Health Canada Santé Canada

Overview of Health Product Advertising

What is health product advertising?

Health product advertising is considered to be any representation, by any means (e.g. television, radio, Internet, print, etc.), for the purpose of promoting directly or indirectly the sale or distribution of any health product (drugs, natural health products, medical devices, vaccines and biological products, etc.).

What health products can be advertised?

Only health products that have been authorized for sale in Canada by the Health Products and Food Branch (HPFB) of Health Canada may be advertised. The advertising must not exceed the terms of market authorization. In addition, specific regulatory provisions exist to limit the type/extent of advertisements of prescription drugs to consumers. Advertising of narcotic and controlled drugs to consumers is prohibited.

How do I know whether a specific health product has been authorized for sale in Canada?

Health products which are authorized for sale in Canada bear an eight-digit identification number preceded by a specific acronym. Authorized drugs bear the acronym "DIN" (Drug Identification Number), while authorized natural health products and homeopathic medicines respectively bear the acronyms "NPN" (Natural Product Number) and "DIN-HM" (Drug Identification Number - Homeopathic Medicine).

Are all messages which refer to health products considered to be advertising?

No. Some messages, depending upon the content and the context in which they are disseminated may be considered non-promotional. These could include press releases, consumer brochures, help-seeking announcements, scientific exhibits and journal articles, if they meet the criteria that are outlined in the Health Canada policy *"The Distinction Between Advertising and Other Activities"*.

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What factors determine whether or not a message is health product advertising?

No one factor alone determines whether or not a message is advertising. Each message must be assessed individually. The purpose, content and context of the message is examined to determine if the intent is to promote the sale of a health product or to provide information. Other factors which must be considered include how and when the message is being delivered, to whom and by whom and how often the message is being conveyed.

Who reviews health product advertising?

- Advertising material for nonprescription drugs and natural health products directed to consumers is reviewed and precleared by independent agencies that have publicly self-attested to meeting Health Canada's recommended attestation criteria.
- Advertising material for all health products directed to health professionals is reviewed and precleared by the Pharmaceutical Advertising Advisory Board (PAAB), an independent agency recognized by Health Canada.
- The PAAB, as well as Advertising Standards Canada (ASC), provide advisory opinions on messages directed to consumers for prescription drugs and on educational material discussing a medical condition/disease to ensure that they meet the regulatory requirements.

Additional information regarding "The List of Canadian Advertising Preclearance Agencies" and their roles in relation to the Department is located on Health Canada's website at:
http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/preclear-preapprob/pca-apa_list_e.html

Why do advertising preclearance agencies review health product advertisements?

Advertising preclearance agencies review and preclear advertising material in order to help industry ensure compliance with the regulatory provisions of the *Food & Drugs Act and Regulations*, the *Natural Health Products Regulations* and the various Health Canada guidance documents and codes of advertising. The regulatory framework is intended to protect the health of Canadians. The agencies also offer independent mechanisms to resolve complaints on advertising for authorized health products.

What is Health Canada's role?

Health Canada is the national regulatory authority for health product advertisements and bears the ultimate responsibility for enforcing the *Food and Drugs Act* and related Regulations. Health Canada:

- Provides policies to effectively regulate marketed health products;
- Develops guidance documents for the interpretation of the regulatory framework; and
- Oversees regulated advertising activities.

Health Canada may intervene:

- When an advertisement poses a significant safety concern;
- In the event that resolution is not achieved through the independent advertising preclearance agencies' complaints mechanisms;
- When a prescription drug is illegally advertised to the general public; or
- When an unauthorized health product is promoted.

Health Canada sets the standards for health product advertising material that is not false, misleading or deceptive. Health Canada reserves the right to enforce the provisions contained in the federal legislation through a national compliance and enforcement program which applies on a risk-based approach.

Is it mandatory to have health product advertisements reviewed prior to their release?

Although it is not mandatory, various manufacturer associations such as NDMAC and Canada's Research-Based Pharmaceutical Companies (Rx&D) support pre-clearance by independent advertising preclearance agencies. Health Canada strongly encourages all sponsors to comply with the voluntary preclearance review prior to exposure to health care professionals and consumers.

Is there a specified format for the submission of advertisements?
Is there a cost?

Advertisers should contact the advertising preclearance agencies listed on the Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/preclear-preapprob/pca-apa_list_e.html to obtain further information on the format for advertisement submissions and the costs involved.

Where can I file a complaint about an advertisement for an authorized health product?

The first route for adjudication of complaints for **authorized health products** is through advertising preclearance agencies. More specifically, complaints related to:

- Consumer advertising of nonprescription drugs and natural health products should be submitted to advertising preclearance agencies that have publicly self-attested to meeting Health Canada's recommended criteria (http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/preclear-preapprob/pca-apa_criter_e.html)

- Health professional advertising of prescription drugs and other health products should be submitted to:

  Pharmaceutical Advertising Advisory Board
  Commissioner
  200-375 Kingston Road
  PICKERING, Ontario L1V 1A3
  Telephone: (905) 509-2275
  Fax: (905) 509-2486
  www.paab.ca

- Direct-to-consumer advertising of prescription drugs should be submitted to:

  Regulatory Advertising and Risk Communications Section
  Marketed Health Products Directorate
  Health Products and Food Branch
  Health Canada
  Address Locator 0701C
  OTTAWA, Ontario K1A 0K9
  Telephone: (613) 948-7973
  Fax: (613) 948-7996
  Email: MHPD_DPSC@hc-sc.gc.ca
  http://www.hc-sc.gc.ca/home-accueil/contact/hpfb-dgpsa/rarc-rpcr_e.html

Where can I file a complaint about an advertisement for an unauthorized health product?

Complaints should be submitted to the Health Products and Food Branch Inspectorate (HPFBI) Office responsible for your province (see list in the document "How to Submit a Consumer Complaint" available at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index_e.html) or by calling 1-800-267-9675.

What information should be provided when filing a complaint?

To the extent possible, the following information should be provided when filing a complaint:

- Your contact information;
- Name of the brand name/common name of the product and name of the sponsor;
- Where and when the ad was heard or seen (name of the TV or radio station, newspaper, where it is displayed, date, time, etc.);
- A description of the ad (enclose or attach a copy of the print ad, video clip, audio, web, if possible); and
- The concerns about the ad and alleged violations;
- Any other information which would assist in verifying the complaint.

What enforcement actions will be taken on non-compliant advertising?

Advertising preclearance agencies have complaint adjudication mechanisms in place which outline appropriate corrective actions.

If an advertisement continues to be non-compliant with the *Food and Drugs Act* and its Regulations, enforcement actions will be undertaken by Health Canada in accordance with the Health Products and Food Branch Compliance and Enforcement Policy available at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/activit/index_e.html

Where can I find additional information about health product advertising requirements and guidance documents?

Advertising guidance documents as well as additional information about health product advertising (reports, consultations, meetings, etc.) are available at: http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/index_e.html