Organisation Mondiale de la Santé Animale | World Organisation for Animal Health | Organización Mundial de Sanidad Animal

Veterinary Medicinal Products

Good Governance

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INTRODUCTION

Benefits

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

Risks

- Animal safety
- User safety
- Food safety
- Environmental safety
- Antimicrobial resistance

*VMP: Veterinary Medicinal Products

Need for Good Governance for VMPs

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

- Chapter 3.2. terrestrial code

"Good governance is the Key to competence, integrity and confidence in organisations"

Governance for VMPs

❑ Requires sound pharmaceutical policy and regulations

– An appropriate legal and regulatory framework

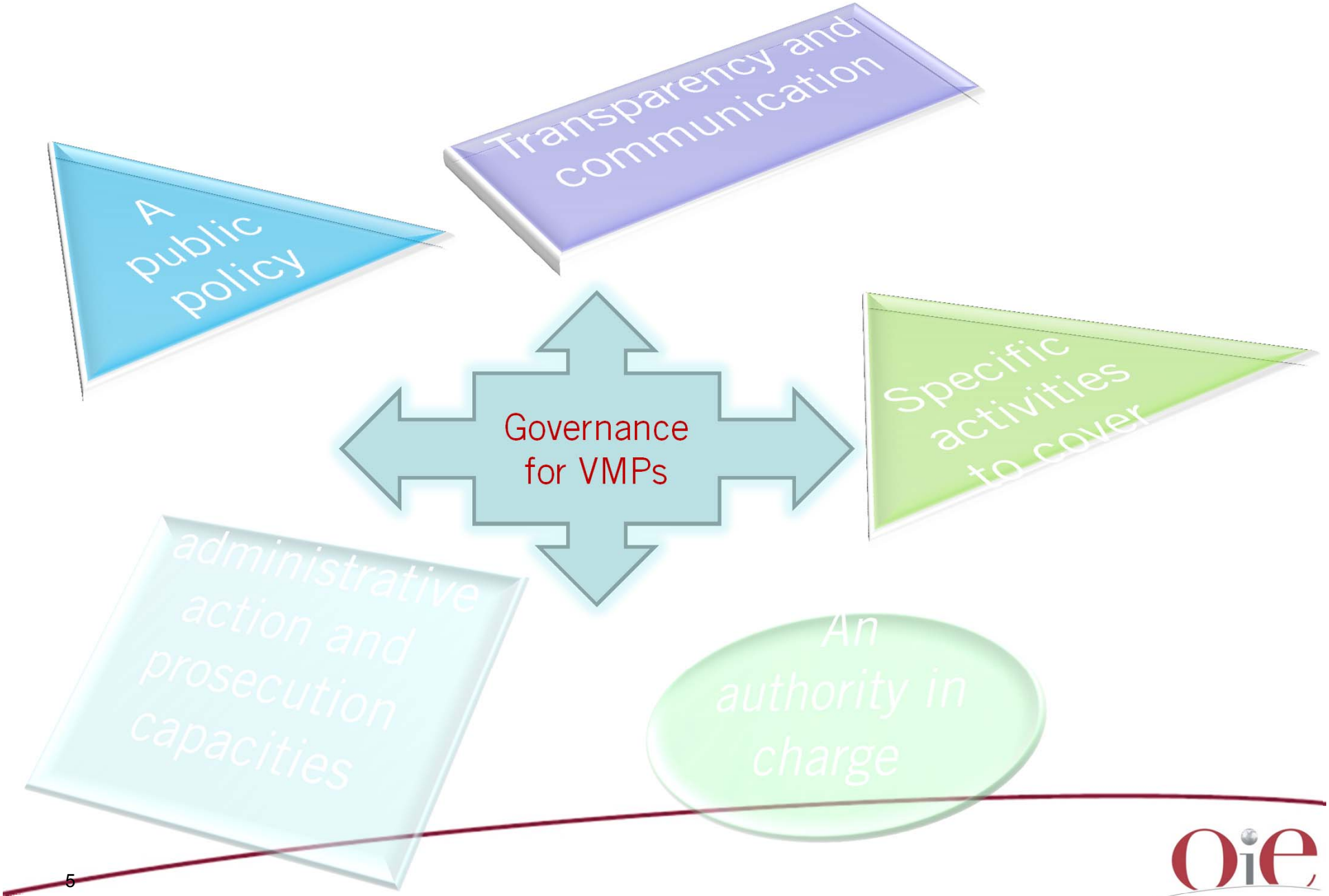
- with quality standards for drugs
- transparent licensing, registration, distribution, use
- control and inspection

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

What is needed?



