

Veterinary Medicinal Products

Good Governance

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INTRODUCTION



Benefits

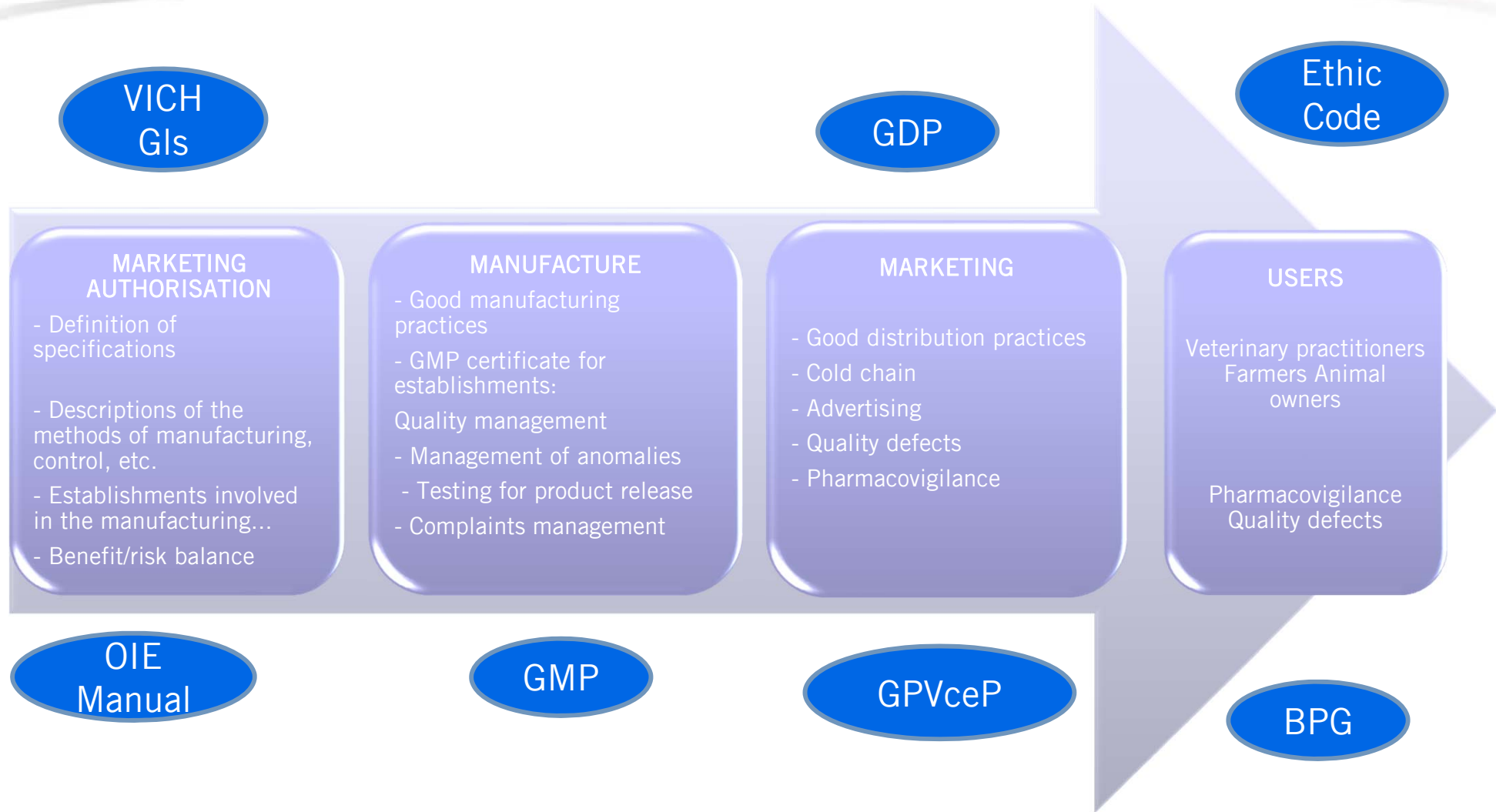
VMPs* are veterinary tools, contributing to the improvement of animal and public health worldwide, and to economical development

