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

Veterinary Medicinal Products

Good Governance

Catherine LAMBERT

Anses/ANMV

OIE Collaborating Centre on Veterinary medicinal products

Catherine.lambert@anses.fr

INTRODUCTION

Benefits

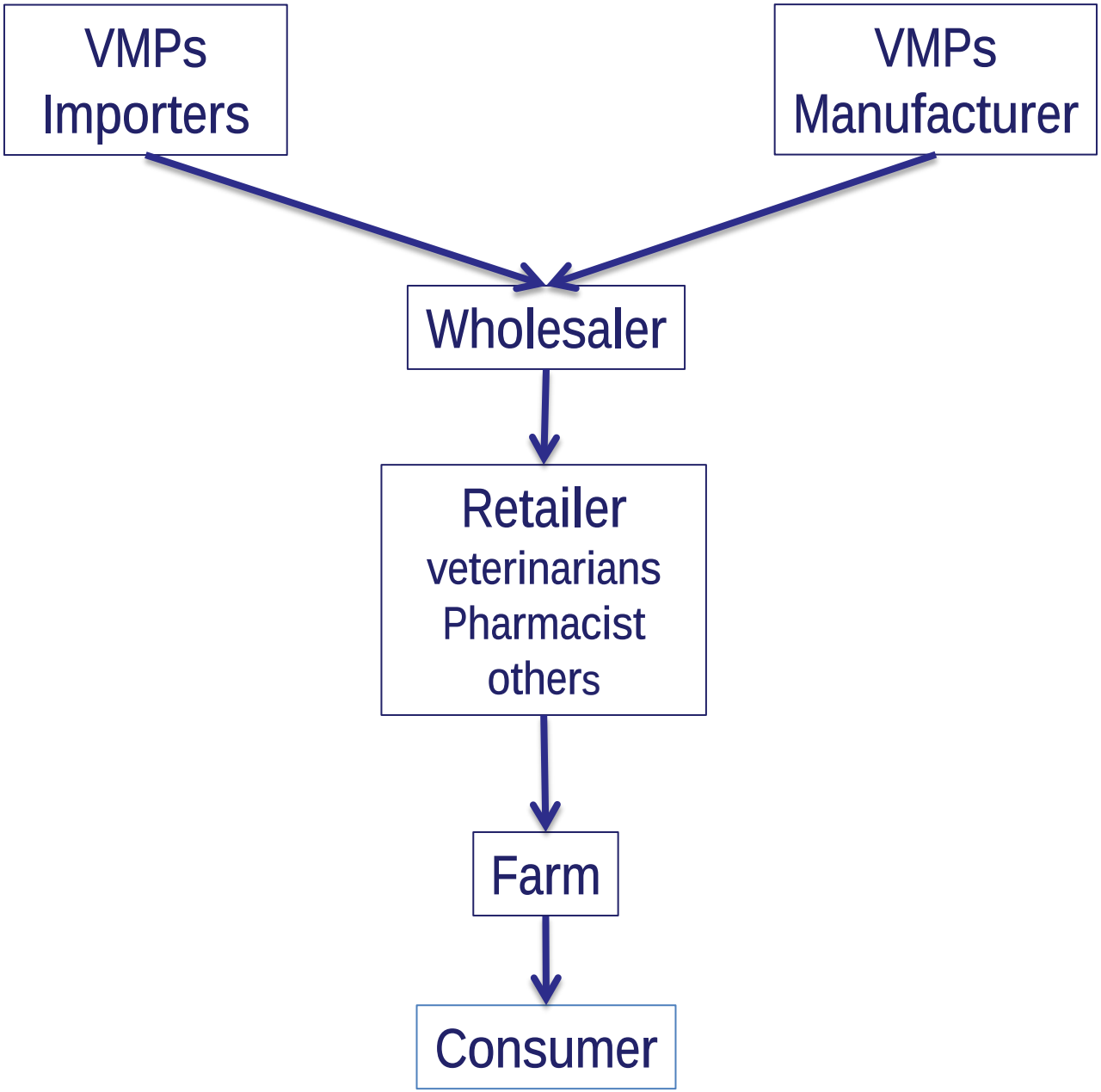
VMPs* are veterinary tools, contributing to the improvement of animal and public health worldwide, and to economical development

