European Veterinary Pharmacovigilance Reporting Form for MAHs

Safety issues in animals ☐ in humans ☐ Lack of expected efficacy ☐ Withdrawal period issues ☐ Environmental problems ☐	**SENDER REPORT IDENTIFICATION – CASE REF. No:** Reporting country: Purchase country: Report source:	1

1. ADDRESS OF COMPETENT AUTHORITY

2. NAME AND ADDRESS OF SENDER

Date complaint received by sender:
(dd/mm/yy)

Type of report: Initial ☐ Follow-up ☐ (date, case number)

Person who reported the reaction: veterinarian ☐ owner ☐ physician ☐ pharmacist ☐ other:

3. VETERINARIAN / PHYSICIAN / PHARMACIST

Name:

Address:

Telephone No.

4. ANIMAL OWNER / HUMAN PATIENT

Name *(according to the confidentiality legislation in EU country)*:

Address:

Telephone No.

5. ANIMAL DATA **No. of animals treated:** **No. of animals showing signs:** **No. of animals died:**

Animal characteristics (animal(s) showing signs):

Species: Breed/production type:

Sex/physiological status: female ☐ male ☐ pregnant ☐ neutered ☐ lactating ☐ other:

Weight (kilos): Age:

State of health at time of treatment: good ☐ fair ☐ poor ☐ critical ☐ unknown ☐

Reason(s) for treatment (prevention against what disease(s) or initial diagnosis):

6. PRODUCT DATA # 1

Trade name (include dosage form and strength): **M.A. number:**

Active substance(s) (INN): **ATC vet code(s):**

Batch No.: **Expiry date:** **Storage details:**

Treatment details:

Dose/frequency: Route/site of administration:

Start date of treatment: Stop date or duration: Who administered the product:

veterinarian ☐ owner ☐ other ☐

Use according to label: yes ☐ unknown ☐ no ☐ explain:

Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐

Did reaction abate after stopping drug ? yes ☐ no ☐ not applicable ☐

Did reaction reappear after reintroduction ? yes ☐ no ☐ not applicable ☐

List all other relevant medications given to animal(s):
Give the list of the other veterinary medicinal products used concurrently and go to special field for completion of details (page 3)

7. REACTION DATA (*applicable for all types of adverse reaction(s) reported following administration of veterinary product(s)*

Date of onset of signs:
Duration of reaction:

Describe the sequence or events including administration of product(s), all clinical signs, site of reaction, severity, pertinent lab tests, necropsy results, possible contributing factors (if necessary use extra sheet): Include details of treatment given to address this adverse reaction.

Were the signs treated?

No ☐ **Yes** ☐

Outcome of reaction to date:

	Killed/euthanised	died	under treatment	alive with sequalae	recovered	unknown
No. of animals:						
Date when:						

8. ATTENDING VETERINARIAN'S LEVEL OF SUSPICION THAT PRODUCT #1 CAUSED REACTION

possible ☐ unlikely ☐ no attending vet ☐

9. PREVIOUS EXPOSURE AND REACTION(S) TO PRODUCT #1

Previous exposure to this product? no ☐ yes ☐ Date(s):

Previous reaction to this product? no ☐ yes ☐ Describe:

De-challenge information:

10. DETAILS OF SUSPECTED ADVERSE REACTION(S) IN HUMANS

Patient details Sex: Age/date of birth: Occupation (with relevance to exposure):

Date of exposure: Date of reaction:

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

11. CAUSALITY ASSESSMENT RELATED TO PRODUCT #1

Classification: A (probable) ☐ B (possible) ☐ O (unclassified) ☐ N (unlikely) ☐

Reason for classification:

12. OVERALL CAUSALITY ASSESSMENT RELATED TO ALL SUSPECTED PRODUCTS

FOR COMPETENT AUTHORITY USE ONLY

Name and title of person responsible for the accuracy of the information **Signature** **Date**

To replicate for each product used concurrently

SENDER CASE REF. No:	3

6. DATA FOR PRODUCTS ADMINISTERED CONCURRENTLY – PRODUCT # <Enter sequential number; 2 or higher>

Trade name (include dosage form and strength): **M.A. number:**

Active substance(s) (INN):: **ATC vet code(s):**

Batch No.: **Expiry date:** **Storage details:**

Treatment details:

Dose/frequency: Route/site of administration:

Start date of treatment: Stop date or duration: Who administered the product:

veterinarian ☐ owner ☐ other ☐

Use according to label: yes ☐ unknown ☐ no ☐ explain:

Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐

Did reaction abate after stopping drug? yes ☐ no ☐ not applicable ☐

Did reaction reappear after reintroduction? yes ☐ no ☐ not applicable ☐

8. ATTENDING VETERINARIAN'S LEVEL OF SUSPICION THAT REACTION WAS CAUSED BY PRODUCT #

possible ☐ unlikely ☐ no attending vet ☐

9. PREVIOUS EXPOSURE AND REACTION(S) TO PRODUCT #

Previous exposure to this product? no ☐ yes ☐ Date(s):

Previous reaction to this product? no ☐ yes ☐ Describe:

De-challenge information:

11. CAUSALITY ASSESSMENT RELATED TO PRODUCT #

Classification: A (probable) ☐ B (possible) ☐ O (unclassified) ☐ N (unlikely) ☐

Reason for classification: