



Health
Canada

Health Products
and Food Branch

Santé
Canada

Direction générale des produits
de santé et des aliments

- Interim Guidance - Fair Balance in Direct-to-Consumer Advertising of Vaccines

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Scope

This Interim Guidance applies to Schedule D (*Food and Drugs Act*) vaccine advertisements directed to consumers in all types of mediums (television, radio, print, Internet, social media etc.).

Vaccination campaigns such as public health messages that do not promote a specific product would not qualify as advertising of a health product, and would not be subject to the fair balance requirements outlined in this Interim Guidance.

Preclearance

All direct-to-consumer advertisements and related advertising materials should be submitted for review and preclearance to either the Pharmaceutical Advertising Advisory Board (PAAB) or Advertising Standards Canada (ASC), prior to dissemination to the target audience. See list of Advertising Preclearance Agencies at: http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/preclear-preapprob/pca-apa_list-eng.php

General Guiding Principles

- 1) The health and safety of Canadians is paramount.
- 2) Advertising must comply with Section 9(1) of the *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".
- 3) Advertising of vaccines should be in accordance with the principles of the following Health Canada guidance documents: the *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)* and the *Therapeutic Comparative Advertising Directive and Guidance Document*.
- 4) Advertising should present accurate, truthful, objective and balanced information on the benefits and risks of a health product to provide consumers with useful

Canada

information to make sound decisions about their health, in collaboration with a healthcare professional.

- 5) Advertising which emphasizes only positive features of a health product while ignoring or minimizing significant negative findings is not acceptable. The overall content and context of an advertisement will always be considered in order to determine if a message provides fair balance.
- 6) Disclosure of health product risks and benefits in all advertising medium should be sufficiently noticeable for an average person to read and comprehend and shall always be of visually comparable type size, duration, pace, shade, location and displayed in sufficient contrast with the background, where applicable.

Compliance with the General Guiding Principles

Adherence to these general guiding principles may be accomplished through the inclusion of a combination of the following elements (not an exhaustive list):

- Information about the indications, benefits, most common and serious side effects, allergic reactions, important precautions and warnings, contraindications in certain populations, etc.
- Information related to the protection offered by the vaccine, such as duration of protection, need for booster doses, time to onset, clear identification of types of disease-causing microorganisms the vaccine offers protection against and any limitations of strains.
- Indication of the preventative role of vaccines as opposed to treatment.
- An explanation that everyone may not be fully protected by the vaccine.
- Where applicable, information about the need and importance of continuing specific testing, screening or monitoring by a healthcare professional.
- Inclusion of a reference to Health Canada's authorized consumer information, where complete and objective information about the risks and benefits of the product can be found.
- Inclusion of a reference on broadcast ads or shorter media to another source of additional complete, objective and balanced information about the risks and benefits of the product (e.g. print ad, Web site, toll-free telephone number, etc.).
- Inclusion of a generic statement advising consumers to consult and discuss the advantages and disadvantages of the product with their healthcare professional, to make sure that it is suitable for them.