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## ***VICH Workshop***

***Presentation of 2 Pharmacovigilance guidelines***

***GL24 – PV of Veterinary Medicinal Products:  
Management of Adverse Event Reports (AERs)***

***GL29 – PV of Veterinary Medicinal Products:  
management of Periodic Summary Update  
Reports***

Workshop for OIE National Focal Points on Veterinary Products (2<sup>nd</sup> Cycle)  
Casablanca, 6-8 Decembre 2011, Morocco

## ■ Reminder (VICH charter)

### ● **VICH Objectives:**

- Establish and implement harmonised regulatory requirements for veterinary medicinal products in the VICH regions
- Provide a basis for wider international harmonisation of registration requirements
- ...
- Also establish guidelines on the pharmacovigilance for veterinary medicines

### ● **OIE Role:**

- VICH was established with the support of the World Organisation for Animal Health (OIE)
- Countries not involved in VICH will be informed of the activities of VICH and consulted via the OIE

## **Reminder**

### **● Purpose Workshop for OIE National Focal Points on Veterinary Products**

- **Interface with OIE for all questions related to Veterinary Medicinal Products (VMPs)**
- **Receive from the OIE Main Office information on VICH activities**
- **Organise, on request of countries, consultations with recognised experts in VMPs on current projects on guidelines and related recommendations**
- **Prepare comments for the Delegation on all these discussions taking into account point of view and scientific recommendations of the OIE member and /or the concerned region, to present specifically the recommendations and observations on the proposed new or revised OIE guidelines on VMPs**

# ■ Reminder on Pharmacovigilance

## ● Definition

- detection and investigation of effects of the use of VMPs mainly aimed at safety and efficacy in animals and people exposed to the products.

## ● Why

- Because when first put on the market, only very common adverse reactions are known
- When on the market the product will be used very differently than in clinical studies
- Products used in a different region could also show a different safety and efficacy profile
- To detect product defect issues impacting safety/efficacy

# VICH Guidelines related to Pharmacovigilance of VMPs

## Five PV Guidelines

Title	Status
GL24: Management of adverse events reports (AERs)	Step 6 <sup>1</sup> : October 2007 Step 7 <sup>2</sup> : pending GL 35
GL29: Management of Periodic Summary Update Reports (PSURs)	Step 6: June 2006 Step 7: June 2007
GL30: Controlled list of terms	Step 6: June 2010 <b>Step 7: date to be set by VICH ESI EWG<sup>3</sup></b>
GL35: Electronic Standards for the transfer of regulatory information	Step 4 <sup>4</sup> : June 2010 Step 5 <sup>5</sup> : closed March 2011
GL42: Data elements for submission of adverse events reports	Step 6: June 2010 <b>Step 7: date to be set by VICH ESI EWG<sup>3</sup></b>
<sup>1</sup> Step 6: adoption by VICH steering committee - <sup>2</sup> Step 7: implementation in the 3 regions <sup>3</sup> <b>ESI EWG: electronic standards implementation experts working group</b> <sup>4</sup> Step 4: adoption by VICH steering committee - <sup>5</sup> Step 5: consultation in the 3 regions	

# Guideline 24 on management of Adverse Event Reports (AERs) – Overview - 1

- **Introduction**
- **Scope**
- **Definitions**
  - Veterinary Medicinal Products (VMP)
  - Adverse event (AE)
  - Serious adverse event
  - Unexpected adverse event
  - Adverse event report (AER)
  - Marketing Authorisation Holder (MAH)
  - Regulatory Authority (RA)
  - Periodic Summary Update (PSU)
  - International Birth Date (IBD)

# Guideline 24 on management of Adverse Event Reports (AERs) – Overview - 2

- **The Pharmacovigilance process**
  - Information flow in the pharmacovigilance system
  - Informational unit
  - Recording AERs
  - Submitting of AERs
  - Expedited AER submission
  - Periodic AER submission
  - Reporting source

## ● Objectives

- Cover only spontaneous reporting aspect of PV
- Legal obligations for commercial party responsible for VMP regarding adverse events
- Need **harmonising** common systems, common definitions and standardises terminology within PV to **facilitate reporting** for the MAHs and **faciliate the inter-regional comparison** of data and exchaneg of information , thereby **increasing the knowledge of the safety and performance profile** of the products.

## ● Scope

- Management of the detection and investigations of the clinical effects of marketed VMPs, mainly safety and efficacy effects in animals and safety in people exposed to VMPs.



## ■ GL24 - Definitions -1

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- **Adverse event**

- An adverse event is any observation in animals whether or not considered as drug related that is unfavorable or unintended and that occur after any use of the VMP
  - On and off label
  - Suspected lack of efficacy
  - Noxious reactions in humans

- **Serious adverse event**

- An adverse event that results in death, is life threatening, results in persistent or significant disability/incapacity or congenital anomaly or birth defect

## ■ GL24 - Definitions -2

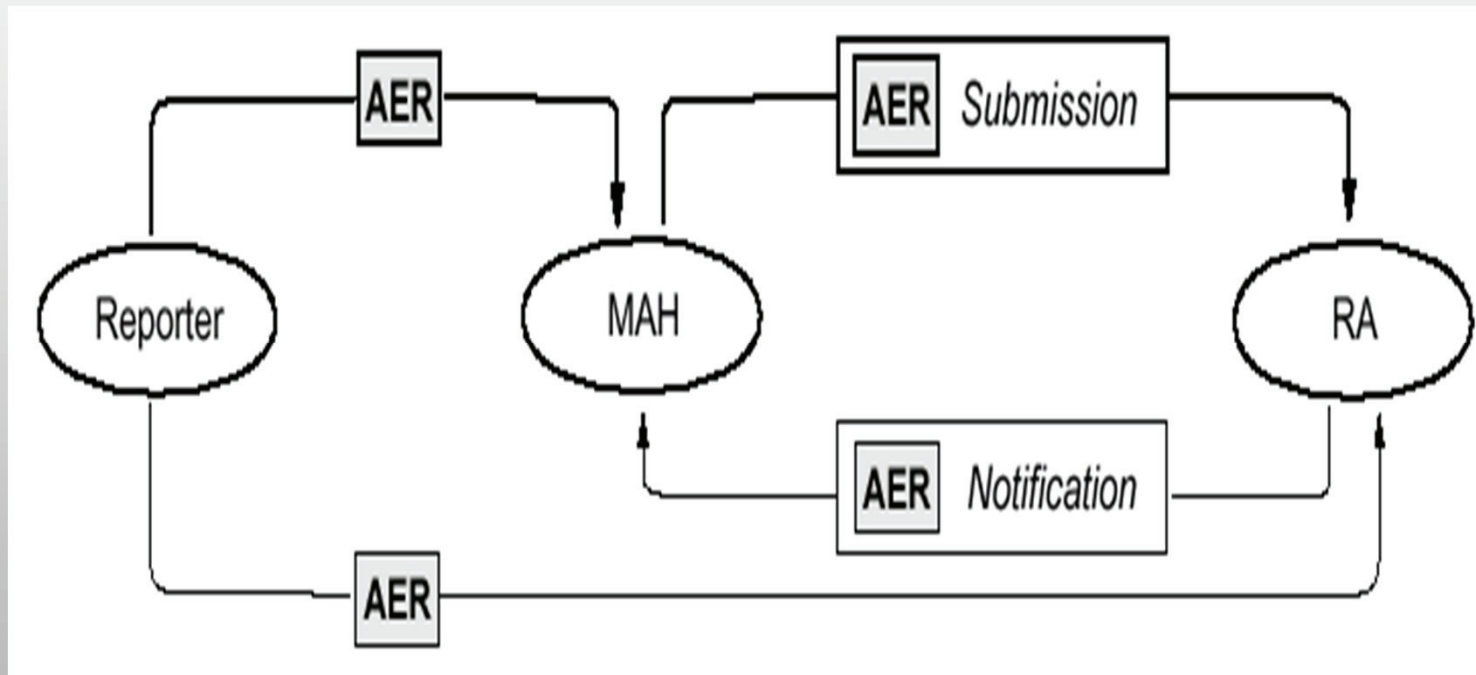
- **Unexpected adverse event**
  - An adverse event of which nature, severity or outcome is not consistent with approved labelling
- **Adverse Event Report (AER)**
  - An identifiable reporter
  - An identifiable animal or human
  - And identifiable VMP
  - One or more adverse events
- **Marketing Authorisation Holder (MAH)**
  - The commercial party who according to the regulatory body is responsible for the pharmacovigilance of the VMP

## ■ GL24 - Definitions - 3

- **Regulatory Authority (RA)**
  - The RA responsible at national or regional level by legislation for issuing, adapting, or withdrawing marketing authorisations/licences of VMPs and for pharmacovigilance activities
- **Periodic Summary Update (PSU)**
  - Document submitted to RA at set intervals to support the continued marketing and the adequacy of the labelling, will include an analysis of all AERs received during the interval
- **International birth date (IBD)**
  - Date of the first marketing authorization for same or similar product in any VICH region

# ■ GL 24 – The Pharmacovigilance process -1

## ● Information Flow



- Information unit: the AER

## GL 24 – The Pharmacovigilance process - 2

### ● **Submission of AERs**

- **Submissions does not imply endorsement or agreement with the content of the AER**
- **Expedited submission for AERs**
  - May be required for serious or unexpected AERs
  - May be required in another VICH regions if same VMP is approved in another VICH region, the species involved is also approved in another VICH region, or there are serious implications regarding human safety
- **Periodic submission**
  - At regular interval

### ● **Source of reports**

- **Anyone directly involved with the event, either to the MAH or to the RA**

## ■ VICH GL29 – brief presentation -1

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- **Objective:** to standardise the data for submission in a Periodic Summary Update to harmonise the approach for detection and investigation of AERs for VMPs and increase public and animal health
- GL provide guidance on
  - scope
  - Timing
  - Content

## ■ VICH GL29 – brief presentation - 2

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- **Scope:** only refer to PSU and its content, no guidance on interpretation of data
- **Timing:** an International Birth Date (IBD) is defined. Timing depends on local regulatory needs and the time on market
  - Recommendation :
    - every 6 months for the first two years

# ■ VICH GL29 – brief presentation - 3

## ● Contents

- MAH and VMP details
- Time period covered
- All AERs for same and similar products
- All data described in GL 42
- Bibliographic listing and review
- Sales volume of the VMPs
- Update on any actions taken by MAH or RA related to safety or efficacy of the VMP
- Critical analysis and opinion on benefit/risk profile with conclusion on whether data remains in line with cumulative experience to date.



# Thank you for your attention



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de la santé animale

World Organisation  
for Animal Health

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