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# HOW TO ENSURE THE QUALITY OF VMPS ?

**REGIONAL WEBINAR –VMPS FOCAL POINTS**
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Jean-Pierre Orand
French agency for veterinary medicinal products,
OIE Collaborating centre for VMPs
jean-pierre.orand@anses.fr

# Introduction

Ensuring the Quality of Veterinary Medicinal Products (VMPs) is an essential and **basic requirement for the good governance of VMPs.**

Use of non good quality VMPs presents risks :

- For animal health : inefficient medicines
- For human health :
  - Risk of residues in food
  - Inefficient vaccines could have impact on zoonosis outbreak
- For environment : pollution

# Definition

**Marketing authorisation** :

- Composition : API, dosage
- specification

**NO**

**Unenregistered/ Unlicensed VMP**

**YES : registered VMP**

Analysis

**Compliance with MA**

Good Quality

**Non compliance**

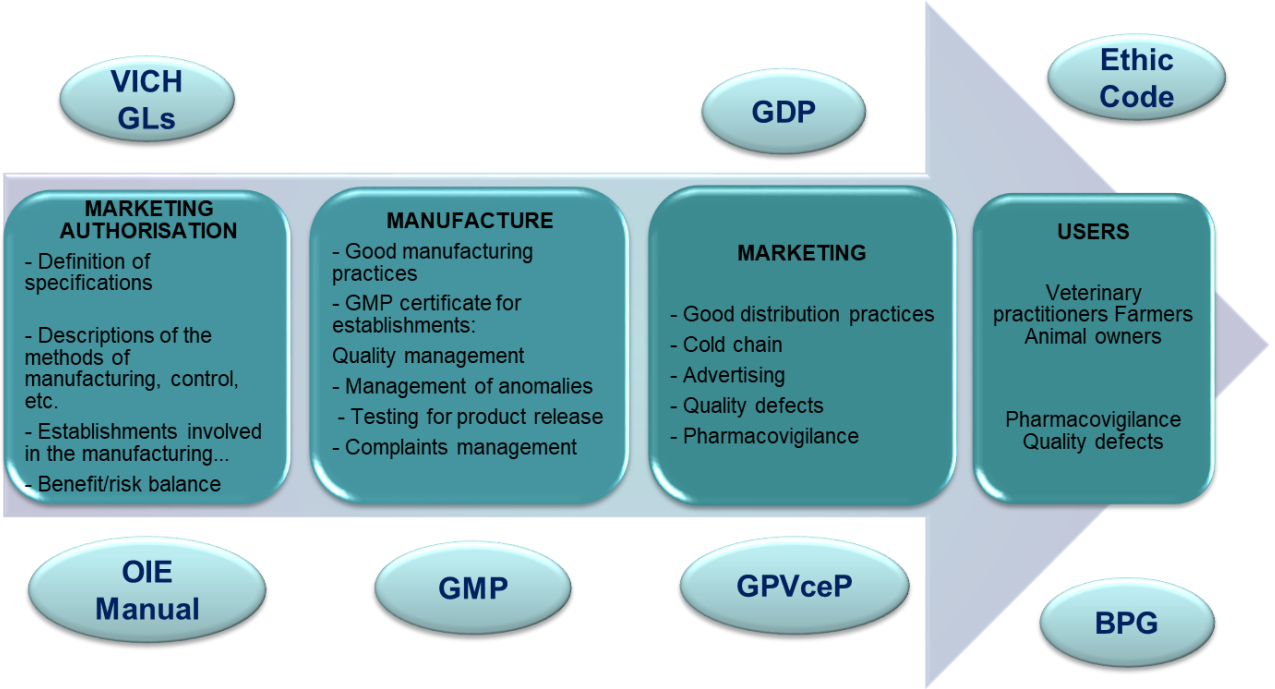
**Substandard :**

- Pb of manufacturing
- Pb of dosage…

**Falsification:**

- No API
- False API…

# Quality at all steps of VMPs life



# Quality during manufacturing, storage, distribution and use

**Transparency :**

- Official list of the registered VMP
- Official list of the authorised premises
- website

**VMPs Importers**

**VMPs Manufacturer**

**GDP**

**GMP**

**Wholesaler**

**Retailer**
**veterinarians**
**Pharmacist**
**others**

**Farm**

**Good practices :**

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

**Notifications :**

- Substandards, Quality defects
- Adverse effects : Pharmacovigilance

# Inspection and control

VMPs Importers

VMPs Manufacturer

GDP

GMP

Wholesaler

Inspection

Sampling

Retailer
veterinarians
Pharmacist
others

**Control of :**

- List of VMPs (only VMPs authorised)
- Conditions of manufacturing
- Traceability
- Conditions of Storage
- Conditions of Retail

Quality Control

Farm

# Manufacturer, importer and wholesaler

# GMP at OIE level

## *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2017*

### *Summary*

# PIC/S and Working group on VMPs

## What is PIC/S?

- PIC/S is a non-binding co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use.