Risks

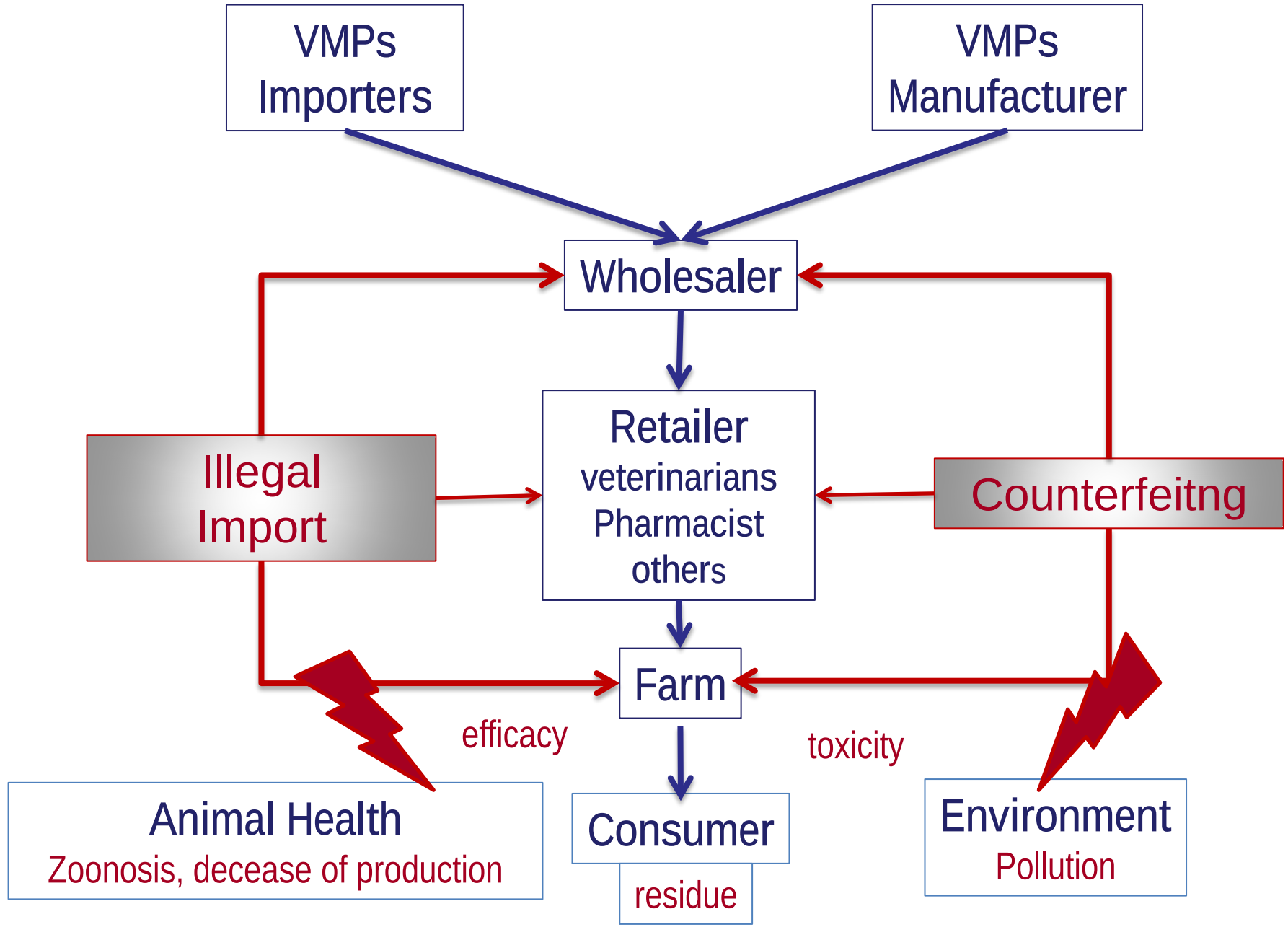
- Animal safety
- User safety
- Food safety
- Environmental safety
- Antimicrobial resistance