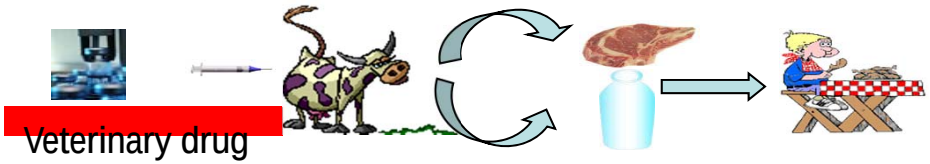
What is needed?

- A public policy: governing principles (see chap. 3.4 – art 3.4.4 & 3.4.5 Terrestrial Animal Health Code)
  - A legislation with a clear definition of the scope and objectives (proportionate)
  - (An) involved authority(ies)
  - A strong commitment to ensure efficiency, competence and impartiality

activities to cover

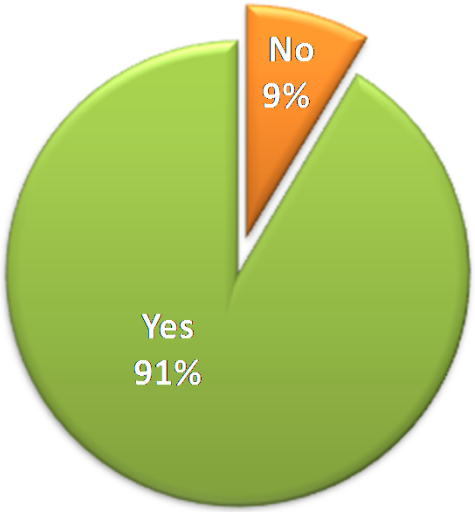
Activities to be covered

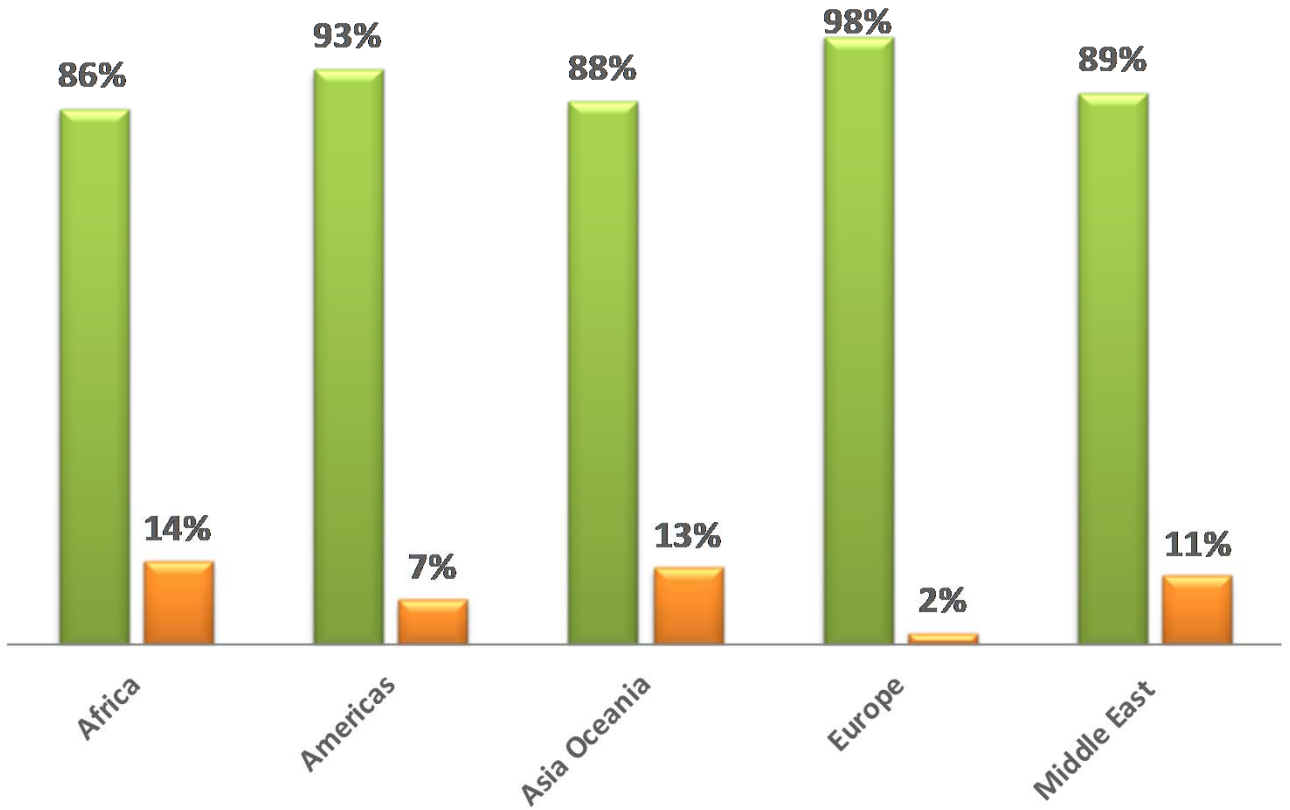
- All activities along the entire life of VMPs from development to usage, including residues aspects (Terrestrial Animal Health Code - see chap. 3.4 – art 3.4.11)



