorisation (all should receive any requests for additional data)

– Examples of “un-level playing field”

• **No reduced time or cost for product development**

– But reduced time for regulatory approval process

3. IFAH-Europe Strategic objectives

- Stimulate innovation - improved data protection
- Reduce time and cost to market
- Reduce administrative burden
- True single market for ALL veterinary medicines with an efficient regulatory system
- Level playing field - make the system fair to all

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4. IFAH-Europe Policy Workshops

Strategic objectives - questions

- What is needed to achieve our strategic objectives?

Need a new approach to risk assessment
i.e. re-think the data requirements

- Can all our strategic objectives be achieved through amendments to the current legislation?

Unlikely
– need a radical re-think
- need separate approach for veterinary legislation

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« Complete re-think » needed according to EMEA¹

Current framework:

*“...an expansion of a system thought up 30 years ago when the Community had six members.” Since then, every new challenge has led to “a new layer of legislation and creation of additional groups and committees”, but “without a global vision of the European regulatory system”. ...has created a **system of extreme complexity** that “cannot continue to be handled with the current working model”.*

Drug approval procedures:

*“...everybody acknowledges that current proceedings are very lengthy and very resource intensive”. ...“a **complete re-think of the system is necessary in order to prepare for the 20-30 coming years**”.*

¹ Schofield,I, EMEA Speaks Out Over the Future of Pharma, *The Regulatory Affairs Journal – Pharma*, 2008, **19**(1), 1

The high level « Common Goals » - and IFAH-Europe strategic objectives

- **Public and animal health protection; safe food supply**
- **Lisbon Agenda (competitiveness of European industry)**
 - Protect and stimulate innovation
 - Reduce time/cost/maintenance by/to 20%
- **Reduction of administrative burden / Better Regulation**
 - Reduce administrative burden
 - Fair and equitable regulatory environment proportionate to needs of veterinary medicine sector
- **Single market - realise the full potential**
 - Harmonised and more practical implementation
 - Predictable and efficient
 - Radical re-think of current regulatory system by all stakeholders and starting from **1-1-1 concept**

Single market in food

EU

- A single market in food and animal produce
- Why not in veterinary medicines??



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1-1-1 Concept

How do we get the single market for all VMPs?

Based on concepts already enshrined in EU legislation:

- quality, safety and efficacy described in one single EU dossier as the basis for granting marketing authorisations,
- one single assessment of the dossier employing the best expertise,
- resulting in one decision for marketing authorisation.

The one, one, one (1-1-1) concept applied to all VMPs

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Key events paving the way for regulatory reform

- HMAv Task Force (formed in April 2008)
- AFSSA Public Conference on Regulatory Reform (30 September 2008)

“Do it well ENOUGH and do it once”

- COM Declaration (January 2009) on the revision of Directive 2001/82/EC.... in 2010
- HMAv Reflection Paper (June 2009)

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COM Declaration on the revision of Directive 2001/82/EC

“...in order to address the objectives of

- 1. consumer safety and animal health protection,*
- 2. competitiveness of the veterinary industry*
- 3. reduction of administrative burden,*

the Commission will present in 2010 an assessment of the problems in the application of the VMP directive with a view to making, where appropriate, legal proposals.”

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IFAH-Europe priorities for regulatory reform



1. Data protection for all significant innovation
2. 1-1-1 Concept – simplify procedures to deliver a true single market
3. Fair and equitable system for all companies
4. Rationalise packaging and languages
5. Simplify pharmacovigilance
6. Simplify and rationalise product maintenance

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IFAH-Europe priorities for regulatory reform



1. Data protection for all significant innovation

- 10 years for each major species (to run separately not cumulatively)
 - +1 year for significant new indication for that species
 - i.e. exactly same model as human medicines
 - Avoid food safety issues from off-label use
- 13 years for all minor species (extend fish & bee clause)
- DP for additional data submitted after the first 10 years
 - Can represent major investments
 - Avoid distortion of market competition
- Excipients should be listed only when safety necessitates

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Data protection for line extensions

Cost of line extension
= a significant investment and risk

VS

Smaller market value for species 2
or 2nd indication
(species x disease prevalence)