*VMP: Veterinary Medicinal Products

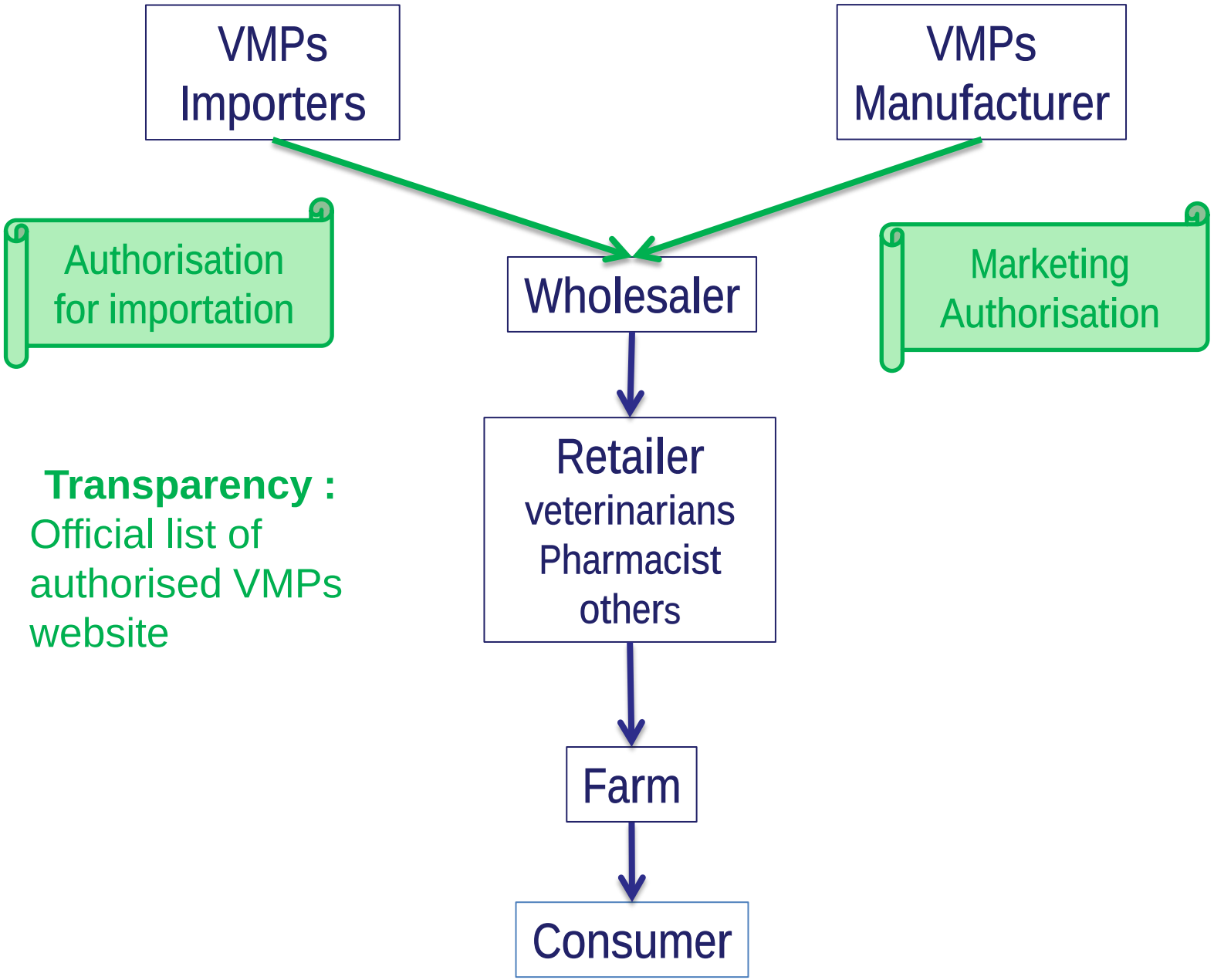
VMPs Chain


VMPs
Importers
VMPs
Manufacturer
Wholesaler
Retailer
veterinarians
Pharmacist
others
Farm
Consumer

VMPs Chain


VMPs Importers
VMPs Manufacturer
Wholesaler
Retailer
veterinarians
Pharmacist
others
Illegal Import
Counterfeitng
Farm
efficacy
toxicity
Animal Health
Zoonosis, decease of production
Consumer
residue
Environment
Pollution

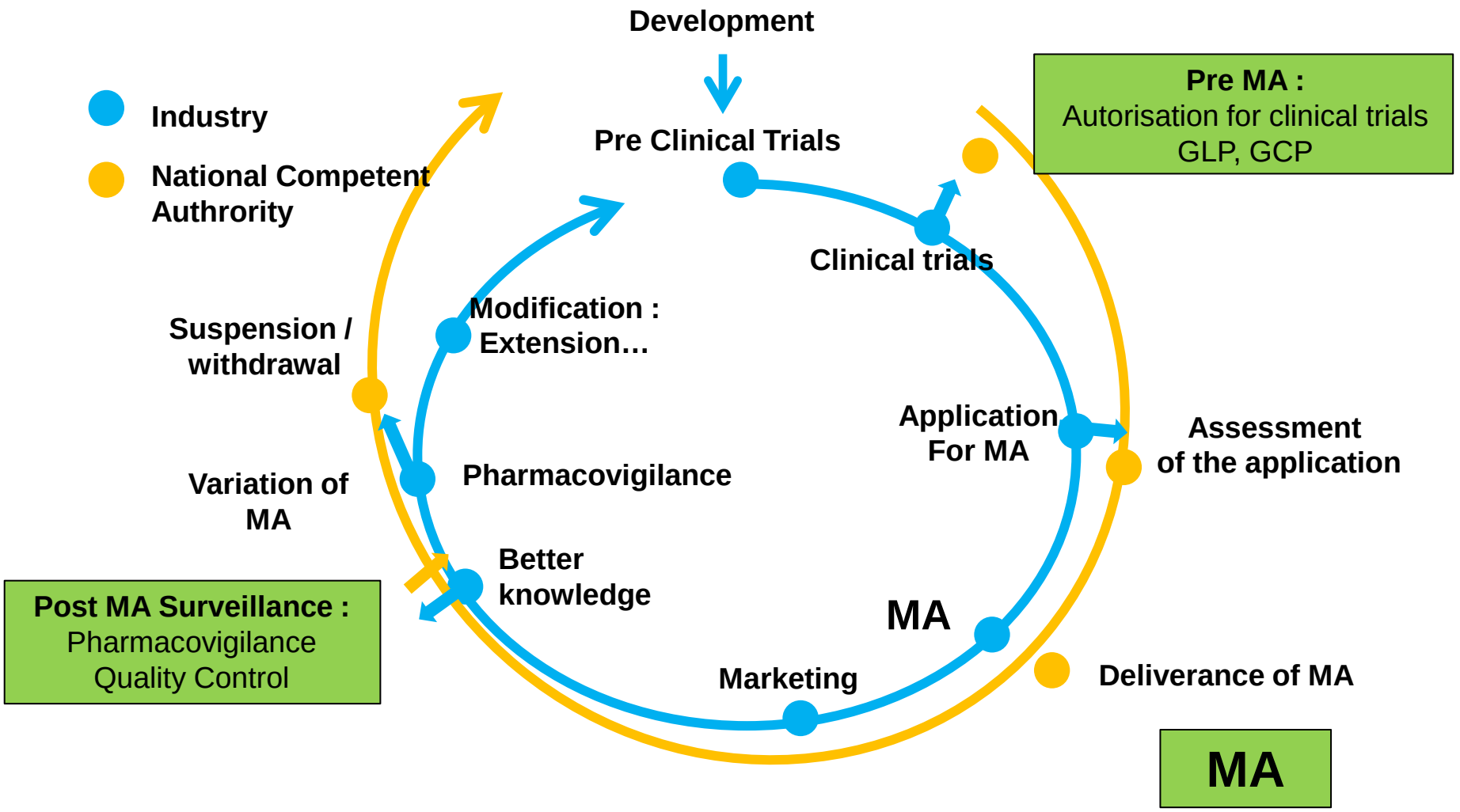
Autorisation of VMPs



Transparency :

