

IFAH-Europe conference



The 2010 review – 1 vision: 1 final step to 1 market?

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Proceedings

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Executive summary

The pharmaceutical legislation last underwent a major review in 2004. This brought some significant improvements and was another important step towards a single market in the EU. However, several serious issues presenting important opportunities to improve the legislation further have come to light with the 2004 legislation.

The intention of the IFAH-Europe annual conference was to build on the momentum of the AFSSA conference held 6 months previously in Paris on 30 September 2008, and set the next milestone in the evolving debate on improvements to the regulatory framework. The conference brought together key opinion leaders to discuss where agreement can be reached on proposals for change, identify those areas where more discussion is necessary and maintain the drive towards the overall goal of a true single market.

The IFAH-Europe annual conference was well timed, as it followed two key events:

1. Firstly, the Commission published in January 2009 a commitment to review the veterinary medicines legislation in 2010.
2. Secondly, HMAV published its draft reflection paper in June 2009, just prior to the conference, which provided an ideal venue to launch the public consultation of this draft document and to obtain immediate feedback via the conference workshops.

In the opening speech from EU Commissioner Androulla Vassiliou (DG Health and Consumers), delivered by a member of her cabinet, the conference delegates were given a reminder of the ultimate reason why we were all there - to contribute to the protection of animal health through the provision of veterinary medicines. The Commission noted that an action plan had been adopted in September 2008 implementing the new community animal health strategy (2007-2013), which has the overarching theme of "prevention is better than cure". The availability and innovative development of veterinary medicines, including vaccines and diagnostic tools, is clearly of major importance to the strategy.

Ms Vassiliou noted that a fully harmonised legal framework ensuring a single European market for live animals and animal products had been achieved. Other speakers later remarked how nonsensical it was that the medicines used to treat those animals could not move freely in Europe, whereas treated animals and their produce could.

The Commissioner concluded that the IFAH-Europe conference would contribute to the development of better diagnostics, vaccines and medicines to treat all species and conditions (including small market sectors) - to the benefit of both public and animal health.

Rolf Eriksson, Swedish State Secretary for Agriculture, also spoke in the opening session about the animal health strategy and future animal health regulation. He declared that Sweden, during its presidency of the EU in the second half of 2009, intends to co-operate closely with the Commission and other stakeholders to take the strategy forward.

Mr Eriksson reminded the conference participants that there is an increasing public interest in animal welfare, which has a high economic impact, as animal diseases not only cause economic losses to producers, which in the end are paid for by consumers, but they can also be a threat to human health. Consequently, the funding of veterinary measures, both at national and EU level, is important to society and priority should be given to developing systems that will provide incentives at all levels to reduce the risks of animal health threats.

As the review of the veterinary medicines legislation in 2010 approaches, it was pleasing to note from the public debate at this conference that all stakeholders are moving in one direction. There is broad support for the principles of IFAH-Europe's 1-1-1 concept for the regulation of veterinary medicines, for the need to provide adequate incentives to stimulate innovation in the veterinary medicines sector and the necessity to improve access to veterinary medicines in Europe.

These potential improvements would contribute to the wider European objectives of the Lisbon agenda and improved animal health and welfare, which in turn contribute to improved public health. Improved access to a wider range of veterinary medicines will also support the community animal health strategy, and at a global level, the principles of "One World One Health", which recognise that the health and well-being of man is inextricably linked to animal health, particularly in developing countries.

In conclusion, the conference has confirmed that all stakeholders are moving in one direction with one vision - to develop a true single market for veterinary medicines in Europe.

Opening session

Chair: Jochen Wieda, IFAH-Europe Chairman



Jochen Wieda
IFAH-Europe Chairman

Jochen Wieda welcomed all participants and opened the conference with a personal note. 50 years ago he was walking in a wood with his parents when he suddenly stumbled across some slugs.

He asked his mother why they were bright red. She answered that god painted them like that. "God must have a long brush", he responded.