= Need same data protection period
to achieve similar time to return on investment as
species 1

**DECISION
POINT**

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Data protection for line extensions

A significant investment and risk vs Smaller market value

= Need same data protection period
to achieve similar time to ROI as species 1

>**DECISION POINT**

- **10 years data protection period for each species**
(not cumulative)
- **Data protection for other major product developments**

Cost of R&D has more than doubled since 1990;
but no overall increase in length of DP

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IFAH-Europe priorities for regulatory reform

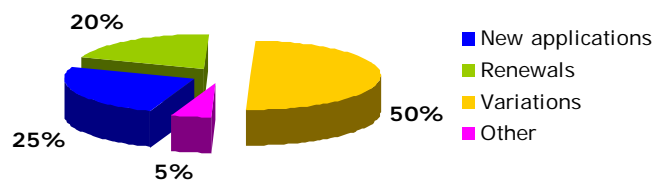
- 1-1-1 Concept – to deliver a true single market
 - Simplified and fully harmonised resource-efficient regulatory system
 - Based on 1 dossier, 1 scientific assessment, and 1 decision
 - Simple system to extend existing products to all EU MSs
 - Any MA in a MS should be allowed to be used in all MSs
 - Provided the MA is in compliance with EU legislation
 - Use best EU expertise via coordinated EU Regulatory Network
 - “virtual centers of resources”
 - Single assessment available to all MSs

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IFAH-Europe priorities for regulatory reform

- 2. 1-1-1 Concept – to deliver a true single market
 - Simplified and fully harmonised resource-efficient regulatory system
 - Current system is not resource-efficient
 - 32% of MRP procedures are repeat-use (2008)
 - 75% of company effort goes into existing products

Industry survey 2005



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IFAH-Europe priorities for regulatory reform

3. Fair and equitable system

- Type 1 variation to harmonise Eur.Ref.Product SmPC
- All MAHs responsible for post-authorisation data requests
- Allow applicant to refer a negative RMS opinion to CVMP

4. Rationalise packaging and languages

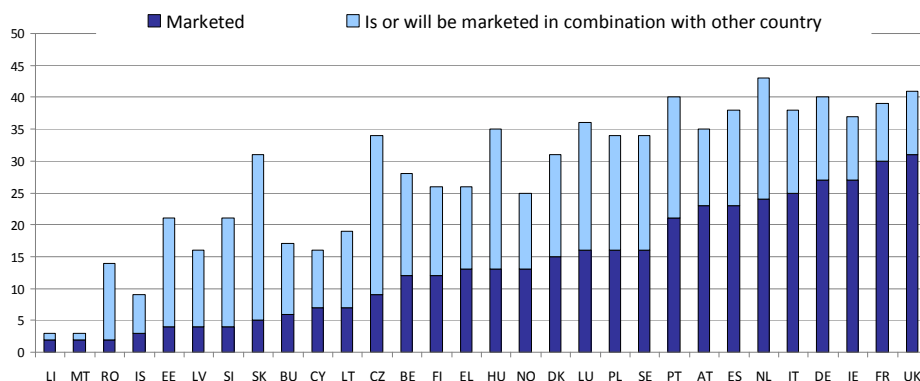
- Minimise information on immediate packaging (labels)
- Maximise ability to produce multilingual labels
- Tailored for the veterinary sector

5. Simplify pharmacovigilance

- Target limited resources where they will have most impact
- Tailored for the veterinary sector

Impact of packaging costs and market size

Marketing of 47 CAPs, (in local language packs)
June 2009



Conclusions

- To stimulate investment in research in Europe - need data protection period of 10 years for each species
- Simplify procedures & single market – 1-1-1 Concept
- HMA Reflection paper proposals are an excellent start
- Impact Assessment important next step – must examine the right issues