- Official list of authorised VMPs
- website

Marketing Autorisation Cycle



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 → VICH GLs

- 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

Marketing authorisation for VMPs

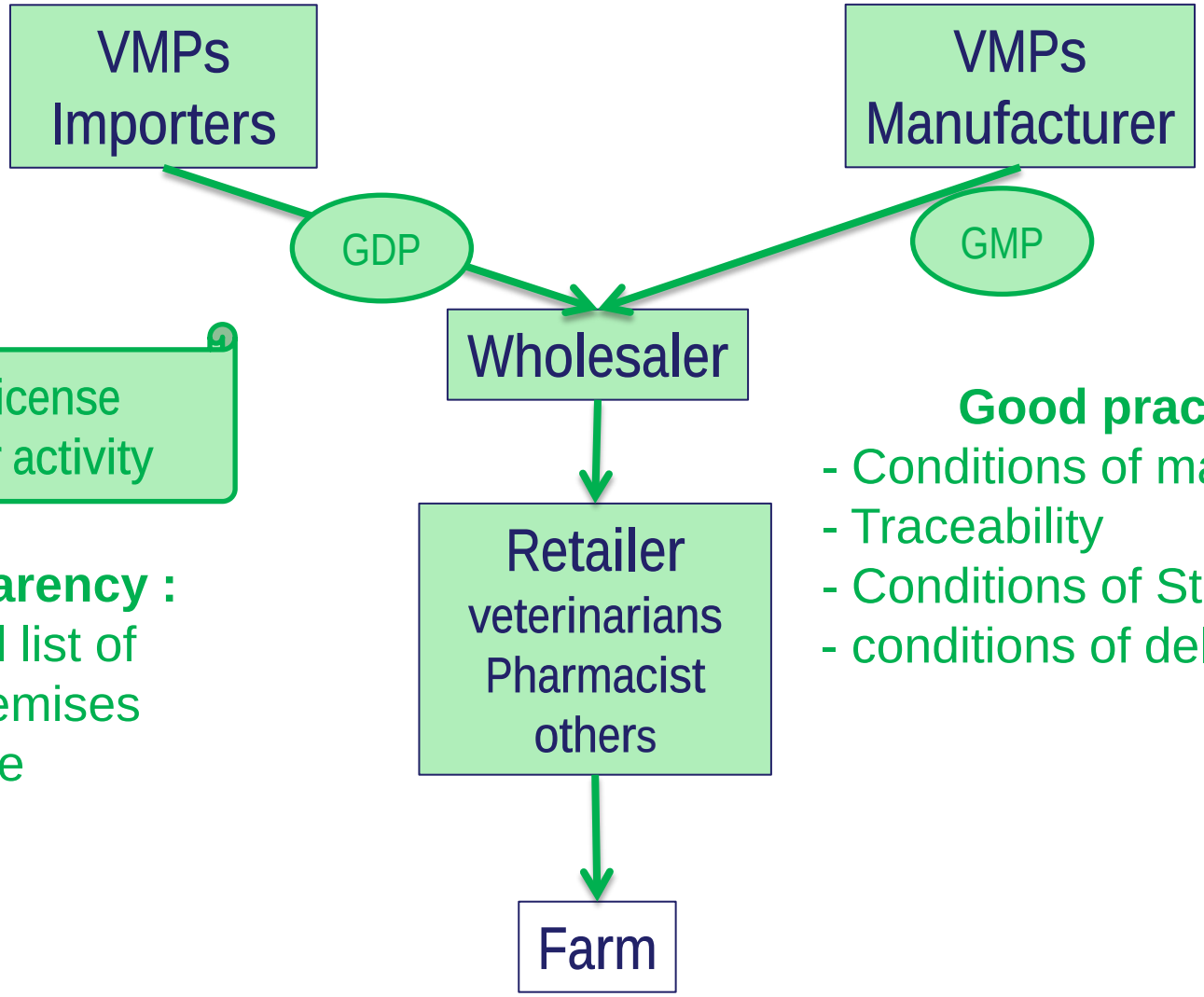
Autorisation, registration, licence product, for import, for marketing…

- National Marketing autorisation :
  - National Experts assess the dossier
  - National Competent Authority delivers the MA
- Regional system for authorisation :
  - Experts from the region assess the dossier
  - Regional marketing authorisation, or national MA based on regional assessment (same MA)

