Workshop Session 7 – Key Enabling Factors

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Improved Market Access for Authorised Veterinary Medicines – The Asian Perspective

Organising Committee:
Focus of this session are the following aspects:

- Encouraging investment: enabling market access/
  What prevents companies bringing products to
  market?/Protection of technical documentation
- Benefits of regulatory convergence and harmonisation;
  Regional cooperation
- Prioritisation and best use of resources
An Indian example (2012):

“Veterinary medicine market in India – very small Vs world market;

Drug Discovery and Development – costly affair, 5-15 years;

Veterinary medicine approval process well regulated globally
Indian regulatory process for Vet medicine ≅ human medicine

A global perspective on regulatory approval process is essential to change regulatory process in India – ‘at par’ globally, to develop expertise in regulatory studies (and) to attract top R&Ds to India – tap the resources”
Encouraging investment: enabling market access/
What prevents companies bringing products to market?/Protection of technical documentation

Industry want quick access to market so Industry need to provide:

- Clear, structured and correct information in the application dossier submitted for assessment;
- Prompt responses to questions from Regulators;
- The commitment to keep the product up to the required standard
Encouraging investment: enabling market access/
What prevents companies bringing products to market?/Protection of technical documentation

What needs to be considered by Regulators?

- Predictability of registration timelines, dossier content requirements & outcome of the evaluation on science-based requirements
- Reliability - consistent evaluation criteria applied to all submissions
- Approval decision based on benefit-risk evaluation
Encouraging investment: enabling market access/
What prevents companies bringing products to market?/Protection of technical documentation

What needs to be considered by Regulators?

- A **predictable system** – an unpredictable system will discourage applicants from applying for marketing authorisations and will mean fewer veterinary medicines available

- **Veterinary-specific aspects** to be taken into account – cannot be treated the same as medicines for human use – appropriate and proportionate regulatory guidelines are needed

* Market size is 2 - 3 % of the human medicines sector, with no re-imbursement possibilities (source: IFAH Europe)
Encouraging Investment

What needs to be considered by Regulators?

• **Encouraging investment**: 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** needs to be in place to effectively deal with unauthorised products/falsified medicines

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Encouraging investment: Variations

After authorisation, marketing authorisation holders will need to change their dossier content – these can involve many different types of changes e.g. manufacturing changes, changes to active substance and finished product, addition of species, routes of administration etc. etc.

Major changes (variations) assumed to need a longer period of assessment; small changes – consider: do they need assessment or should they just be notified to the regulatory authority?
Encouraging investment: variations

What needs to be considered by Regulators?

• Once a product is authorised – the work really starts!

• Authorisations, once granted need to be maintained efficiently by companies and changes approved by the Regulators

• Build into the system the possibility to have proportionate timelines for assessment of major and minor changes to the marketing authorisation
Security – will the data package be submitted into a secure environment?

Encouraging investment: enabling market access/
What prevents companies bringing products to market?/Protection of technical documentation

- Substantial investment in product development -
  - A return on investment is essential
  - May need to have a period of market exclusivity
  - E.g. EU – 10 years market exclusivity

Data security is important to companies
- Lack of security is a major disincentive to submit data
- Safe receipt, handling and storage of data
- Safe from loss, disclosure and theft

*Article 13 of Directive 2001/82/EC: “1. By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 5 for not less than eight years in a Member State or the Community. A generic veterinary medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product”

- Data security is important to companies
  - Lack of security is a major disincentive to submit the data dossier
  - Safe receipt, handling and storage of data by the regulator is critical
  - Data handling and storage systems must prevent loss, disclosure and theft of the data
Key Enabling Factors

Questions:

1. How predictable do you think your approval system is for applicants?

2. What could you do to make it more predictable?

3. Is obtaining/maintaining/changing a marketing authorisation in your region easy?

4. Do you allow periods of data protection for products?


Notes
Benefits of regulatory convergence and harmonisation; Regional cooperation & Prioritisation and best use of resources

- 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.”

Benefits of regulatory convergence and harmonisation; Regional cooperation & Prioritisation and best use of resources

- Increases predictability
- Increase of quality standards and harmonisation of product quality
- Quicker new product registration for Industry and availability of product on market

Joint assessments
Decentralised procedure

Benefits of regulatory convergence and harmonisation;
Regional cooperation & Prioritisation and best use of resources

• Veterinary medicines market much smaller than for human medicines – resources of regulators and industry are also very much smaller in the veterinary sector

• If the assessment has already been done – does it need to be done again?

• In the European Union, Member States have come together to allow consensus via Mutual Recognition, Decentralised and Centralised procedures

• ASEAN M.R.A.

Benefits of regulatory convergence and harmonisation; Regional cooperation & Prioritisation and best use of resources

Communication!

Dialogue between the Regulator and the applicants is essential to clarify expectations and understanding – good experience with this in the EU.

Pre-submission meetings between the regulator and the industry are frequent in the EU; clarifies understanding but it is not a pre-assessment. Assessment report is also provided (justifies the list of questions to the applicant).
Key Enabling Factors

Questions:

► Which areas do you think should be the focus (Initial marketing authorisations?)
► Can Regional cooperation work for you?
► Can you and do you apply VICH guidelines?
► Could you accept a product authorisation/licence granted by another competent authority in the same or a different region (i.e. one that has done the dossier assessment already)?
► Do you meet with applicants prior to submission of their applications?


Notes
Key Enabling Factors

We work in a complex environment - so let’s work together!

Key Enabling Factors

Workshop 7: Team members:

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