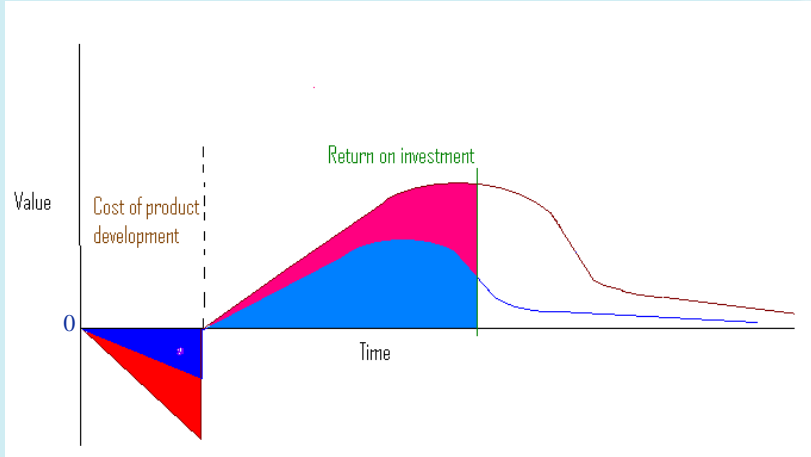
Maximise the opportunity from the review – there is a need to revise the legislation

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Thank you

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Time to breakeven or return on investment will be equivalent



PARALLEL WORKSHOPS

THE HMA REFLECTION AND
THE IFAH-EUROPE 1-1-1 CONCEPT

WORKSHOP 1:

HOW TO ACHIEVE THE OBJECTIVES OF A TRUE SINGLE MARKET FOR VETERINARY MEDICINES?

Chair: Martin Terberger (European Commission/DG Enterprise & Industry)

See biography on page 14.

Questions:

1. What do we mean by a true single market and what are the drivers towards this objective?
2. What are the hurdles to reaching the objective of a true single market in veterinary medicines?
3. What more needs to be done to achieve this objective, and what are the priorities for changing the legislation? What aspects of the HMA Reflection Paper address the objectives of a true single market, for both authorisation and post-authorisation maintenance of products?
4. How do we include existing products into a true single market (automatic mutual recognition)? How do we maintain harmonised products?
5. How do the single market objectives, drivers and hurdles differ between human and veterinary sectors?
6. What are the benefits to public health and animal health?

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Workshop 1:

How to achieve the objectives of a true single market for veterinary medicines?

Chairperson: **Martin Terberger**
Rapporteur: **John FitzGerald**

25 June 2009



Workshop 1:

How to achieve the objectives of a true single market for veterinary medicines?



Question 1: What do we mean by a true single market and what are the drivers towards this objective?

Conclusions:

- Free movement of authorised veterinary medicinal products between Member States (MS) for use in accordance with national distribution systems
- Should the product be identical e.g. labelling in MS?
- Remember medicines are not toys.



Workshop 1:

How to achieve the objectives of a true single market for veterinary medicines?



Question 2: What are the hurdles to reaching the objective of a true single market in veterinary medicines?

Conclusions:

- 1:1:1 is a good concept but devil is in the detail
- Labelling, language requirements
- Authorisation procedures – marketing authorisation holder (MAH) chooses where to market the product? data set dependant on where product to be marketed, who decides the language to be used, what are the limits of flexibility?
- Pharmacovigilance (Phv) implications
- Climatic impact on withdrawal (wd) periods
- Need for profitability in each MS could lead to discrimination.

Workshop 1:

How to achieve the objectives of a true single market for veterinary medicines?



Question 3: (a) What more needs to be done to achieve this objective and what are the priorities for changing the legislation?

Conclusions:

- Authorisation
- Post-authorisation
- Distribution
- Reduced admin burden = headroom for other changes
- Main cost drivers.

Workshop 1:

How to achieve the objectives of a true single market for veterinary medicines?



Question 3: (b) What aspects of the HMA Reflection Paper address the objectives of a true single market, for both authorisation and post-authorisation maintenance of products?

Conclusions:

Not discussed.

Workshop 1:

How to achieve the objectives of a true single market for veterinary medicines?



Question 4: How do we include existing products into a true single market (automatic mutual recognition)?

Conclusions:

- Do we have a safety issue? Do we need more data? Products not brought up to EU standards on accession
- Decentralised (DCP) and Mutual Recognition (MRP) procedures – extend coverage automatically
- National – product separately in more than one MS with same/similar indications – extend coverage OR – one MS. Authorised in accordance with 81/851 or later – extend coverage. Not authorised under EC legislation; needs reassessment.
- Summary of product characteristics (SPC) harmonisation gives one dossier across EU
- Grandfather rights system as used in USA.

