INTERIM NOTIFICATION PROGRAM

LOW RISK VETERINARY HEALTH PRODUCTS

OVERVIEW

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1.0 Purpose

The purpose of this document is to provide an overview of the Interim Notification Program (INP) for Low Risk Veterinary Health Products (LRVHPs).

2.0 Background

Health Canada considers the INP to be a temporary measure pending the new veterinary drug framework to improve the regulation of LRVHPs.

This INP allows for LRVHPs to obtain a Notification Number, if certain conditions have been met. The Notification is valid for one year and can be renewed using a simplified procedure. Participation in the INP is voluntary and industry members may instead prefer to obtain a Notice of Compliance (NOC) and Drug Identification Number (DIN) through the normal regulatory process. The INP is accessible to all individuals or companies that want to sell a LRVHP in Canada. The Notification process is administered by the Program Administrator, operating independently of Health Canada. The role of the Program Administrator is to process the notification applications to ensure that products notified under the INP meet the conditions established by Health Canada, and issue a unique product specific Notification Number (NN). The Program Administrator will recover costs by charging fees for new Notifications, Annual renewals and amendments.

Given the INP safeguards, Health Canada considers it unlikely that a product satisfying all applicable requirements could present a significant risk to the health of humans or animals. Consequently, in the case of a product that meets all conditions of the INP and has been assigned a notification number by the independent Program Administrator, Health Canada would not prioritize the enforcement of the regulatory requirements related to the importation, manufacture, or sale of those veterinary drugs notified within the program and would not normally seek to prevent the importation, manufacture, or sale of such a product, unless a health risk is identified.

Health Canada may take enforcement action should it have reasons to believe that a product is not compliant with the requirements of the INP, is unsafe or causes the public to be deceived.

The issuance of a Notification number does not exempt any product from the application of legislation administered by other entities such as the Canadian Food Inspection Agency (CFIA), the Pest Management Regulatory Agency (PMRA) or other government regulatory authorities. For example, if the product includes animal derived ingredients, it may be subject to the importation requirements of the *Health of Animals Act*. The Notifier is responsible for ensuring compliance with applicable legislation.

3.0 Scope

The INP originally applied to LRVHPs for sale in Canada that are for use in cats, dogs, and horses that are not intended for food. LRVHPs may only contain admissible substances that are found on the *List of Substances* including homeopathic medicines, botanicals, vitamins, minerals, fungi, bacteria, etc. Pet food products, dewormers, insect repellents, shampoos and veterinary health products intended for food-producing animals, such as beef cattle, swine and poultry are not covered under the INP.

The scope has been expanded to a limited group of LRVHPs including oral Calcium supplements and udder creams and lotions for dairy cattle only. These products present minimal risk to animals and food safety and are important tools to maintain animal health and welfare.

4.0 Definitions

Notifier:
The Notifier is the person, including an association or partnership, who under their own name, or under a trade-, design- or word mark, trade name or other name, word or mark controlled by them, interested in importing or manufacturing a LRVHP for sale in Canada. The Notifier does not need to be the actual fabricator. The Notification number is issued to the Notifier. The Notifier is responsible to ensure that all the conditions of the INP are met and must have systems in place to be able to effect a recall or take corrective action in a timely manner, as well as collection all adverse events and reporting serious adverse events. If the Notifier is not located in Canada, a person in Canada must be designated as a Canadian Representative.

Canadian Representative:
A Canadian Representative must be designated when the Notifier is not located in Canada. There can only be one Canadian representative for each product. The Canadian Representative is responsible for ensuring the product meets the requirements of the INP and must have systems in place to be able to affect a recall or take corrective action in a timely manner, as well as collection all adverse events and reporting serious adverse events.

Low-Risk Veterinary Health Product (LRVHP):
A product that meets the requirements of the Notification Program (see section 6 below).

Notification Form:
The application form submitted to the Program Administrator in order to obtain a Notification Number for a LRVHP.

Notification Number:

A number that is issued for a Low Risk Veterinary Health Product by the Program Administrator after the Program Administrator has ensured that the product meets all the requirements under the INP.

Notified product:

A Low Risk Veterinary Health Product that has received a Notification Number which has not been suspended or otherwise rendered invalid. The Notified Product has met the conditions of the INP by completing the application process.

Notified Product List
A list of Notified products maintained by the Program Administrator and made available to the public.

Marketed Product:
A product that is available for sale in Canada.

Program Administrator:
An administrative entity that is independent of Health Canada and industry participants and that issues a Notification number for a veterinary health product after ensuring that products meet the requirements of the INP as established by Health Canada.

List of Substances (admissible and non-admissible)
This list was developed by Health Canada, and is updated periodically.