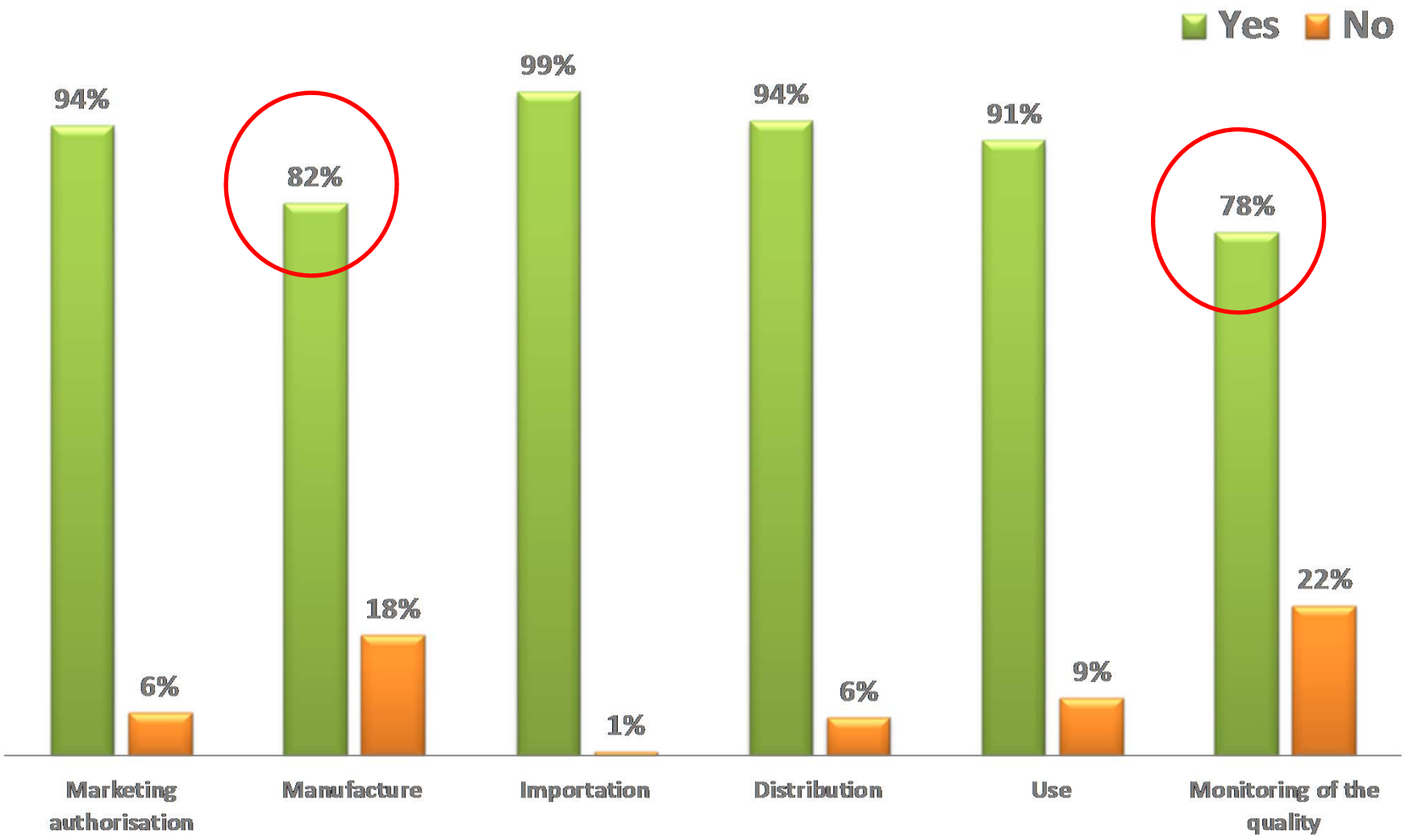
- Pre marketing authorisation
- Marketing authorisation (MA)
- Post MA
- Consumer safety
- Distribution
- Use

Proportion of OIE Member Countries having legislation covering Veterinary Medicinal Products





Aspects covered by legislation



Importance of quality of veterinary Medicinal Products

- Control of Manufacturing
- Marketing autorisation dossier
- Control of the quality of products on the market
- Counterfeit products
- Importance of inspection
- (See Quality of Veterinary Drugs session)

Marketing Authorisation of a Veterinary Medicinal Product

activities to cover

INDUSTRY

AUTHORITIES

Pre MA

MA

MA

Ouch!!