Workshop 1:

How to achieve the objectives of a true single market for veterinary medicines?



Question 4: (b) How do we maintain harmonised products?

Conclusions:

- Concern about possible extra costs and loss of products
- Recognise that sub-standard dossier does not = sub-standard product.

Workshop 1:

How to achieve the objectives of a true single market for veterinary medicines?



Question 5: How do the single market objectives, drivers and hurdles differ between human and veterinary sectors?

Conclusions:

- Agree that there are different drivers and should not slavishly follow changes from either sector in the other.

Workshop 1:

How to achieve the objectives of a true single market for veterinary medicines?



Question 6: What are the benefits to public health and animal health?

Conclusions:

- Scientific scrutiny in accordance with EU legislation
- Wider availability of products in which the consumer has confidence.

WORKSHOP 2: HOW DO WE ACHIEVE 1 ASSESSMENT & 1 DECISION?

Chair: Brigitte Boenisch (IFAH-Europe/Merial)

Biography

Brigitte Boenisch is Head of Worldwide Regulatory Affairs Lifecycle Management & International at Merial S.A.S. in Lyon, France. She also represents R&D on the Executive Committee of that entity.

Prior to joining Merial in early 2000, she worked with Boehringer Ingelheim Vetmedica GmbH in Germany, first in Pre-clinical Development and from 1993 as Head of Regulatory Affairs. From 1987 to 1990 she was involved in the pre-clinical testing and registration of a medical device at the Technical University in Munich, Germany.

Dr. Boenisch is chairperson of the 1-1-1 Concept Project Team in IFAH-Europe and also a member of the trade association's Technical and Regulatory Committee, which she chaired from 2003 until recently.

A German national, she graduated in veterinary medicine from Munich University, where she obtained her doctorate in veterinary immunology. She was awarded a Diploma in Regulatory Affairs by the University of Wales.

Questions:

1. What objectives are we seeking with a system of 1 assessment and 1 decision?
2. What do we mean by 1 assessment? by 1 decision?
3. How do we achieve 1 assessment? 1 decision? What are the options (preferably to achieve one system for all products)?
 - I. For new products?
 - II. For new technology products?
 - III. For existing products (what would be the impact on existing products)?
4. How should the European Medicines Regulatory Network organise itself to deliver 1 assessment?
5. How should the legislation be changed to achieve this (1 assessment & 1 decision)?
6. What do we balance in the use of resources between pre- and post-marketing activities?
7. How does this new veterinary system accommodate the specific characteristics of the vet sector? How will it co-exist with the current procedures in the human sector? What are the benefits to joint agencies?

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Workshop 2:

How do we achieve 1 assessment & 1 decision?

Chairperson: **Brigitte Boenisch**
Rapporteur: **Melanie Leivers**

25 June 2009



Workshop 2:

How do we achieve 1 assessment & 1 decision?



Chairperson's Introduction

• Objectives of the workshop

- exchange views – discuss
- deliver a set of recommendations and conclusions on possible solutions to improve the veterinary legislation in a short or longer term.

(unanimity – majority view – points of total disagreement as appropriate)



Workshop 2:

How do we achieve 1 assessment & 1 decision?



Chairperson's Opening comments

Global vision is a legislative system that:

- Will provide the greatest range of safe and effective authorised veterinary medicinal products (VMPs) for use in each Member State in order to
 - protect public health
 - to safeguard European food production and
 - to respond adequately to disease and animal welfare threats?
- Will help the realisation of the single market of VMPs in the spirit of
 - The European Single Act
 - The Lisbon Agenda and contributing to
 - The European Sustainable Strategy?

3

Workshop 2:

How do we achieve 1 assessment & 1 decision?



Chairperson's Opening comments

To achieve this vision*, the legislation needs:

- to provide authorisation processes that maintain proportionate safeguards for humans, animals and the environment with the least administrative and development costs for companies
- to strengthen cooperation and confidence between National Competent Authorities (NCAs)
- to enhance confidence and transparency regarding the public decision making process
- ...notwithstanding the specificities of the veterinary sector:
Stand alone consideration.

