

CAHI CODE OF MARKETING PRACTICE

INTRODUCTION

The Canadian Animal Health Institute (CAHI) is the trade association representing companies that develop, manufacture, and distribute pharmaceuticals, biologicals, feed additives, animal pesticides, and veterinary health products. Membership includes the major firms that collectively manufacture approximately 95 percent of all animal health products marketed in Canada thus providing a significant contribution to our economy. Associate members include representatives of allied industries, media and other interested groups. CAHI member business activities are part of a dynamic and diverse marketplace that is highly competitive. The CODE OF MARKETING PRACTICE is not intended to restrict competition.

Our mission is to meet the needs of Canadian animal agriculture, to ensure the Canadian public of a safe and wholesome food supply, and to help maintain the health of our nation's companion animal population.

It is the CAHI's policy that high ethical standards be the cornerstone of all our business activities. Holding our members accountable and responsible to a high standard of ethics may be our best strategy to ensure the orderly marketing and correct usage of our products in the marketplace.

An objective of the CAHI is to provide a "CODE OF MARKETING PRACTICE" by which members should conduct daily business that results in activities leading to increased value, today and in the future, for our stakeholders. We recognize our stakeholders to include animal health care professionals, the public, customers, employees, shareholders, animals and their owners.

The **CODE** emphasizes the importance in the public interest of providing accurate, fair and objective information on animal health products so that rational decisions for prescribing and use can be made.

This Code is consistent with the following Acts: [Food & Drugs Act](#) & [Regulations](#), [Health of Animals Act](#), [Pest Control Products Act](#), and the [Competition Act](#).

The **CODE** represents an act of self-discipline. Acceptance and observance of its provisions are a condition of membership in the CAHI. Member companies also acknowledge that the **CODE** itself is to be applied in the spirit as well as in the letter.

In order to widely disseminate the information contained in this **CODE** to members of the veterinary profession and to ensure that its provisions become better known, a link to the **CODE** is posted in the online Compendium of Veterinary Products and on the [CAHI website](#).

The CAHI urges its member and associate member companies to publicly affirm their respective corporate commitment to the principles and the obligations of the animal health industry as outlined in this CODE OF MARKETING PRACTICE.

1. GUIDING PRINCIPLES

The CAHI recognizes that sound animal health management is fundamental to production efficiency, and helps maintain the international competitiveness of Canadian agriculture. Keeping animals healthy is the reason for the animal health industry's existence, and is the underlying goal of all industry activities.

1.1 The health and well-being of animals and all Canadians is our first priority.

- 1.2 All interaction with animal health care professionals is to be conducted in a highly professional, business like, and ethical manner.
- 1.3 All product information provided to animal health care professionals and animal owners must be accurate and fair.
- 1.4 Clinical trials are developed to further science, support product label claims and prudent use
- 1.5 Prescription antimicrobials must be sold on their own merit with the intent that prescribing is under the full control of the veterinarian.
- 1.6 All Full and Associate Members marketing product must adhere to the **Code** and its intent as a condition of membership.

Recognizing that its animal health products have been, and will continue to be, an important factor in modern animal care practice, the industry undertakes:

- 1.7 To provide animal health products that conform to the highest standards of safety, quality and efficacy as defined by appropriate Canadian regulatory authorities.
- 1.8 To ensure that animal health products are supported by comprehensive technical and information services in accordance with currently accepted medical and scientific knowledge and experience.
- 1.9 To use candour in dealing with animal health care professionals, public health officials, and the general public.

The industry is committed to the prudent use of animal health products by an informed public, and urges that its products be used only in accordance with the label directions and/or directions of animal health care professionals.

All companies that are engaged in animal care marketing but are not members of the CAHI are also urged to adhere to this **CODE** to ensure the good health and best interest of the Canadian public and their animals.

2. DEFINITIONS

- 2.1 The term "**Promotion**" means all marketing activities, coming under the control of the manufacturer and/or distributor, which are for the purpose of encouraging the prescribing or use of a manufacturer's products, including but not limited to the activities of representatives, various aspects of sales promotion such as journal and direct mail advertising; the use of films and other audio-visual material, websites and all digital media as well as exhibitions; and the provision of samples and gifts.
- 2.2 The term "**Animal Health Products**" means any product intended for and labelled for use in animal care and/or production. This includes innovative or generic products that are approved for use under the [Food and Drugs Act](#) and [Regulations, Health of Animals Act, Pest Control Products Act](#) and the [Feeds Act](#).
- 2.3 The term "**Animal Health Care Professionals**" includes Veterinarians, Agrologists, Animal Health Technicians, Nutritionists, and others who provide animal health care services.
- 2.4 The term "**Prescribing Information**" includes the following; indications, contra indications, dosage, cautions, warnings, and withdrawals.
- 2.5 The term "**Promotional Material**" includes various aspects of sales promotion including information provided in journal and direct mail advertising; the use of films and other audio-visual material, websites and all other digital media as well as exhibitions, and the provision of samples and gifts.

- 2.6 The term “**Market Research**” means information that points out and defines marketing opportunities and problems; information that generates, refines, and evaluates marketing programs; information that monitors marketing performance; and information that improves understanding of marketing as a process. Market research details the information needed to address these issues, designs the method for collecting information, manages and implements the data collection process, analyzes the results, and communicates the findings and their implications. It is carried out within the framework of various forums including studies, individual and group interviews, and focus groups etc.
- 2.7 The term “**Direct To Consumer Advertising**” refers to any advertising directed to the lay public.

3. ADVERTISING AND INFORMATION DISSEMINATION

3.1 Advertising

The guidelines for advertising are:

- a) Animal Health Drugs
Guideline for Advertising of Drugs for Veterinary Use ([Appendix I](#))
Issued by: Veterinary Drugs Directorate
Health Products and Food Branch
Health Canada
- b) Veterinary Biological Products
Guideline for Advertising of Veterinary Biologics ([Appendix II](#))
Issued by: Canadian Food Inspection Agency
Canadian Centre for Veterinary Biologics
Animal Health Division
- c) Animal Health Pesticides
Guideline for Advertising of Animal Pesticide Products Marketed by CAHI Member Companies ([Appendix III](#))
Issued by: Canadian Animal Health Institute
- d) Veterinary Health Products
Guideline for Advertising of Veterinary Health Products ([Appendix IV](#))
- e) [Competition Act](#) –
[Ensuring Truth in Advertising](#)

CAHI members should comply with the above guidelines for all animal health product advertising and promotion, including Direct to Consumer Advertising (DTCA). Prescription drugs cannot be advertised to the general public except for name, price and quantity. Advertising of non-prescription drugs should follow the [Guidelines for Consumer Advertising of Consumer Health Products](#).

CAHI members should be aware of the regulatory requirements DTCA of prescription animal drugs under the Food and Drugs Act and Regulations, as well as potential enforcement actions that could be taken by Health Canada. More information about DTCA:

- Refer to the Health Canada letter to CAHI regarding DTCA of prescription veterinary drugs ([Appendix V](#)).
- Health Canada’s policy entitled The Distinction Between Advertising and Other Activities:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/policies-guidance-documents/policy-distinction-between-advertising-activities.html>

It is the intent of the Code that no animal health product shall be advertised in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. All animal health product advertising and promotion should be managed as per the three-phase complaint process identified in [Section 10: COMPLAINT RESOLUTION PROCESS](#) of the Code.

3.2 New Product Information

At any public relations event to announce a new product, a new indication for an existing product or new scientific findings, members must ensure that all of the facts given to the media are correct and objective.