Marketing authorisation for VMPs

- Recognition of MA delivered in a foreign country
  - Recognition of expertise made by a foreign country
  - Limited assessment made at national level
  - Deliverance of the MA based on the foreign MA
- Need trust the NCA from the foreign country
  - International criteria : follow VICH GLs,
- Be sure to have official document
  - Certificate from OIE Laboratory,
  - GMP certificate from recognised competent authorities

Autorisation of premises and activities



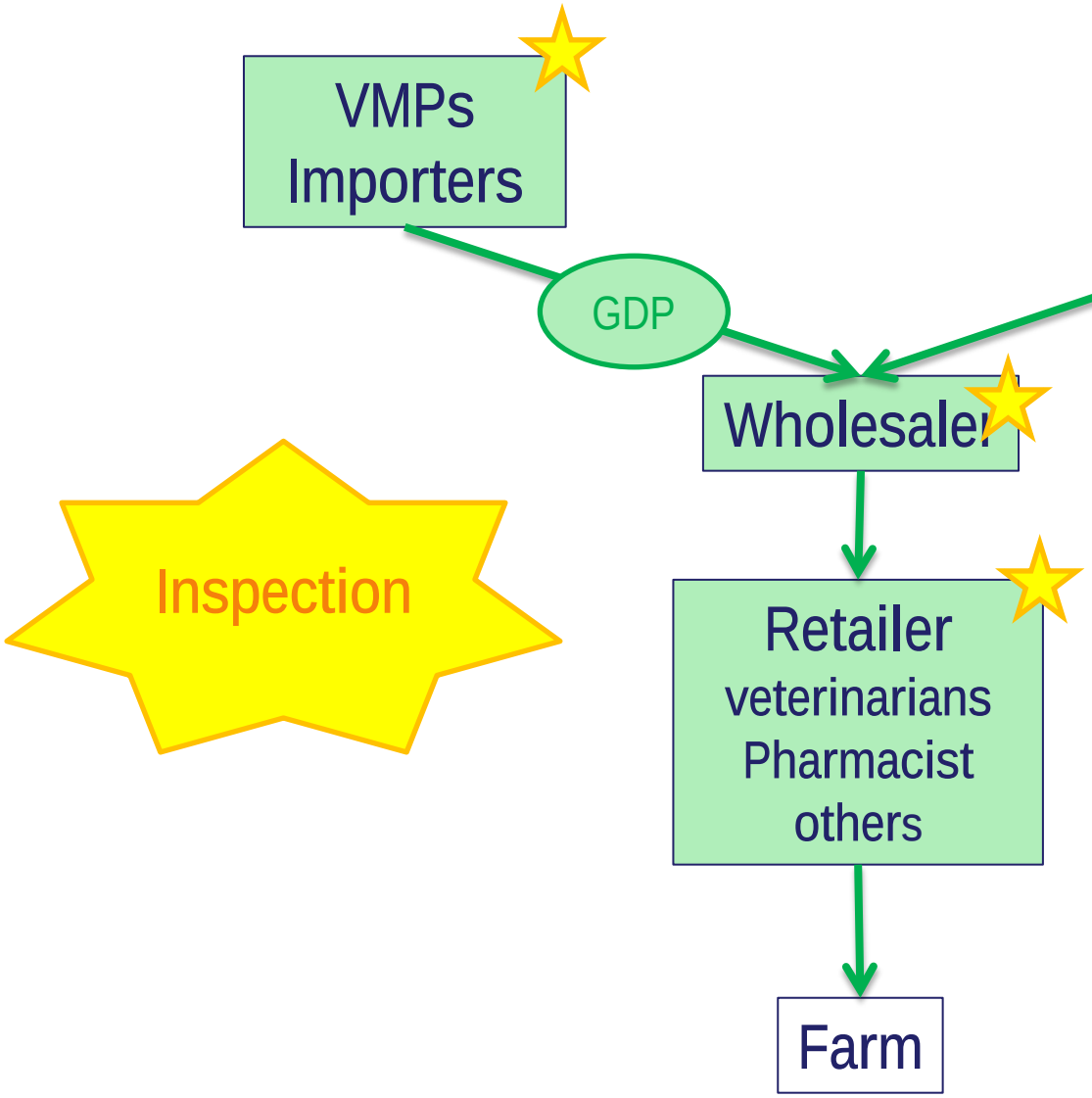
Transparency :

- Official list of the premises
- website

Good practices :

- Conditions of manufacturing
- Traceability
- Conditions of Storage
- conditions of deliverance