* HMA TFWG HMAv Draft Reflection Paper on the Improvement of Veterinary Pharmaceutical Legislation – June 2009

4

Workshop 2:

How do we achieve 1 assessment & 1 decision?



Question 1: What objectives are we seeking with a system of 1 assessment and 1 decision?

- Simplification
- 1 market
- Avoid referrals
- More efficiency
- Predictability
- Availability
- Homogeneity
- Optimal use of best resources
- Avoids duplication of work
- Public confidence-transparency – single interpretation leading to increased public confidence
- Build trust in system.

5

Workshop 2:

How do we achieve 1 assessment & 1 decision?



Question 2: What do we mean by 1 assessment? by 1 decision?

- 1 single assessment report valid throughout EU based on objective criteria (Quality, Safety & Efficacy)
- Like CVMP assessment report – no national deviations
- 1 TEAM (not one individual assessment) = 1 Decision
- No new assessment for e.g. Second wave –
- Using optimum European-level expertise available
- One valid, binding decision – possibility to market in all MSs; can be administrative to go into others and automatically applicable decision e.g. post further accession of new MSs

Subsidiarity principle: MSs may prohibit placing on the market as currently but no re-adoption of decision when situation changes.

6

Workshop 2:

How do we achieve 1 assessment & 1 decision?



Question 3: How do we achieve 1 assessment? 1 decision? What are the options (preferably to achieve 1 system for all products)?

- For new products - For new technology products
- For existing products (what would be the impact on existing products)

- For all new products – best expertise; no differentiation between types of new products or between markets; scientific assessment centrally;

- Data requirements as per Annex I

Existing

- Needs trust between authorities

- Benefit-risk assessment

- Recently approved products to follow same system – but In-between system?

7

Workshop 2:

How do we achieve 1 assessment & 1 decision?



Question 4: How should the European Medicines Regulatory Network organise itself to deliver one assessment?

HMA: developing network of 43: best use of existing resources?

- Specialised centres of resources (competences)?

- Use EMEA structure as co-ordinating body?
- Possible risk- excessive focus on co-ordination can diminish efficiency
- Does current system favour resource-rich competent authorities (NCAs), rather than scientific expertise

- Efficient system – don't think in NCAs – think science-based expertise/ efficiency.

8

Workshop 2:

How do we achieve 1 assessment & 1 decision?



Question 4: How should the European Medicines Regulatory Network organise itself to deliver one assessment?

- Trust between MSs vital
- NCAs not to be deleted !
- NCAs delegating scientific assessment to central assessment; need NCAs for Pharmacovigilance (PhVig), placing on market, enforcement/ inspection/control etc.
- Should have optimum resources
- Should have flexibility in system.

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Workshop 2:

How do we achieve 1 assessment & 1 decision?



Question 5: How should the legislation be changed to achieve this (1 assessment & 1 decision)?

- Allow Commission Decisions for national legislation ??
- NCAs sign off on decision acknowledging assessment and allowing placing on the market;
- Need to be sure of reasonable timespan re: implementation
- Replace Directive by Regulation to enforce
- Separate human and vet legislation – inherent differences.
 - Fee for assessment;
 - Fee for placing on market.

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Workshop 2:

How do we achieve 1 assessment & 1 decision?



Question 6: What do we balance in the use of resources between pre- and post-marketing activities?

- Who does what e.g out-sourcing opinion
- Look at data requirements:
Earlier access to new medicines via reduced data requirements for pre-marketing and more post-authorisation
- Commitments – conditional authorisation etc.
- Work-sharing – scientific assessment delegated to central pool of expertise
- Very important to differentiate between human and vet.

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Workshop 2:

How do we achieve 1 assessment & 1 decision?



Question 7: How does this new veterinary system accommodate the specific characteristics of the vet sector? How will it co-exist with the current procedures in the human sector? What are the benefits to joint agencies?

- Better use of existing resources to keep joint human and vet agencies where exist – but risk of losing advantages from common infrastructure.
- Scientific assessment principles will remain the same but will be organised differently.
- Less complex procedures
- Clear differences between human and vet although some similarities e.g. some toxicological tests
- N.B.
- Synergies for human sector: gain experience with a new way of operating !!