Risks

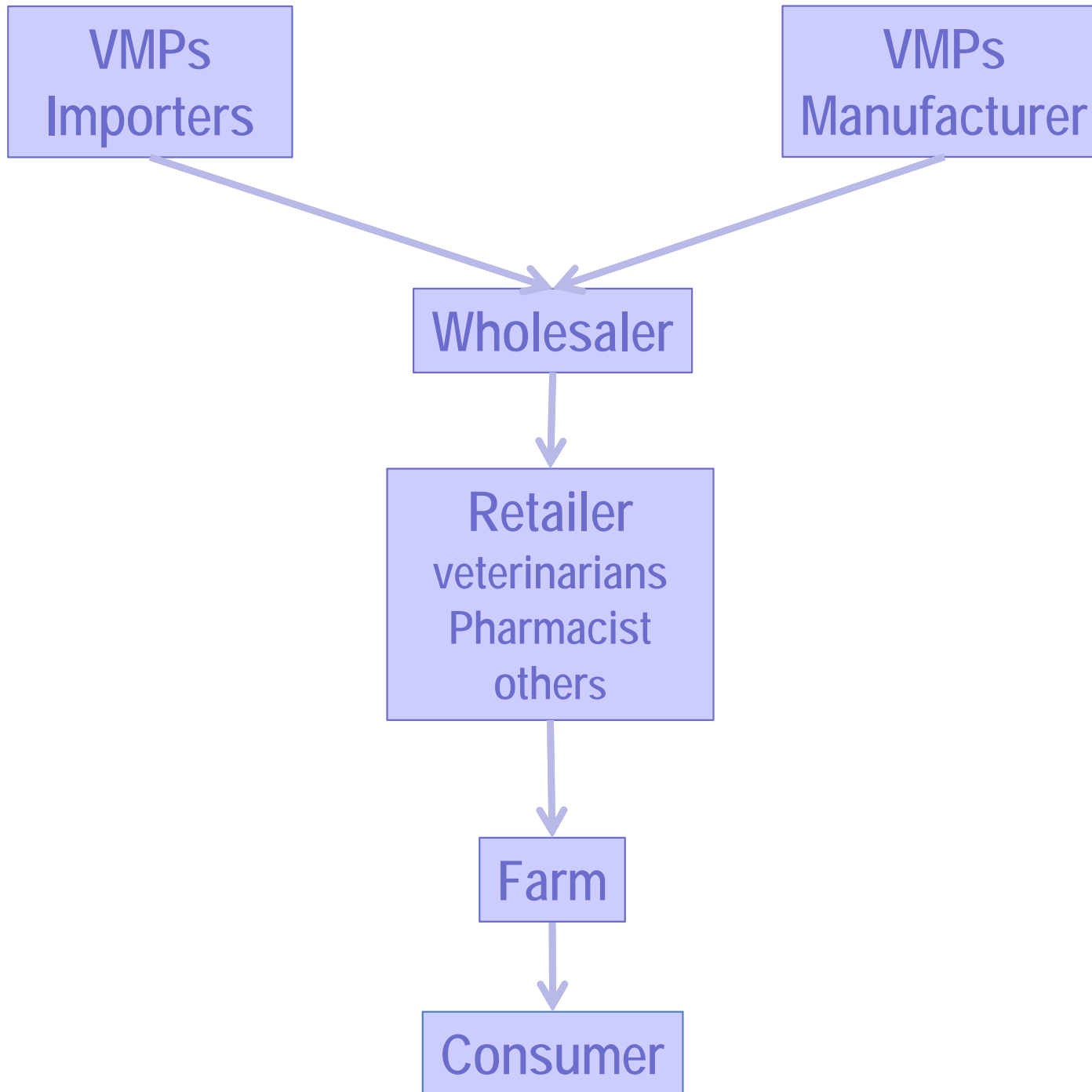
- Animal safety
- User safety
- Food safety
- Environmental safety
- Antimicrobial resistance

