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Inspection

Workshop for OIE national Focal Points for Veterinary Products
23– 26 November 2010, Johannesburg, South Africa

Stakes

- Animal health protection and food safety : a need for economic development and poverty reduction
- Veterinary Medicinal Products (VMPs) are essential to animal health and welfare and to public healh (resistance, residues, chronic diseases, death…)
- Need fast access to **Quality**, **Safe** and **Effective** VMPs at a reasonnable price.

An appropriate regulatroy framework

⇨ An appropriate regulatory framework is essential

⇨ VMPs legislation should cover all activities :

- Pre-marketing authorization (research and development)
- Marketing autorization
- Manufacturing
- Wholesaling
- Retailing
- Prescription and Use

An appropriate regulatroy framework

⇨ When appropritate a **Prior authorisation** (manufacturer, wholesaler …) should be delivered

⇨ These activities should be governed by rules :

- Good practices as
  - Good manufacturing practices (GMP)
  - Good distribution practices (GDP)
  - Good prescription practices …

An appropriate regulatroy framework

⇨The mechanism should be backed (where necessary) by **Administrative and/or penal sanctions:**

- For example: why asking for a control laboratory to verify the quality of a VMP if it is not possible to take action when an anomaly is identified?

⇨Control policy accompanied by suitable sanctions isn't **effective** without **effort of transparency and communication**

An appropriate regulatroy framework

The mechanism should be backed (where necessary) by :

- **Administrative sanctions** as
  - Recall and destruction of products
  - Suspension or withdrawal of product, manufacturing or other licences
- To **correct anomalies** with a potential impact on health
- Implemented by the comptent authorities

An appropriate regulatroy framework

The mechanism should be backed (where necessary) by :

- Penal measures for :
  - Repeat offending
  - Counterfeiting
  - Fraud, fraudulent intent
  - …
- For most serious situation
- Fall under the relevant jurisdiction (a judge)

An appropriate regulatroy framework

⇨Role of associations / statutory bodies

- The system relies also on the involvement of professional associations in
  - Developing guidelines
  - Improving adherence to professional codes of practices / conduct.
- The system should impose penalties for breaches of legal and ethical standards.

Inspectorate Body

⇨Need for an approach in terms of inspection on the whole chain of VMPs

⇨Inspectorate body should be given the necessary ressources : legal and technical

- Inspectors : Power
  Duties
  Qualifications
- transparence and communication : procedure, accreditation

Powers of inspectors

⇨Should be included in the legislation

- Access to premises dedicated to veterinary pharmacy
  - ✓Manufacturer
  - ✓Wholesaler
  - ✓Veterinarian (in certain conditions)
  - ✓Farmer
- Communication of all necessary documents
- Veterinary products sampling
- Collection of information on site or on notification: specific report
- Sanction

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Duties of inspectors

- Impartiality : Public declaration of interest
- Independance : legal status of inspectors (free from any pressure)
- Confidentiality : Asermentation
- Integrity : Independant payment

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Competences of inspector

⇨Relevant qualification

⇨Initial training of inspectors

- should be included in the legislation
- Inspectors may be:
  - ✓Veterinarians
  - ✓Pharmacists
  - ✓Other

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Qualification of inspector

Requirements: Knowledge in

- Assurance quality management
- Pharmaceutical manufacture
- Dosage forms
- Quality control
- Distribution
- Inspection management






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Accreditation

- ⇨ Accreditation : formalised quality approach, rationalise the organisation
- ⇨ Purpose: accreditation for all types of inspection (GMP, GDP…)
- ⇨ Maintenance of the accreditation based on:
  - Regular inspection
  - meetings with other inspector
  - Annual supervision by a senior inspector
  - On going training
  - Regular meeting with other pharmaceutical organisations



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General points about inspection

⇨Definition

Inspection:

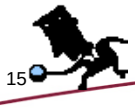
"Careful examination in order to control, to supervise and to check"

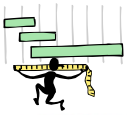
Observation
Investigation
Study
Inquiry

Compliance Assessment

Monitoring

Confrontation with facts





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General points about inspection

- 2 kinds of Inspection:
  - *Documentary study : establishment file; report of inspection, plan of surveillance recall...*
  - *Inspection on site : investigation, observation*
- risk assessment and professional judgment
- Report – action plan – follow up

Planning and programmation

⇨Risk based programmation : need a good knowledge regarding veterinary drugs and their use

- Adjustement to the market and the veterinary drugs network evolution
- Pharmacovigilance, quality defaults, batch recall, rapid alert system

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Planning and programmation

⇨Risk based programmation : need a good knowledge regarding veterinary drugs and their use

- Plan of residue surveillance : unauthorised substances, misuse, withdrawal period
- Information concerning fraud, copy, counterfeiting and illegal market
- Information from other official services

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Planning and programmation

⇨ Programming of inspections :

- List of authorised establishments and date of their last control
- Review of the previous year :
  - delayed or cancelled inspections
  - Monitoring inspections
- Rythm and frequencies of inspection

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At manufacturing and wholesaling level

⇨ Control of opening and working conditions for

- Manufacturers : respect of GMP, Product inspection
- Importers : control quality and control of batch release
- Wholesalers : respect of GPD
- traceability

At manufacturing and wholesaling level

⇨ Examples of inspection : *(for manufacturers, distributors)*

- Programed and planned inspection : Good Manufacturing Practices , repeated inspection, product inspection

- Non planned inspection :
  - Specifics inquiries : batch recall, pharmacovigilance
  - Opening authorisation request
  - Variation request

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At prescription level

- Inspection relies on:
  - Data collection,
  - Results of inspections at farm level
  - Monitoring and control plans for residues
  - Coordination of official services

At prescription level

⇨ Control of

- Authorisation of VMP's
- Conditions of VMP's storage
- way of dispensation
- records

At farm level

⇨ Programming of inspections

- Routine inspection
  - ✓ Based risk programmation : follow up of plan of surveillance
  - ✓ Control of VMPs use during other control conducted on farms
- Specific investigations : detection of residues of unauthorised substances

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At farm level

- Inspectors should verify record keeping :
  - Respect of the prescription rules
  - Compliance with the prescription
  - Veterinary medicinal products administered to the animals, dates of administration and respect of withdrawal periods
  - Results of any analysis carried out on samples taken from animals (residues ...)

At farm level

- Inspectors should verify VMPs present on farm :
  - Quality of VMPs distributed and used
  - Absence of counterfeits into the market place or unauthorised products
  - Good conditions of storage
  - Use of VMPs (no misuse, no mix-ups, no adulteration, no contamination)

Conclusion

- Inspection is indispensable and need :
  - Legislative framework
  - Sufficient ressources
  - Inspectors : independant, impartial, well qualified, integre and confidential
  - Appropriate power of sanction

Thank you for your attention

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