**VETERINARSKI ZAVOD SUBOTICA**

**ADVERSE REACTION REPORTING FORM**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Form to be sent to**  Veterinarski Zavod Subotica,  Beogradski put 123, 24106 Subotica, Republic of Serbia Fax: +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 issue in animals in 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 /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 | | | | | | 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) | | | | | | | | | | | | | | | | |