*VMP: Veterinary Medicinal Products

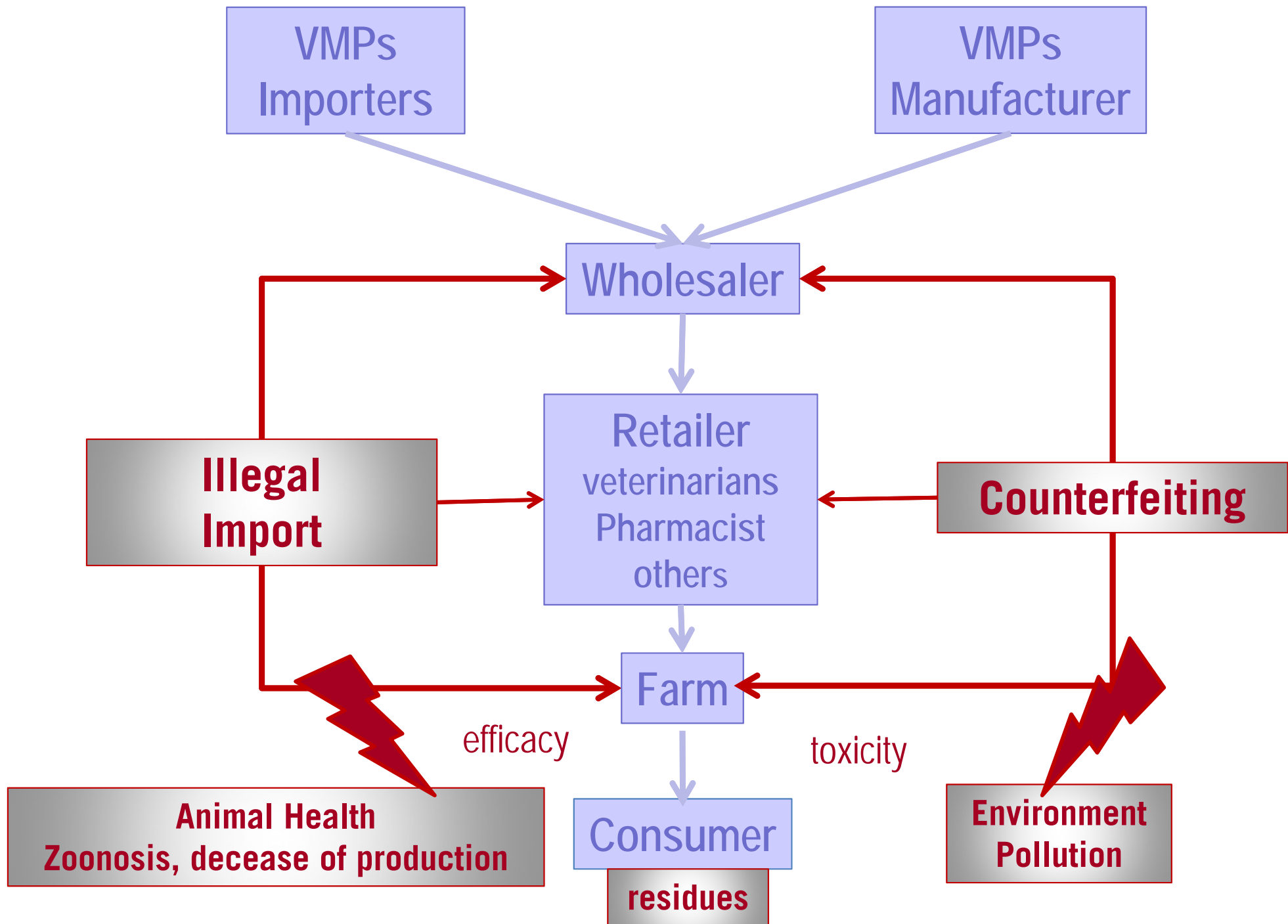
Good governance for good quality



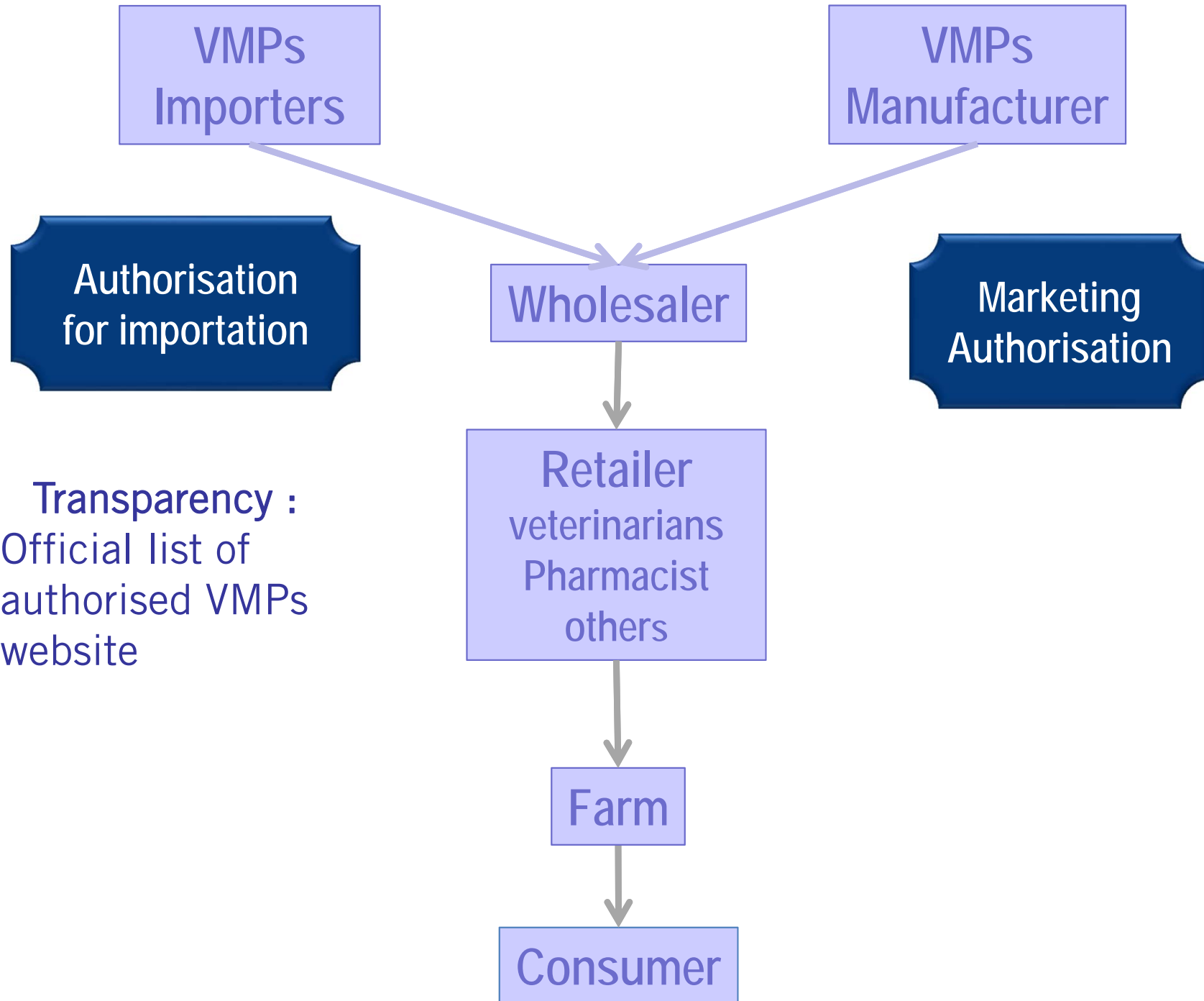
VMPs Chain – knowledge of the actors



VMPs Chain and risks to manage



Role of National Competent Authorities



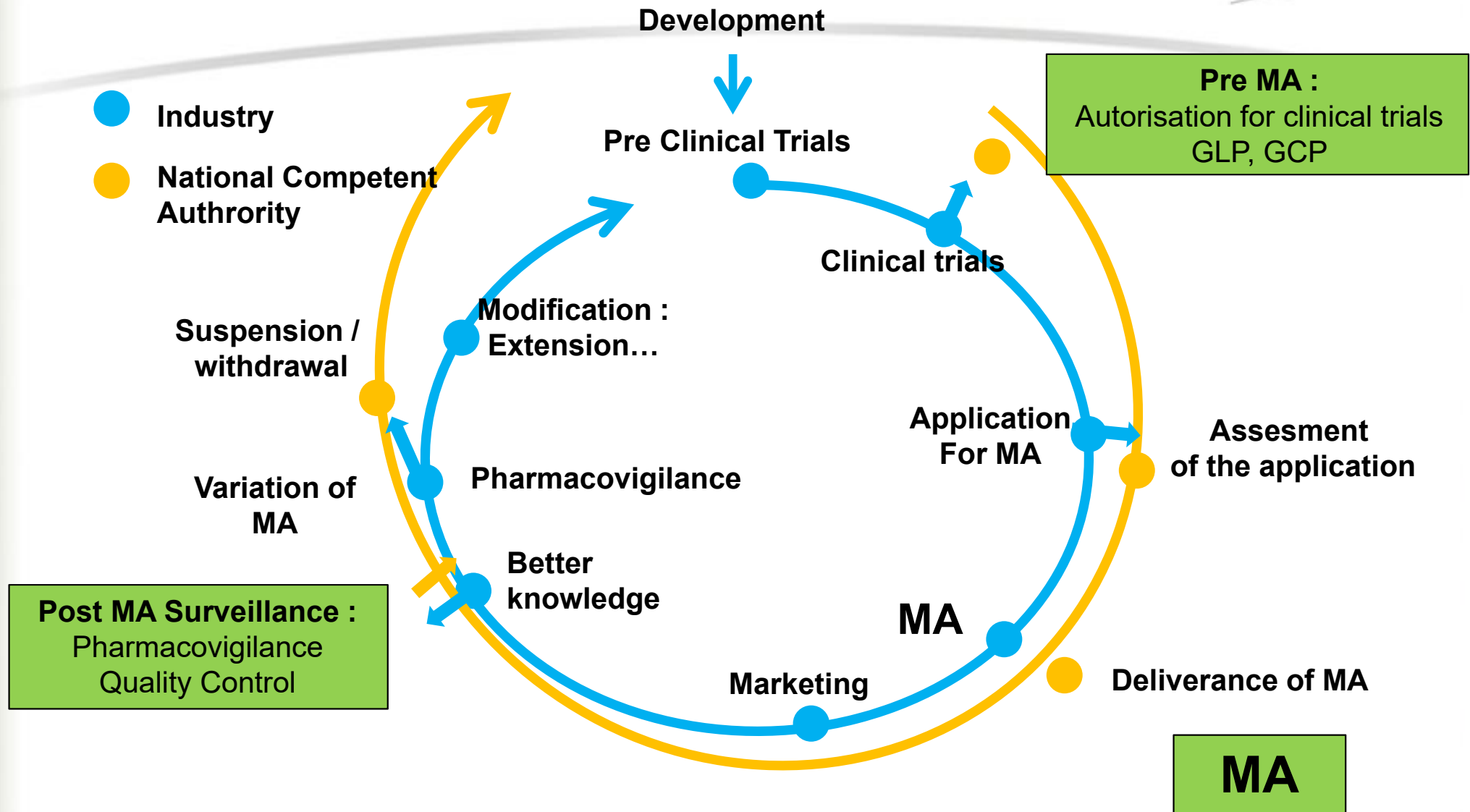
Authorisation
for importation

Marketing
Authorisation

Transparency :

- Official list of authorised VMPs
- website

Marketing Authorisation Cycle



Marketing authorisation for VMPs



