



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scanning the Horizon - a Regulatory Perspective

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An agency of the European Union





Presentation

- Background, rationale and format
- Major trends and issues
- International perspective
- EMA response and outlook



Background, rationale and format

- Series of meetings held with major animal health companies during 2012-2013
- Confidential, open discussion of product development pipeline, future needs and regulatory challenges
- What works well, what does not work well and what should be put in place for the future
-not an opportunity for product-specific discussions or regulatory advice.



Trends and new challenges

- The pipeline for development of innovative veterinary medicines remains healthy overall
- A healthy pipeline of new products is essential for the continued viability of the innovative animal health industry
- Major focus for innovation is on companion animal sector more than food producing species
- Broad range of product types being developed, particularly for companion animals
- Consolidation within the veterinary industry has increased access to novel molecules and technology developed for human use



Trends and new challenges

- There is considerable interest in developing novel biological products that do not fit the current definitions of pharmaceutical or immunological products
- Innovation in formulations, combination products
- Several novel 'Platform Technologies' intended for use across a range of different products/diseases
- Adjuvants, vectors, devices or delivery systems
- Development of biomarkers and need for validation and qualification of
- New methods
- Alternatives to animal tests (3Rs)



International perspective

- Development programmes for novel technologies need to be global
- Environment in USA generally considered more receptive to new technologies than in EU
- Developing regions (BRIC countries and South East Asia) increasingly important and a focus for investment and new product development
- Public acceptance of novel technologies is an issue with wide variation in acceptance between countries and regions



Antimicrobials – a particular challenge

- Increased public concern and increasing requirement for demonstration of positive B:R balance with respect to human health make the market for new antimicrobials unattractive for investment
- Alternatives to antibiotics an area of particular interest
- Several companies requested a greater emphasis be placed on PK/PD studies in place of *in vivo* studies



What is needed?

- 'Upstream' advice for new technologies
 - 'Flexible' but consistent advice from initiation to authorisation
 - Should provide the opportunity for dialogue with regulators
 - Technology or platform-based and not product by product
 - Not a replacement for scientific advice
- Increased liaison with FDA and regulators in other regions
- Importance of VICH Outreach for harmonised regulation in developing regions
- Need to manage expectations in relation to MUMS; scope is limited for reducing data requirements for innovative products, especially for food producing animals



EMA response

- Innovations Task Force opened up to veterinary products
- Parallel scientific advice with FDA and informal exchanges on new technologies actively promoted
- Full engagement with VICH Outreach Programme and other international activities to support harmonisation of requirements with emerging regions
- Proposals under discussion to increase the range of expertise on Scientific Advice Working Party and to expand the opportunities for exchange of information with applicants



EMA response

- In depth reflection by EMA/CVMP on how best to provide appropriate guidance on new technologies at platform and individual level
 - Proposal in preparation for a dedicated group for new veterinary therapies
- Revision of MUMS scheme initiated, including an analysis of the scope for reduced data requirements, bearing in mind the need to maintain high standards for protection of public and animal health



EMA response

- Transparency raised as a concern by several companies
 - ‘Principles for publication of agendas and minutes of EMA scientific committees’ (EMA/555647/2013) recognises the particular nature of the veterinary domain
 - Publication of agendas and minutes of the scientific committees including CVMP as from December 2013
 - Greater consistency in EPARs and the information made public



Conclusions

- A useful exercise to be repeated at 2-3 year intervals
- Action taken in response to the major issues raised
- Supports and stimulates a greater level of international cooperation
- Useful input into the next EMA Roadmap



Update on e-Submission for Veterinary Products

- **eAF** : new eAFs for vet initial MAA, variation and renewal were published on the e-submission website (<http://esubmission.ema.europa.eu/eaf/index.html>)
 - ⇒ Their use is strongly recommended and any change requests should be sent to esubmission@ema.europa.eu
 - ⇒ For info: A procedure is now in place to add controlled terminology (incl. substances)
- **EMA Gateway / Web Client**: From 1st April 2014, all vet applications can be submitted via the EMA Gateway / Web Client
 - ⇒ Applicants will need to register in advance
 - ⇒ No hard-copy cover letter needed for Gateway / Web-Client submission
 - ⇒ Webinar on the use the eSubmission Gateway / Web Client for veterinary submissions has been organised for 24th of March 2014
 - ⇒ For more info: <http://esubmission.ema.europa.eu/esubmission.html>