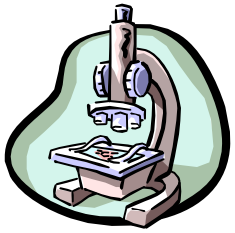
Post MA

Product on the market

activities to cover

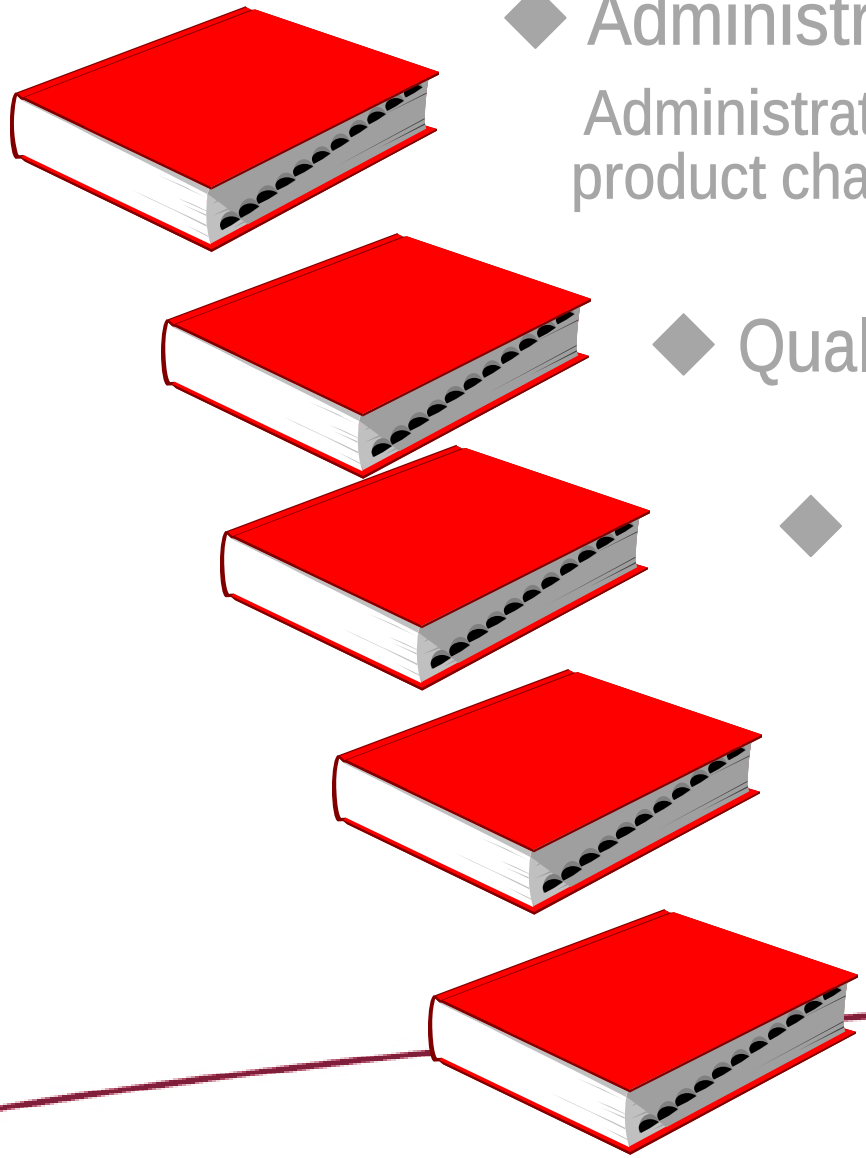
Activities to be covered

- Pre Marketing Authorisation
  - Definition of Maximum Residue Limits (MRLs)
  - Clinical trials



activities to cover

Marketing authorisation dossier



- Administrative part

  Administrative informations, Summary of product characteristics, Labelling

- Quality part
- Safety part
- Residue part
- Efficacy part

activities to cover

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 environnement) 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?*

Tranparency 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)

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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

OIE

- 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 work-sharing approach and when possible a regional approach*
  - *Transparency and relationships among stakeholders*

Thank you for your attention

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