Authorisation, registration, licence product for import, for marketing...

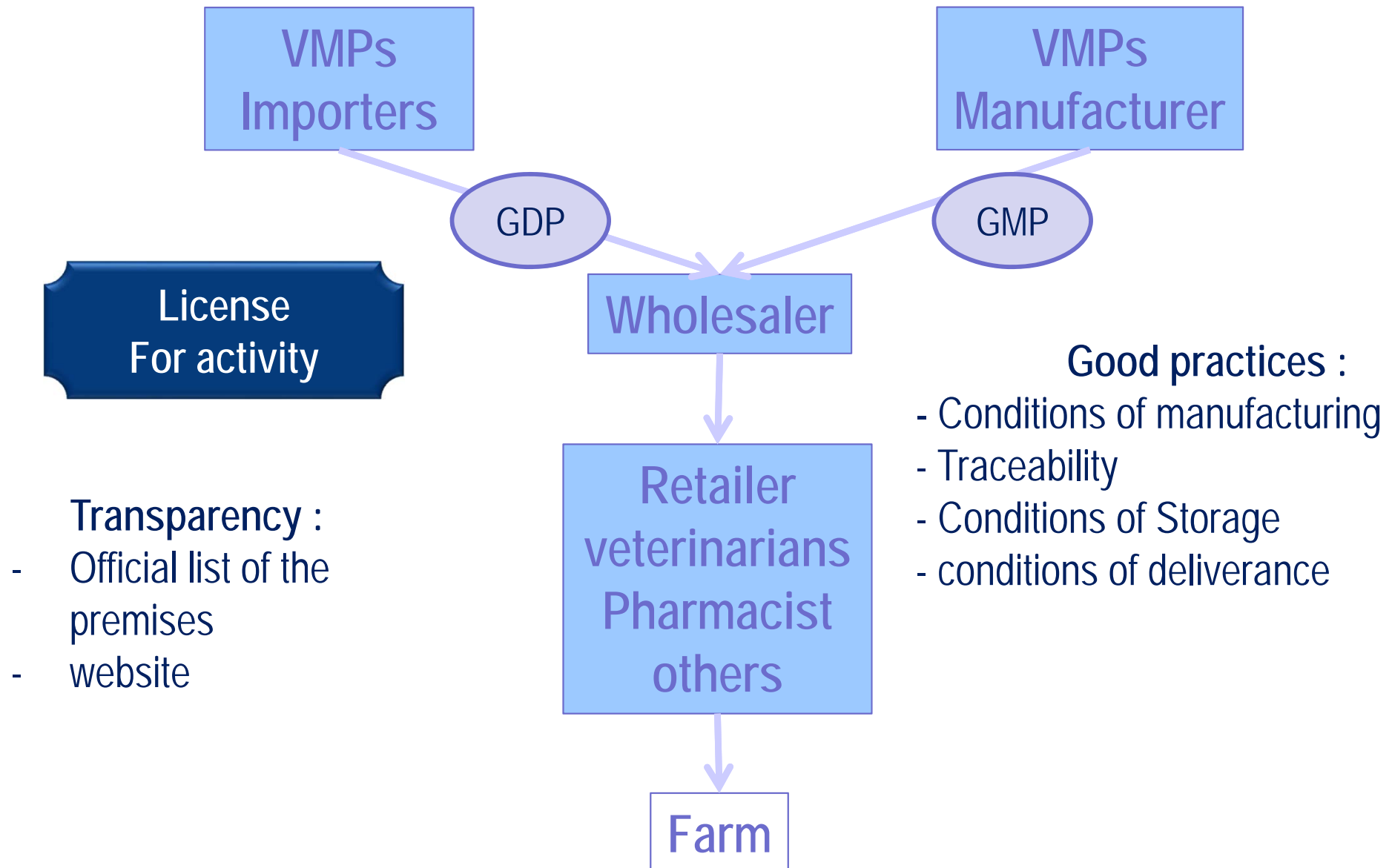
- **National Marketing authorisation :**
 - National Experts assess the dossier
 - National Competent Authority delivers the MA
- **Regional system for authorisation :**
 - Experts from the region assess the dossier
 - Regional marketing authorisation, or national MA based on regional assessment (same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