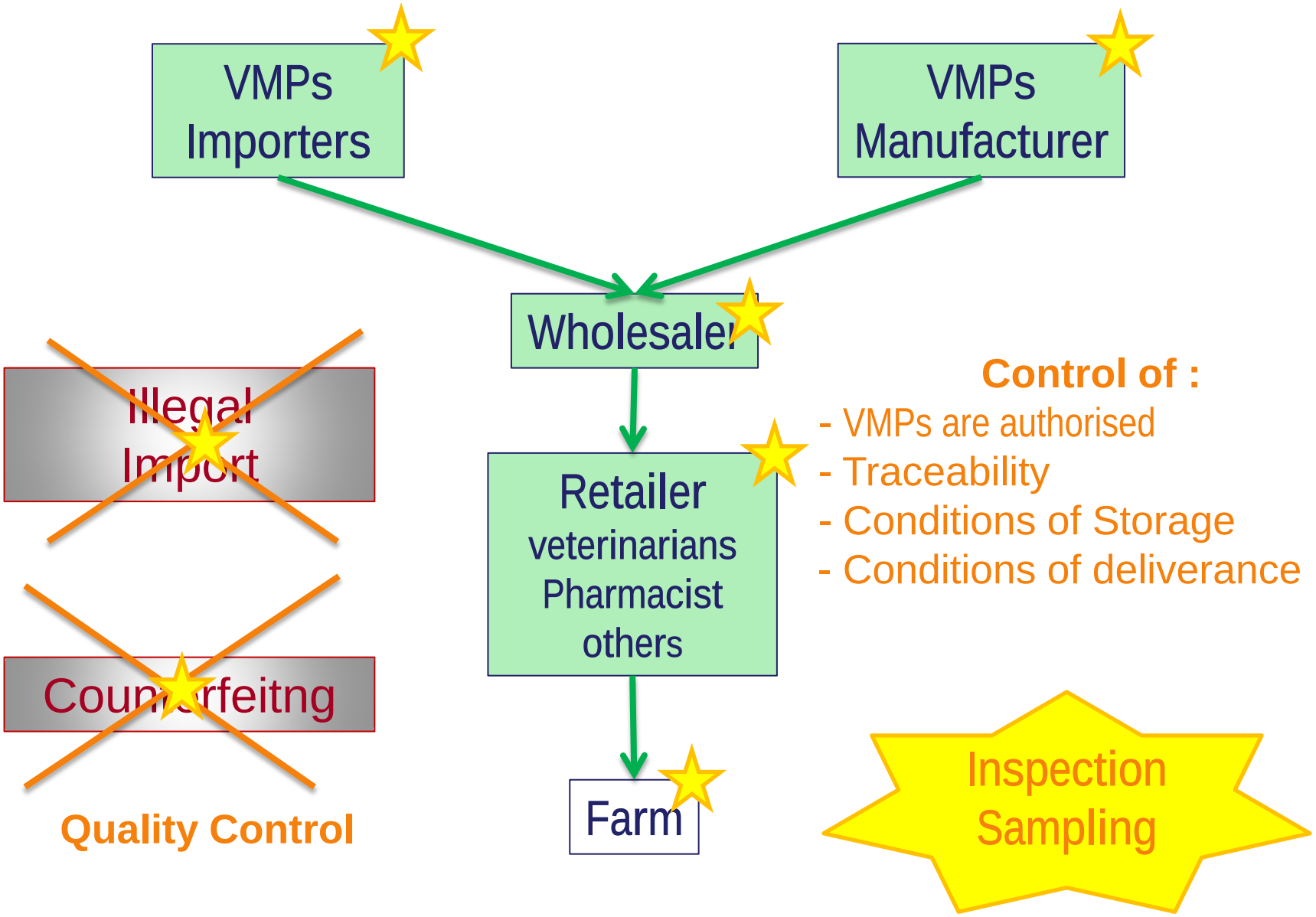
Autorisation of premises and activities



Control of :

- Conditions of manufacturing
- Traceability
- Conditions of Storage
- Conditions of deliverance
- List of VMPs

Control of VMPs



Inspection and control
(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

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

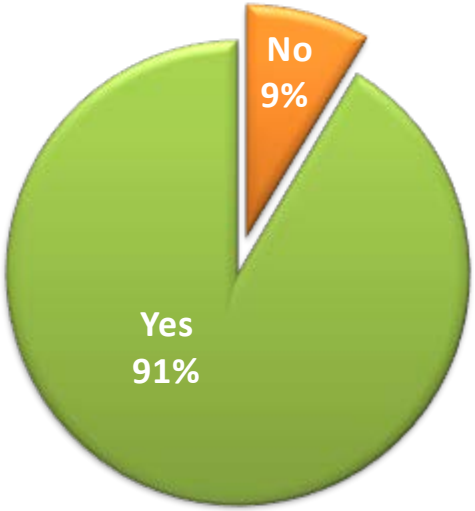
❑ Requires pharmaceutical policy and regulations

