

## Pharmacovigilance Policy - Duggan Veterinary Supplies Limited

Duggan Veterinary Supplies Limited (DVS) provides high quality veterinary medicinal products to its customers by ensuring products are fit for purpose as per intended use. These medicinal products must meet stringent quality, safety and efficacy requirements prior to being placed on the market. The post market surveillance of each marketed product with respect to the safety profile of the product is called "Pharmacovigilance". It is DVS's legal obligation to undertake pharmacovigilance activities in order to ensure that appropriate actions are taken to reduce the risks and increase the benefits of medicinal products.

A written policy describing DVS's obligations under the pharmacovigilance regulations is provided herein. The essential elements of our pharmacovigilance system are written in accordance with "Volume 9B Part 1 of the Rules Governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use". Our Qualified Person Responsible for Pharmacovigilance (QPPV) ensures the maintenance, evaluation and performance of the system. The QPPV is registered with Eudravigilance Veterinary, which is a European Medicine Agency's central computer database for suspected adverse events related to veterinary medicinal products. Staff members are suitably trained to undertake pharmacovigilance related activities at DVS.

### Pharmacovigilance Policy

The safety of both animals and humans administering the veterinary medicinal product is very important to DVS. If there are any safety concerns, customers using our product(s) must contact us in order for DVS to obtain the necessary information and to arrange for any follow up as deemed necessary under its pharmacovigilance obligations. We will promptly provide feedback on any safety issues. The procedure for contacting, follow-up and compilation of the information on safety issues is described herein in detail under its pharmacovigilance policy. These procedures describe DVS's legal responsibility to monitor the safety profile of marketed products as part of its pharmacovigilance system.

A brief overview of our policy is provided and the technical information is adapted from the pharmacovigilance policy in this website version.

### Abbreviations/Definitions

**ADVERSE EVENT:** Any observation in animals, whether or not considered to be product-related, that is unfavourable and unintended and that occurs after any use of DVS marketed veterinary medicinal product.

**DVS:** Duggan Veterinary Supplies Limited and will be stated as "we", "our" and "us" in this website version of policy.

**HUMAN ADVERSE REACTION:** A reaction which is noxious and unintended and which occurs in a human being following exposure to a veterinary medicinal product marketed by DVS.

**PHARMACOVIGILANCE DATA:** Any original information obtained from the primary reporter for the first time related to the administration of one or more DVS marketed veterinary medicinal products at a certain time point.

**PRIMARY REPORTER:** Any living identifiable individual reporting the original information to DVS for the first time related to the administration of one or more DVS marketed veterinary medicinal products at a certain time point. Primary reporter can be a Veterinarian, Farmer, Animal Owner, Medical Doctor or Healthcare Practitioner and will be stated as “you” and “your” in this website version of policy.

### **Scope**

The scope of this website version of the policy applies to DVS marketed product related information collected from you by phone, fax, email, post or *in person* by our Sales Representative(s).

If you are an animal owner or suffering from human adverse reaction, your Veterinarian/Medical Doctor/Healthcare Practitioner/others can also report us any suspected adverse event affecting your animal or you.

### **Specific information we need to collect from you**

When you call our staff at DVS to report a complaint, we need to collect specific information from you in order to meet our legal pharmacovigilance obligations. Under the pharmacovigilance law, we need to collect detailed information on every suspected adverse event reported to DVS. The information reported will be communicated to the Marketing Authorisation Holder(s) and other Licensing Partners in order to investigate, evaluate, validate and collate with any other product related suspected adverse events. The information we need to collect from you is as follows:

- **Contact details:** You need to provide your contact details which include name, address, phone number and email address. We need to record your contact details to meet our obligations under the pharmacovigilance regulations which require each suspected adverse event to be detectable and available for follow-up, if required.
- **Relationship:** We need to know your relationship with the affected animal or human. Please specify if you are a Veterinarian, Distributor, Farmer, Animal Owner, Healthcare Practitioner, Medical Doctor or other.
- **Product Details:** You need to provide the details of the veterinary medicinal product which caused the suspected adverse event. The details include name of the product, batch number, expiry date, date of opening, dose administered, reason for administration and the name of the person who administered the product.
- **Details of affected animals or human:** You need to provide details of the affected animals including species, breed, age, sex, number of animals treated, number of animals affected and treatment details. If there is an adverse event associated with the person who administered the product, then provide details of the patient including age, sex, occupation/status and contact details of the Medical Doctor, if consulted.
- **Suspected adverse event details:** You need to provide details of the suspected adverse event in the affected animals or humans, any prescribed treatment and outcome of the reaction.

- Other treatment details: You need to inform us about the details of other medicines the affected animal or human is receiving at the time of the reaction. We also need to know about the dose, duration and reason for the treatment.
- Description of suspected adverse event: You need to provide an accurate description of the suspected adverse event incidence.
- Animal/Medical history: You need to provide details of any relevant previous animal/patient history.

We advise you to report us any suspected adverse event immediately after its occurrence. You can observe suspected adverse event in one of the following situations:

- Adverse reactions in the treated animal(s) after recommended use of the product
- Adverse reactions in the treated animal(s) after off-label use, *i.e.* non-recommended usage of the product
- Suspected lack of expected efficacy, *i.e.* inability of the product to work as per intended use
- Adverse reaction in humans after exposure to the product
- Validity of the withdrawal period, *i.e.* detection of residues of the veterinary medicinal product in tissues or food products of treated food producing animals
- Potential environmental problems

### **Processing and communication of information**

Pharmacovigilance laws require us to process and communicate your information to the Marketing Authorisation Holder(s) and other Licensing Partners in order to:

- Investigate and evaluate the suspected adverse event
- Follow up with you for any additional information
- Validate the information about the suspected adverse event
- Report the adverse event to the Competent Authorities

### **Pharmacovigilance Database**

Pharmacovigilance laws require us to maintain a database of all suspected adverse event reports received for our marketed products. The reports stored in our database are shared with the Marketing Authorisation Holder(s) and other Licensing Partners. The information recorded in the reports is uploaded to the Eudravigilance Veterinary database. If your contact detail is changed, you can inform us by email: [info@dugganvet.ie](mailto:info@dugganvet.ie) or phone: 00353 504 43169. You need to provide an appropriate identification before we can make any change(s) in your contact details. Our pharmacovigilance obligations restrict us from making any changes in the information collected in the suspected adverse event report.

### **Contact details**

If you have any questions, please email us at [info@dugganvet.ie](mailto:info@dugganvet.ie). We will make all possible efforts to answer your questions within a reasonable time frame.