3.3 Nature and Availability of Information

- 3.3.1 Upon reasonable request, members shall promptly provide animal health care professionals and the public with appropriate information about the animal health products, which they market. In the case of economic analysis, companies will promptly provide assumptions made in the analysis.
- 3.3.2 Information provided about animal health products should reflect current knowledge or responsible opinion.
- 3.3.3 Information provided about animal health products must be accurate, balanced and must not mislead, either directly or by implication, so that critical unbiased judgements and decisions can be made.

Explanatory Notes:

Reference to peer reviewed published articles, data presented as a poster during an international meeting and studies used in support of marketing authorization are permitted in promotional materials.

Where promotional material refers to supporting information, such information must be available on request, or a clear reference must be given to where it can be found. The phrase 'Data on File' should not be used as reference unless a company is willing to share the data upon request. Comparative data and references to published information, regardless if it is a section of a dossier or from an external source, should also be provided. When comparative data is presented to other company products, such information must be available upon request, whether it is an internal study, a poster or an article as described above. A clear reference as to where it may be found must be provided. Non-comparative study data remains proprietary.

Trials conducted post-marketing authorization which are used to promote a product must be of the highest standard where by:

- Products compared must have the same use;
- Comparisons must be done under the same conditions of use in a similar population;
- The claim cannot conflict with the marketing authorization;
- The claim must be conclusive and based on relevant data, current scientific standards using established research methodologies and endpoints as well as statistical analysis; and,
- The compared drug cannot be disparaged in any way.

- 3.3.4 All members shall have a SOP (Standard Operating Procedure) in place addressing

dissemination of extra-label information by itself and/or its representatives. This SOP shall be consistent with this Marketing Code of Practice, the Food and Drugs Act and Regulations and any other applicable legislation. ([Appendix VI](#))

- 3.3.5 Promotional materials prepared and distributed by the member company and its employees or agents shall not present information or claims that are at variance with those contained in the approved label.

Explanatory Notes:

Promotion materials include product information on websites. Website information is subject to the same scrutiny as other forms of advertising or promotion. It is the responsibility of the Canadian animal health company to ensure Canadian websites are up-to-date.

Non-therapeutic product claims such as syringe-ability and cost effectiveness require support from adequate, unbiased and statistically valid data in promotions.

- 3.3.6 The products or services of other companies must not be disparaged either directly or by implication.
- 3.3.7 The clinical and scientific opinions of members of the veterinary and associated animal health professions must not be disparaged either directly or by implication.

3.4 Signing of Promotional Material by Veterinary/Medical/ Scientific Personnel

An individual's job title and company name must be disclosed on signed promotional material such that use of a title or degree would not lend undue credibility to "promotional material." "Promotional materials" are communications where the intent is the commercial promotion of animal health products to animal care professionals and the public.

4. SAMPLE DISTRIBUTION

- 4.1 Member sampling policy must comply with applicable Federal (Section 14 of the Food and Drugs Act and Regulations) and Provincial regulation.
- 4.2 Samples of drug products (DIN) shall only be given to licensed veterinarians and/or pharmacists who have filled out a request form for the sample. (See Section C.01.048 and C.01.049 of the Food and Drugs Act and Regulations for prescribed conditions for the distribution of samples.)
- 4.3 Advertising for drug sampling is unacceptable and thus advertisements must not include offers for samples to the general public.

5. CONVENTION / CLINIC DISPLAYS

The principal objective of the display shall be to disseminate accurate information concerning the properties of the products being displayed.

- 5.1 A convention/clinic display should be attended by at least one suitably qualified representative of the displaying company.
- 5.2 Promotional and educational materials prepared by the company and available at the display shall not present information or claims that are at variance with those contained in the approved label.
- 5.3 Reprints of scientific papers may be available at the display, provided they are reprinted verbatim.
- 5.4 Representatives attending a display shall abide by the standards specified in this **Code** for

Animal Health representatives.

- 5.5 Payment or donation for shelf space placement of point of purchase exhibits and/or veterinary waiting room displays is considered inappropriate.
- 5.6 Promotion of a drug and/or biologic at an international conference in Canada must be in accordance with [Appendix VII](#).

6. GIFTS

Gifts and hospitality must be nominal and must not bring discredit upon or reduce confidence in the industry.

Explanatory Notes:

Promotional items must reflect the spirit of the Code. Promotional items offered in advertisements must be related directly to the product or its use(s), or be of practical value to the health professional or pet owner. Such items must withstand professional and public scrutiny. Items intended for distribution to patients via a health professional must be useful as aids to patients' understanding of, or adaptation to, their condition(s) or for encouraging compliance with recommended therapy.

7. REPRESENTATIVES

Ideally, Member representatives should be graduates of universities or community colleges or hold a designation in the animal health care field.

Standards for Employment and Training

- 7.1 When a representative is hired, supervised training must be provided to enable the person to become familiar with and carry out their responsibilities. This training will require new employees to acquire both technical and scientific information on Member products, as well as knowledge of the ethical principles and standards of conduct set out in this **Code** (please refer to [Appendix IX](#) for a sample training procedure).
- 7.2 From time to time, Members shall conduct refresher courses for representatives. Members should also encourage all representatives to take courses of study and self-improvement.
- 7.3 Member representatives must display the highest professional and ethical standards at all times. This must be reflected in both their conduct and appearance. Representatives are expected to understand and abide by established codes of conduct and courtesy in veterinary clinics and wherever they may appear in a professional capacity.
- 7.4 Representatives must provide full and factual information on products, without misrepresentation or exaggeration. Representatives' statements must be accurate and complete; they should not be misleading, either directly or by implication. Their assertions must be scientific and should not vary in any way from the official product label and current Canadian veterinary thinking.
- 7.5 Under no circumstances shall Member representatives pay a fee in order to gain access to an animal health care professional.

8. PRICE RELATED MATTERS

All member companies must abide by Federal and Provincial laws and regulations relating to product pricing.

9. MARKET RESEARCH

General Principles

- 9.1 The purpose of an individual or group interview must be made clear to the participant(s).
- 9.2 Market research must not be a disguise for selling or developing sales contacts.
- 9.3 Participation in a market research project must not be used to deliberately sway the opinion of the participant.
- 9.4 Honoraria offered to animal health care professionals who gather or provide market research information should be based on rates similar to (and not higher than) their usual rate of pay.
- 9.5 Even when a consent form is not signed, the confidentiality of participant(s) must be preserved. The identity of the participant(s) must not be revealed for purposes of promoting Member products to them in the future.

10. COMPLAINT RESOLUTION PROCESS

The dispute resolution process is comprised of 3 phases:

- Company to company discussion involving the company business heads.
- Expert Opinion Assessment coordinated by the CAHI, using the services of the Pharmaceutical Advertising Advisory Board (PAAB).
- Arbitration under the authority of the Marketing Practices Review Committee

11. ENFORCEMENT AND FEES

- 11.1 Companies are encouraged to make every attempt to resolve differences on their own before referring them to mediation(s) or to the Marketing Practices Review Committee. A company may escalate a complaint to the next phase of the dispute resolution process at any time if it is thought adequate progress is not being made. It is recommended that the CAHI President be copied on correspondence in relation to a dispute or complaint early in the process to establish transparency and a timeline. As a guideline, an offending company should be given five (5) days to respond to an initial complaint.

A call for Expert Opinion Assessment will proceed once payments of \$5,000 have been received from both parties. CAHI will hold all funds in trust until an Expert Opinion Assessment is provided and there is agreement between the plaintiff and defendant on a course of action to be followed. The maximum time to complete an Expert Opinion Assessment and identify a follow-up course of action between the plaintiff and defendant should be 15 working days. The funds held in trust by CAHI will be returned to the plaintiff and defendant less expenses.