Jochen Wieda continued by saying that we tend to think in black and white, in a simple way. However, the world is more complex than that. An illustration of this is the fact that animal health is different from human health and these divergences need to be reflected in the regulatory framework. He concluded by saying that joint thinking about future legislation should echo these differences.



Philip Tod
Cabinet member
Commissioner Vassiliou

Philip Tod welcomed the conference as a good opportunity to share and explore issues concerning animal health and, particularly, animal health law, as well as the broader issue of the veterinary sector and its regulatory aspect.

In 2007 the European Commission published the communication on a new animal health strategy with the theme 'prevention is better than cure'.

September 2008 saw the adoption of an action plan implementing the strategy with 31 actions and 4 pillars:

- Prioritisation of EU intervention
- Modern European animal health framework
- Improving prevention and crisis preparedness, and
- Science, innovation and research.

He continued saying that there was room for improvement and mentioned the ETPGAH as a first example. He emphasised the need for a single and clearer animal health law to address some fundamental issues such as the responsibility of the actors; disease prevention and biosecurity; linking animal health policy to other community policies; flexibility in the legislation; and keeping the legislation up to date regarding new technology.

The availability and innovative development of veterinary medicines is of major importance to community animal health policy. He added that some successes have already been noted, such as the reduction of rabies and classical swine fever in Europe. Bluetongue has shown the importance of vaccination in controlling diseases, but also to tackle food safety issues and the economic costs that come with disease outbreaks.

He pointed out that antimicrobial resistance is an important issue in human and animal health. The Commission will put together a report summarising available scientific information on this topic covering various sources.



Rolf Eriksson
Swedish State Secretary
for Agriculture

Rolf Eriksson took the floor by saying that there is an increasing interest in animal welfare issues, including the health of animals. He pointed out that animal diseases cause economic losses to producers and that consumers end up paying for these losses.

Animal diseases can be a threat to human health, he continued. He announced the priorities of the upcoming Swedish presidency from the EU agricultural point of view, namely:

- The fishing sector: the common fisheries policy;
- Agriculture and climate change globally; and
- A sound animal husbandry and healthy animals.

The latter is key to the wellbeing of animals, consumer confidence, public health and for economic reasons. Rolf Eriksson, on behalf of the Swedish authorities, welcomed the Commission's animal health strategy, especially the motto 'Prevention is better than cure'.

He pointed out the importance of simplifying legislation and lessening the administrative burden and of increasing awareness that animal health and public health are linked. He alluded to the Sweden experience in handling the bluetongue crisis.

Rolf Eriksson highlighted that antibiotics are important. However, he added, preventive measures will need to be used more so that the use of antibiotics can be reduced. He affirmed that the prevention of the spread of disease and the reduction in the need of antibiotics will positively affect human health.

R&D and innovation are important. Through R&D there is knowledge about disease and their spread and their prevention. However, as diseases are still spreading, farming practices need to be improved and incentives to do so are necessary, he concluded.

Session I: Objectives of the review in 2010

Chair: Jiri Bureš, Czech Republic (Presidency of the Heads of the Medicine Agencies)



Jiri Bureš
HMA Presidency

Jiri Bureš opened the session by referring to the conclusions of the AFSSA 2008 conference on the regulation of animal health products. He mentioned the HMAv reflection paper, which was finalised during the Czech Presidency of the EU (1st half of 2009) and became public ahead of the IFAH-Europe conference.

He explained that the Czech Presidency of the EU focused on work-sharing initiatives and building mutual trust. He added that, alongside the important topic of the future of medicines, other general aspects of the presidency comprised peace, competitiveness, international affairs and the needs of EU citizens.

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

Avril Doyle MEP



Avril Doyle
Member of
the European Parliament

Avril Doyle started her presentation by saying that IFAH-Europe's 2005 conference had the Lisbon agenda on its title and that it felt embarrassing referring to its goals in light of the actual achievements. Ambitious goals are needed, she added.

She referred to the key findings from IFAH-Europe's benchmarking study on competitiveness confirming negative developments over the past 15 years. She felt that incentives were necessary for companies to be able to innovate.

