Optimising the Regulatory Framework

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Improved Market Access for Authorised Veterinary Medicines – The Asian Perspective
Aspects to be addressed will be:

- Optimising the regulatory framework to promote access to market for quality products
- Ensuring predictability and minimising risk of failure
- Funding mechanisms for regulatory activities
- Pre-submission dialogue

_N.B._

A number of these topics have been highlighted and discussed in the various workshops; the aim of this presentation is to provide information on what has been learned in the EU context and which may be of use to the audience at this Conference.
The EU guiding principles include:

- A strong regulatory framework
- Consistent standards
- Clarity and availability of guidance associated with the framework
- Communication
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• A predictable system – an unpredictable system will discourage applicants from applying for marketing authorisations and will mean fewer veterinary medicines available

• Predictability and Consistency of registration timelines, dossier content requirements & outcome of the evaluation on science-based requirements
The world is getting smaller!

- Recognition of International standards
  - Manufacturing and control procedures
  - Technical requirements (e.g. VICH)

- At the 33rd VICH Steering Committee meeting, Stefano Soro (European Commission):

  “VICH has now been active for 20 years and has become a reference in the world; the growing interest of third countries in the activities of the VICH Outreach Forum shows the importance of the VICH Guidelines in the international environment – the Guidelines are increasingly recognised in all parts of the world.”
• Medicines regulation should cover all activities from manufacture through to dispensing and promotion

• Standards/guidance relevant to the different activities needs to be in place to ensure quality, safety and efficacy

• There should be mechanisms in place to ensure that all involved in the chain are authorised/licensed and subject to oversight/inspection to ensure compliance

• Administrative measures/legal sanctions need to be in place to effectively deal with unauthorised products/falsified medicines
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- Reliability - consistent evaluation criteria applied to all submissions
- Approval decision based on benefit-risk evaluation
- Veterinary-specific aspects to be taken into account — appropriate and proportionate regulatory guidelines are needed
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Network Model in the EU:

Essential components for an effective network

- Harmonised legal and technical requirements
- An effective infrastructure for coordination and cooperation
  - Co-ordinating body
  - Established and agreed procedures
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Network Model in the EU:

• Effective IT systems
  • EU-wide Telematics programme

• A common understanding

• Mutual trust and transparency

• An interest in work sharing
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The European Medicines Agency model:

- **Agency** is an interface of co-operation and co-ordination of Member States’ activities with respect to medicinal products
- National competent authorities in **28 Member States + 3**
- **European experts’ network** vital for the work of the Agencies’ Committees and working parties
- **Expert list** of over 4,500 nominated experts (of whom some 600 are nominated as veterinary experts)
- **Scientific competence** is guaranteed by their nominating authority, **independence and integrity** assured through public declaration of interests
BEMA (Benchmarking of European Medicines’ Agencies) across the EU:

• The programme aims to contribute to the development of a world-class medicines regulatory system based on a network of agencies operating to best practice standards

• BEMA is assessment of systems and processes in individual agencies against a set of indicators which have been agreed in for management systems, assessment of marketing authorisation applications, pharmacovigilance activities and inspection services

• Gives an opportunity to identify strengths and best practices in agencies and any opportunities for improvement; it is not an audit designed to identify non-compliance nor is it a ranking of agencies - Agencies are encouraged to install suitable best practices in order to enable an improved operation of the network of agencies
EU Network Training Centre

Single European platform for exchange of trainings, enhance share and reuse of expertise

Establishment of recognised system for continuing professional development

Maximise value of resources committed to training and create economies of scale in funding sources

Fostering collaboration, sharing of best practices, and lessons learned across the Network
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Funding mechanisms for regulatory activities

- There are a wide variety of options possible and there is no ideal model

- In different Member States in the EU (depending on the legal provisions for fees) the fee for assessment work might be met by Ministry budgets or the work may be totally (or partially) paid for from the fee paid by the applicant

- The fee should be proportionate to the service provided (based on the amount of assessment work required) - Need to build into any system the possibility to also have proportionate timelines for (major and minor) changes to the marketing authorisation
Funding mechanisms for regulatory activities

- Transparency of fee calculation information
- Very useful to have fee information available on the Regulator’s website with other guidance
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Pre-submission dialogue

• Dialogue between the Regulator and the applicants is essential to clarify expectations and understanding

• Helpful for authorities and applicants to discuss the application before dossier submission – but this is not a pre-assessment!

• Early dialogue enables regulatory aspects to be checked ahead
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Pre-submission dialogue – examples from the EMA

Several instruments available to applicants:

- Guidance and guidelines on EMA website on procedural, regulatory and scientific issues

- Pre-submission meetings some months (or even years) before dossier application submission

- Scientific advice request possible to assist in product development (not just for applications for the centralised procedure) - Possibility of International scientific advice (parallel US FDA/EMA)
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Pre-submission dialogue – examples from the EMA

Conclusions:

• Ensure a solid framework for the regulation of veterinary medicines

• Recognition of International standards – improves predictability for everyone

• Communication and consistency are key
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Thank you for your attention!