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WORKSHOP 3:

HOW DO WE STIMULATE INNOVATION?

Chair: Jim Scudamore (Consultant)

Biography

Jim Scudamore is Professor of Livestock and Veterinary Public Health at the Faculty of Veterinary Science at Liverpool University and visiting Professor at the Veterinary School of Bristol University. He has also been working as an independent consultant with assignments for the UK government, overseas governments, the Food and Agriculture Organisation of the UN and the European Union during the past 5 years.

He acts as consultant to the European Technology Platform for Global Animal Health and for the EU research project DISCONTTOOLS, which aims to identify new and improved tools for the control of major diseases.

From 2001 until his retirement in 2004, Prof. Scudamore was Director General for Animal Health and Welfare and a member of the Management Board of the Department for Environment, Food and Rural Affairs.

Previously, he was appointed as Chief Veterinary Officer for the UK in 1997, after spending a year as Assistant Chief Veterinary Officer in headquarters in 1996 with responsibility for meat hygiene and the regulation of import, export of meat and animal products. He was Assistant Chief Veterinary Officer for Scotland from 1990 until 1996, prior to which he held a number of posts in the State Veterinary Service.

Prof. Scudamore is Diplomat of the European College of Veterinary Public Health and a member of the Royal College of Veterinary Surgeons.

A UK national, Prof. Scudamore studied veterinary science and genetics.

Questions:

1. What are the main European policy drivers towards the EU objective to stimulate innovation and investment in research?
2. What do we mean by innovation?
3. Does the current legal framework stimulate and/or restrict innovation? How can the current legal framework be improved to address any deficiencies?
4. How can the regulatory process keep up with new technologies?
5. How can the approval process create better acceptance of innovative products?
6. What are the benefits to public health and animal health?

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Workshop 3:

How do we stimulate Innovation?

Chairperson: **Jim Scudamore**
Rapporteur: **Rick Clayton**

25 June 2009



Workshop 3:

How do we stimulate Innovation?



Question 1: What are the main European policy drivers towards the EU objective to stimulate innovation and investment in research?

- Lisbon Agenda; Better Regulation
- Regional Economic Development and Sustainability
- Knowledge based bio-economy; European Technology Platform for Global Animal Health (ETPGAH)
- Public Health and animal welfare; Community Animal Health Strategy (CAHS)
- Climate change; environmental benefits
- Facing new challenges; climate change, new diseases.



Workshop 3:

How do we stimulate Innovation?



Question 2: What do we mean by innovation?

Conclusions:

- New science, new products, new technology
- Significant developments; new species; new indications; new routes of administration (improve compliance); new formulations (heat stable vaccine); new manufacturing processes
- Veterinary sector specific:
 - small incremental steps are v important
 - smaller playing field (less target indications, cow with high-blood pressure)

Recommendations:

- Recognise that innovation is not only new and improved products but also processes and methods
- Recognise the challenges to innovation in vet sector are very different to human sector and should be catered for accordingly
- Need data protection (DP) to stimulate research into significant developments.

3

Workshop 3:

How do we stimulate Innovation?



Question 3: Does the current legal framework stimulate and/or restrict innovation?

Conclusions:

- New legislation has brought improvements (10 years; 13 fish/bees; 3 years MRL)
- It restricts innovation by
 - link to global marketing autorisation (MA) concept and
 - Interpretation of the data requirements, cost of prod. devel.
 - diversion of resources to defensive research.

Recommendations:

- Needs to be improved to give return of investment for innovation
- De-link DP from the global MA concept (need DP for separate MAs)
- There is some flexibility in legislation; needs to be publicised/fully utilised
- System to fasttrack beneficial products?

4

Workshop 3:

How do we stimulate Innovation?



Question 3: How can the current legal framework be improved to address any deficiencies?

Conclusions:

- Clearly differentiate human and vet requirements to ensure needs of animal health are recognised and incorporated into the most appropriate legislation
- Need to allow suitable ROI to stimulate investment
- The group fully endorsed the 1-1-1 Concept.

