Governance of Veterinary Medicinal Products

Legislation – registration – distribution

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INTRODUCTION

Need for a clear and strong policy for VMPs

• To protect Animal health
• For Food safety
• For Environmental safety

VMPs* are veterinary tools, contributing to the improvement of animal and public health worldwide, and to economical development

*VMP: Veterinary Medicinal Products
Governance for VMPs

- Requires sound pharmaceutical policy and regulations
  - An appropriate legal and regulatory framework
    - with quality standards for drugs
    - transparent licensing, registration, distribution, use
    - control and inspection
  - A favorable environment
    - Communication
    - Relationship authorities/authorities and authority/stakeholders
What is needed?

- Governance for VMPs
- Transparency and communication
- A public policy
- An authority in charge
- Specific activities to cover
- Administrative action and prosecution capacities
What is needed?

• A public policy: governing principles (see chap. 3.4 – art 3.4.4 & 3.4.5 Terrestrial Animal Health Code)

  – A strong commitment to ensure efficiency, competence and impartiality

  – A clear definition of the scope and objectives (proportionate)

  – (An) involved authority(ies)
Activities to be covered

- All activities along the entire life of VMPs from development to usage, including residues aspects (Terrestrial Animal Health Code - see chap. 3.4 – art 3.4.11 )

- Pre marketing authorisation
- Marketing authorisation (MA)
- Post MA
- Consumer safety
- Distribution
- Use
Proportion of OIE Member Countries having legislation covering Veterinary Medicinal Products

Analysis of the OIE survey on monitoring of the quantities of antimicrobial agents used in animals
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Marketing Authorisation of a Veterinary Medicinal Product
Activities to be covered

• Pre Marketing Authorisation
  – Definition of Maximum Residue Limits (MRLs)
  – Clinical trials
Marketing authorisation dossier

- **Administrative part**
  Administrative informations, Summary of product characteristics, Labelling

- **Quality part**

- **Safety part**

- **Residue part**

- **Efficacy part**
Marketing authorisation for VMPs

Use of pre-defined guidelines to assess quality, safety (for the treated animal, for the user, in foodstuffs and for the environment) and effectiveness

- **Quality part**: composition, method of preparation, controls, tests on finished products, stability
- **Safety part**: toxicological and pharmacological data, risk for the animal, user, environment, consumer
- **Residue part**: withdrawal period
- **Efficacy part**: pharmacological part, trials
Activities to be covered
Post marketing authorisation activities

- Different stages of manufacture, storage, import, distribution and use (including prescription and dispensing)

- Surveillance: Pharmacovigilance, residues (data collection, Monitoring and control plans for residues)

Need for rules as good practices and inspections
Activities to be covered
Inspection
(see chap. 3.4 – art 3.4.5 -1)

- Inspectorate Body
- Powers of Inspectors
- Duties of Inspectors
  - Impartiality
  - Independence
  - Confidentiality
  - Integrity

Need for rules as good practices
Set up of the authority/ies in charge

(see chap. 3.4 – art 3.4.5 -1)

– An independent competent authority with:

- Human Resources;
- Scope of responsibilities and mission clearly defined;
- Science based decision making process;
- Transparent and independent decision making process;
- Transparency and communication.
Evaluation of the authority

• Why?
  – for measurement of effectiveness

• How?
  – By periodic review of the implementation of the tasks of the authority
  – in a quality control process
Administrative actions

• To correct any anomaly with a potential impact on health
  – Recall and destruction of the product,
  – Inspection
  – information alert
  – …

• Suspension / withdrawal of product, manufacturing, import …
Prosecution capacity

- In serious situations:
  - Offending,
  - counterfeiting,
  - fraud, fraudulent intent …

Essential to provide such a mechanism:
  - Why asking for laboratory control to verify the quality of a VMP if it is not possible to take action when an anomaly is identified?
Transparency and communication
(see chap. 3.4 – art 3.4.3-3)

• With the general public

• With stakeholders (Pharmaceutical industry, veterinarians, pharmacists, farmers ... they need to create associations or professional organisation)
  • *To build trust in the rigour and the relevance of the mechanism as a whole*

• How? Information, communication, trainings
A broader vision

• Networking:
  – Optimise and preserve resources
  – Exchange of information
  – Cross border cooperation
  – Mutual recognition of authorisation, inspection ...
  – Regional authorisation

• Examples:
  – European Union
  – WAEMU (West African Economic and Monetary Union)
Role of the OIE

• OIE assists its members in the governance of VMPs:
  – Guidelines for the development of VMPs legislation available (see chap. 3.4 Terrestrial Animal health Code)
  – Nomination of Focal points for VMPs in all countries
  – Trainings for FP for VMPs per region
  – PVS tool and PVS gap analysis
  – Legislation missions – assistance with the analysis of existing legislation and proposals for revision
  – Conferences
  – Development of Guidelines (antimicrobial resistance)
  – Support of VICH activities

• OIE supports international cooperation:
  – strengthening Veterinary Services
  – development of twinnings
• Collaborating Centers related to VMPs:
  – ANSES (ANMV), Fougères, France
  – NVAL, Tokyo, Japan
  – FDA (CVM), Rockville, USA
  – USDA, Ames, USA
Conclusion

• Considering the impact of VMPs on the global animal health policy, the market globalisation and the limited resources, the way forward implies:

  ➢ *A strong political commitment*
  ➢ *A proportionate and targeted action*
  ➢ *A networking and worksharing approach and when possible a regional approach*
  ➢ *Transparency and relationships among stakeholders*
Thank you for your attention