**VETERINARY PHARMACOVIGILANCE**

**FORM FOR REPORTING SUSPECTED ADVERSE EVENTS**

1 - SUBSIDIARY OR COMPANY:

Name of sender:
Country:
Case reference:
Type of report: □ Initial  □ Follow-up
Date of First info Receipt (DFR):

2 - ORIGINAL REPORTER

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

Name:  Firstname:
Address:
Telephone/ Email:
☐ Identical to original reporter

4 - □ ANIMAL OWNER □ HUMAN PATIENT

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 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

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Action after event (drug withdrawn, dose reduced)?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

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

#### CHRONOLOGY

<table>
<thead>
<tr>
<th>Date of onset of event</th>
<th>Time to onset between the start of exposition and the event (in seconds, minutes, days,...)</th>
<th>Duration of the event (in seconds, minutes, days,...)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Euthanized</th>
<th>Died</th>
<th>On going reaction</th>
<th>Under treatment</th>
<th>Recovered without sequelae</th>
<th>Recovered with sequelae</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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