VETERINARY PHARMACOVIGILANCE
FORM FOR REPORTING SUSPECTED ADVERSE EVENTS

1 - SUBSIDIARY OR COMPANY:	**2 - ORIGINAL REPORTER**
Name of sender : **Country :** Case reference : Type of report : ☐ Initial ☐ Follow-up **Date of First info Receipt (DFR) :**	Name: Firstname: Address: Telephone / Fax / Email : **Occur country :** ☐ Veterinarian ☐ Physician ☐ Pharmacist ☐ Owner ☐ Other :

If the original reporter does not agree that his/her complete name and address are sent to MAH, please tick this box ☐

3 - ☐ VETERINARIAN ☐ PHARMACIST ☐ PHYSICIAN	**4 - ☐ ANIMAL OWNER ☐ HUMAN PATIENT**
Name : Firstname: Address : Telephone/ Email: ☐ Identical to original reporter	Name : Firstname: Address : Telephone/ Email: ☐ Identical to original reporter

5 - ANIMAL DATA

N° of animals treated/exposed : **N° of animals affected :** **N° of animals dead :**
Affected animals characteristics : Species: Identification :
Breed/production type : Weight : Age :
Sex/physiological status : ☐ Female ☐ Male ☐ Unknown / ☐ Pregnant ☐ Neutered ☐ Lactating ☐ Unknown
State of health at time of treatment : ☐ Good ☐ Fair ☐ Poor ☐ Critical ☐ Unknown
Concomitant medical conditions:

6 - PRODUCTS DATA AND TREATMENT DETAILS

List of all relevant medication(s) administered before the event (one product per column; if more products are concerned, please use extra sheet) – *NA = Not applicable – Unk = Unknown*

Product name Company name MA number				
Pharmaceutical form & concentration				
Batch Number Expiry date				
Stored correctly? If No, explain	☐Yes ☐No ☐ Unk	☐Yes ☐No ☐ Unk	☐Yes ☐No ☐ Unk	☐Yes ☐No ☐ Unk
Dose & Frequency of the administered treatment				
Used Route & Administration site				
Treatment administered by (veterinarian, owner, ...)				
Reason for use or initial diagnosis?				
Use according to label ? if No, explain	☐Yes ☐No ☐ Unk	☐Yes ☐No ☐ Unk	☐Yes ☐No ☐ Unk	☐Yes ☐No ☐ Unk
Start date of treatment				
Stop date or duration of treatment				
Action after event (drug withdrawn, dose reduced)?				
Did event abate after stopping drug treatment?	☐Yes ☐No ☐NA ☐Unk	☐Yes ☐No ☐NA ☐Unk	☐Yes ☐No ☐NA ☐Unk	☐Yes ☐No ☐NA ☐Unk
Did event reappear after reintroduction?	☐Yes ☐No ☐NA ☐Unk	☐Yes ☐No ☐NA ☐Unk	☐Yes ☐No ☐NA ☐Unk	☐Yes ☐No ☐NA ☐Unk
Is the event related to this product according to original reporter?	☐Yes ☐No ☐Unk	☐Yes ☐No ☐Unk	☐Yes ☐No ☐Unk	☐Yes ☐No ☐Unk

7 - EVENT DATA

☐ **Safety issue in animals** ☐ **Lack of expected efficacy** ☐ **Withdrawal period issue**
☐ **Environmental problem** ☐ **Transmission of infectious agents**

CHRONOLOGY		
Date of onset of event :	**Time to onset between the start of exposition and the event (in seconds, minutes, days,…):**	**Duration of the event (in seconds, minutes, days,…):**

Describe the sequence of events incl. administration of product(s), all clinical signs, site of reaction, severity, laboratory tests, necropsy results, possible contributing factors (if necessary use extra sheet) :

Treatment given to address this adverse event : ☐ Yes ☐ No Details :

Outcome of event to date :

	Euthanized	Died	On going reaction	Under treatment	Recovered without sequelae	Recovered with sequelae	Unknown
N° of animals :							☐
Date when :							☐

Has reporter seen similar adverse events before with other product(s) on this (these) animal(s) ? ☐Yes ☐No ☐unknown (if yes, describe):

8 - PREVIOUS EXPOSURE AND EVENT(S) TO PRODUCT(S) :

Previous exposure to product(s) ? ☐ Yes ☐ No Which one(s): Date :

Previous reaction to product(s) ? ☐ Yes ☐ No Which one(s): Date :

Description of event, treatment given and outcome :

9 - DETAILS OF SUSPECTED ADVERSE EVENT(S) IN HUMANS

Sex : Age/Date of birth : Occupation (with relevance to exposure) :

Physiological status : ☐ Pregnant ☐ Breastfeeding ☐ Unknown

Date of exposure : Date of reaction :

Nature and duration of exposure, reaction details (including symptoms and treatment of the reaction) and outcome :

Identification of the physician or poison center or pharmacovigilance center if consulted :

10 - FOR SUBSIDIARY OR COMPANY USE / CAUSALITY ASSESSEMENT

☐ **A** (probable) ☐ **B** (possible) ☐ **O** (unclassified) ☐ **O1** (inconclusive) ☐ **N** (unlikely)
Reasons for assessment and comments :

Name of the original reporter (see section 2 of the document) or the person responsible for completing this form :

Date : **Signature (if reporting form printed) :**

☐ Attachments included *☐ Reports to follow :*

Has competent authority or pharmacovigilance center been notified with this case? ☐ Yes ☐ No ☐ Unknown