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Veterinary Pharmacovigilance: Introduction

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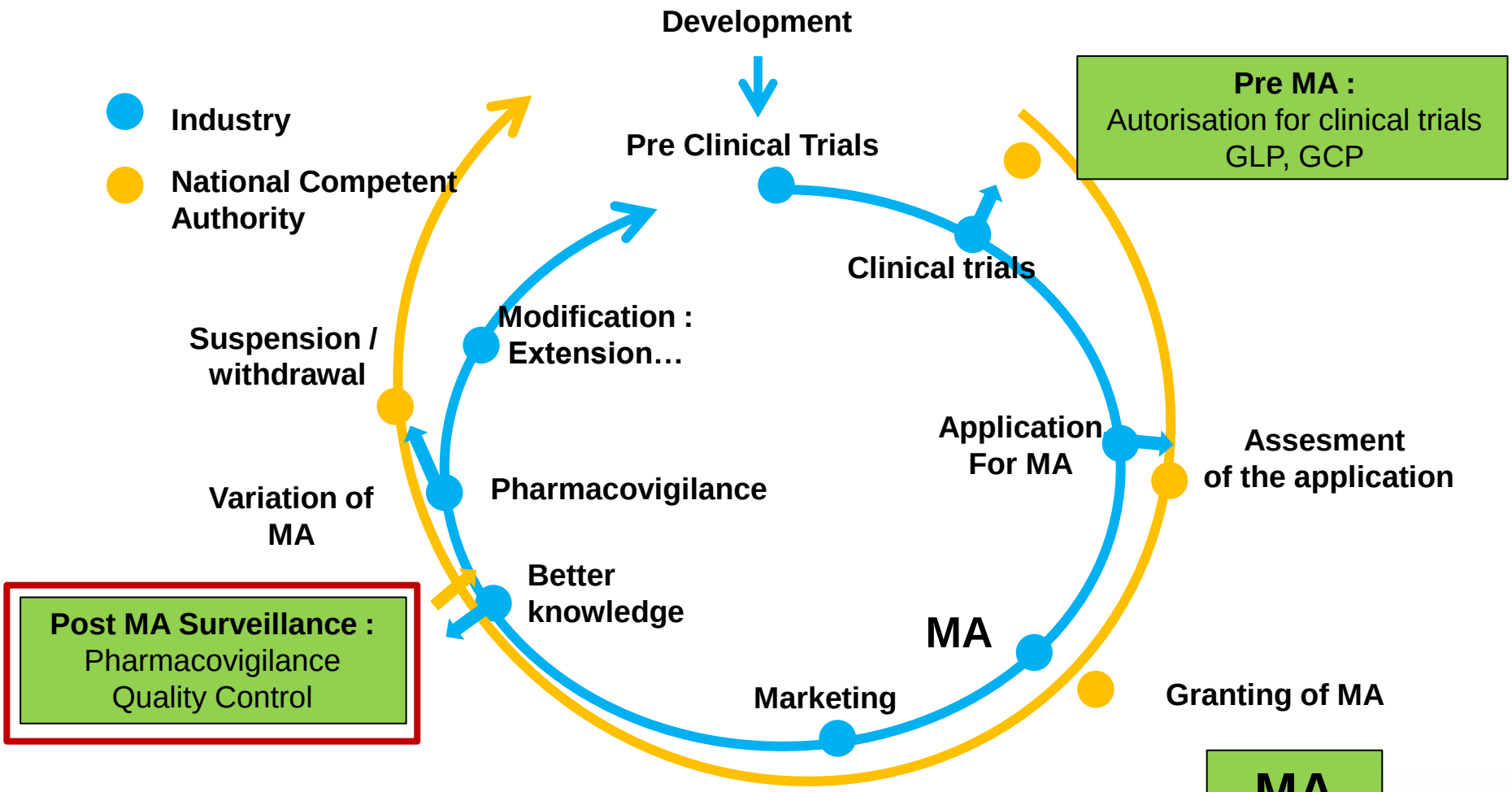
Marketing Authorisation Cycle



Pharmacovigilance: an important step in the drug development process

- Products are granted a MA on the basis of a favorable benefit/risk balance…BUT:
- Despite the rigor of the pre-approval drug development process, it is impossible to have complete information about the safety of a drug at the time of approval.
- The safety profile of a product can evolve over time.

⇒ Ongoing collection and evaluation of post-market adverse event reports and other safety information is essential to ensure safe and effective use of a product over its lifetime in the marketplace.

Pharmacovigilance - Definition

Pharmacovigilance (PV) is defined by the World Health Organization as the science and activities related to the **detection, assessment, understanding and prevention of adverse effects** or any other drug-related problem.

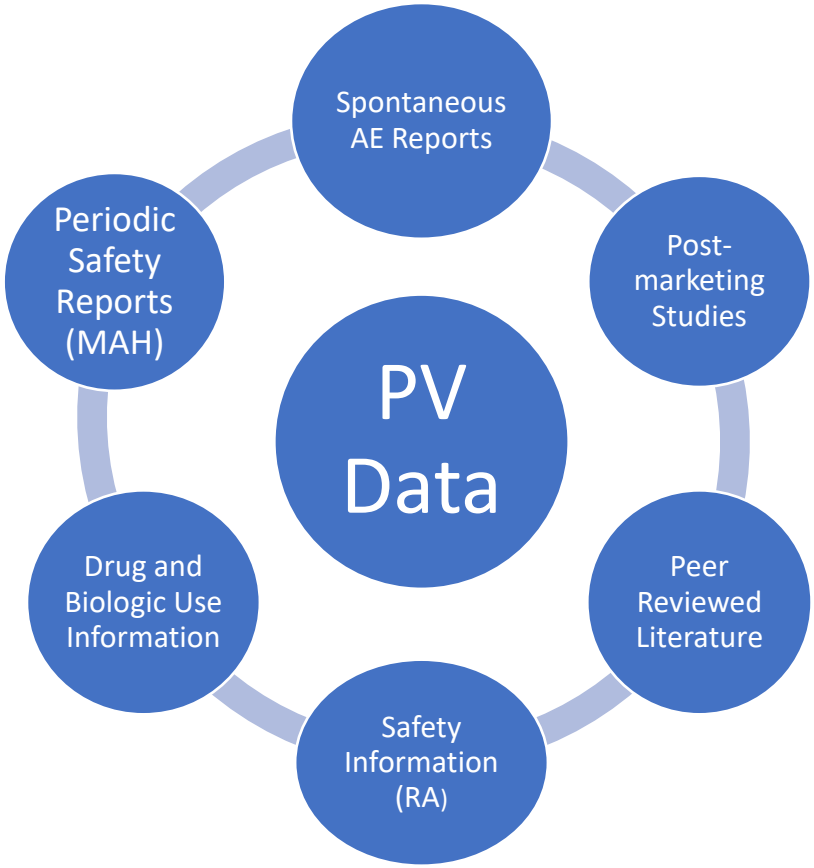
⇒ Monitoring of the benefit/risk balance of each product

⇒ Actions to maintain a favorable benefit/risk balance

The complex scope of veterinary pharmacovigilance worldwide:

Spontaneous Adverse Event Reports
Solicited Reports (e.g., post market clinical studies)
Medication Errors
Product Quality Issues
Environmental Issues
Validity of Withdrawal Period
Off-label Use
Therapeutic Failures/Lack of Effect
Human Exposures to Veterinary Products
Reports of Adverse Events in Unapproved Products

What pharmacovigilance data is available for assessment?



A note about challenges with assessing spontaneous reports

- Assessment of spontaneously reported adverse events is the primary post market surveillance method for veterinary medicinal products.

- Analysis of individual case reports can be challenging. Training is necessary.
  - With small numbers of reports, individual case review and assessment may be feasible.
  - Large volumes of AE reports may necessitate implementing signal detection/management tools; however, assessment of individual cases contributing to a “signal” remains necessary.

A note about challenges with assessing spontaneous reports (continued)

- Spontaneous adverse event reporting is passive surveillance system and has limitations:
  - Underreporting of adverse events is considered significant
    ⇒Incidence of adverse events cannot be *reliably* determined
  - Observational data (reporting biases)
    ⇒Causality link between a product and an adverse event cannot be *definitively* determined
  - Highly depending on the quality of data
    ⇒Incomplete or inconsistent data prevent conclusions being drawn

Global harmonization helps navigate the complexity

The VICH Pharmacovigilance Guidelines (GLs) were developed to facilitate information exchange of any type of adverse event report between manufacturers and regulatory authorities. If you are developing a PV system, start small:

- **GL24** AE Terms, Definitions, Management
- **GL29** PSUR Standardization, Management

Start with GL24 and GL29

Note: Some regional legislation has evolved since implementation of the above two Management GLs and may impact pharmacovigilance requirements referenced in the above two GLs

- **GL42** Data Elements for Submission of AE
- **GL30** Controlled Lists of Terms (24 lists!)
- **GL35** Electronic Standards (Data Transfer)

Reporting forms can be developed/structured using these elements

https://vichsec.org/en/guidelines/pharmacovigilance/vich-gls-24-29-35-42.html

VICH Technical Guidelines **do not…**

- Provide information on establishing regulations or describe how to set up a pharmacovigilance center
- Establish record keeping/reporting timelines (those currently exist in regional regulations)
- Provide instructions on how to analyze individual adverse event reports or conduct signal detection activities
- Provide guidance on developing a reporting form for consumer to report directly to agency (although some data elements could be leveraged to develop this). The existing technical guidelines DO advise on *electronic* exchange of individual case reports from manufacturer to regulatory authority *or* between regulatory authorities.

An effective pharmacovigilance system…

- Is a key component of drug regulation systems
- Promotes public health through early identification, assessment and risk mitigation of drug safety issues not identified pre-approval
- Informs communications (labels, product information sheets, safety alerts) that help ensure approved products remain safe and effective
- Promotes public trust/confidence

Information on the French agency for veterinary medicinal products:
https://www.anses.fr/en/thematique/veterinary-medicine-anmv
Our online reporting tool for adverse events:
https://pharmacovigilance-anmv.anses.fr/

Thank you!