She went on by saying that there is no public veterinary medicine sector, but an entirely privately-driven one, which means that there is no research without financial return. The European Parliament's Environment Committee - where she sat - challenged this situation and urged member states to pursue a pan-European licensing system in 2000.

She said that there will never be a workable system for animal health products unless they stand alone. There is a need for a veterinary medicines Directive fit for this purpose. She added that the review of the MRL legislation brought along a significant simplification and will facilitate enforcement.

Avril Doyle emphasised the importance of science-based decisions. As rapporteur for the MRL Regulation review, she introduced amendments that she considered should also be reflected in the veterinary medicine products Directive on 1st April 2009.

Commissioner Verheugen is committed to the review of animal health products in 2010. He or his successor needs to be held to that, she stated. A true single market should be based on sound science in line with the EU's strategic objectives for animal health products. She concluded by saying that a pan-European authorisation is necessary as food, live animals and people travel around the EU.

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

Martin Terberger, European Commission DG Enterprise and Industry



Martin Terberger
DG Enterprise and Industry

Martin Terberger opened his presentation by referring to better regulation as an important element of the Lisbon agenda, to which the last Commission put a high level of importance. The MRL legislation, he continued, was part of the better regulation package adopted in 2005.

He said that the European Commission has made a great effort to reduce the administrative burden over the past years, including simplification and partly de-regulation.

Additionally, the revision of annex I was finalised in 2008. The new variations Regulation was useful to combine the human and veterinary pharmaceutical approach.

He stressed the importance of being committed to the objectives during the implementation. He felt that there is a risk that scientists see only part of the picture. The best objective cannot be achieved if we don't see the wider picture, he added. He mentioned an example illustrating the importance of using the right wording: 'If appropriate' means that there may be or there may not be changes, while 'where appropriate' implies that there might be changes in certain areas.

He summarised the Commission's key points as being:

- The specificities of the veterinary sector;
- Innovation;
- Medicine availability; and
- Reducing the administrative burden.

As for the latter, he felt that the challenge is how to simplify the whole system without compromising the overall objectives. In general, it will even increase the level of public health and animal health protection and the 1-1-1 concept will play a key role there.

He concluded that it is important to get the impact assessment right from the beginning and that the European Commission will continue to work so that the vision of 9 years ago - a pan-European licensing system - becomes a reality.

■ Questions and answers

Jan Vaarten (FVE) said that it essential to rely on the veterinarian and his expertise. It is important to look at practical solutions and make use of the knowledge of the veterinarian in the field.

A representative from diagnostic manufacturers pointed out that diagnostics are not regulated at EU level and there are different batch regulations depending on the member state. She wondered whether there is a possibility to harmonise batch control and to include them in the review.

Martin Terberger answered that this touches upon the definition of a medicinal product, which differs between the human and veterinary sectors. Currently it is up to each member state to decide this. There are increasingly problems to identify what is what and it is complex to find a solution, he added.

Patrick Dehaumont commented that there is a strong need to harmonise diagnostics. The OIE has a diagnostic certification system and wondered whether the EU could benefit from it.

Session II: Possible solutions

Chair: Consuelo Rubio, Deputy Director General of the Spanish Medicines Agency



Consuelo Rubio
Deputy Director
Spanish Medicines Agency

Consuelo Rubio opened the session by welcoming the speakers and inviting the participants to contribute to a fruitful discussion on solutions to the review 2010.

- **The HMA Task Force reflection paper on opportunities for the review**
Patrick Dehaumont, Chair of the Heads of Medicine Agencies' Task Force



Patrick Dehaumont
Chair, HMA Task Force

Patrick Dehaumont said the HMA has reviewed the background to the current regulatory system and is developing consensus on the need for change. An important aspect is to balance the risk of authorising a product with the risk of not authorising it.

The HMAv Task Force was established in April 2008 to look at short-, medium- and long-term improvements to the interpretation of the legislation and amendments to it.