## PIC/s Goal

- "To lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products"

## Exchange of letters with OIE

**www.picscheme.org**

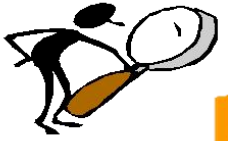
# GMP Inspection System

## Inspection steps:

- Programming
- Planning

**Preliminary stage**

- Preparation for inspection
- Carrying out the inspection
- Writing and sending initial report
- Assement of QP responses and conclusion
- Compliance status of VPC et decision



**Inspection stage**

# Control of retailer and control at farm

# Veterinarians / Pharmacists

- Sell only authorised VMPs
  - Capacity to check on a public accessible list
- Respect of condition of storage
- Role in the detection of quality defects
  - Visual aspects (colour, consistency, particle…
  - Defect in the label …
- Pharmacovigilance
  - VICH GL24: “Pharmacovigilance of veterinary medicinal products (VMPs) can be defined as the detection and investigation of the effects of the use of these products, mainly aimed at the safety and efficacy in animals and safety in people exposed to the products.”

# At farm level

- Farmers shall use only good quality products :
  - absence of counterfeits, falsified or unauthorised products
  - Respect the conditions of storage defined in the MA
  - Keep record
  - Respect the conditions defined in the prescription (dose, withdrawal period…)

# A specific issue: internet sales

- Increasing problem in Europe
- Concerns:
  - **may be a way of sales for falsified or counterfeit** VMPs
  - **unfair competition** in the field of VMP
  - source of **illegal import** without any authorization
  - source of **illegal retail** : VMPs on prescription sold without control and prescription
- Should be controlled, regulated

# Quality control of VMPs

# Control of the Market

## Objectives :

- Detection of substandard and falsifiedVMPs
- Surveillance of the Legal Market
- Surveillance of illegal market

## How ?

- Need a competent authority, a legal basis for sampling…
- Need an official accredited laboratory
- Need a programme of surveillance

## Programme of surveillance with a risk analysis

# Quality control analysis

## Control of veterinary medicinal products on legal market : programme of surveillance

- Risk based approach
  - Identification of priorities on the list of registered products based on defined criteria

**For examples:**

- ✓ Products used for food producing animals
- ✓ Focus on antibiotics and antiparasitics
- ✓ Products that present a risk for the users (vet, farmers,etc.)
- ✓ biologicals involved in the control of zoonosis

- Campaign of products
  - Same category of VMPs : AB , AP
  - Same API….

# Quality control analysis

- The sampling:
  - by a mandated person : inspector
  - at wholesaler level, at market level, on internet….
  - traceability of samples : record
- Registration of the samples at the laboratory
- Request to the MAH (if the VMP came from legal market = is authorized)
  - reference standard of the active substance with documentation
  - certificate of the batch control analysis realized for the batch release

# Follow up

- Conformity:
  - Letter to inform the MAH
- Non-compliance:
  - Action on the MAH or the VMPs owner, wholesaler, retailer where the VMPs has been sampled :
    - ✓ Letter asking the MAH to comment
    - ✓ May Lead to variations in some cases
    - ✓ If falsification or counterfeit → prosecution, legal action
  - Action on the products : risk analysis of the quality defect

# Assessment of a Substandard

- Falsification products

  → **batch recall and destruction**

- Substandard → Risk assessment

  - Assessment standardisation : same kind of defects leads to the same decision of batch recall
  - Criteria of assessment shared with Industry (transparency)
  - *Risk assessment taking into account :*
    - ✓ *Impact on human health*
    - ✓ *Impact on animal health*
    - ✓ *Incident already observed or not*
    - ✓ *Substandard observed on one batch or several batch…*

# OMCL Network of the Council of Europe

General European OMCL Network

- Network :

70 national Official Medicines Control Laboratories (OMCLs) from 40+ countries : 26 from EU, 8 European non EU : BLR, BIH, RUS, SRB, MKD, UKR, UK, NO, SW + observers

- Missions :
  - for public and animal health (common or separated OMCLs)
  - based on Ph. Eur. standard (EDQM)
  - ISO 17025 quality Management System
  - impartiality, independence, confidentiality and absence of conflicts of interest
- General activities :
  - Mutual Joint audits (external audits with peer review)
  - Proficiency Testing Scheme (organised by EDQM)
  - Market surveillance studies, collaborative studies, testing of API, counterfeiting…

# Conclusion

- ***Ensuring quality of Veterinary medicinal products is essential.***
- ***Appropriate legislation and Staff (trained inspectors, laboratory capacities) are needed.***

  - *Efficient systems of Authorisation (VMP and companies)*
  - *Transparency and communication*
  - *Efficient Inspectorate body with appropriate power.*
  - *The possibility to survey both the legal and illegal market*

***are essential as well as :***

***The capacity of prosecution and recalling products***