OIE Conference on Veterinary Medicinal Products
In the Middle East

“Towards harmonisation and improvement of registration, distribution and quality control”

Damascus, Syria
2-4 December 2009
A model for regional approach, harmonisation of control over veterinary medicinal products

DAMASCUS; 2-5 December 2009
Introduction

Veterinary Medicinal Products (VMPs):
- Veterinary tools, contributing to the improvement of animal and public health worldwide, and of food security

The VMPs policy as part of the animal health policy

Need of a strong legislative and regulatory framework implemented through a strong and comprehensive governance linked to national veterinary services
Summary

- Need of a comprehensive set of legislative and regulatory requirements

- Benchmarking of the national competent authority, a tool for efficiency

- Enforcement of the policy through a favourable environment
Summary

- Need of a comprehensive set of legislative and regulatory requirements
  - Benchmarking of the national competent authority, a tool for efficiency
  - Enforcement of the policy through a favourable environment
Legislative and regulatory requirements

- Public policy
- Activities to be covered
- Institutional organization
- Penalties and administrative action
Legislative and regulatory requirements

- Public policy
  - Written mandate with proportionate objectives and strong commitment to ensure efficiency, competence and impartiality

- Activities to be covered
- Institutional organization
- Penalties and administrative action
Legislative and regulatory requirements

- Public policy
- Activities to be covered
  - All activities along the entire life of VMPs from development to usage, including residues aspects
- Institutional organization
- Penalties and administrative action
Veterinary Medicinal Product’s life

Pre-MA

MA Procedure

Ow!!!

Post MA

MARKETING

or

MA

Ow!!!
Legislative and regulatory requirements

- All activities, that includes…
  - Clinical trials
  - Assessment and licensing of products
  - Laboratory testing and batch release
  - Assessment and licensing of process and facilities
  - Inspection (including advertising)
  - Post marketing surveillance (e.g.: pharmacovigilance and residues)

*But proportionate and relying when possible on international or regional systems*
Legislative and regulatory requirements

- Public policy
- Activities to be covered
- Institutional organization
  - Scope of responsibilities and mission statement
  - Science based decision making process
  - Human resources
  - Fee system
  - Transparency and communication responsibilities
- Penalties and administrative action
Legislative and regulatory requirements

- Public policy
- Activities to be covered
- Institutional organization

Penalties and administrative action

- Administrative capacities of NCAs
- Prosecution capacities
- Coordination among official services
- Transparency and communication
Summary

• Need of a comprehensive set of legislative and regulatory requirements

• Benchmarking of the national competent authority, a tool for efficiency

• Enforcement of the policy through a favourable environment
Efficiency of the legislation: need of benchmarking

- Need to benchmark the implementation of the legislative corpus

- Key issues to be addressed for implementation
Efficiency of the legislation: need of benchmarking

- Need to benchmark the implementation of the legislative corpus through a quality assurance process
  - Possible use of existing standards: (WTO; OIE; ISO; PIC/S; BEMA-Europe…)
  - Need of periodic review of the legislation and its implementation

Key issues
Efficiency of the legislation: need of benchmarking

Need to benchmark the implementation...

Key issues:
- management
- scientific and technical assessment
- inspection and laboratory control
- surveillance (pharmacovigilance; residue control)
Efficiency of the legislation: need of benchmarking

- Need to benchmark the implementation...

Key issues:

- Management
  - Governing principles
  - Relationship with stakeholders: Transparency
  - Risk management policy
Efficiency of the legislation: need of benchmarking

- Need to benchmark the implementation...

- Key issues:
  - Scientific and technical assessment
    - Resources
    - Competences
    - Opinion making process
    - Coordination with inspection and pharmacovigilance
Efficiency of the legislation: need of benchmarking

- Need to benchmark the implementation...
- Key issues:
  - Inspection and laboratory control
    - Competences and resources
    - Existing good practices
    - Laboratory control
    - Rapid alert system and batch recall (traceability)
    - Follow up of inspections and controls
    - Coordination of official services
Efficiency of the legislation: need of benchmarking

- Need to benchmark the implementation...
- Key issues:
  - surveillance (pharmacovigilance; residue control)
    - Data collection
    - Monitoring and control plans for residues
    - Coordination of official services
    - Resources
Summary

- Need of a comprehensive set of legislative and regulatory requirements
- Benchmarking of the national competent authority, a tool for efficiency
- Enforcement of the policy through a favourable environment
Efficiency of the legislation: need of a favourable environment

- Information and Training

- Communication and Transparency with all the stakeholders and the public

- Role of associations / statutory bodies

- Involvement and powers of veterinary services, VMPs being part of their duties
Efficiency of the legislation: need of a favourable environment

Regional networking

- Common knowledge
- Exchange of information
- Common requirements
- Using existing standards
- Relying on existing systems and setting priorities

... building trust, not reinventing the wheel!
Efficiency of the legislation: need of a favourable environment

Regional networking a step towards the OIE global approach

OIE support to international cooperation:

- strengthening Veterinary Services
- development of twinnings
- Conferences and training
- Focal points
CONCLUSION
Conclusion

Considering the impact of VMPs in the global concept “One world / one health”, the way forward implies:

- A strong political commitment
- A proportionate and targeted action
- A networking and work sharing approach and when possible a regional approach between authorities, using international standards
- Transparency and relationships among stakeholders
Thank you for attention
World organisation for animal health

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