Marketing authorisation for VMPs

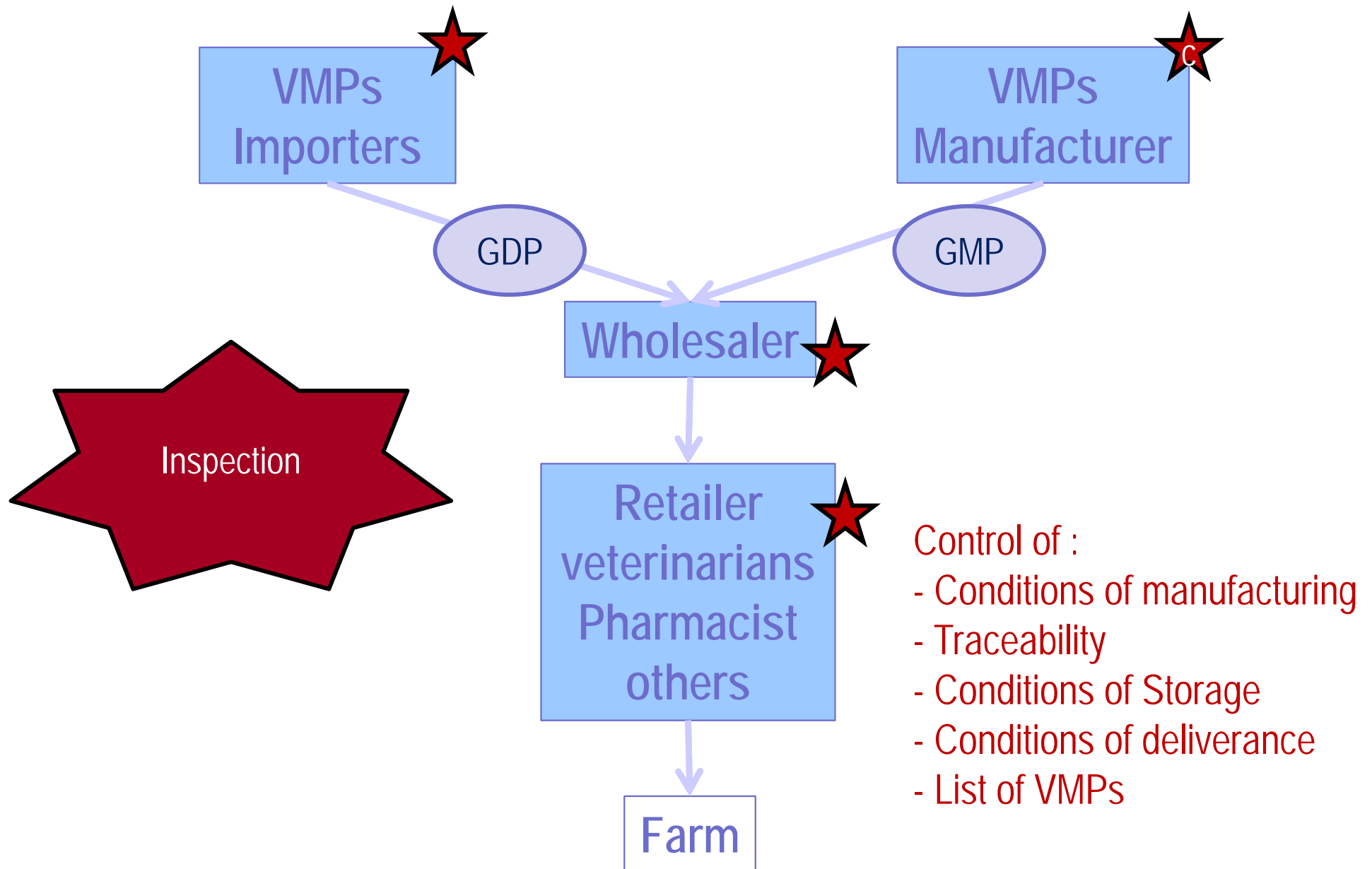


- **Recognition of MA delivered in a foreign country**
 - Recognition of expertise made by a foreign country
 - Limited assessment made at national level
 - Deliverance of the MA based on the foreign MA
- **Need to trust the NCA from the foreign country**
 - International criteria : follow VICH GLs,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