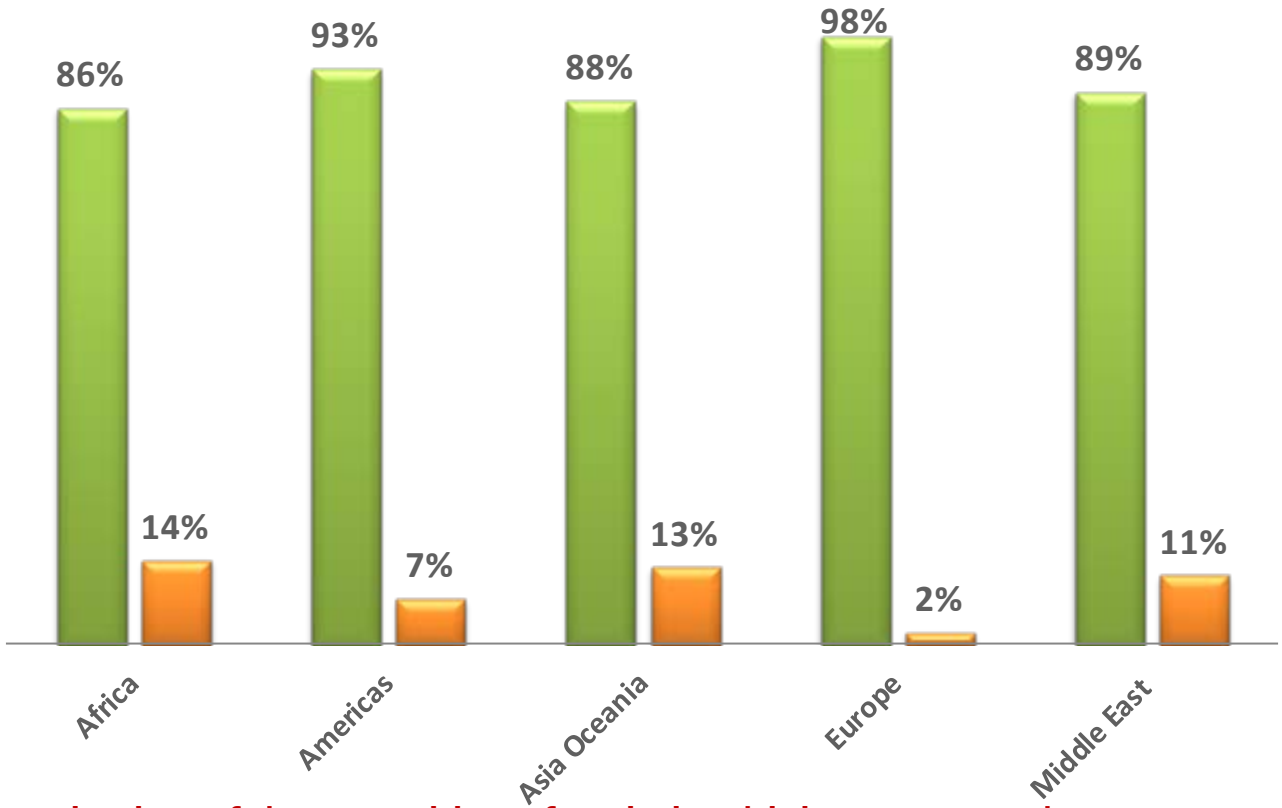
– An appropriate legal and regulatory framework
  - with quality standards for drugs
  - transparent licensing, registration, distribution, use
  - control and inspection

  Terrestrial animal health code: Chapter 3.4. :*« Legislation is a Key element in achieving good governance »*

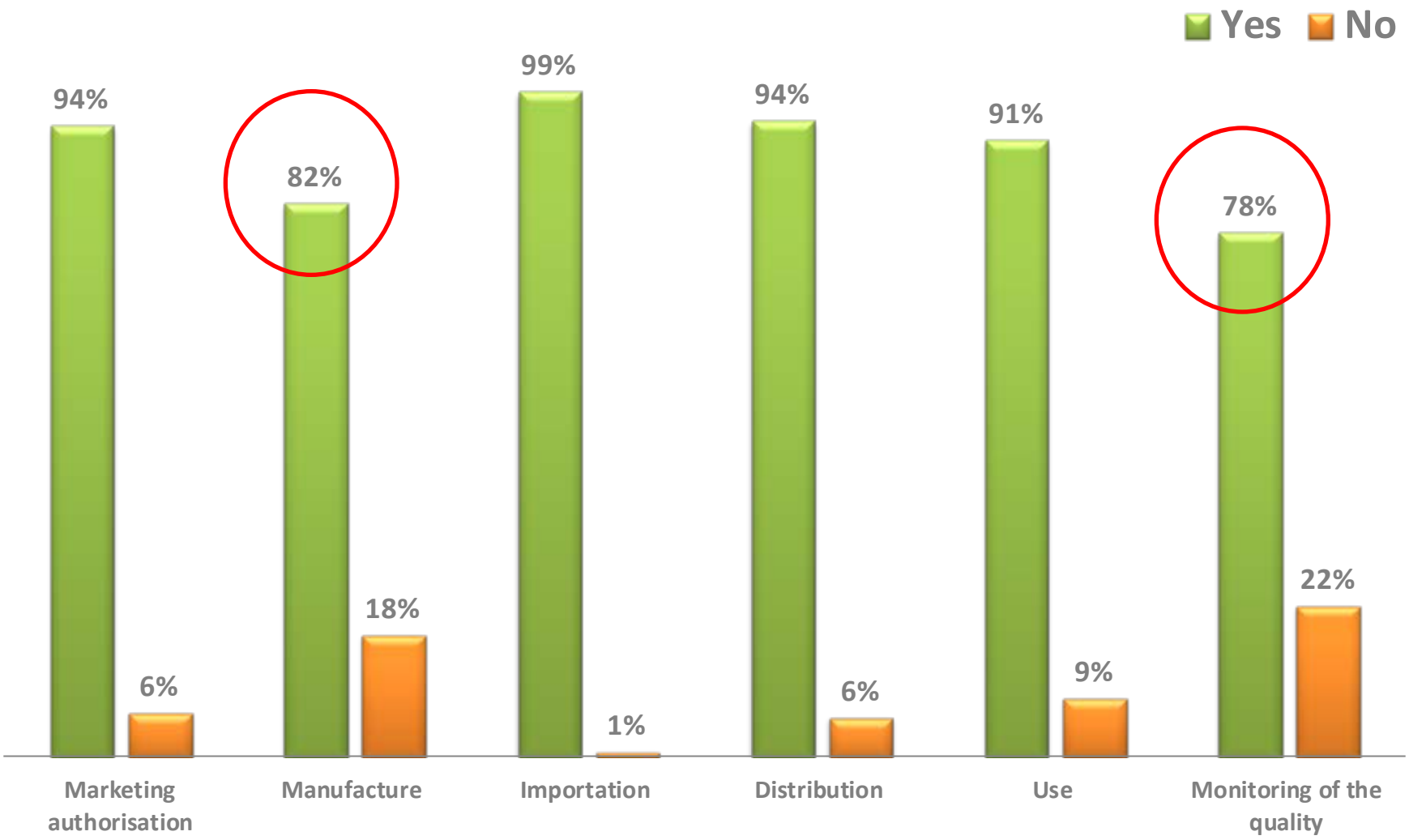
– A favorable environment
  - Communication
  - Relationship authorities/authorities and authority/ stakeholders