The HMAv paper was published the week of the conference and is currently under consultation, he said. The vision is a legislative system that provides the greatest range of authorised veterinary medicines in each member state, maintains protection for people, animals and the environment, and reduces administrative and development costs for companies.

He emphasised the need for stand-alone consideration of the specificities of the veterinary sector. The HMAv paper outlines a number of areas for proposed improvement, including:

- Data protection: to stimulate innovation of medicines for new species, new formulations and new routes of administration;
- Generics: a multi-dimensional issue with many aspects to be considered;
- Pharmacovigilance: There is a need to simplify while keeping the system robust;
- Packaging and labeling improvements and flexibility for member states;
- Simplification of authorisation procedures;
- Suggested need for harmonisation of reference products, particularly to solve the difficulties encountered with the authorisation of generics.

He concluded that a focus group has been planned as a follow up to the 2-month consultation.

■ The animal health industry's proposals towards the review

Neil Craven, IFAH-Europe/Pfizer



Neil Craven
IFAH-Europe/Pfizer

Neil Craven gave an overview of the drivers and factors for success and of the problems linked with the current legislation.

The EU regulation does not currently stimulate or reward innovation. Time and cost to market are key factors for success and are largely determined by the EU regulatory framework. He remarked that the time and cost to develop new products have increased very significantly since 1990.

He referred to the lack of a true single market for all veterinary medicines combined with a lack of level-playing field between different types of marketing authorisation. He then outlined the 1-1-1 concept, i.e. one dossier subject and one assessment resulting in one decision applied to all veterinary medicines, both new and old ones.

IFAH-Europe believes that it is now time to create a true single market for veterinary medicines, as with food produce, and that the motto should be, "Do it well enough and do it once".

Neil Craven outlined IFAH-Europe's priorities for regulatory reform and industry's proposals:

- Data protection for all significant innovation;
- Simplification of procedures to deliver a true single market, reduction of time/cost to market and avoiding wasted administrative resources;
- A fair and equitable system for all companies;
- Rationalisation of packaging and language requirements;
- Simplification of pharmacovigilance, and
- Simplification and rationalisation of product maintenance.

He concluded that IFAH-Europe's thoughts fit well with the proposal in the HMAv reflection paper and the European Commission's plans to carry out an impact assessment and emphasised the need to revise the current legislation.

■ Panel discussion

The following aspects were tackled during the discussion:

- How much science is enough in the dossier? The system is effective in being protective, but it may be over-protective and may even undermine confidence in it. Can strengthening of pharmacovigilance in recent years enable some reduction in pre-authorisation data requirements?
- What is the role of national authorities in a new system? There is a clear need for the system to be re-thought and national authorities will continue to have an important role, particularly in local control and enforcement. The precise nature of that role is open for discussion in the coming months.
- Problems arising from registration processes often involve putting more costs onto the originator, such as the suggestion in the HMAv reflection paper for innovators to help solve a problem for authorities resulting from different summaries of product characteristics (SmPC). This is often a result of different conclusions reached by the authorities themselves for the same data.

There is general agreement that having different SmPCs in different member states is undesirable, but is not a real public health issue (otherwise the issue would have been referred to the CVMP).

- How can we stimulate research into new antibiotics in a regulatory environment that is continually pushing for more restriction on use? It is agreed that there is a need for strong veterinary input into discussions spanning human and veterinary health, and that the solution to the dilemma is not clear. More discussion will be needed.