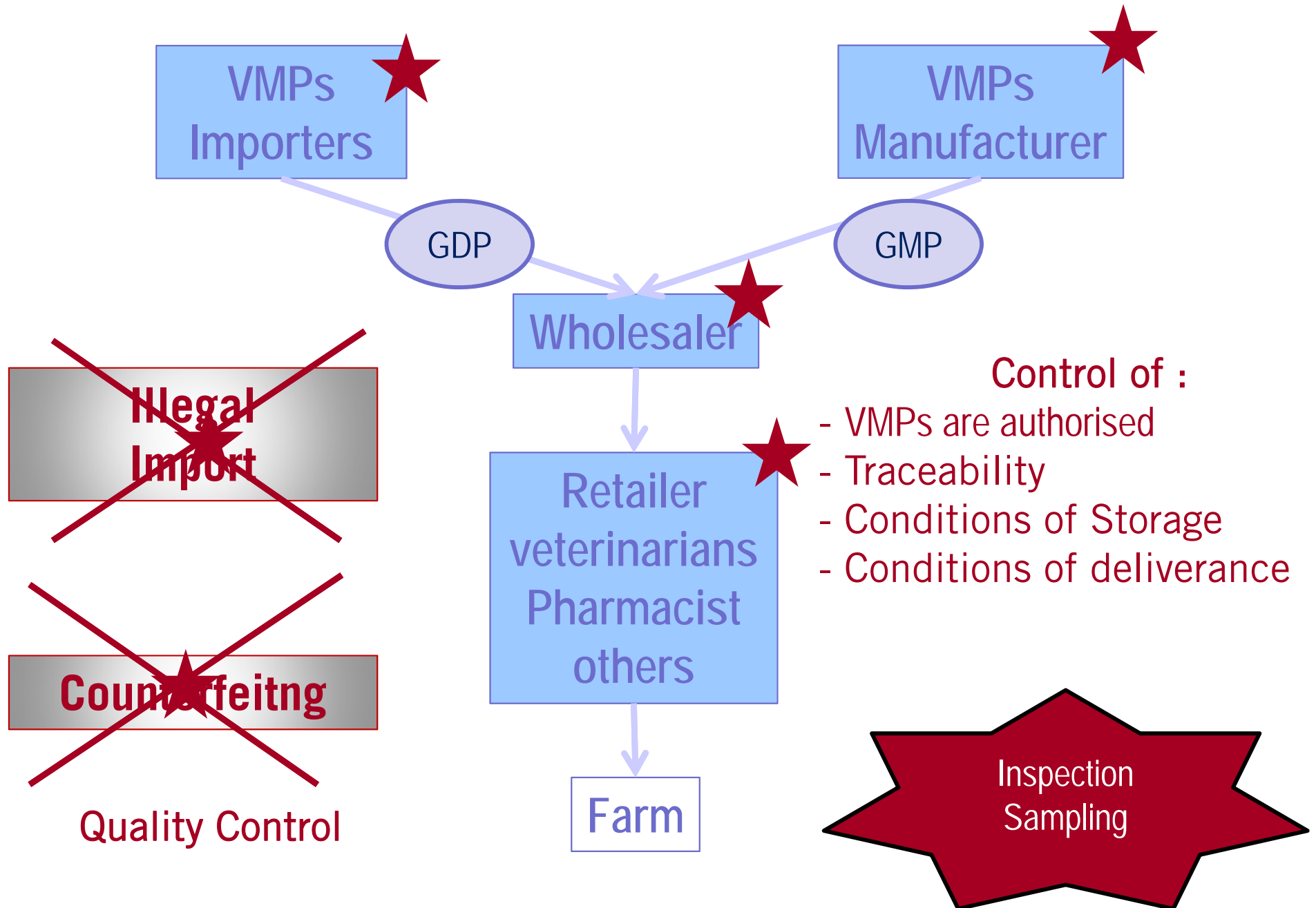
Authorisation of premises and activities



Authorisation of premises and activities



Authorisation of premises and activities



Need for Good Governance and good stewardship



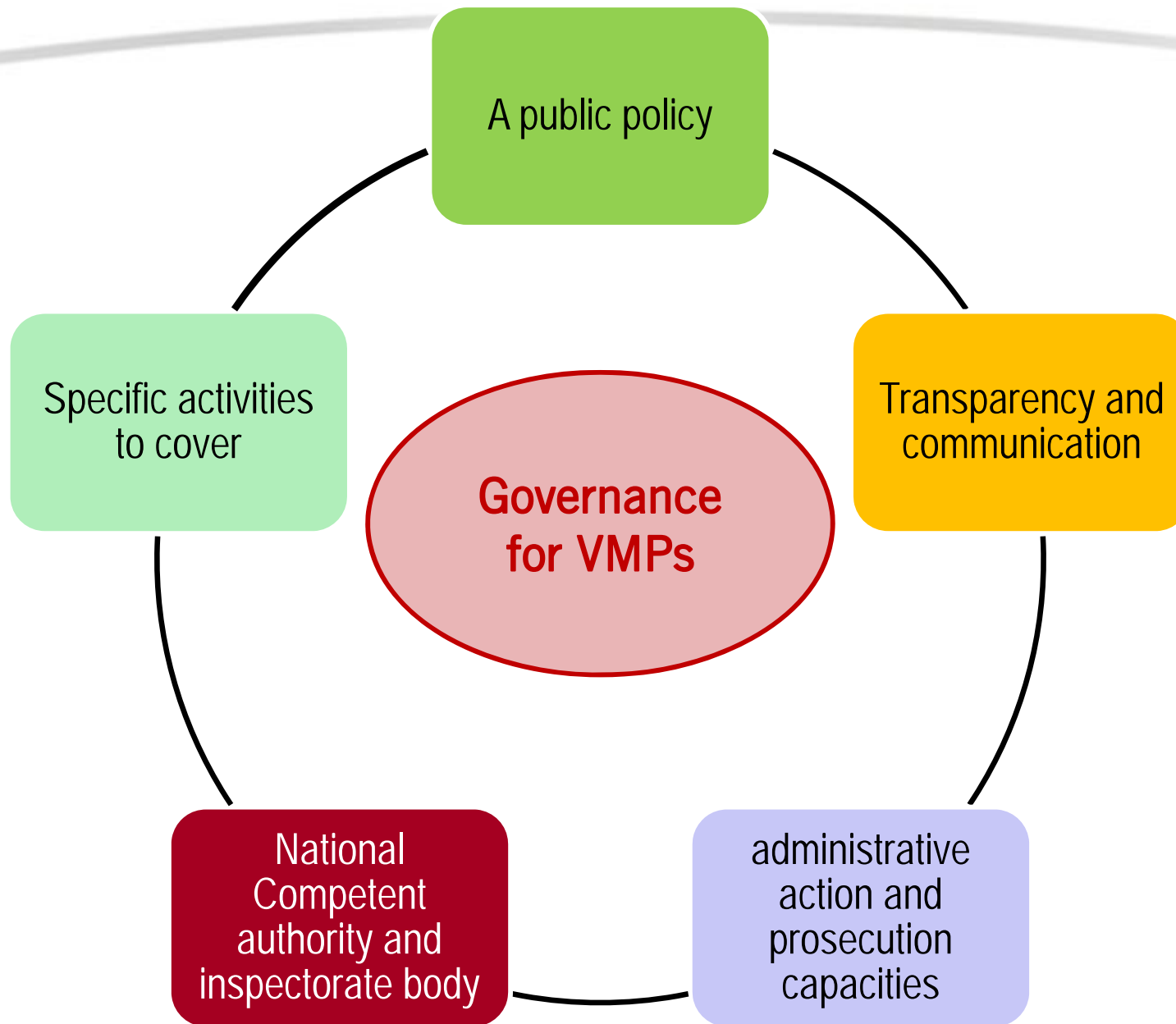
Need for government to have **clear and strong policies for VMPs** and have them effectively implemented and ensure that they provide effective **stewardship**