Posting of the Expert Opinion Assessment and the ensuing follow-up will be done on the Members only side of the CAHI website for the purpose of internal learning and is not for recirculation in the field.

In the event that an Expert Opinion Assessment results in no successful outcome, each party must submit in writing confirmation that no agreement was reached. Subsequently, each party has 5 working days to submit \$10,000 in fees demonstrating intent to go to arbitration. Arbitration dates are then to be set within 60 days of receipt of plaintiff and defendants' cheques.

Funds for arbitration are held in trust until a decision is made by the Committee. The party found at fault will forfeit all mediation(s) and arbitration fees while the funds for the party found not to be at fault will be returned in full.

It is the responsibility of the party found to be at fault to cover all external costs associated with the mediation and arbitration process. Where the schedule of fees laid out within section 11.5 does not cover the total costs, the Committee will assess an additional penalty to cover those costs.

Any party found to have lost three decisions before the Committee in a two-year period will be surcharged an additional penalty of \$15,000.

11.2 The **Code** is enforced by a Marketing Practices Review Committee appointed by the CAHI Board of Directors. The Marketing Practices Review Committee, with an independent, legally qualified Chairman from outside the industry, comprises two practicing veterinarians, two public representatives and four industry members that are drawn from senior management, two of which are veterinarians. The Chairman of the Committee is empowered to call witnesses in addition to the parties if their input is determined to be necessary. CAHI Members of the Marketing Practices Review Committee must, if possible, not be employed by a company marketing product within the same therapeutic class as the product for which the complaint was filed.

11.3 The Marketing Practices Review Committee will meet as required.

11.4 This Committee is only available to resolve complaints between member companies. A company initiating a complaint (the plaintiff) should forward their case, in writing accompanied by payment to the CAHI Marketing Practices Review Committee (c/o CAHI President, 160 Research Lane, Suite 102, Guelph, ON, N1G 5B2) for adjudication. A copy of the letter is to be sent simultaneously to the defending company (defendant). The Marketing Practices Review Committee will review the complaint at the next meeting. The decision will be communicated in writing, by registered mail, to the parties involved within 7 days of the meeting.

The decisions of the Committee are final. There is no appeal process and member companies agree to abide by the decisions of the Committee.

11.5 Costs of industry members attending the meeting will be borne by their companies while the costs of outside members will be paid for by the CAHI. These costs should largely be covered by the penalties levied by the Committee.

The following is the fee schedule for Committee activities.

Charging Categories	Plaintiff Individual Meeting Charge	Defendant Individual Meeting Charge
Expert Opinion Assessment	\$5,000	\$5,000
Arbitration	\$10,000	\$10,000
Party at fault (as described above)	All monies submitted to CAHI from point of initial expert opinion assessment through to arbitration forfeited.	
Party not at fault (as described above)	All monies submitted to CAHI from point of initial expert opinion assessment through to arbitration refunded.	
Additional penalty for loss after 3 losses over a 2-year period	\$15,000	

11.6 Where a decision is rendered following **Arbitration** that a company is in noncompliance with the **Code** the following actions will be taken:

11.6.1 **Code Infraction Letter to Company** – Should a company be found guilty of an infraction, in addition to the costs mentioned above, a letter will be sent to the offending company listing the corrective measures determined by the Committee. These measures will depend on the nature of the case and may include instructions to cease and desist advertising, recall of promotional materials and/or writing of a letter of apology or correction for circulation either by mail or publication.

11.6.2 **Notice of Code Infraction to Veterinary Professionals, Publics and CAHI Membership** – Details of **Code** violations will be published in the next available publication of the

Canadian Veterinary Journal, appropriate trade journals when deemed necessary by the Committee and posted on the CAHI website.

See [Appendix VIII](#) for **Standard Operating Procedure (SOP) for a Complaint Filed Before the Canadian Animal Health Institute (CAHI) Marketing Practices Review Committee.**

12. REVISIONS TO THE CODE

- 12.1 The **Code** will be reviewed every 2 years, or as needed, and updated if deemed necessary by the Code of Marketing Practice Committee and approved by the CAHI Board of Directors. Member input is encouraged.
- 12.2 Authorized representatives of CAHI member firms will be asked annually, or as needed, to be signatory to the intent of this **Code**.
- 12.3 This is the **2017 edition** of the **CODE OF MARKETING PRACTICE** for the promotion of animal health products. It embodies the basic principles and provisions which the Animal Health Industry believes are essential for the conduct of its marketing activities and for the maintenance of standards which are in the interests alike of the Animal Care Profession, Publics and all those who use animal health products.

DRAFT GUIDELINE FOR ADVERTISING OF DRUGS FOR VETERINARY USE

Prepared by the former Bureau of Veterinary Drugs, now Veterinary Drugs Directorate, Health and Food Products Branch, Health Canada.

1. INTRODUCTION

This guide was developed by the former Bureau of Veterinary Drugs, currently Veterinary Drugs Directorate, Health Products and Food Branch, Health Canada in consultation with representatives of the veterinary drug industry in Canada. It is intended for use by all who advertise drugs for veterinary use to health professionals or to the general public.

This publication is designed to assist manufacturers in developing advertising material in compliance with Canadian requirements. The two key quotations from the Food and Drugs Act and Regulations impacting on the advertising of drugs for veterinary use are the following:

“Advertisement” includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device.” (Section 2, FOOD AND DRUGS ACT AND REGULATIONS).

“No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.” (SUBSECTION 9(1), FOOD AND DRUGS ACT AND REGULATIONS).

Certain regulations have been enacted to prohibit the advertising of particular drugs to the general public or to restrict the claims, which may be made.

2. GENERAL ADVERTISING POLICY

2.1 DRUGS WHICH CANNOT BE ADVERTISED TO THE GENERAL PUBLIC

(A) Narcotic Drugs

A narcotic drug, as defined by the Narcotic Control Act.

Section 70 of the Narcotic Control Regulations provides that “No person shall publish or cause to be published or furnish any advertisement to the general public respecting a narcotic”.

(B) Controlled Drugs

A controlled drug, as included in Schedule G to the Food and Drugs Act and Regulations.

The advertising to the general public of a controlled drug is prohibited by Section G.01.007 of the Food and Drugs Act and Regulations.

(C) Schedule F Drugs

Drugs listed and described in Part I of Schedule F to the Food and Drugs Act and Regulations cannot be advertised to the general public, except for name, price and quantity. (C.01.044)

Drugs listed and described in Part II of Schedule F may be advertised to the general public provided:

1. The drug is in a form not suitable for human use (medicated feed).

2. The drug has been labelled in accordance with subsection C.01.046 (b)

(D) New Drugs

Any "New Drug" as defined by Section C.08.001

Any drug classified as a new drug cannot be advertised unless those conditions listed in section C.08.002 have been met.

2.2 INTERPRETATION OF SECTION 9 (1) PROHIBITIONS

(A) False Advertising

False advertising is advertising which is not consistent with label claims.

(B) Misleading Advertising and Erroneous Impression

1. Product Endorsement

a) Professional Endorsement

Product endorsement by veterinarians or other health professionals is not permitted.

b) Quotations from the Media

The use or quotation of media articles may be misleading, particularly if they contain statements to which exception would be taken if they had been developed for use in advertisements.

Statements taken out of the context of the article are often misleading, and a particular statement used in isolation may express a view entirely different from the conclusions reached by the writer or speaker.

c) Seals or Certificates of Approval

The logo of an organization must not be used as a seal of approval, but may appear only to show affiliation of the advertiser.

