EU Veterinary Suspected Adverse Reaction Report Form for Veterinarians & Health Professionals

Form to be sent to

Finnish Medicines Agency
Veterinary SAR Registry
P.O. Box 55
FI-00034 FIMEA, FINLAND

Fax: 029 522 3015 **Phone:** 029 522 3341
E-mail: vethava@fimea.fi **Website:** www.fimea.fi

IN CONFIDENCE
For official use only
Ref. Number:

IDENTIFICATION	**SENDER**	**OWNER**
Safety issue in animals ☐ in humans ☐ **Lack of expected efficacy** ☐ **Withdrawal period issues** ☐ **Environmental problems** ☐	Veterinarian ☐ Pharmacist ☐ Other ☐ NAME AND ADDRESS Phone: Fax: E-mail:	NAME & ADDRESS / REF. OF PATIENT

PATIENT(S) *Animal(s)* ☐ *Human(s)* ☐ *(for humans fill only age and sex below)*

Species	Breed	Sex	Status	Age	Weight	Reason for treatment
		Female ☐ Male ☐	Neutered ☐ Pregnant ☐			

VETERINARY MEDICINAL PRODUCTS ADMINISTERED BEFORE THE SUSPECTED ADVERSE REACTION

(if more products are administered concurrently than the number of boxes available, please duplicate this form)

	1	2	3
Name of the veterinary medicinal product (VMP) administered			
Pharmaceutical form & strength (ex: 100 mg tablets)			
Marketing Authorisation number			
Batch number			
Route/site of administration			
Dose / Frequency			
Duration of treatment /Exposure Start Date End Date			
Who administered the VMP? (veterinarian, owner, other)			
Do you think that the reaction is due to this product?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Has the Marketing Authorisation Holder (MAH) been informed?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

SUSPECTED ADVERSE REACTION DATE	Time between administration and event in minutes, hours or days		Duration of the adverse reaction in minutes, hours or days
____/____/____	____	Number treated ____ Number reacted ____ Number dead ____	____

DESCRIPTION OF THE EVENT *(Safety issues in animals or Safety issues in humans/Lack of expected efficacy/Withdrawal period issues/Environmental problems)*

Indicate also if the reaction has been treated, how and with what and what was the result?

OTHER RELEVANT DATA (ATTACH FURTHER PAPERS IF NECESSARY e.g. investigations carried out or ongoing, a copy of medical report for human cases)

HUMAN CASE
If the reported case refers to a human being, please also complete the details of exposure below

- Contact with treated animal ☐
- Oral ingestion ☐
- Topical exposure ☐
- Ocular exposure ☐
- Injection exposure ☐ finger ☐ hand ☐ joint ☐ other ☐
- Other (deliberate….) ☐

Exposure dose:

If you do not agree that your name and address are send to the MAH, please tick the box ☐

Date: **Place:** **Name and signature of sender:**

Contact point (phone) (if different from the number on page 1)