**VETERINARSKI ZAVOD SUBOTICA**

**ADVERSE REACTION REPORTING FORM**

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| **Form to be sent to**Veterinarski Zavod Subotica, Beogradski put 123, 24106 Subotica, Republic of SerbiaFax: +381 24 567 736 Phone: +381 24 624 100E-mail: farmakovigilanca@vetzavod.com Website: http://www.vetzavod.com | **IN CONFIDENCE***For official use only*Ref. Number: |
| **IDENTIFICATION** | NAME AND ADDRESS OF SENDER |
| Safety issuein animalsin humans**Lack of expected efficacy****Withdrawal period issues****Environmental problems** | **[ ]** **[ ]** **[ ]** **[ ]** **[ ]**  | Veterinarian  [ ]  Animal owner  [ ]  Other  [ ]      Phone:       Fax:       |
| 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)* |
| **Name of the veterinary medicinal product (VMP) administered** | 1  | 2 | 3  |
|  |  |  |  |
| Pharmaceutical form & strength (ex: 100 mg tablets) |       |       |       |
| Marketing Authorisation number |       |       |       |
| Batch number |       |       |       |
| Route/site of administration |       |       |       |
| Dose / Frequency |       |       |       |
| Duration of treatment /ExposureStart DateEnd 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      | Number treated      Number reacted      Number dead       | **Duration of the adverse reaction** in minutes, hours or days      |
| **DESCRIPTION OF THE EVENT** *(Safety issues in animals or Safety issues in humans/Lack of expected efficacy/Withdrawal period issues/Environmental problems) – Please describe:*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:       |
| **Date:       Place:       Name and signature of sender:*****Contact point (phone)*** (if different from the number on page 1)       |