No implication of approval by the Health Protection Branch may appear in any advertisement. Section C.01.007 of the Regulations prohibits any reference, direct or indirect, to the Food and Drugs Act and Regulations in a drug advertisement unless such mention is specifically required.

d) Testimonials

Testimonials and reports of individual cases frequently constitute an unfair selection. Testimonials, which emphasize only positive features of a product while ignoring negative aspects, are not acceptable.

If testimonials are used, any statement made therein becomes the responsibility of the advertiser. In addition, the testimonial must not violate the Food and Drugs Act and Regulations.

2. Comparisons

Advertisers are encouraged to promote drugs on their own merits in a positive manner and not by comparison with other products.

Comparisons of products must be factual, fair and capable of scientific substantiation. Care must be taken to ensure that they do not mislead by distortion, by undue emphasis or in any other way. Where comparisons include results of a comparative trial the level of statistical significance must be included.

a) Composition and Potency

The word "Concentrated" is rarely applicable to synthetic drugs, since the manufacturer has full control over their composition. When two strengths of a drug product are supplied, the stronger of the two is not necessarily concentrated.

To say that a drug is "Rich in" a factor implies a standard against which the drug can be measured and so introduces a comparison. The terms "High" and "Low" also imply a comparison and should be avoided.

The quantitative composition of a drug is known and should be stated rather than using vague terms such as those outlined above.

"Potency" and "Strength" are difficult terms to use without creating a false impression as to the merits of the drug. Terms such as "Double strength" and "Triple strength" require pre-existence of a stated or recognized normal strength to which the product can be compared. Such terms, if used at all, should be restricted to differentiating between two strengths of a drug marketed by the same manufacturer.

b) Dangling Comparatives

Such words as "Better" and "Richer" imply a comparison, often without indicating the basis of the comparison. If the product is an improvement over one previously made by the same firm, it should be so stated.

3. Negative Statements

As stated above, drugs should be promoted in a positive fashion to provide the consumer with useful information. Negative statements are not recommended because they may confuse or mislead the consumer by requiring an interpretation of the implications of the statement.

On those occasions that a chemical substance is prohibited in drugs by a Federal or Provincial agency, it is permissible to include a statement that the drug does not contain that ingredient. Such a statement will be considered acceptable for twelve (12) months following the date of the action, for products that did or did not previously contain the subject ingredient.

4. Scientific or Technical References

Statistics or references selected from technical literature are generally unsuitable for advertising to the general public. The vocabulary of the advertisement should be that of the audience to whom the advertisement is directed.

Trial data presented in advertisements should support claims not exceeding those which appear on the labelling of the drug.

5. Other Practices Which May Be Misleading

a) Accepted Opinions and Claims

Claims made in an advertisement must not exceed the label claims for a drug product or the terms of a Notice of Compliance. The use of unjustified claims in the advertising of any drug could lead to the product being classed as a "New Drug".

b) Questionnaires

Questionnaires are used to obtain from selected groups of people their opinions upon various subjects as suggested by the questioner. In most cases, the opinions thus obtained are of no scientific consequence or significance even when they can be classed as Case Reports.

c) Qualifying Statements

Advertisers sometimes attempt to justify the presence of unacceptable claims for a product by inserting a qualifying statement elsewhere in the advertisement, which rarely achieves equal

prominence in the presentation. Such practices are objectionable in drug advertising. Claims should be able to stand on their own merit, without requiring an explanation elsewhere in the advertisement.

d) Examples of Misleading Terminology

- *Fortification, Enrichment or Added*

“Fortification”, “Enrichment” and similar terms are exceedingly difficult to employ without creating an erroneous impression, particularly where the actual operation carried out is merely an addition of an ingredient to the formulation or an increase in the quantity of a constituent which is already present. This would apply generally to products derived from natural sources to which a factor has been added, in such cases, “Added” would be the correct term to use.

Where a manufacturer formulates a product and thus has a complete choice of the ingredients and their proportions, there can be no “Enrichment” or “Fortification” through a variation of quantities. Indeed, the designation of an ingredient as “Added” in such a product would probably be considered misleading.

- *Guarantee*

The word “Guarantee” should not be used to create the impression that successful results will be achieved with the use of the product.

Guarantees, which refer to the quality of the product, are generally acceptable, provided that the manufacturer will support the guarantee. If there are conditions under which the guarantee is invalidated, such conditions should be stated.

- *Need*

Objection is taken to the word “Need” when used in a statement such as “(The Drug) Your Animals Need....”. There is no particular brand of a drug, which is essential to the well-being of an animal.

- *Prescribed*

“Prescribed”, when referring to drugs, generally implies a recommendation by a veterinarian. Since the general public lacks the veterinarian’s knowledge and judgement the word should be avoided in advertisements directed at the general population.

6. Scare Advertising

The promotion of a drug product should not provoke purchase of the drug by means of fear-inducing copy. It is improper to suggest that, unless the particular drug is used, the animal’s health will or may suffer.

7. Illustrations

Pictures and charts are a common and valuable aid in advertising. However, they must not be employed in a manner which will exaggerate, mislead or misrepresent the value of the product.

Any drug label being reproduced in an advertisement should represent a current and acceptable Canadian label.

8. Use of “New” and “Improved”

The word “New” should not be used in advertising to describe a drug product unless it is a new product marketed in Canada for the first time or a different version of an existing medicine.

Although the use of “New” should be limited to a period of time not to exceed one year, it may be used for a similar period of time outside a test marketing area, providing agreement has been reached with the Health Protection Branch that such a test area will be used for a defined period.

The word “Improved” should not be used in advertising unless the advertisement presents the previous version of the product.

The use of this word should be limited to a period of time not exceeding one year.

2.3 GENERAL DRUG USAGE AND STORAGE

Objection will be taken to advertising material, which illustrates unsafe drug storage or encourages excessive drug use.

If advertisements illustrate the storage of drugs, the storage illustrated should be in accordance with storage recommendations for the product and should reflect general inaccessibility to small children.

3. MASS MEDIA ADVERTISING

3.1 RADIO AND TELEVISION

Effective May 1, 1997 it is no longer a requirement to have mass media veterinary advertisements precleared.

3.2 POINT OF PURCHASE MATERIAL

Display material, which does not normally accompany a drug and is designed to draw special attention to the drug, is considered to be advertising.

This material is expected to meet all legislative requirements for advertisements which appear in the Food and Drugs Act and Regulations. It should be noted that such material cannot be used to draw attention to drugs which cannot be advertised to the general public.

GUIDELINE FOR ADVERTISING OF VETERINARY BIOLOGICS

Prepared by: Canadian Food Inspection Agency, Canadian Centre for Veterinary Biologics, Animal Health Directorate. Veterinary Biologics Guideline 3.5E: Guideline For Advertising of Veterinary Biologics

1. INTRODUCTION

The purpose of this guideline is to provide information on the requirements for the advertising of veterinary biologics in Canada. The advertising of veterinary biologics in Canada is regulated by the Canadian Centre for Veterinary Biologics of the Canadian Food Inspection Agency (CFIA) under the legal authority of the *Health of Animals Regulations*. There is no requirement for approval of an advertisement by the CFIA-CCVB prior to its publication. Consequently, the CFIA-CCVB does not ordinarily review and provide comments on the acceptability of draft advertisements; however, the CFIA-CCVB investigates all complaints about inappropriate advertising, and will take necessary actions against false or misleading advertisements.

2. LEGAL AUTHORITY

Health of Animals Regulations, Part XI

135. (1) No person shall, in any advertisement for the sale of a veterinary biologic, make any claim with respect to the purity, safety, potency and efficacy of the veterinary biologic that is not supported by the product outline for such veterinary biologic.

