Supporting the future of animal health

Guidance Note

Pharmacovigilance Distributor Guidance

Scope

The contents of this document are intended for Marketing Authorisation (MA) holders and those companies that act as distributors for an MA holder i.e. a third-party carrying out pharmacovigilance activities on behalf of an MAH, in accordance with a written contract (PV agreement) and in compliance with existing legislation/guidelines.

Definition: *(Veterinary Medicines Directorate and VICH)*

Adverse events – Any observation in animals, whether or not considered to be product-related, that is unfavourable and unintended and that occurs after any use of a Veterinary Medicinal Product (off-label or on-label uses). Included are events related to a suspected lack of expected efficacy or noxious reactions in humans after being exposed to a veterinary medicine.

Lack of expected efficacy is defined as any observation of a lack of efficacy of a veterinary medicinal product following its administration to an animal, whether or not in accordance with the summary of product characteristics.

Distributor contracts

The marketing authorisation holder (MAH) should appropriately define, agree and control any pharmacovigilance activity it outsources to a third party. The MAH may transfer any or all of the pharmacovigilance tasks and functions, including the role of the qualified person for pharmacovigilance, to other person or organisations, but the ultimate responsibility for the fulfilment of all pharmacovigilance obligations and the quality and integrity of this always resides with the MAH. It is the MAH's responsibility to ensure that contracts include;

- A clear description of all contracted out activities (and the relevant responsibilities), such as:
    - The role of the QPPV and deputy where applicable
    - Communication of adverse events including follow up and reporting
    - Management of any databases that are used to support the PV system
    - Archiving of information
    - Signal detection and evaluation of potential safety concerns
    - PSUR compilation and submission
    - Literature searches
    - Requests received from the competent authorities in relation to the safety of the product.
    - Safety concerns identified via social media platforms
    - Sponsored post authorisation safety studies
- Timelines for conducting each of the subcontracted activities – including timelines for data transfer

- List of veterinary medicinal products covered by the contract
- Provision that any activity subcontracted by the distributor should be approved by the MAH
- Provision that the MAH is entitled to carry out audits of the distributor and any other subcontractor
- Provisions linked to the termination of the contract
- Provisions linked to training
- Provisions to avoid duplicate submissions by products which are identical in all aspects except in their invented names.

Process of reporting adverse events

For a complete report these four criteria are needed:

1. The source must be identifiable (veterinarian, pharmacist, animal owner) and should include the name and contact details e.g. postal address, email address or telephone number of the reporter.

2. The animals/human being involved must be identified – species (minimum requirement), desired additional information: sex, age, weight and number of animals treated. Human: name, sex, age, child/adult.

3. Details of the product used – names of the product (active substance alone is not enough) and the market authorisation holder (MAH), if available.

4. Details of the reaction, or suspected lack of expected efficacy – as detailed a case description as possible in chronological order documenting the event. A report describing the clinical findings should be provided whenever possible.

Distributors must report the cases to the MAH, irrespective of whether all of the 4 criteria above are available. The time frame should also be outlined in the PV agreement. Distributors should report adverse events to the MAH and not directly to the National Competent Authority (NCA) in order to help prevent duplicates.

The MAH is responsible for submission of all qualifying reports to the competent authority and they co-ordinate any further action. The date of first receipt for the MAH is the date that the distributor becomes aware of the adverse event. The MAH is required to transmit all serious adverse event reports to the competent authority within 15 calendar days of the date of first receipt.

Serious adverse event reports include any animal adverse events involving death, permanent disability, life-threatening illness or congenital abnormality. All adverse events occurring in humans are classified as serious and require expedited reporting to the National Competent Authority (NCA).

If there is no other agreement between the parties, the MAH is responsible for causality assessment because the MAH has the background and R&D knowledge relating to the product.

Due to GDPR only relevant information can be retained, MAH holders should make clear to the distributor how the information should be provided.

Practical options are;

- to collect initials of the reported and the beginning of postcode to avoid duplication or

- a standard GDPR statement could be supplied to the reporter allowing distributors to include full reporter details.

Depending on how the information is provided to the MAH, either the distributor or the MAH can contact the reporter directly for follow-up information but this responsibility should be clearly outlined in the contract.

Training

Staff involved to any extent in pharmacovigilance activities should be trained at an appropriate level and on a continuous base in pharmacovigilance. The process of training for all staff should be described in the contract and training should be carried out annually for staff directly involved in the receipt and recording of complaints and refreshed at suitable intervals for all other staff.

The MAHs should ensure the training of external staff, who encounter pharmacovigilance activities concerning veterinary medicinal products of the MAH, by including them in their own internal training programs or by auditing the training. Contracts should include the training requirements of external staff and the MAHs right to have oversight and to audit the training.

PV reconciliation

There must be routine reconciliation of the adverse events that have been shared between the parties which must be suitably documented to ensure that all cases received have been processed appropriately.

Documentation

- Distributor storage/retention of PV data
    - Relevant documentation should be kept for the duration of the agreement and passed over to the MAH on termination/expiry of the contract.

Auditing

- Frequency and Process
    - Distributor agreements should state that the MAH has the right to audit, with sufficient notice, to review compliance with the agreement and identify training were needed. Distributors are to comply and provide any documentation required as per the contract. The distributor should maintain written procedures and records.

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