Adverse events reporting form RF-906.6

This form has been developed in order to support the reporting of adverse events. Although any one can report an adverse event, it is preferable that this form is completed by a veterinarian.

Please complete all the questions on this form if possible. The more detailed the information provided is, the more accurate our assessment of the case will be. If currently not all information is available to you, please still submit this form. The missing details can always be added at a later date.

For any questions regarding this form or regarding pharmacovigilance in general please feel free to contact Nathalie Jehee, QPPV, or Mathilde Louwerens, deputy QPPV at Dopharma Research B.V.

Contact details

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1. Type of adverse event

2. Reporter / Veterinarian	
Name	
Name practice	
Address	
Postal code, city	
Country	
Phone number	
E-mail	

3. Animal owner / Farmer	
Name	
Address	
Postal code, city	
Country	
Phone number	

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4. Administered drug(s) *In case of more than 3 administered drugs please use a second form*			
	Product 1	**Product 2**	**Product 3**
Name of product			
Registration number			
Batch number			
Administration route			
Administration site			
Dosage			
Dosage interval			
Treatment start date			
Treatment end date			
Administered by ...			

5. Animal(s) involved	
Species	
Breed	
Gender	
Age	
Weight	
Lactating	
General health	

6. The adverse event	
Date onset	
Duration of adverse event	
End date	
Number of treated animals	
Number of affected animals	
Number of recovered animals	
Number of dead animals	

7. Narrative

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8. Additional questions	
What was the indication?	
What were the symptoms?	
Were any further diagnostics performed?	
If yes: What kind?	
What were the results? (results can be added as an appendix)	
Are there any health problems/issues that might play a significant role?	
If yes: Which one?	
Was the adverse event treated?	
If yes: How, when and with which result?	
Have these animals been treated with this product before?	
If yes: Where there any events on those occasions?	

9. Adverse event report	
To whom have you reported this case?	
Do you have objections against having your initials and first two digits of your postal code linked to this case in the European database for adverse events?	

Print form

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