> **Admissible Substances:**
> A list of substances including active (medicinal) and non-active (excipients or non-medicinal) ingredients considered low risk. Low risk status is valid only when certain conditions are complied with, such as specific route of administration, target species, limitations, cautions, and/ or contraindications, as indicated on the list. Substances on this list are not expected to present a significant risk to humans or animals.
>
> **Non Admissible Substances:**
> List of Substances determined to present an unacceptable health risk and/or requiring a higher level of oversight when administered to animals. Substances on this list may have the potential risk of causing irreversible damage, potentially lethal, toxicity to major organs, carcinogenic activity, teratogenic activity or abortifacient activity. Also, they may have a narrow margin of safety or a significant likelihood of contamination, adulteration, and/or substitution.

5.0 Identification of a Notified Product

When a Notification Number is issued for a LRVHP, the Notifier must display it on the marketed product label. However, there may be cases where the product has been labelled prior to the issuance of a Notification Number. In such a case, the label should be updated within a maximum period of six (6) months after a notification number is issued, unless otherwise recommended by Health Canada. A *Notified Products List*, which is publically available and maintained by the Program Administrator, lists all products with a valid Notification Number. This list should be consulted to verify if a product has been issued a Notification Number.

6.0 Requirements under the Interim Notification Program

6.1 Product Notification Criteria

Products eligible for Notification must meet the requirements of the INP including:

- The product is for use in dogs, cats, or horses that are not intended for food, as well as dairy cattle (i.e., oral Calcium supplements and udder creams and lotions).
- All ingredients are listed in and meet the conditions of admissible substances in the *List of Substances* established by Health Canada.
- With respect to horses and dairy cattle, the product is not to be mixed with feeds by a feed manufacturer in circumstances where the *Feeds Regulations* would apply.
- If the product is intended for horses, the label will state either "*Do not use in horses intended for food*" or "*Do not use in horses intended for food as a withdrawal period has not been established*".
- There is objective and credible evidence demonstrating that the product is safe.
- There is objective and credible evidence to support a reasonable expectation of effectiveness when the product is used as intended.
- Product labeling information and any other information supplied to the users will match the information provided on the notification form (e.g. health claims) and comply with the conditions of admissible substances (e.g. contraindications, cautions and warnings).
- Either the Notifier or the Canadian Representative, if applicable, will inform the Program Administrator of any change concerning the information provided in the Notification Form or of any change that would relate to any of the above.
- All the conditions of the Interim Notification Program are met;
- All information presented in the Notification Form is true and correct.

6.2 Products not eligible for Notification

Veterinary health products that meet any of these exclusion criteria listed below are not eligible for a Notification Number as these types of products require a higher level of oversight with respect to safety, efficacy and quality assessment.

6.2.1 Products delivered through the following **routes of administration** are not eligible for the program:

- Implants;
- Injectable;
- Inhalation;
- Intra-mammary;
- Intra-uterine;
- Ophthalmic; and
- Transdermal patches.

6.2.2 The following **product types** are not eligible for the program:

- Antibiotics and hormones, except for plants and whole herb extracts with antimicrobial or mild hormonal activity;
- General anesthetics-drug involving loss of consciousness; and
- Tranquilizers, except for products having mild calming effects.

6.2.3 The following **designated substances** are not eligible to the program:

- Radiopharmaceuticals listed in Schedule C of the *Food and Drugs Act*;
- Substances listed on Schedule I to V of the *Controlled Drugs and Substances Act*;
- Substances listed in the Prescription Drug List (for veterinary use) are not eligible for the program, except for:
  - Products prepared according to the *Homeopathic Pharmacopoeia of the United States (HPUS)*, the *Homöopathische Arzneibuch (HAB)*, the *Pharmacopée française (PhF)*, the *European Pharmacopoeia (Ph.Eur)* or the *Encyclopedia of Homeopathic Pharmacopoeia (EHP).* The potency should be at or above one of the following: The OTC limit in the *HPUS* monograph; 4D in the *HAB* monograph, and 12 CH for the remaining accepted Pharmacopoeias if no minimum potency is identified and for *Aristolochia spp.* and *Asarum spp.*);

- Veterinary biological products such as vaccines, except for:
  - Products prepared according to the *Homeopathic Pharmacopoeia of the United States (HPUS)*, the *Homöopathische Arzneibuch (HAB)*, the *Pharmacopée française (PhF)*, the *European Pharmacopoeia (Ph.Eur)* or the *Encyclopedia of Homeopathic Pharmacopoeia (EHP)*. The potency should be at or above one of the following: The OTC limit in the *HPUS* monograph; 4D in the *HAB* monograph, and 12 CH for the remaining accepted Pharmacopoeias if no minimum potency is identified and for *Aristolochia spp.* and *Asarum spp.*;
  - Products prepared from or produced by algae, bacteria or fungi on the condition that no genetically modified microorganisms or their recombinant genes (if applicable) are present in the finished product; and
  - Colostrum when intended as a source of nutrition and not for the provision of antibodies against infectious disease.
- Specified risk materials (SRMs) i.e. the skull, brain, trigeminal ganglia (nerves attached to the brain), eyes, tonsils, spinal cord and dorsal root ganglia (nerves attached to the spinal cord) of cattle aged 30 months or older; the distal ileum of cattle of all ages. This does not apply to material originating from a country that is designated as being free from Bovine Spongiform Encephalopathy (BSE) in accordance with the *Health of Animals Regulations*.

