INTERIM NOTIFICATION PROGRAM

LOW RISK VETERINARY HEALTH PRODUCTS

ADVERSE EVENT REPORTING

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1.0 Purpose

This document is intended to provide guidance on the requirements for Adverse Event Reporting for notified Low-Risk Veterinary Health Products (LRVHPs).

2.0 Definitions

An ‘‘adverse event’’ is any observation in animals, whether or not considered to be product-related, that is unfavourable and unintended and that occurs after any use of LRVHP (off-label and on-label uses). Included are reactions in humans occurring after unintended exposure (e.g. accidental ingestion.)

A ‘‘serious adverse event’’ is any adverse event which results in death, is life-threatening, results in persistent or significant disability/incapacity, congenital anomaly or birth defect.

For animals managed and treated as a group, only an increased incidence of serious adverse events as defined above exceeding the rates normally expected in that particular group is considered a serious adverse event.

3.0 Requirements

3.1 Serious Adverse events

A Notifier or Canadian Representative (if the Notifier is located outside Canada) must report to the Third Party Administrator (https://www.lrvhp.ca/) (or alternatively directly to Health Canada at http://www.hc-sc.gc.ca/dhp-mps/vet/applic-demande/form/dar-rim_form_cp-pc-eng.php) all information in respect of any serious adverse event that has occurred either in Canada or internationally with respect to the LRVHP, within 15 calendar days of receiving the information.

3.2 All adverse events

All Adverse Events reported to the product Notifier or Canadian Representative (if the Notifier is located outside Canada) are to be recorded, maintained and kept on file by the Notifier or the Canadian representative. Records of all individual Adverse Events Reports (AERs)s, annual summary reports that includes the number of units/doses

shipped or sold, should be easily accessible to Health Canada upon request. This information should be provided within 72 hours of the date of the request.

3.3 Summary reports

While non-serious AERs do not need to be reported to the Administrator or Health Canada on a routine basis, the Notifier or the Canadian Representative may be required to submit the following information to Health Canada if Health Canada has reasonable grounds to believe that the LRVHP has an unfavourable risk-benefit profile when used under the recommended conditions of use:

> (a) within 72 hours, a copy of one or more past annual AER summary reports, containing a concise and critical analysis of all adverse reactions related to the LRVHP that have occurred inside Canada and any known serious AERs that have occurred internationally;
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> (b) within 30 calendar days after the day on which the request is received, an interim summary report containing a concise and critical analysis of all adverse reactions related to the LRVHP that have occurred inside Canada and any known serious AERs that have occurred internationally so far in the current year or for a period of time that will be specified by Health Canada.