

# 6<sup>th</sup> Cycle Regional training seminar for OIE Focal Points for Veterinary Products

# Pharmacovigilance working group session

14-16 February 2020 - Kuala Lumpur, Malaysia

Review the case study (1, 2 or 3 attached) and prepare to answer the following questions:	
Case study number:	
1. What are the signs associated with the report?	
2. VeDDRA code for the signs identified?	
3. Based on the information presented in the case please provide your assessment on t	:he
causality (Yes/No/Maybe). Provide your reason for the assessment	
4. What (if any) fallow up actions would you advice fallowing receipt of this case?	
4. What (if any) follow-up actions would you advise following receipt of this case?	

### CASE STUDY #1



Patient details

Species: Dog (unknown) Breed: null

Sex: Male

**Date of Birth:** null **Age:** 2 Year(s)

Weight (kg): 22.68 Weight (lbs): 50

Condition of animal prior to treatment:no responseDid new illness develop after dose:no responseHas animal previously reacted to other drugs:no response

Autopsy performed: No

Concomitant medical conditions pertinent to the case: no response

Suspect product details

Brand name: Product X

Concomitant product details

Brand name: Ivomec; with which dog was treated PO at 132 mcg/kg SID from 1-Sept-2010 – 30-Sept-

2010

#### **EVENT NARRATIVE:**

On 04-Oct-2010, a pet owner reported a potential adverse drug experience involving Product X in an unknown breed dog. The dog has received Product X for approximately 1.5 years prior to this without incident.

On 01-Sept-2010, the dog was diagnosed with Demodicosis and started on an off-label high-dose treatment of 0.3 ml Ivomec once daily for 30 days duration.

On 01-Sept-2010, the dog received his Product X dose without incident.

On 01-Oct-2010, the dog received a dose of Product X, and about one-hour post administration, he was ataxic, hyperactive, was having seizures and was blind. The pet's owners induced emesis and treated him with activated charcoal tablets, and he recovered.

The dog has a history of hip dysplasia. It was unknown if he was on any other medications.

On 04-Oct-2010, follow up information was obtained. The attending veterinarian clinic has not seen this patient since October 2008. There has been no recent interaction with this client. It is unknown who started the high dose ivermectin on the dog or if the pet owner did it themselves. No further information is expected.

# CASE STUDY #2



**Cattle #12345:** The reporter, an animal owner, notified the registrant on 22-Mar-2019 of a possible adverse reaction in cattle to oxytetracycline injection.

According to the reporter, a Beefmaster cow (14-15 months old, 409.1-454.5 kg) that had just had a calf 2.5 weeks prior was suspected to be suffering from foot rot. The cow was administered 27mL of oxytetracycline intramuscularly split into 3 injections in the neck, right hip, and left hip on 19-Mar-2019. The cow was also administered ivermectin pour-on at the same time and had recently been treated for worms on 14-Nov-2018. The cow had no history of pre-existing medical problems and had no prior treatment with oxytetracycline.

Within 18 hours, the cow was found dead on 20-Mar-2019.

The case was closed.

# CASE STUDY #3



**Species:** Bovine

**Breed:** Charolais

**Sex:** Female

**Weight:** 80-90 kg

Age: 1 month

No. exposed: 90

No. affected: 1

No. dead: 1

**Product name:** HIPRABOVIS SOMNI/Lkt emulsion for injection for cattle

Dose: 2ml

**Route:** Subcutaneous

Start date: 18-Dec-2018

The veterinarian reported 90 calves, aged 1 month, had been vaccinated with HIPRABOVIS SOMNI/Lkt emulsion for injection for cattle on 18-Dec-2018 by the owner. Less than 2 minutes later, one calf presented with convulsion, mooing, paddling, breathing difficulties and death. No treatment implemented considering the time within which the symptoms progressed (about 10 minutes). The case was closed.