Proportion of OIE Member Countries having legislation covering Veterinary Medicinal Products

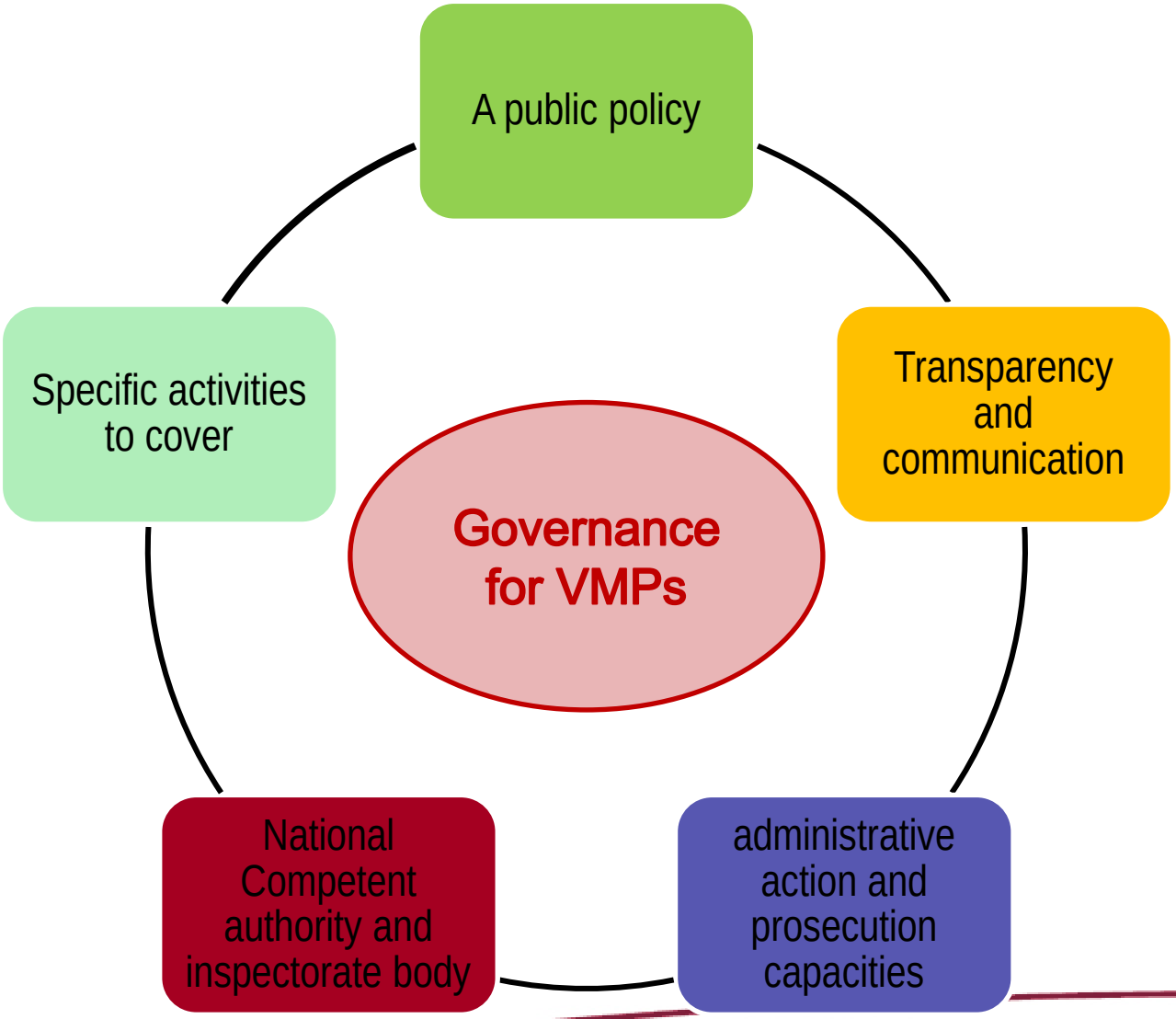




Aspects covered by legislation



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) : for autorisation, for inspection, for quality control
  - A strong commitment to ensure efficiency, competence and impartiality

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

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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de la santé animale

World Organisation
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