Parallel workshops around the HMA reflection paper and the IFAH-Europe 1-1-1 concept

Recommendations on key themes

- Data protection and innovation
 - The legislation should be amended to provide improved data protection for new indications or species. (WS4)
 - De-link data protection from the global MA concept (need data protection for separate marketing authorisations). (WS3)
 - The veterinary sector needs improved data protection to stimulate research into significant product developments. It should be recognised that time to return on investment, or similar business models, are key to investment decisions. (WS4)
- The 1:1:1 concept
 - Support the 1:1:1 concept; in-depth discussions are required on the detail. (WS1)
 - Consider the benefits of a system with 1 assessment and 1 decision such as: simplification, reduced referrals, more efficiency (avoid duplication of work) and optimal use of best resources, predictability, and increased availability of VMPs. (WS2)
 - The legislation should be revised to implement the principles of the “1-1-1 Concept” and to make the legislation “enabling” and not restricting. (WS3)
 - For all new products and for all product types there should be 1 single system based on a single scientific assessment utilising the best European expertise and resulting in a single binding decision for MA. The same principle would apply to scientific assessments required during a product’s lifecycle such as required for line extensions, variations or PSURs. (WS2)
 - For all existing products the scope of the MA should be extended to all EU countries automatically if licensed according to European legislation such as via DCP and MRP; the detailed proceeding for products approved via the national procedures requires further elaboration. (WS1) (WS2)
- The link between human versus veterinary pharmaceutical legislation
 - There are different drivers between the human and veterinary sectors and legislation should not automatically follow changes from one sector to the other. (WS1)
 - The human and veterinary legislation should be separate (while maintaining synergies). (WS2)
 - When revising the legislation it is important to identify where it is useful to be the same as the human legislation and where it is important for the veterinary legislation to be different. A separate co-decision procedure for the veterinary legislation is needed. (WS3)

■ **Workshop 1: How to achieve the objectives of a true single market for veterinary medicines?**
Chair: Martin Terberger, European Commission DG Enterprise and Industry

Conclusions

- A true single market is one that allows free movement of authorised veterinary medicinal products between member states, without additional national regulatory obstacles, for use in accordance with national distribution systems.
- Labelling and language requirements, authorisation procedures, pharmacovigilance implications, the need for profitability in each member state (MS), are examples of obstacles to reaching the objective of a true single market in veterinary medicines.
- To achieve a true single market the main cost drivers should be identified and the legislation should be amended, particularly to reduce the administrative burden and simplify the authorisation and post-authorisation procedures.
- In order to include existing products into a true single market we must first ask whether there is a safety issue, and is there a justifiable need to request more data. It was recognised that some products were not brought up to EU standards on accession to EU.
- For existing products authorised via the decentralised procedure (DCP) and the mutual recognition procedure (MRP), the marketing authorisation (MA) should be extended to all member states automatically. For existing products authorised nationally in one or more member states the MA should be extended to all member states provided the product was authorised in accordance with the Community law in force at the time (i.e. Directive 81/851 or later).
- Any system to maintain harmonised products must avoid extra costs and loss of products.
- It was acknowledged that the single market objectives, drivers and hurdles differ between human and veterinary sectors, and we should not slavishly follow changes from either sector to the other.
- Public health and animal health would benefit from a true single market in veterinary medicines by more consistent scientific scrutiny in accordance with EU legislation, and a wider availability of products in which the consumer has confidence.

Recommendations on key themes

See page 12.

Additional recommendations

- Labelling and language requirements (and their limits of flexibility) should be reviewed with the aim of reducing the administrative burden on industry and allowing MS to determine their own language requirements.
- The legislation should also aim to reduce the administrative burden for industry and authorities to allow headroom for other changes. It will be important to identify the main cost drivers.
- Recognise that a sub-standard dossier does not necessarily mean it is a sub-standard product.

Conclusions

- The objectives in seeking a system of 1 assessment and 1 decision include simplification, 1 market, reduced referrals, more efficiency (avoiding duplication of work) and optimal use of best resources, predictability and increased availability of veterinary medicines.
- The objectives would also build trust and public confidence in the system through increased transparency and from a single interpretation of the rules leading to single decisions.
- A single assessment should mean a single assessment report valid throughout the EU based on the objective criteria of quality, safety and efficacy. This would resemble the CVMP assessment report, but with no national deviations, and would be carried out by a single team (not one individual assessment) using the best European-level expertise available. It would be valid throughout the EU, negating the need for any subsequent new assessments.
- A single decision should mean 1 binding decision valid throughout the EU, allowing the possibility to market in all MSs; placing on the market in each MS would then be an administrative procedure (including for further accession of new MSs).
- 1 assessment and 1 decision for all new products and all product types should be achieved via a single scientific assessment utilising the best European expertise.
- Automatic mutual recognition should be possible for all existing products provided they were authorised in compliance with European legislation.
- To deliver 1 assessment the EMRN should organise itself to make efficient use of the network's resources within the NCAs. This might involve specialised centres of resources (competences), using the EMEA as a co-ordinating body.
- NCAs would delegate scientific assessment to a single European assessment team, and would maintain full control of their national market (i.e. surveillance, pharmacovigilance and enforcement/inspection); there should be flexibility in the system.
- The legislation should be changed to achieve the objectives of 1 assessment and 1 decision and the Directive should be replaced by a Regulation. Separate the human and the vet legislation - in order to accommodate the inherent differences.

Recommendations on key themes

See page 12.

Additional recommendations

- The EMRN should organise itself to make efficient use of the network's resources within the NCAs, at the same time ensuring that there is no excessive focus on co-ordination risking to neutralise the efficiency gain.
- Need to elaborate the best approach to ensuring timely national implementation of the binding MA decision (e.g. Commission Decision, system of NCAs signing off on decision acknowledging assessment and allowing placing on the market).
- An efficient future European regulatory system above all needs to think in terms of science-based expertise and efficiency.
- NCA will continue to play an important role in enforcement (placing on the market, Pharmacovigilance, inspections, control, etc.). Fees could take account of this by splitting them into a fee for assessment and a fee for placing on the market.

■ **Workshop 3: How to achieve the objectives of a true single market for veterinary medicines?**
Chair: Jim Scudamore, ETPGAH/consultant

Conclusions

- The main European policy drivers towards the EU objective to stimulate innovation and investment in research include the Lisbon Agenda, the European Commission Better Regulation programme, the Regional Economic Development and Sustainability initiative, the Community Animal Health Strategy, the primary legislative objectives of improved public health and animal welfare, and the need to respond to new disease threats.
- By 'Innovation' we mean both new science/new products/new technology, and also significant developments to existing products (additional species; new indications; new routes of administration; new formulations; and new manufacturing processes).
- The current legal framework has brought improvements to data protection but these are completely negated by the link to the global MA concept and the interpretation of the data requirements, leading to the high cost of product development.
- In Europe innovation is also restricted by diversion of resources to defensive research.
- The current legal framework could be improved by clearly differentiating human and veterinary requirements, and by introducing measures to stimulate investment.
- The workshop fully endorsed the principles of the "1-1-1 Concept".
- The current veterinary medicines legislation is not designed to cope with new technologies.
- Public confidence in the product approval process is necessary to create better acceptance of innovative products. The general public is largely unaware of the MA process.
- Public confidence will be improved if there is 1 single decision from a transparent science-based system, with good communication addressing both safety and also the benefits.

Recommendations on key themes

See page 12.

Additional recommendations:

- Recognise that innovation is not only about new and improved products but also processes and methods.
- Recognise that the innovation challenges in the veterinary medicines sector are very different to the human sector and should be reflected in the veterinary legislation.
- There is some flexibility in legislation; this needs to be publicised and fully utilised.
- The data requirements for veterinary medicinal products (VMPs) should be reviewed with a view to improving availability.
- The veterinary legislation should be revised to include provision on advanced therapies.
- Workshops on new technologies should be organised periodically.
- Public confidence should be improved by implementing a system leading to 1 single decision from transparent science-based system; the system should include good communication about both safety and also the benefits of new technologies.
- Communication on new technologies should be agreed centrally and widely communicated nationally so that common information is provided to the public in every MS. Divergent or inconsistent messages create mistrust.