Recommendations:

- Implement the 1-1-1 Concept
- Be enabling and not restricting
- Hu vs vet: Identify where useful to be the same and important to be diff
- Separate co-decision procedure (this is now foreseen...)
- Review data requirements; e.g. excipients data reqs, and DP
- Make better use of limited resources (admin costs and defensive R&D) 5
- IFAH-Europe should also do an impact assessment on 1-1-1 Concept.

Workshop 3:

How do we stimulate Innovation?



Question 4: How can the regulatory process keep up with new technologies?

Conclusions:

- The legislation is not designed to cope with new technologies
- Separate human legislation covers advanced therapeutics.

Recommendations:

- Include provision in vet legisl on advanced therapies (and not force fit)
- Workshops on new technologies
- Start a very early communication with regulators (and politicians)
- European list/network of experts
- Expertise may already exist on human side within joint agencies
- ETPGAH/DISCONTTOOLS as a forum with a section looking at new technologies

Workshop 3:

How do we stimulate Innovation?



Question 5: How can the approval process create better acceptance of innovative products?

Conclusions:

- Need public confidence in the approval process
- Public really only concerned by safety
- General public is largely unaware of the MA process.

Recommendations:

- 1 single decision from transparent science based system
- Good communication, about safety and also the benefits
- Need unanimity: Common information provided to the public in every Member State.

WORKSHOP 4:

WHAT MEASURES DO WE NEED TO TAKE TO IMPROVE ACCESS TO VETERINARY MEDICINES?

Chair: Jan Vaarten (Federation of Veterinarians of Europe)

Biography

Jan Vaarten is the Executive Director of the European Federation of Veterinarians (FVE), representing 41 veterinary organisations in 36 European countries. He holds this position since 2003.

Previously, he served at the Dutch Ministry of Agriculture, Nature and Food Quality as Senior Policy Officer in the field of zoonotic diseases, after having worked with the Royal Netherlands Veterinary Association as Veterinary Policy Officer.

Mr. Vaarten's career started in a mixed practice in the Eastern part of the Netherlands and, subsequently, he joined the pharmaceutical industry, where he worked in the development of companion animal vaccines.

He is a member of the Head of Medicines Agencies' Task Group on the availability of veterinary medicinal products and co-chairs the European Technology Platform on Global Animal Health.

A Dutch citizen, Jan Vaarten studied veterinary medicine at the University of Utrecht.

Questions:

1. What do we mean by "access" to veterinary medicinal products (VMP) and "availability" of VMPs? And what factors are currently hindering these?
2. What is the impact of data protection on the availability of new products?
3. What recommendations from the HMA Task Force report on the availability of VMPs (i) have been acted on (ii) are in progress (iii) have yet to be addressed (iv)? Will these measures be sufficient?
4. How can we improve access to (a) new and (b) existing products across Europe?
5. Which aspects of the legislation require a specific approach for veterinary medicines?
 - i. Within the veterinary Directive
 - ii. Within the Regulation
 - iii. Within the annex: quality, safety and efficacy
6. What are the benefits to public health and animal health?

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Workshop 4:

What measures do we need to take to improve access to veterinary medicines?

Chairperson: **Jan Vaarten**
Rapporteur: **Philip Sketchley**

25 June 2009



Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question 1: What do we mean by “access” to VMPs and “availability” of VMPs?

Conclusions:

- Availability = registered and on the market.
- Access = can use in the field in a legal way.
- Through what routes- vet , pharmacist, professional supplier, internet, retail.
- Difference in legal classification across the member states therefore access and availability is different.



Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question 1: What do we mean by “access” to VMPs and “availability” of VMPs?

Recommendations:

- Make conditions for cascade more flexible
- Change order of cascade and make step (b)(ii) «same indication in same species» before (b) (i.e. before having to go to another Member State or before having to use human medicine)

Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question (1b): What factors are currently hindering the availability of VMPs and access to VMPs?

Conclusions:

- Off-label, cascade, new guidelines
- Economics
- Language requirements in small markets
- Lack of data protection restricts research and hence availability.

Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question 2: What is the impact of data protection on the availability of new products?