6.2.4 Homeopathic and Traditional Chinese Medicine **Combination Products**

Products that are prepared with acceptable homeopathic ingredients or products containing acceptable Traditional Chinese Medicine (TCM) ingredients will be excluded from the program when they are combined with other types of ingredients, such as vitamins or western herbs, which are not established within the same healing paradigm.

6.2.5 Products that contain a **claim relating to the treatment, prevention or cure of any disease or disorder**

Only products with general health claims are eligible for Notification under the INP. Specific therapeutic claims (claims to diagnose, prevent, treat, or cure a disease or abnormal physiological condition) are not allowed. For example, a product could carry the claim that it "may help in the improvement of joint health and function," but not that it is "for the treatment of osteoarthritis". See the Claims Guidance for more details.

6.3 Requirements to Report Recalls and Adverse Events

A post-market surveillance program must be established by the Notifier and adverse events must be recorded and reported in accordance with the Adverse Event Reporting guidelines.

All product recalls are to be reported to the Health Products and Food Branch Inspectorate. Further information can be found in the Inspectorate's Recall Policy (POL-0016) at the following URL: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php .

6.4 Requirements for Manufacturing Practices and Quality Control systems

The manufacturing practices and quality control systems used to manufacture, package, label, distribute and store this product must comply with the Good Manufacturing Practices requirements described in the GMP Guidance Document. These requirements are similar to those applicable to Natural Health Products used in humans.

If the veterinary health product will be imported, the Canadian representative must attest that the manufacturing practices and quality control systems outside Canada comply with the above requirements.

6.5 Labeling Requirements of a Notified Product

Labeling must comply with the requirements as described in the Labeling Guidance Document and will appear in the two official languages, English and French.

If the product is to be used on horses, the label will state "Do not use in horses intended for food" or "Do not use in horses intended for food as a withdrawal period has not been established".

All notified products will have a Notification number on their label. In cases of uncertainty, the *Notified Products List* should be consulted.
Once a notification number is issued, the label should be updated within a maximum period of six (6) months after the Notification Number has been issued unless otherwise recommended by Health Canada.

6.6 Change to a Notified Product

Should the Notification number holder wish to make changes to the Notified product, the Program Administrator should be contacted. Amendment Fee chart

These changes may include but are not limited to:

- The company information
- The manufacturing information
- The addition, substitution or removal of a non-medicinal ingredient (excipient)
- The brand name of the product
- The common or proper name of the active ingredients
- The change of safety information
- Changes to the recommended dose, duration or recommended use or purpose
- Deletion or modification of risk information
- A change to the source material or potency of any active ingredient

These changes may have an impact on the safety, efficacy or quality profile of the product and may significantly impact the assessment of information for which the Notification number was issued.

7.0 Compliance and Enforcement Approach under the INP

Given the INP safeguards, Health Canada considers it unlikely that a product satisfying all applicable requirements could present a significant risk to the health of humans or animals. Consequently, in the case of a product that meets all conditions of the INP and has been assigned a notification number by the independent Program Administrator, Health Canada would not prioritize the enforcement of the regulatory requirements related to the importation, manufacture, or sale of those veterinary drugs notified within the program and would not normally seek to prevent the importation, manufacture or sale of such a product, unless a health risk is identified.

Health Canada may take enforcement action should it have reasons to believe that a notified product is not compliant with the requirements of the INP, is unsafe or causes the public to be deceived. These actions are outlined in Health Canada's Compliance and Enforcement Policy (POL_001) which is available at the following website: **http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php**

7.1 Notified Products being advertised, labeled, or sold in a false or misleading manner

The labeling, sale or advertising of any veterinary product must be done in a manner that is not false, misleading or likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. A product that is being labeled sold or advertised in a manner consistent with that product's Notification Form would not generally be false or misleading or likely to create an erroneous impression with respect to its character, value, quantity, composition, merit or safety. Any products or advertising

materials brought to the attention of Health Canada will be evaluated and may be subject to compliance and enforcement actions in accordance with section 9 of the *Food and Drugs Act*. A product may be subject to compliance and enforcement actions if the product being marketed differs from the Notification Form for which a Notification number was issued.

Contact

To apply for a Notification Number please go to www.lrvhp.ca

For further inquiries regarding the Interim Notification Program, please contact the Program Administrator:

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