■ Workshop 4: What measures do we need to take to improve access to veterinary medicines?
Chair: Jan Vaarten, Federation of Veterinarians of Europe

Conclusions

- By “availability” of VMPs we mean a product is registered and on the market.
- By “access” to VMPs we mean a product can be used in the field in a legal way. There are differences in legal classification across the member states therefore access varies.
- The factors currently hindering the availability of VMPs and access to VMPs include economics (small market sizes), language requirements in small markets, and lack of data protection (restricts research and hence availability of products).
- Data protection can impact the availability of new products. A short data protection period or no data protection period will create higher prices or will restrict innovation and investment in product development. Improved data protection is needed.
- The HMA Task Force report on the availability of VMPs has led to progress in improving access to products through discussions on product labelling, and application of the “cascade”. However greater trust between CAs and more consistency in interpretation of the legislation is needed.
- Access to products across Europe can be improved by facilitating multi-lingual labelling (e.g. by using pictograms), by creating true mutual recognition of products (if authorised in one MS then allow in other states without re-assessment), and allow national stocks of ‘emergency’ medicines for Cascade use.
- Several aspects of the legislation require a specific approach for veterinary medicines, including the authorisation of generics and data protection (delink from Global MAs), environmental safety requirements, more appropriate quality requirements, more appropriate standard withdrawal periods.
- The benefits are better public health and animal health and safer food. A complete range of veterinary medicinal products is beneficial for animal health and animal welfare.
- Prevention is better than cure. The “One world one health concept” recognises that human welfare is entirely dependent on animal health and welfare, particularly in developing countries.

Recommendations on key themes

See page 12.

Additional recommendations

- The conditions for the cascade should be made more flexible:
 - Amend the ‘cascade’ (articles 10 and 11 of Directive 2001/82/EC) to enable the use of products authorised in another MS for the same indication and species, before having to use products authorised for another species or indication.
 - Allow national stocks of ‘emergency’ medicines for ‘cascade’ use.
 - Reduce the standard withhold times within the ‘cascade’ i.e. not the default 28days/7days.
- The factors hindering access to VMPs should be addressed in a review of the legislation, such as off-label use, the cascade, the impact of new guidelines, the language requirements in small markets and the lack of adequate data protection.
- Allow appropriate use of pictograms on packaging to facilitate multi-lingual packaging.
- Simplify the pharmacovigilance systems.

- The EMRN should consider establishing centres of excellence, training and exchange of expertise within the network.
- There should be a European database of all nationally licensed products and/or a list on all NCAs websites.
- More publicity is needed for the 2007 HMA report on availability of veterinary medicines. Interested parties should report back on progress with the recommendations in the HMA report.
- Encourage greater public/private investment; e.g. use the principles of ETPGAH.
- There should be more proportionate use of quality requirements; these should be better adapted to vet medicines.

Closing session

Chair: Jochen Wieda, IFAH-Europe Chairman



Speaker panel
closing session

Jochen Wieda gave the floor to the rapporteurs of the four workshops.

John Fitzgerald (W1), Melanie Liewers (W2), Rick Clayton (W3) and James Scudamore (W4) each presented a summary of their respective workshop. (see pages 9-14).

Declan O'Brien, IFAH-Europe Managing Director, summarised the contents of the conference and thanked all participants for their contributions.

Acronyms

AFSSA:	French Food Safety Agency
CA:	Competent authority
CVMP:	Committee for Medicinal Products for Veterinary Use
DCP:	Decentralised procedure
DG:	Directorate General
EMA:	European Medicines Agency
EMRN:	European Medicines Regulatory Network
ETPGAH:	European Technology Platform for Global Animal Health
FVE:	Federation of Veterinarians of Europe
HMAv:	Heads of medicine agencies (veterinary)
MA:	Marketing authorisation
MEP:	Member of the European Parliament
MRL:	Maximum residue limit
MRP:	Mutual recognition procedure
MS:	Member state
NCA:	National Competent Authority
OIE:	World Organisation for Animal Health
PSUR:	Periodic safety update report
R&D:	Research and development
SmPC:	Summary of product characteristics
VMPs:	Veterinary medicinal products



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