135. (2) No person shall, in any advertisement for the sale of a veterinary biologic, make any representation that is false, misleading or deceptive or that is likely to create an erroneous impression regarding the character, value, quality, composition, merit or safety of the advertised veterinary biologic.

3. SCOPE AND DEFINITION OF AN ADVERTISEMENT

Advertising includes all information about a veterinary biologic intended for publication in order to present a product to a target audience. This can be done through television, radio, the Internet, newspapers, magazines, scientific journals, promotional brochures, and handouts. Items bearing the logo or trade name of a veterinary biologic, but not making claims about the product, are not covered by the scope of this Guideline. Peer-reviewed published scientific articles are not considered to be advertisements, provided they are available in a complete unedited format.

4. GENERAL GUIDANCE

Advertisers should observe the following general guidelines when preparing advertising materials:

- Veterinary biologics should be advertised and promoted on their own merits, in a positive manner.
- Veterinary biologics that are not licensed for general sale and distribution in Canada should not be advertised or promoted in Canada.
- All advertisements must be consistent with the approved label claims.
- All claims must be supported by the most recent version of the Outline of Production and research reports, filed with the CFIA-CCVB.
- All statements about the safety and efficacy of a product should be supported by references to pertinent studies.

- Descriptive adjectives must be supported by data.
- Comparisons of products must be audience appropriate, factual, and fair. Specific comparisons between competing products must be based on objective scientific data that can be made available on request to all interested parties. The relative merits of a product should be presented in a positive manner.
- The use of unsubstantiated superlative statements, negative statements, absolute statements, and vague comparisons are generally considered to be misleading and therefore should not be used.
- Testimonial statements are not exempt from other requirements listed in this guideline, and should be referenced to clearly identify the source.
- Guarantees, which apply to the quality of the product, are generally acceptable, provided the manufacturer will support the guarantee. If there are conditions under which the guarantee is void, such conditions must be stated.

All complaints about published advertisements, along with the details of the complaints and supporting documents, should be submitted to the CFIA-CCVB in writing.

**GUIDELINE FOR ADVERTISING OF ANIMAL PESTICIDE PRODUCTS*
MARKETED BY CAHI MEMBER COMPANIES**

* Animal Pesticides include those animal health products registered under the Pest Control Products Act.

While member companies are not allowed to promote or advertise unregistered products for sale, it is recognized by industry, consumers and government, that there is a need to communicate information about products in development.

Within the current legislation, Croplife Canada has developed with PMRA (Pest Management Regulatory Agency) an understanding of acceptable communication activities as they pertain to New Product in Development and Unregistered Use Extensions as outlined in the following charts. The intent of this communication must be to inform and to educate, not to sell, or promote non-registered use. CAHI agrees with these activities.

Registration Status	Do's	Don'ts
New product in development (Registration must have been applied for)	All information must be technical in nature and must bear or contain the description *RESEARCH PRODUCT* in a bold and prominent fashion. Include research, environmental, animal and human safety information.	<ul style="list-style-type: none"> • No advertising or promotion for selling purposes. • No speculation on the registration approval or dates. • No selling prior to receipt of registration certificate. • No reference to the specific content of the final label.
Label extension in development. (Registration must have been applied for)	All information must be technical in nature and must bear or contain the description *THIS PRODUCT NOT REGISTERED FOR THIS USE. IT IS A VIOLATION OF THE PEST CONTROL PRODUCTS ACT TO USE THIS PRODUCT IN A NON-REGISTERED APPLICATION* in a bold and prominent fashion. Include research, environmental, animal and human safety information.	<ul style="list-style-type: none"> • No advertising or promotion for selling purposes. • No dosages or other information that would encourage unlabelled applications. • No speculation on the registration approval or dates. • No selling of product with new label prior to receipt of registration certificate. • No reference to the specific content of the final label.
Newly approved product or newly approved label extension prior to receipt of registration certificate.	Label copies must indicate "Draft". Advertising copy must include the draft claim, dosage and warnings and a statement "The clearance of the product in Canada is pending receipt of the registration certificate".	<ul style="list-style-type: none"> • No sale of product prior to receipt of registration certificate.

GUIDELINE FOR ADVERTISING OF VETERINARY HEALTH PRODUCTS (VHPs)

Prepared by: Canadian Animal Health Institute, December 2012

1. INTRODUCTION

This guideline draws from the Veterinary Drugs Directorate, Health Products and Food Branch, Health Canada Guideline for the Advertising of Drugs for Veterinary Use, but is intended for use by all who advertise notified veterinary health products for use in companion and production animals.

This publication is designed to assist manufacturers in developing advertising material in compliance with Canadian requirements. The two key quotations from the Food and Drugs Act impacting on the advertising of drugs for veterinary use are the following:

“Advertisement” includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device (Section 2, FOOD and DRUGS ACT).”

“No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety” (SUBSECTION 9(1), FOOD AND DRUGS ACT).

2. GENERAL ADVERTISING POLICY

2.1 The veterinary health product has been labeled in accordance with the labelling requirements for the VHP Notification Program.

2.2 PROHIBITIONS

(A) False Advertising

False advertising is advertising which is not consistent with label claims.

(B) Misleading Advertising and Erroneous Impression

1. Product Endorsement

a) Professional Endorsement

Product endorsement by veterinarians or other health professionals is not permitted.

b) Quotations from the Media

The use or quotation of media articles may be misleading, particularly if they contain statements to which exception would be taken if they had been developed for use in advertisements.

Statements taken out of the context of the article are often misleading, and a particular statement used in isolation may express a view entirely different from the conclusions reached by the writer or speaker.

c) Seals or Certificates of Approval

The logo of an organization must not be used as a seal of approval, but may appear only to show affiliation of the advertiser.

No implication of approval by the Veterinary Drugs Directorate may appear in any advertisement.

d) Testimonials

Testimonials and reports of individual cases frequently constitute an unfair selection. Testimonials, which emphasize only positive features of a product while ignoring negative aspects, are not acceptable.

If testimonials are used, any statement made therein becomes the responsibility of the advertiser. In addition, the testimonial must not violate the Food and Drugs Act or Regulations.

2. Comparisons

Advertisers are encouraged to promote low risk veterinary health products on their own merits in a positive manner and not by comparison with other products.

Comparisons of products must be factual, fair and capable of scientific substantiation. Care must be taken to ensure that they do not mislead by distortion, by undue emphasis or in any other way. Where comparisons include results of a comparative trial the level of statistical significance must be included.

The terms 'Prescription' or 'Prescribed' cannot be used in advertising to imply a product's equivalence with a drug. If a VHP claim is compared with a drug claim, the VHP manufacturer must have data on file that supports the accuracy of the claim / comparison and that it meets federal advertising & promotional regulation.

3. Dangling Comparatives

Such words as "Better" and "Richer" imply a comparison, often without indicating the basis of the comparison. If the product is an improvement over one previously made by the same firm, it should be so stated.

4. Negative Statements

As stated above, VHPs should be promoted in a positive fashion to provide the consumer with useful information. Negative statements are not recommended because they may confuse or mislead the consumer by requiring an interpretation of the implications of the statement.

5. Scientific or Technical References

Statistics or references selected from technical literature are generally unsuitable for advertising to the general public. The vocabulary of the advertisement should be that of the audience to whom the advertisement is directed.

Trial data presented in advertisements should support claims not exceeding those which appear on the labeling of the VHP.

