Quality control of veterinary products, Tackling falsified and counterfeit products

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Improved Market Access for Authorised Veterinary Medicines – The Asian Perspective

Organising Committee:
Ensuring the quality of Veterinary Medicinal products (VMPs) is an essential and basic requirement for the good governance of VMPs.
Marketing Authorisation dossier

Part 1: Administrative Part
summary of the dossier

Part 2: Pharmaceutical quality Part
Constituents, Manufacturing process, Control of starting materials, tests carried out at intermediate stages of the process, finished product …

Part 3 : Safety and residues tests Part
Toxicology tests (single dose toxicity, repeat dose, effects on reproduction), user safety, environmental risk assessment … (chemical products), administration of one dose, overdose, repeated administration, effects on reproductive performance... (immunological products)

Part 4 : Efficacy tests
Preclinical and clinical trials...
QUALITY PART

A - Qualitative and Quantitative Particulars of the Constituents :
  • Composition
  • Development Pharmaceutics :

C - Control of Starting Materials

E - Tests on the Finished Product
  ➢ Important for the Quality control by the authorities

F - Stability Tests
Issues to be discussed

- Do you know all the actors involved in the distribution of VMPs in your country?
- Do you have importers?
- Do you identify illegal market activity:
  - Illegal import?
  - Black market?
  - Counterfeiting?
Inspection
Inspection and control

• Inspectorate Body

• Powers of Inspectors

• Duties of Inspectors
  – Impartiality
  – Independence
  – Confidentiality
  – Integrity

Need for rules as good practices
Quality during Storage and Distribution

- VMPs Importers
- VMPs Manufacturer
- GDP
- GMP
- Wholesaler
- Retailer (veterinarians, pharmacist, others)
- Farm

License for activity

Transparency:
- Official list of the premises
- Website

Good practices:
- Conditions of manufacturing
- Traceability
- Conditions of Storage
- Conditions of deliverance
Control of VMP companies

- Illegal Import
- Counterfeiting
- Quality Control

Control of:
- Traceability
- Conditions of Storage
- Conditions of deliverance
- List of VMPs (only VMPs authorised)

VMPs Importer

VMPs Manufacturer

Wholesaler

Retailer veterinarians Pharmacist others

Farm

Inspection
Need for government to have clear and strong policies for VMPs and have them effectively implemented.

- Important at the national level
- But also for trade (exports) and donors

An appropriate regulatory framework

أنواعية منظمات تدريس وacionalesية وتيسيرية

Need of prior Authorization and periodic control for Veterinary Product companies
Manufacturer, Importer, Wholesaler...

An appropriate legal and regulatory framework
with quality standards for drugs
transparent licensing, registration, distribution, use
control and inspection
Terrestrial animal health code: Chapter 3.4. «Legislation is a Key element in achieving good governance»

A favorable environment
Communication
Relationship authorities/authorities and authority/stakeholders

These activities should be governed by rules:

- Good practices as
  - Good manufacturing practices (GMP)
  - Good distribution practices (GDP)
  - Good prescription practices...
Good Distribution practices (GDP)

Target/activity?

- MAH and distributors
  - Recall and complaints
  - Quality product review
  - Storage condition: cold chain for vaccines
  - Traceability
Issues to be discussed

- Do you have an inspectorate body defined in the regulation?
- Are they well trained and specialised?
- Do they have power:
  - For inspection?
  - For administrative action?
  - For prosecution?
  - For sampling?
- Shall the companies be authorised or licenced for their activities?

Surveillance

- Legal Market
- Counterfeit products

Control of VMPs on the market

Control of:
- List of VMPs (only VMPs authorised)
- Quality control

Sampling

Quality Control
Surveillance of the Legal Market

Use a risk based programme, coordinated with other services

Examples:
- Food producing animals
- Antibiotics + antiparasitics
- Products that present a risk for the users
- Zoonotic diseases
- Regulated diseases
- Live vaccines

...
Sampling
Done by inspectorates (in wholesalers but also anywhere on the market)

Testing
• Qualitative and quantitative analysis: Active ingredient content
• Efficacy for vaccines
• Accredited laboratory or international recognition (OIE Ref. Lab)
Counterfeit products

- Copy of Authorised products
  - Modifications
  - Labelling

- Need for National, Regional and international cooperation

- Internet sales (a concern)
- See the difference in the MERIAL logo between real and counterfeit product. The letters in Bold and the name of MERIAL is missing
Quality Control Laboratory

Need for laboratory capacities to identify and analyse counterfeit products
At farm level

Inspectors should verify

- The absence of counterfeits or unauthorised products
- The conditions of storage
- The record keeping
- The respect of the prescription rules
- The compliance with the prescription
- Veterinary medicinal products administered to the animals, dates of administration and respect of withdrawal periods
Issues to be discussed

• Do you have qualified laboratory for quality control of VMPs?
  – For all VMPs?
  – Vaccines?
• Are you confronted to counterfeiting?
  • Do you have equipments for their analysis?
• Do you conduct inspections
  – On retailers?
  – On farm?