Conclusions:

- Can the product be protected – Yes / No?
- Agree we need longer data protection (DP) for new products
- If DP is too short it will create higher prices:
Too short DP will reduce research and development for innovation

Recommendations:

- DP needs to be proportional and transparent
- Need DP for new indications/new species (line extensions)
- 1.1.1 would offer a faster return on investment if all markets available from day 1.

Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question 3: What recommendations from the HMA Task Force report on the availability of VMPs (i) have been acted on (ii) are in progress (iii) have yet to be addressed (iv)? Will these measures be sufficient?

Conclusions:

- i) Lot of progress in labelling
Progress made in application of Cascade
- ii) Greater trust between competent authorities (CAs), but more is needed
- iii) Need more consistency in 'reading' of the regulation
- iv) Trust needs to be earned, putting it in the regulations alone will not be sufficient.

Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question 3: What recommendations from the HMA Task Force report on the availability of VMPs (i) have been acted on (ii) are in progress (iii) have yet to be addressed (iv)? Will these measures be sufficient?

Recommendations:

Centres of excellence...

- Training and exchange of expertise within CA
- European database of all products nationally licensed and/or list of all national reg websites
- Simplification of Pharmacovigilance (PhV) systems
- More publicity of 2007 HMA report on availability
- Interested parties/to report back on recommendations in report.

Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question 4: How can we improve access to (a) new and (b) existing products across Europe?

Recommendations:

- Overview of what is available (previous slide)
- Use 'images' (pictograms) on packaging to reduce costs /speed to more markets.
- If authorised in one Member State (MS) then allow in other states without re-assessment.
- Allow stocks of 'emergency' medicines for Cascade use. (UK and Netherlands already have this)
- One off application of Cascade after 1st use first identified for an animal.
- Smaller package sizes.
- Use principles of ETPGAH and minor use/minor species (MUMS) for greater public/private investment.

Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question 5: Which aspects of the legislation require a specific approach for veterinary medicines?

- Within the veterinary Directive
- Within the Regulation
- Within the annex: quality, safety and efficacy

Conclusions:

- Ruling on generics e.g. as human generics for Global marketing authorisations (Mas)
- Ecotox needs to be less burdensome
- Accept the proposals from HMA reflection paper just published.

Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question 5: Which aspects of the legislation require a specific approach for veterinary medicines?

- Within the veterinary Directive
- Within the Regulation
- Within the annex: quality, safety and efficacy

Recommendations:

- Allow import of medicine from other MS before use of human medicine
- Harmonisation of duration of immunity and of withdrawal period
- Proportionate use of Quality requirements part of human meds not adapted to vet medicines. e.g. sterile vs non-sterile example
- Reduce withhold times within Cascade i.e. not the default 28days/7days. (e.g. 1.5 multiplication)

Workshop 4:

What measures do we need to take to improve access to veterinary medicines?



Question 6: What are the benefits to public health and animal health?

Conclusions:

Safer food = safety to human health

- Complete range of products is beneficial for animal health and welfare
- Prevention better than cure
- Together will mean better public health and animal health.

Recommendations:

Adopt 1.1.1. ASAP - or we could face a risk to public health as well as animal health and welfare.

CLOSING WORDS

Jochen Wieda closing the conference

See biography on page 8.

Declan O'Brien closing the conference

Biography

Declan O'Brien is the Managing Director of IFAH-Europe, a position he holds since July 2005. In this role, he has chaired the European Technology Platform for Global Animal Health and is a member of the DG Sanco Advisory Group on the Food Chain and Animal and Plant Health.

Mr. O'Brien has twenty years experience in the animal and plant health sector. He joined the Federation of Irish Chemical Industries in 1989 and in 1994 became the Director of the Animal and Plant Health Association, representing the animal health and crop protection industries in Ireland.

From 1989 until July 2005, Declan O' Brien participated in various government committees established in Ireland to provide advice to the minister for agriculture and food concerning animal health and crop protection matters. During this period, he also participated in various committees in the European organisations representing both the animal health and crop protection sectors and was a director of FEDESA and subsequently IFAH-Europe.

An Irish citizen, Mr. O' Brien studied Agricultural Science at University College Dublin in Ireland.



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