6. Other Practices Which May Be Misleading

a) Accepted Opinions and Claims

Claims made in an advertisement must not exceed the label claims for a LRVHP or the terms of a Notifiable Number.

b) Questionnaires

Questionnaires are used to obtain from selected groups of people their opinions upon various subjects as suggested by the questioner. In most cases, the opinions thus obtained are of no scientific consequence or significance even when they can be classed as Case Reports.

c) Qualifying Statements

Advertisers sometimes attempt to justify the presence of unacceptable claims for a product by inserting a qualifying statement elsewhere in the advertisement, which rarely achieves equal prominence in the presentation. Such practices are objectionable in VHP advertising. Claims should be able to stand on their own merit, without requiring an explanation elsewhere in the advertisement.

d) Examples of Misleading Terminology

- Fortification, Enrichment or Added

“Fortification”, “Enrichment” and similar terms are exceedingly difficult to employ without creating an erroneous impression, particularly where the actual operation carried out is merely an addition of an ingredient to the formulation or an increase in the quantity of a constituent which is already present. This would apply generally to products derived from natural sources to which a factor has been added, in such cases, “Added” would be the correct term to use.

Where a manufacturer formulates a product and thus has a complete choice of the ingredients and their proportions, there can be no “Enrichment” or “Fortification” through a variation of quantities. Indeed, the designation of an ingredient as “Added” in such a product would probably be considered misleading.

- Guarantee

The word “Guarantee” should not be used to create the impression that successful results will be achieved with the use of the product.

Guarantees, which refer to the quality of the product, are generally acceptable, provided that the manufacturer will support the guarantee. If there are conditions under which the guarantee is invalidated, such conditions should be stated.

- Need

Objection is taken to the word “Need” when used in a statement such as “(The VHP) Your Animals Need...”. There is no particular brand of a low risk veterinary health product, which is essential to the well-being of an animal.

- Prescribed

“Prescribed”, generally implies a recommendation by a veterinarian. Since the general public lacks the veterinarian’s knowledge and judgment the word should be avoided in advertisements directed at the general population.

6. Scare Advertising

The promotion of a VHP product should not provoke purchase of the VHP by means of fear-inducing copy. It is improper to suggest that, unless the particular VHP is used, the animal’s health will or may suffer.

7. Illustrations

Pictures and charts are a common and valuable aid in advertising. However, they must not be employed in a manner which will exaggerate, mislead or misrepresent the value of the product.

Any VHP label being reproduced in an advertisement should represent a current and acceptable Canadian label.

8. Use of “New” and “Improved”

The word “New” should not be used in advertising to describe a VHP unless it is a new product marketed in Canada for the first time or a different version of an existing product.

Although the use of “New” should be limited to a period of time not to exceed one year, it may be used for a similar period of time outside a test marketing area, providing agreement has been reached with the Health Protection Branch that such a test area will be used for a defined period.

The word “Improved” should not be used in advertising unless the advertisement presents the previous version of the product.

The use of this word should be limited to a period of time not exceeding one year.

2.3 GENERAL PRODUCT USAGE AND STORAGE

Objection will be taken to advertising material, which illustrates unsafe low risk veterinary health product storage or encourages excessive product use.

If advertisements illustrate the storage of low risk veterinary health products, the storage illustrated should be in accordance with storage recommendations for the product and should reflect general inaccessibility to small children.

3. MASS MEDIA ADVERTISING

3.1 POINT OF PURCHASE MATERIAL

Display material, which does not normally accompany a low risk veterinary health product and is designed to draw special attention to the product, is considered to be advertising.

This material is expected to meet all requirements for advertisements which appear in the CAHI Code of Marketing Practice.



Health
Canada

Health Products
and Food Branch

Santé
Canada

Direction générale des produits
de santé et des aliments

Marketed Health Products
Directorate
A.L. 1912C
OTTAWA, Ontario
K1A 0K9

16-110762-10

Jean Szkotnicki, President
Canadian Animal Health Institute
160 Research Lane, Suite 102
Guelph, ON N1G 5B2

OCT 03 2016

Dear Ms. Szkotnicki,

Re: Direct to consumer advertising of prescription veterinary drugs

This email is in response to Your correspondence dated September 8, 2016, in which the Canadian Animal Health Institute (CAHI) shared concerns regarding the current regulatory restrictions on prescription drug advertising to the mention of name, price, and quantity of the drug when advertised to the public (Section C.01.044 of the *Food and Drug Regulations*). In addition, you point out that the new Health Canada policy, which would transition Over-The-Counter (OTC) antimicrobials to prescription status, will have a significant impact on your association members. Your organization is also concerned about the fact that some prescription veterinary drugs share the same therapeutic class with pesticides, the advertising of which to the general public is not subject to similar restrictions. CAHI has also raised concerns about advertising practices of specific prescription veterinary drug manufacturers. We understand that CAHI also shared these concerns with the Veterinary Drugs Directorate. Please be advised that we discussed this issue with Health Canada's Regulatory Operations and Regions Branch (formerly the Health Products and Food Branch Inspectorate).

As CAHI is aware, advertising of drugs should comply with the regulatory framework and be carried out in a manner that is not false, misleading or deceptive, and not likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety (Section 9(1) of the *Food and Drugs Act*).

Therefore, if Health Canada receives a complaint about an alleged non-compliant direct-to-consumer advertisement for a prescription veterinary drug, it will assess the ad and take appropriate actions, as a standard procedure for all product lines.

Canada

When addressing advertising complaints, Health Canada's first priority is protecting the health and safety of Canadians. Health Canada's approach to addressing and resolving complaints uses the most appropriate level of intervention proportional to the health risk and in most cases; compliance is successfully achieved using a cooperative approach.

Furthermore, in subsequent conversations, you raised the need for disseminating product information to farmers, breeders, producers, etc. We wish to bring to CAHI's attention the policy "The Distinction Between Advertising and Other Activities" available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/policies-guidance-documents/policy-distinction-between-advertising-activities.html>. This policy assists manufacturers and advertisers in determining whether messages constitute advertising or information. Only materials that are considered advertising are subject to the *Food and Drug Act* and associated regulations. You will note that this policy allows for prescription drug messages discussing the indications to be disseminated to the general public under specific requirements. For example, it is possible for manufacturers to provide information/messages of an informational nature about products through the development of balanced consumer brochures (print or electronic). As well, information can be disseminated by healthcare professionals (veterinarians) to persons to whom they have prescribed a drug product that is to be used for their animals (e.g. patient information booklets, websites where access is gated by a request to enter the Drug Identification Number of the prescribed drug, etc.). As such, sources of balanced information about the prescribed product's use, instructions, precautions, warnings, etc. are available. Although the scope of this policy is for drugs for human use, the same principles can be applied to veterinary drugs as well.

It should also be noted that veterinary drug manufacturers can advertise their products within the restrictions set out in Section C.01.044. Such advertisements are referred to as Reminder Ads and are considered compliant when they do not mention or allude to the therapeutic indication or use of the product. Therefore, it is possible to include in these ads statements like "Talk to your veterinarian about product X" and/or include package representations or other contextual elements or features (music, pictures, etc.) as long as they do not refer or allude to the therapeutic indication.

We trust this provides you with the necessary information to clarify the matter.

Sincerely,



Dr. J. Patrick Stewart, MD, CCFP(EM)
Director General
Marketed Health Products Directorate
Tel.: 613-954-6522 Fax: 613-952-7738
e-mail: mhpd_dpssc@hc-sc.gc.ca

GUIDELINE FOR DISSEMINATION OF EXTRA-LABEL PRODUCT-RELATED INFORMATION

1. SCOPE

This document describes a process for addressing dissemination of extra-label scientific information by animal health company veterinarian to a licensed veterinarian in Canada.

2. PROCESS

All product-related information can be categorized as either on-label (per package insert/label) or extra-label (not included in package insert/label). Dissemination of on-label product-related information is not being addressed here since a system for on-label promotional review and distribution already exists.