- **Chapter 3.2. terrestrial code :**

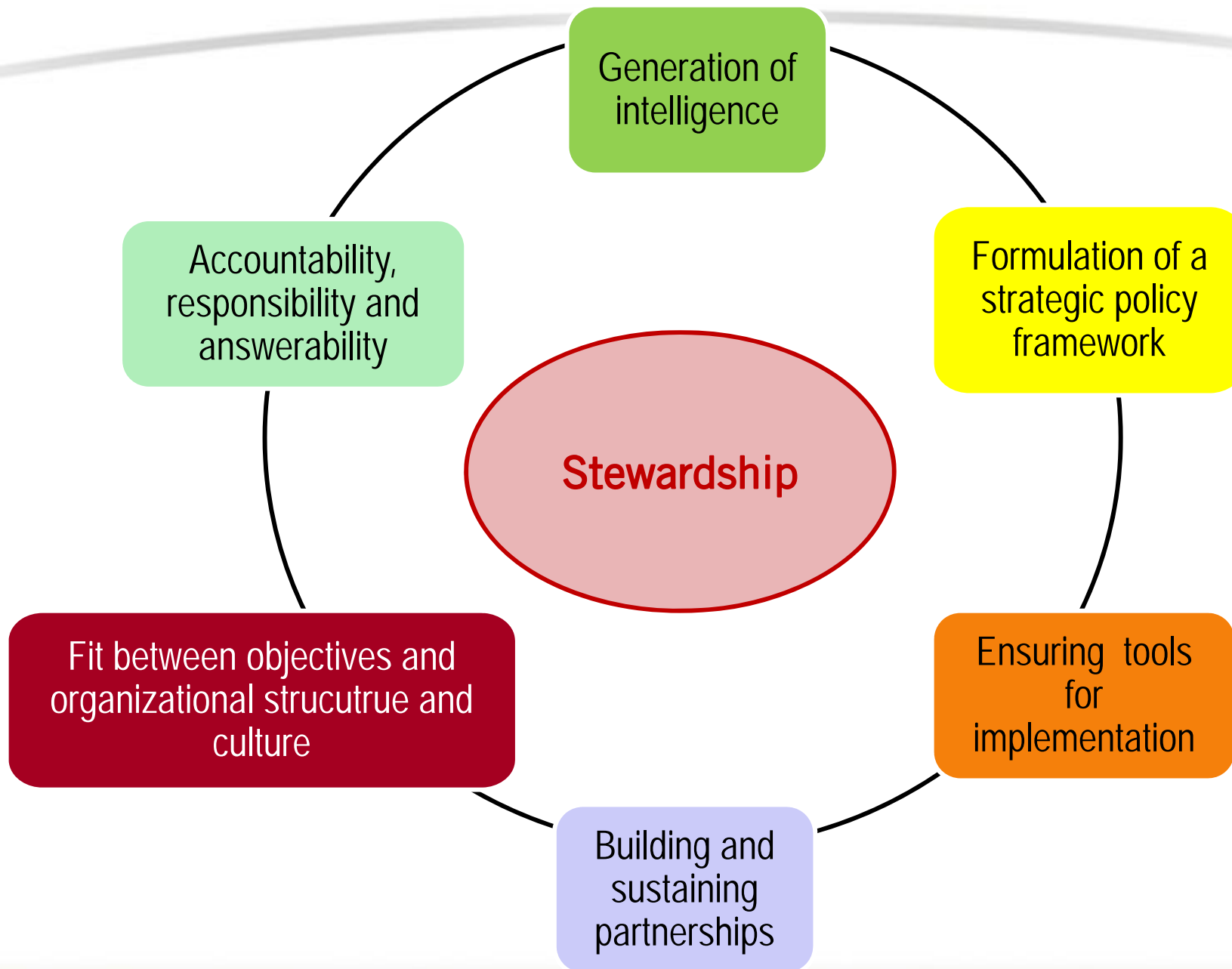
“Good governance is the Key to competence, integrity and confidence in organisations”

- ***Stewardship*** is coordinated interventions designed to improve and measure the appropriate use

Good governance



Good Stewardship



What should be done (Policy, planning, regulation, monitoring and evaluation) and How things should be done (participatory and transparent process)...

Avoid overlap between functions

Core element of *stewardship* :

- Making authoritative decisions
- Creating the means to put these into effect
- Creating support for them

... all this to improve animal and human health

1. Generation of intelligence

- Contribute to more informed decisions
- Good knowledge of all involved actors of the VMPs chain
- all actors have access to information
- NCAs have access to up-to-date information on current and future trends

2. Formulation of a strategic policy framework

- Articulation between goals and objectives
- Clear definition of actors, their role, their responsibilities
- Ascertain that the government take a broad inclusive view of its responsibilities, how the system should be and monitor progress

3. Ensuring tools for implementation : power, incentives and sanctions

- Power of NCA commensurate with their responsibilities
- Ensure enforcement of fair rules, incentives and sanctions
- Ensure that rules for users are defined and exercised fairly
→ **Appropriate and Legal regulatory framework**

