How to set up a pharmacovigilance system for veterinary medicinal products – Version 2 – What is the update?

Training Seminar for Focal Points on Veterinary Products for the Africa region

(English-speaking Africa)
7th cycle

23-24 FEBRUARY 2022

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Health for Animals

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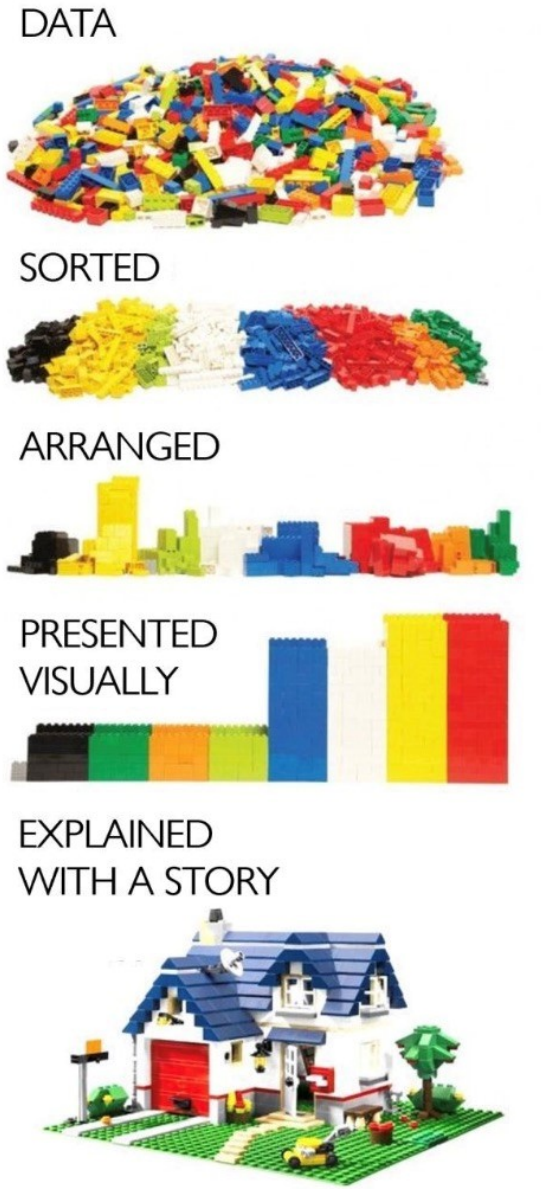
7th Cycle Regional Training Seminar for
OIE Focal Points for Veterinary Products

How to set up a pharmacovigilance system for veterinary medicinal products

Version 2, January 2022

Introduction

- This is a continuation of the 6th OIE Focal Poin training on Pharmacovigilance
- Subsequent to the 6th Cycle , updates were made based on questions and comments from participants.
- The following slides highlight the key updates.



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Key updates to the how to guide

Language and terminology throughout the document has been tidied up and harmonized (e.g. “third country” to “non-local”)

Commonly Used Terms section moved and extended

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Key updates to the how to guide

Role of the National Competent Authority (NCA):

- NCAs must establish procedures and collaboration protocols within the organization and, as appropriate, with external collaborating institutes according the scope and framework of its national pharmacovigilance set up.

Addition of the Legal representative under “Role of Marketing Authorisation Holder (MAH).

Adverse event scope extended to reporting “suspected transmission of extraneous agents”

Key updates to the how to guide

- Addition of recommendation for non-local case reporting :
  - Once the NCAs have an established PV system, they may want to implement “non-local country” case reporting. This will allow the NCAs to have an oversight of the worldwide safety information for the products registered in their country and will aid them in making informed decisions about the continued safe use of products in their jurisdiction. However, in practice this will require VICH compliant databases and IT systems as it will involve (very) large volumes of cases – many 10,000s per annum.

Key updates to the how to guide

Drafting appropriate national legislation and additional guidance:

- Addition of legislation to cover communication with veterinarians and animal owners
- Examples in guidelines of risk management measures (such as reinforced wording on product information on “Precaution and Contraindications”. Also, guidelines for MAH on how to communicate to the NCA and other stakeholders.

In section on Setting up a Pharmacovigilance System:

- In the incremental approach addition of recommendation to utilize a system that already exists in another country that can be adapted. Also liaising and learning from NCAs that have already implemented a PV system.

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Key updates to the how to guide

- Defining the responsibilities for the NCA clarified

Box 1: Responsibilities and obligations of the competent authority include:

- To establish, run and administer a pharmacovigilance system:
  - develop or upgrade relevant legislation
  - engage and liaise with marketing authorization holders
  - develop reporting requirements, reporting templates (see annex) and associated spreadsheet/information management system, and train staff
  - collect information, and consider setting up and maintaining a national database
  - scientific evaluation and product group analysis
  - collate with data on sales or use, and local epidemiology (to assess potential exposure and incidence rates, and to put the data into context of local conditions)
  - monitor compliance of companies
  - do risk-based inspections and perform controls
  - take corrective actions where necessary
- Initiate further investigation and assessment of identified safety concerns
- Implement conditions and restrictions on products
- Promote and ~~E~~encourage reporting of suspected adverse events
- Make companies and veterinarians aware of their obligations
- Communicate important information on pharmacovigilance of VMPs to MAHs/ vets/ animals owners

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Key updates to the how to guide

- An addition to the “The PSR frequency” section for “Standardised periodic summary reports” was made. This includes the exception to the standard schedule to allow for specific safety concern that drive the need for an enhanced PSR submission, taking into consideration the global PSR schedule.
- An important addition in PSR contents in the provision of sales data to include an incidence rate expressed as the number of AERs per unit of sales **(in Doses Sold)**

Key updates to the how to guide

In the section on How to analyse aggregated data, specific mention of VedDRA signs to aid the separation of adverse events.

When putting data into context all AE reports independent of the assessed product relation should be analysed (reporting rate) and, **using medical judgement**, compared with those considered probably or possibly product related and/or unclassifiable (incidence calculation).

In the Risk management and follow-up regulatory measures we defined critically important risk, such as a public health issue.

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Key updates to the how to guide

In the section What and how to communicate pharmacovigilance outcomes, it was reiterated that the information of the label or package safety warning should be clear and comprehensive for the target audience (i.e. veterinarian and animal owner).

For inspections and ensuring compliance the scope has been extended to include any party(ies) involved in the fulfilment of the PV obligations of the MAH. Additionally, the provision for Virtual Inspections has been added as we have all had to adapt to the COVID-19 situation.

Key updates to the how to guide

The following was added for Internal audits:

Internal pharmacovigilance audits are an essential component of any pharmaceutical company's Quality Management System. Auditing can provide an unbiased evaluation of the operational performance of the Pharmacovigilance system, measuring the system against its own procedures and against the regulatory requirements and guidelines, and ensuring that the system itself remains compliant with the regulations

Finally, Definitions have been added as well as references used to create this guide.

Thank you & Discussion