Extra-label product-related information can be separated into 2 general categories (refer to chart):

1. Technically not supportable (no data or adverse data)
2. Technically supportable

Item 1 is quite straightforward; if no data exist, dissemination of information is prohibited. If adverse data exist, a proposed use cannot be recommended but would rather be recommended against and, if warranted, a precautionary statement would be included in the product labelling.

Item 2, dissemination of technically supportable extra-label information is the area which provides the opportunity to share selected scientific information beyond the claims allowed for on our product labelling. Within this area, available technically supportable information can be divided into two additional categories as follows:

1. Rational information but incomplete database (insufficient database to fully support target animal safety, efficacy and human food safety).
2. Database supports safety and efficacy (sufficient data exists to add claim to Compendium of Pharmaceuticals and Specialties).

In both cases, distribution of information is allowed based on Canadian law under the umbrella of scientific exchange between a company's technical services team and animal health care professionals. A determination will be made (by a corporation's internal review group) as to whether the scientific exchange of the information by its technical services team is acceptable. It is the responsibility of those involved in the review process (as defined under "Terms/Definitions") to evaluate the completeness of the database and to determine whether the information qualifies for scientific exchange. Additionally, it is the responsibility of each member company's management to assure that sales representatives are complying with the conditions of scientific exchange (as defined under "Terms/Definitions").

3. TERMS/DEFINITIONS:

- **Promotion** – Product related discussions (including product name and indication/usage information) with customers/potential customers initiated by the animal health company.
- **Review Process** – Each corporation shall identify individuals responsible for evaluating product-related information. These people will be responsible for determining if materials may be disseminated and, if so, how materials may be disseminated. This group will consist of personnel within Canada and usually include individuals representing Research & Development, Technical Services, Marketing, Legal and Regulatory. The REVIEW GROUP will determine if the information that is desired to be disseminated is: 1) consistent with the approved label, 2) consistent with local law, and/or 3) has sufficient detail to be classified as technically supportable (i.e., there is sufficient science involved to conclude that the

information is valid). If information is determined to be technically supportable, the information may be shared based on Canadian law, which permits sharing of information in response to an unsolicited question from a scientific exchange.

- **Scientific Exchange** – A) Presentation of scientific information in an open forum, or B) Dissemination of scientific information in response to questions raised by customers/potential customers (e.g., questions related to extra-label product uses may be legitimately addressed within the context of “scientific exchange” as allowed by in-country law and is not considered promotion as defined above). The intent must be to share information – not promotion in disguise.

Appropriate disclaimers should be used when disseminating extra-label information indicating that the use is not approved (e.g., acknowledgment that information is provided per request, that information pertains to an unapproved indication, and that information discussed must be limited to the original conclusions stated in the report).

- **Publication** – Publication of research or presentation at a scientific meeting (i.e., within a “scientific exchange” forum) is acceptable and is not considered promotional activity.
- **Distribution of Reprints of Publications/Proceedings** – Unsolicited distribution of reprints of publications and/or proceedings (whether a corporation’s research or other research describing the corporation’s product) is a promotional activity as defined above.

Distribution of extra-label information in response to an unsolicited question may be done as scientific exchange and should be handled as described above.

DISSEMINATION OF PRODUCT-RELATED INFORMATION				
On Label	Extra-Label			
	Technically Supportable		Technically NOT Supportable	
Can promote	Rational product information; Incomplete database	Database supports safety and efficacy	Adverse data	No data
	<ul style="list-style-type: none"> • Can disseminate information within scientific-exchange 	<ul style="list-style-type: none"> • Can disseminate information within scientific-exchange • Can promote if additional label claim approved 	<ul style="list-style-type: none"> • Cannot disseminate information within scientific-exchange • Cannot promote 	<ul style="list-style-type: none"> • Cannot disseminate information within scientific-exchange • Cannot promote

GUIDELINE FOR THE PROMOTION OF VETERINARY DRUGS AND/OR BIOLOGICS AT INTERNATIONAL CONFERENCES HELD IN CANADA

**Provided by: Veterinary Drugs Directorate, Health Canada
Canadian Centre for Veterinary Biologics, Canadian Food Inspection Agency**

1. PROMOTION OF VETERINARY DRUGS

Section 9 of the Food and Drugs Act says that no person shall advertise a drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, merit, quantity, composition, or safety. In accordance with Section C.08.002, drugs that are not approved for sale in Canada cannot be advertised. In accordance with Section 9, claims made in advertising must be consistent with the product's Terms of Market Authorization - unapproved dosing and indications cannot be advertised, as this would be considered misleading. If a message is not considered to promote a drug's sale, then it is not subject to the advertising provisions of the Food and Drugs Act and Regulations. So it is important to distinguish between promotional and non-promotional material. Health Canada has a policy called The Distinction between Advertising and Other Activities which provides guidance on this distinction. In the context of a conference or medical symposium, messages may not be promotional if they are considered part of scientific exchange, and the main purpose is not to promote the sale of a drug (e.g., in a poster presentation or as part of a balanced presentation given by a researcher). However, even in these cases, the message would have to meet the criteria outlined in the policy.

Key considerations are:

- the context in which the message is delivered;
- who delivers the message;
- who sponsors the message;
- the influence of the manufacturer on the message; and
- the content of the message.

A booth at a conference manned by a sales representative would be promotional. Any promotion of unauthorized drugs, indications, doses, etc. would not be in accordance with current legislation and would not be permitted for Canadian manufacturers. The only exception is International Conferences with a significant proportion of international attendees. This type of promotional material must come from the international parent company and needs to be clearly marked as not being authorized in Canada (so, for example, a banner at a booth, stickers on any handouts). Material is not to be redistributed outside the conference. Other exceptions would require a regulatory change.

Information on unauthorized uses can be provided to an individual about a drug treatment by a Canadian manufacturer in response to an unsolicited request for information by an attendee at a conference, but it must be in the form of a scientific paper, not a promotional piece, must be clearly marked as not authorized in Canada and must be distributed by medical personnel, not a sales representative.

2. PROMOTION OF VETERINARY BIOLOGICS

Promotion of a biologic must meet similar principles outlined for drugs in 5.6.1. As long as the unlicensed veterinary biologics are not advertised for sale to Canadian customers who would not be in a position to purchase the products, the Canadian Centre for Veterinary Biologics (CCVB) would not object to exhibitors displaying samples for international attendees. If a commercial display requires samples of actual veterinary

biologics for an exhibit, then the CCVB must have issued an import permit to authorize the importation of samples of specific products, on the understanding that all imported material was solely for the purpose of display, and would be either returned to the country of origin at the conclusion of the display or destroyed as biomedical waste. There is an applicable fee for these import permits. The import permit could include various conditions and restrictions, including a condition that no product samples could be distributed, not even to international participants.

All promotional material must conform with the Health of Animals Regulations, Part XI Veterinary Biologics, Section 135 and the Veterinary Biologics Guideline 3.5E Guidelines for Advertising of Veterinary Biologics. These regulations and guidelines are available at the following links.

Health of Animals Regulations, Part XI Veterinary Biologics, Section 135

http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._296/page-16.html#h-70

135. (1) No person shall, in any advertisement for the sale of a veterinary biologic, make any claim with respect to the purity, safety, potency and efficacy of the veterinary biologic that is not supported by the product outline for such veterinary biologic.
- (2) No person shall, in any advertisement for the sale of a veterinary biologic, make any representation that is false, misleading or deceptive or that is likely to create an erroneous impression regarding the character, value, quality, composition, merit or safety of the advertised veterinary biologic.