4. Creating a fit between policies objectives and organisational structure

- Effectiveness defined by management culture
- Policy stability and institutional memory
- Resources available and quality of bureaucracy

5. Building and sustaining partnerships

- NCAs cannot influence factor by acting alone and must involve other actors,
- Shall build and maintain variety of relationship, type and nature depending of the party
- It is not only communication but alliance, need good understanding of the party, their values and motivation
→ Essential requirement = **good communication** (see chap. 3.4 – art 3.4.3-3)

6. Ensuring accountability, responsibility, answerability to the population

- Transparency
- Reduce the waste, the misuse of resources, negligence
- Strong commitment to ensure efficiency, competence and impartiality
- Specific procedure for disciplinary sanction

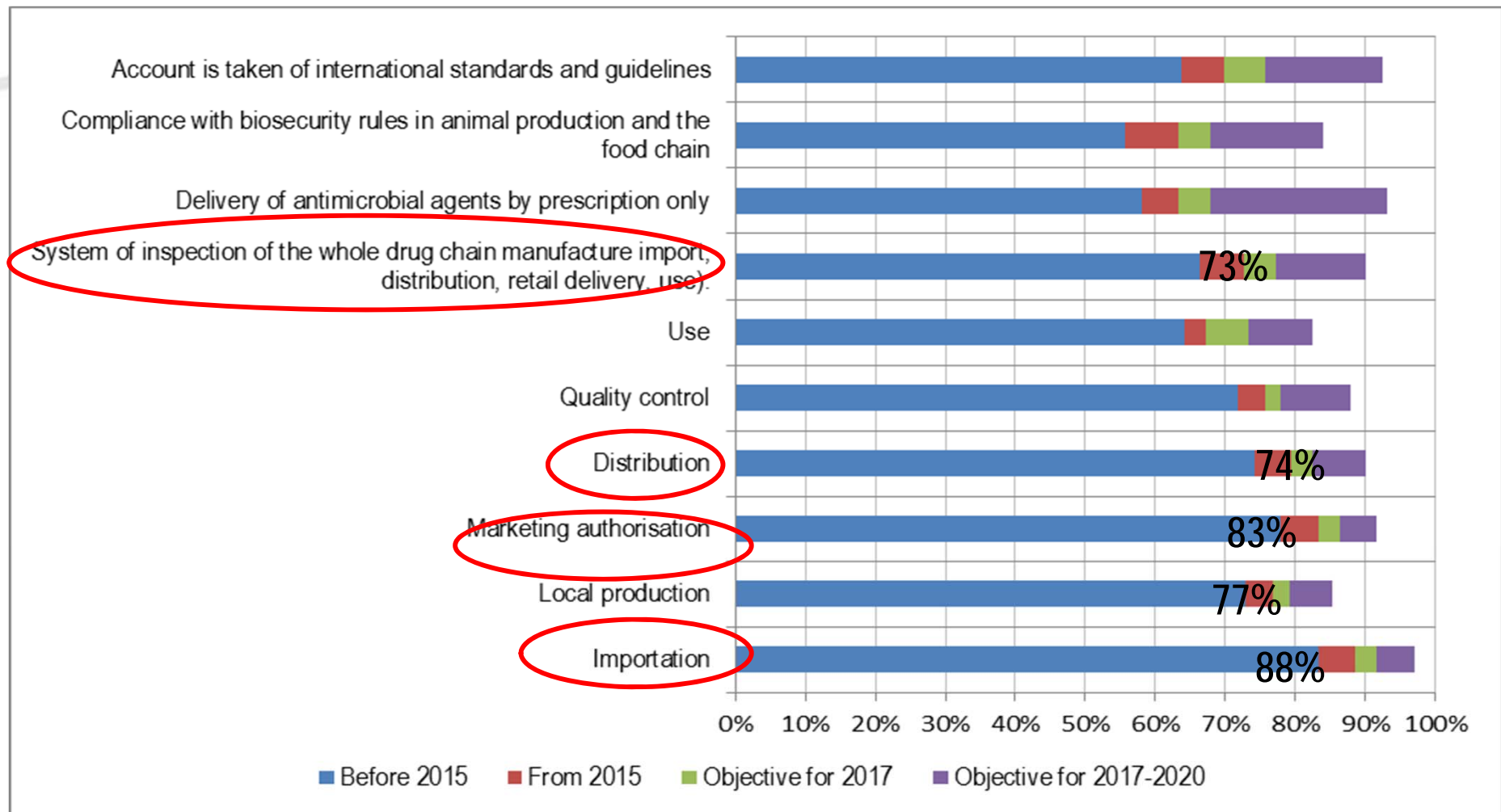
Inspection and control (see chap. 3.4 – art 3.4.5 -1)



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

*Need for rules
as
good practices*

Some figures : Aspects covered by legislation



Change in the proportion of Member Countries having put in place actions relating to good governance

Ref: GLOBAL ACTION TO ALLEVIATE THE THREAT OF ANTIMICROBIAL RESISTANCE, Khadija Id Sidi Yahia (ONSSA), Morocco- 85th OIE General Session, May 2017

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 ...

Monitoring of stewardship



- Importance to ensure that the system is **efficient**
- There is **not One system** but many different approaches depending on the local organisation, politics...
- Different way to evaluate them : surveys, benchmarking at local level between different sector, or at regional level
- **OIE surveys, PVS system**
- Exemple : **BEMA** exercise in EU

HMA (Human and Veterinary) has established a benchmarking programme with the following broad aim:

To contribute to the development of a world-class medicines regulatory system based on a network of agencies operating to best practice standards.

BEMA is based on assessment of the systems and processes in individual agencies against a set of indicators which have been agreed in the following areas: Management systems; Assessment of marketing authorisation applications; Pharmacovigilance; and Inspection services.

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

*Develop good governance through good **stewardship***

Thank you for your attention



**Organisation mondiale
de la santé animale**

**World Organisation
for Animal Health**

**Organización Mundial
de Sanidad Animal**