HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Pharmacovigilance for products for to be registered in accordance with Article 5(6) of Regulation (EU) No 2019/6

Paul McNeill
Veterinary Assessment Manager

31 March 2021

What is the legal basis for pharmacovigilance of veterinary medicinal products registered in accordance with Art 5(6)?

Article 2.4 of Regulation (EU) 2019/6:

4. By way of derogation from paragraphs 1 and 2 of this Article, only Articles 55, 56, 94, 117, 119, 123, 134 and Section 5 of Chapter IV shall apply to veterinary medicinal products authorised in accordance with Article 5(6).

Section 5

Pharmacovigilance

Article 73

What do I need to do to meet pharmacovigilance responsibilities?

- Suspected adverse event:
  - unfavourable and unintended reaction in any animal;
  - observation of a lack of efficacy following administration to an animal (including off-label use);
  - noxious reactions in humans exposed to the product;

What do I need to do to meet pharmacovigilance responsibilities?

- Establish and maintain a system for collecting, collating and evaluating information on suspected adverse events concerning the registered product i.e. a 'pharmacovigilance system'.
- Have in place a Pharmacovigilance System Master File (PSMF) which describes in detail the pharmacovigilance system.
- Designate a Qualified Person for Pharmacovigilance (QPPV) who shall reside and operate in the EU. Needs to be appropriately qualified and permanently available to the holder of a registration for a veterinary medicinal product. (Provide the HPRA with name, location and contact details of the QPPV).
- Record all suspected adverse events relating to the registered product within 30 days of becoming aware of the adverse event. (Assumed that this will be to the Union PhV database but TBC).

What do I need to do to meet pharmacovigilance responsibilities?

- Where necessary (based on pharmacovigilance data), notify the HPRA of any changes (including labelling/leaflet) required to ensure safe use of the product. Approval needs to be sought.
- Communicate any regulatory action taken in another Member State in respect of the registered product.
- Possibility to contract out one or more pharmacovigilance tasks to a third party - arrangement needs to be described in the PSMF.
- Comply with 'Good Pharmacovigilance Practice' – guidelines currently being developed by the European Medicines Agency.
- Perform 'signal management' (identify risks or associations with adverse events) and record findings at least annually.

Further details and guidance relating to pharmacovigilance can be obtained from relevant guidelines available (and being developed) on the European Medicine's Agency's website.

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Thank you

- Follow @TheHPRA 
- newvetreg@hpra.ie 
- www.hpra.ie