Veterinary Biologics Guideline 3.5E Guidelines for Advertising of Veterinary Biologics

<http://www.inspection.gc.ca/english/anima/vetbio/info/vb305e.shtml>

STANDARD OPERATING PROCEDURE (SOP) FOR A COMPLAINT FILED BEFORE THE CANADIAN ANIMAL HEALTH INSTITUTE (CAHI) MARKETING PRACTICES REVIEW COMMITTEE

1. PURPOSE

The purpose of the Standard Operating Procedure (SOP) is to enable parties to have a clear understanding of the dispute resolution process administered by the Marketing Practices Review Committee and to ensure a just, speedy and cost-effective determination.

2. INTERPRETATION

- “Code” – refers to the CAHI CODE OF MARKETING PRACTICE.
- “Marketing Practice Review Committee” – refers to the nine (9) individuals appointed by the CAHI Board of Directors to serve as arbitrators of disputes pursuant to the CODE OF MARKETING PRACTICE.
- “Chair” – means the person appointed by the CAHI to Chair the Marketing Practice Review Committee.

3. APPLICATION AND TIMEFRAMES

All Full and Associate Members marketing animal health products will agree to be signatory to the **Code**.

Companies are encouraged to make every attempt to resolve differences on their own before referring them to mediation(s) or to the Marketing Practices Review Committee. A company may escalate a complaint to the next phase of the dispute resolution process at any time if it is felt adequate progress is not being made. It is recommended that the CAHI President be copied on correspondence in relation to a dispute or complaint early in the process to establish transparency and a timeline. As a guideline, an offending company should be given five (5) days to respond to an initial complaint.

A call for an expert opinion assessment will proceed once payments of \$5,000 have been received from both parties. Subsequently, meetings on the same complaint will require payment of an additional \$2,500 by each party per mediation session. CAHI will hold all funds in trust until a successful mediation outcome occurs at which time funds will be returned to the plaintiff and defendant less expenses.

In the event that an expert opinion assessment results in no agreed upon follow-up, each party must submit in writing confirmation that no agreement was reached. Subsequently, each party has 21 working days to submit \$10,000 in fees demonstrating intent to go to arbitration. Arbitration dates are then to be set within 60 days of receipt of plaintiff and defendants' cheques.

Funds for arbitration are held in trust until a decision is made by the Committee. The party found at fault will forfeit all mediation(s) and arbitration fees while the funds for the party found not to be at fault will be returned in full.

It is the responsibility of the party found to be at fault to cover all external costs associated with the mediation and arbitration process. Where the schedule of fees laid out within section 11.5 does not cover the total costs, the Committee will assess an additional penalty to cover those costs.

Any party found to have lost three decisions before the Committee in a two-year period will be surcharged an additional penalty of \$15,000.

4. ADMINISTRATIVE FEE SCHEDULE

By agreeing to the **Code**, CAHI Members and Associates marketing animal health product agree that mediation(s) and/or arbitration shall be administered by the Institute in the event where parties are unable to resolve differences. The Institute shall prescribe the fees outlined in the **Code** under Enforcement and Fees, Section 11 to compensate it for its administrative services. All fees are payable to the CAHI 'in trust' in the form of a cheque at the time the complaint is lodged. The fees will be treated as an advance for the anticipated costs and expenses of holding the Marketing Practice Review Committee meeting and expenses and fees of those serving on the Committee. If the required fees are not paid, the Marketing Practice Review Committee may order suspension or termination of the proceeding.

5. DELIVERY OF DOCUMENTS

- (i) Subsequent to written confirmation that an Expert Opinion Assessment was unsuccessful in having a mutually agreed upon follow-up, the plaintiff must provide CAHI and the defendant with concise written documentation outlining a Statement of Claim and request that the Claim be referred to arbitration. The Claim must be submitted by personal delivery, mail, email or facsimile to the CAHI office.
- (ii) The defendant in the case of the Claim will then have fourteen (14) days to provide concise written documentation in defense of their alleged violation by personal delivery, mail, email or facsimile to the CAHI office.
- (iii) Both the plaintiff and defendant's documents will then be distributed to the Marketing Practice Review Committee.

6. CONDUCT OF THE MARKETING PRACTICE REVIEW COMMITTEE

- (i) The Marketing Practice Review Committee may conduct the arbitration in the manner it considers appropriate.
- (ii) Each party shall be treated fairly and shall be given fair opportunity to present its case. Two (2) individuals from each party shall be provided opportunity to attend the arbitration meeting for the portion of the meeting they are participating in.
- (iii) Minutes of the meeting will be prepared by the CAHI.

7. SETTLEMENT

If, during the Arbitration proceedings, the parties settle the dispute, the Marketing Practices Review Committee shall terminate the proceeding and, if requested by both parties, record the settlement in the form of an Arbitration award on agreed terms. Should settlement be reached up to 15 days in advance of the arbitration hearing, Mediation(s) and Arbitration fees submitted to CAHI will be refunded less committed expenses.

8. DECISION

The Marketing Practice Review Committee will make its final decision within thirty (30) days of the arbitration proceeding. Decisions of the Marketing Practice Review Committee shall be in writing and shall, unless the parties otherwise agree, state the reasons upon which they are based. The decision shall be made by a majority of the Marketing Practice Review Committee. Where there is no majority decision, the decision of the Chair shall be final. The decision of the Marketing Practice Review Committee will be published in appropriate publications and on the CAHI website.

STANDARD OPERATING PROCEDURE FOR STAFF TRAINING - EXAMPLE

SUGGESTED GUIDELINES FOR USE:

- The template set out below is to be part of the Code of Conduct CAHI members use for all senior managers, marketing, veterinary services and regulatory affairs personnel to ensure awareness and compliance with CAHI's **Code**.
- The template may be edited as needed so long as the basic tenets of the CAHI Letter of Intent signed by each member are maintained.
- It is recommended that this procedure be reviewed with all new employees and employees returning to work after a leave. Subsequently this procedure should be reviewed on an annual basis.

Company Name			
Standard Operating Procedure			
Canadian Animal Health Institute Code of Marketing Practice			
Originator:	Approver:	Version:	
Purpose: To ensure Company Name personnel are aware of and comply with the CAHI Code of Marketing Practice.			Scope: All personnel
<p>The undersigned hereby acknowledges and agrees unconditionally to adhere to the requirements of the Canadian Animal Health Institute's Code of Marketing Practice ("the Code") as a condition of employment with Company Name.</p> <ol style="list-style-type: none"> 1. The Employee has received a complete copy of the Code and has had an opportunity to fully review the document. 2. The Employee understands and agrees to comply with and be bound by all of the provisions of the Code and complies to the jurisdiction of the CAHI Marketing Practices Review Committee and Secretariat, through Company Name's membership in CAHI, for the resolution of disputes in relation to the subject matter of the Code, unless and until Company Name advises CAHI in writing of their intent to no longer be bound by the provisions of the Code. 3. The Employee acknowledges that the Code may be amended from time to time and agrees that upon a receipt of a copy of any revised Code, the Employee shall be bound by same unless and until Company Name advises CAHI in writing of their intent to no longer be bound by the provisions of the Code as amended. 4. The Employee affirms that they will ensure all marketing / advertising / public relations agencies employed by the Company Name are made aware of the Code and its provisions and agrees that it may be held responsible for any breaches of the Code by such agencies in the course of their employment by Company Name. <p>If the foregoing is in accordance with your understanding and is acceptable to you please indicate this by signing this Standard Operating Procedure.</p>			
Position:			
Name (please print):			
Signature:			Date:
Reporting Manager Signature:			Date: