

Fact Sheet: Veterinary Natural Health Products and CQM

Introduction:

The Canadian Quality Milk (CQM) program is aware of the use of veterinary Natural Health Products (vNHPs) for cattle; however, the CQM program does not have the authority to address the acceptability of products, and must, therefore, rely on the regulatory authorities, the Veterinary Drugs Directorate (VDD), for this information.

The Natural Health Products Division at Health Canada is responsible for approving Human Natural Health Products, which are regulated under the Natural Health Products Regulations. vNHPs used on animals are currently regulated under the *Food and Drugs Regulations*, and the VDD is responsible for approving them. However, most vNHPs have not been approved, as the current regulatory process is difficult to apply to them.

The VDD is developing a new regulatory framework for vNHPs, based on risk assessment, which should ensure a more appropriate approval process for vNHPs. The VDD has a fact sheet on vNHPs on its website (Click on "Veterinary Drugs" and then "Factsheets & FAQ").

CQM Requirements:

The CQM program has two main requirements for the application of medications and chemicals used on animals, which includes vNHPs:

1. Livestock medicines (including medicated foot-baths) must be approved in Canada for use in cattle. The CQM program also accepts the use of products listed in **Section 5** of the Permitted Substances Lists for Livestock Production (CAN/CGSB-32.311-2006) according to the specifications indicated, and the use of veterinary Natural Health Products (vNHPs) as listed on the list of Animal Health Care Products and Production Aids.
2. Livestock medicines must be used according to the label or according to written instructions from a veterinarian.

The Issue:

The primary goal of the CQM program is to ensure that producers are producing safe milk and meat. The program requirements are designed to ensure that producers use products in a manner that will not compromise food safety for the milk or meat their cattle are producing.

Many vNHPs have not been approved by the VDD yet. If they are not approved by the VDD; they are not approved for use in cattle. Producers may make home-made products, such as tinctures; however, these products must be administered only topically or orally and their ingredients must be listed on the Permitted Substances Lists or the list of Animal Health Care Products and Production Aids to be acceptable. If they are not, producers must obtain veterinary prescriptions to use them. Veterinarians often cannot write a prescription for these products because they do not know what the active ingredients are, their toxicity levels, their efficacy or whether or not they pose a food safety risk.

Please note: The CQM program recognizes that the herd veterinarian has the professional expertise, access to information databases and knowledge of the particular farm situation that would permit him/her to determine the risks to food safety of using unapproved drugs. This does not mean that the CQM program expects veterinarians to provide prescriptions. Veterinarians have professional and legal obligations that restrict the situations where they can provide prescriptions. They must first be faithful to these requirements.

The main issue with vNHPs is that without regulatory approval or veterinary prescriptions, the CQM program does not know whether these products are safe for use in food producing animals through different routes of administration (e.g. intra-mammary, intra-muscular, etc).

Some products are used as feed or feed additives and not for medicinal purposes. To help determine when a feed or feed additive is not a medicine, please see the definitions for a drug, biologic, and feed/feed additive on the next pages.

The National Organic Standards:

The organic industry has developed the National Organic Standards which require that all inputs used in organic production (e.g. fertilizers, feeds, veterinary treatments, etc.) shall be approved by the appropriate government regulatory agency for the products' intended use, where regulations govern the use of such inputs (section 1.7). The National Organic Standards also prohibit the use of substances that are not included in the Permitted Substances Lists (published on the Canadian General Standards Board website (click on "Publications Source" and "Standards on the Net"))).

What is a veterinary Natural Health Product?

According to the Food and Drug Regulation, vNHPs are drugs. The VDD has drafted another definition for vNHPs, completed public consultation on the definition, and posted the "Consultation Summary Report on the Draft Definition of a Veterinary Natural Health Product" on the website (under "Consultations").

Approval Process Definitions

The current drug approval process recognizes or separates animal health products into three categories: drugs, biologics, and feeds/feed additives.

1) **Drug:** the definition for a drug in the Food and Drugs Act is:

"drug" includes any substance or mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) restoring, correcting or modifying organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept;

Note: The CQM Reference Manual refers to medicines, which is another word for drug.

2) **Biologic:** the definition of a veterinary biologic in the Health of Animals Act is:

"veterinary biologic" means

(a) a helminth, protozoa or micro-organism,

(b) a substance or mixture of substances derived from animals, helminths, protozoa or micro-organisms, or

(c) a substance of synthetic origin

that is manufactured, sold or represented for use in restoring, correcting or modifying organic functions in animals or for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in animals;

The CQM Reference Manual states that biologics are medicines obtained from animal or plant tissue. The biologics most commonly used on dairy farms are vaccines and immunoglobulin (antibody) preparations. The Canadian Food Inspection Agency's website also states that veterinary biologics include vaccines, bacterins, bacterin-toxoids, immunoglobulin products, diagnostics kits, and any veterinary biologic derived through biotechnology.

3) **Feed or feed additive:** the definition for a feed in the Feeds Act is:

"feed" means any substance or mixture of substances containing amino acids, anti-oxidants, carbohydrates, condiments, enzymes, fats, minerals, non-protein nitrogen products, proteins or vitamins, or pelletizing, colouring, foaming or flavouring agents and any other substance manufactured, sold or represented for use

(a) for consumption by livestock,

- (b) for providing the nutritional requirements of livestock, or
- (c) for the purpose of preventing or correcting nutritional disorders of livestock, or any substance for use in any such substance or mixture of substances;

Conclusion:

As long as a product is being used as a drug or a biologic (according to the definitions above), not as a feed or feed additive, the CQM program requires the following:

Dairy producers: consult with your veterinarian on any products that you are using as drugs (i.e. for medicinal purposes) that are not approved for use in dairy or that you are using extra label. Obtain a veterinary prescription for these products to ensure that you are following appropriate withdrawal times.

Products listed in **Section 5** of the Permitted Substances Lists for Livestock Production or vNHPs listed on the list of Animal Health Care Products and Production Aids can be used according to the specifications indicated. Any product used in a manner that is not described on the lists needs a veterinary prescription.

If your veterinarian cannot provide you with a prescription, talk to your veterinarian about an approved, on-label alternate treatment.

CQM Validators: all products being used as drugs should be used according to the label, the Permitted Substances Lists, the list of Animal Health Care Products and Production Aids or a veterinary prescription. Look for a DIN number to indicate VDD approval. Read the label to identify if the product is approved for use in cattle. Finally, check how the producer is using the product and ensure that it coincides either with the label, the Permitted Substances Lists, the list of Animal Health Care Products and Production Aids or a valid veterinary prescription.

Veterinarians: because of the lack of standards and lack of depletion information for vNHPs, the Canadian gFARAD cannot give specific withdrawal information regarding the use of such products. Because they are not approved products, requests cannot be submitted through the CgFARAD website but veterinarians can contact CgFARAD at 306-966-2543.

Who can I contact for more information?

1. Your provincial producer association and Provincial Coordinator
2. Visit: www.dairyfarmers.org/cqm