POSITION STATEMENT

ANIMAL HEALTH PRODUCTS SUPPORT ANIMAL WELFARE – A KEY FACTOR IN PRODUCT RESEARCH, DEVELOPMENT AND POST-APPROVAL MONITORING PROGRAMS

March 22, 2017

Animal health companies respect animals and are dedicated to safeguarding good animal health and welfare. We work with pet owners, farmers and veterinarians to empower them to make informed decisions regarding the care of their animals. Animal health and welfare are primary considerations in all animal health product research and development, as well as in post-approval monitoring programs.

All drugs, including vaccines, are authorized on the basis that they will benefit animal health and efficiency and support animal welfare. As required, animals may be used in animal health product development following rigidly controlled standards for animal ethics and care which are developed by the Canadian Council on Animal Care. The welfare of animals is overseen by veterinarians throughout the drug development stage, is considered in the approval process, and also is a part of post-approval monitoring of the safety and efficacy of animal health products. The Canadian Animal Health Institute (CAHI) and its members strongly support these processes as an integral part of responsible product development and sale.

The review and approval of animal health products are based on scientific and regulatory technical requirements involving safety to humans and animals, effectiveness, and effect on the environment. Food products from treated animals must also be demonstrated to be safe for human consumption. In Canada, animal health products are reviewed and approved by one of the following:

- Pharmaceuticals – the Veterinary Drug Directorate (VDD) at Health Canada;
- Vaccines – the Canadian Center for Veterinary Biologics (CCVB) at the Canadian Food Inspection Agency; and
- Topical (on-animal) pesticides – the Pest Management Regulatory Agency (PMRA) at Health Canada.

Canada has rigorous pre and post-marketing assessment and monitoring programs, which include the impact of a drug on animal welfare. After a drug has been approved by the VDD or CCVB, companies participate in pharmacovigilance, also known as post-market surveillance. Pre and post-marking assessments are designed to protect both human and animal health and welfare for the entire life cycle of a product.

As a part of continuous improvement and our dedication to animal care, we are active in the VICH process, which is an international program involving the European Union, Canada, USA, Japan, Australia, New Zealand, and South Africa. One of its objectives is to establish and implement harmonized requirements for the registration of veterinary medicinal products including a commitment to minimize the use of test animals. This goes beyond typical animal welfare values to replace, reduce and refine procedures where animals are used in research.

CAHI and its members work with veterinarians, animal owners, federal and provincial governments, and special interest groups to support responsible animal health product use, from product development to approval and sale to the end user.

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Glossary:

An **Adverse Drug Reaction** is an unintended reaction to a drug at doses that are recommended and on-label.

Animal Health Products include pharmaceuticals, vaccines, and feed additives and are used to keep animals healthy and productive. They include medicines like anti-inflammatories, anesthetics, biologicals, pesticides and antibiotics. They may be given to an animal by mouth (e.g. feed, water), injection or topically. For more information about animal health products please visit the Health for Animals website.

Animal Welfare means how an animal is coping with the conditions in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress. (OIE, Terrestrial Animal Health Code, Chapter 7)

Pharmacovigilance means the reporting and/or post-market surveillance to monitor the safety and effectiveness of veterinary drugs (animal health products). Canada's *Food and Drugs Act and Regulations* require manufacturers to report suspected adverse reactions to an animal health product to Health Canada's Veterinary Drugs Directorate. Veterinarians are encouraged to also report these incidences to VDD, but are under no legal obligation to do so.

Pre and Post-Market Surveillance is an integrated set of activities for the monitoring, assessment (evaluation), and risk management of health products. It is also a continuation of the regulated health product review process initiated in the pre-approval stages of product development. Post-market surveillance includes:

- Adverse reaction reports are received and assessed by Health Canada.
- Additional information is gathered from literature scans, other regulatory agencies, the World Health Organization, and health product manufacturers.
- New risks are detected with increased use of products in the marketplace.

Additional Resources:

Once animal health products are in the Canadian marketplace, the monitoring of these products follow guidelines established and administered by Health Canada and the Canadian Food Inspection Agency.

- Canadian Food Inspection Agency, Meat Hygiene Manual of Procedures, Chapter 5 Sampling and Testing
  http://www.inspection.gc.ca/food/meat-and-poultry-products/manual-of-procedures/chapter-5/eng/1395150894222/1395150895519?chap=2
- Health Canada, Drugs and Health Products, Adverse Drug Reactions (Pharmacovigilance)
  http://www.hc-sc.gc.ca/dhp-mps/vet/advers-react-neg/index-eng.php
- Health Canada, Drugs and Health Products, For Your Information: Pharmacovigilance
  http://www.hc-sc.gc.ca/dhp-mps/vet/advers-react-neg/adr-rim_fyi-pvi-eng.php
- Health Canada, Drugs and Health Products, The Post-Market Surveillance Continuum - Maximizing Safety, Minimizing Risk
  http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_fs-if/2008-pmsc-csamm-max/index-eng.php