

Health Products Advertising on Physician Web Sites – Questions & Answers

Recently, Health Canada wrote to the registrars of the provincial medical regulatory authorities about physicians promoting health products¹ on their Web sites. Health Canada has received complaints about this practice and is therefore providing this guidance to help physicians comply with federal advertising requirements. These requirements apply to everyone who advertises health products to Canadians, not just to physicians. Our aim is to increase awareness among all those who advertise health products of the importance of complying with the Canadian *Food and Drugs Act* and *Food and Drug Regulations*.

The following questions and answers are meant to respond to some of the questions we have received. Please note that the following information relates only to federal regulatory requirements. Each province may have its own requirements for physician advertising which may impose additional restrictions.

How is health product advertising defined, for regulatory purposes?

Section 2 of the *Food and Drugs Act* defines “advertisement” as “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”. This definition applies to advertising in any medium, such as print, broadcast, the Internet, social media, etc. All messages which fit this definition must comply with the advertising provisions of the *Food and Drugs Act* and its associated regulations. The most relevant provisions are excerpted in the accompanying document “Regulation of Health Product Advertising in Canada – Overview for Physicians”.

Are all health product messages considered to be advertising?

No. Messages may be non-promotional information if they do not promote a health product. Whether or not a message can be interpreted as advertising depends upon the content and the context in which it is disseminated. No one factor alone will determine whether a message is advertising. Health Canada’s policy “The Distinction between Advertising and Other Activities”² contains examples of health product messages and factors used to assess whether they are likely to be advertising. Considerations include the message’s audience, content, context, sponsor, and provider, as well as the influence of the manufacturer.

Certain types of messages are less likely to be advertising, such as press releases, scientific exhibits and journal articles. But even these may be promotional in some contexts. The distinction is important: if a message constitutes advertising, it must comply with the federal advertising prohibitions, while non-promotional information is not subject to these provisions. This means, for example, that disease information pieces may discuss prescription drugs and other therapeutic options, as long as there is no emphasis on a specific drug. However, under Section C.01.044 of the *Food and Drug Regulations*, an advertisement for a specific prescription drug is prevented from mentioning more than the drug’s name, price and quantity, when it is directed to the general public. Prescription drug advertising to healthcare professionals does not have this particular restriction.

Health product messages on most physician Web sites are in the context of promoting physician services. Is this considered health product advertising?

The *Food and Drugs Act* and its associated regulations do not apply to advertising of services. However, if physician Web sites promote specific products, they must comply with the Act and its associated regulations.

¹ Health products include prescription and non-prescription medications, biologics (including vaccines), natural health products, medical devices and radiopharmaceuticals. “Drugs”, as defined in s. 2 of the *Food and Drugs Act*, include all of the preceding health products, except medical devices.

² http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/actv_promo_vs_info-eng.php

For example, Section C.01.044 of the *Food and Drug Regulations* states that prescription drug advertising to the general public must not exceed mention of name, price and quantity of the drug. As well, advertising of any health product to the general public for the treatment, prevention or cure of certain serious diseases is prohibited by Section 3 of the *Food and Drugs Act* (although prevention claims are permitted by regulation for over-the-counter drugs and natural health products).

Health Canada strongly encourages health product advertisers to take advantage of Canada's voluntary advertising preclearance system. Under this system, independent advertising preclearance agencies³ will review advertising messages (including Web sites) prior to dissemination to the target group, to ensure that they comply with Canadian advertising legislation.

Why has this issue been raised now?

Health Canada has received complaints regarding direct-to-consumer advertising of prescription drugs on Web sites of some cosmetic surgeons. In addressing the complaints, it was noted that this practice was widespread. Health Canada suspects that physicians may not be aware of the federal advertising prohibitions or their application to physician advertising.

What about other health products, such as over-the-counter drugs, vaccines, natural health products and medical devices?

Advertising for these products is not subject to Section C.01.044 of the *Food and Drug Regulations*. Therefore, they may be advertised to the general public beyond name, price and quantity. Advertisers must still comply with other advertising regulations: for examples, messages must not be false, misleading or deceptive, and must not make claims to treat or cure any disease listed on Schedule A to the *Food and Drugs Act*⁴. Advertising claims should be consistent with Health Canada's authorized indication for the product (as found in the Product Monograph⁵ or Product Licence⁶ for example).

What kind of information about prescription drugs can pharmaceutical manufacturers direct to the general public?

Web sites of pharmaceutical manufacturers must either be nonpromotional in nature, or they must comply with federal advertising requirements. Under the regulatory framework, Health Canada has permitted two types of prescription drug messages directed to consumers, Reminder Ads and Help-Seeking Messages:

- Reminder Ads, where the name of a prescription drug is mentioned, but no reference to a disease state appears in the ad, are interpreted as not going beyond the name, price and quantity restrictions of Section C.01.044.
- Help-Seeking Messages, where a disease state is discussed, but no reference is made to a specific prescription drug product, are considered information and not advertising when they meet the criteria outlined in the policy, "The Distinction Between Advertising and Other Activities"⁷.

³ http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/preclean-preapprob/pca-apa_list-eng.php

⁴ <http://www.laws-lois.justice.gc.ca/eng/acts/F-27/page-17.html#h-18>

⁵ <http://web.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php>

⁶ <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/lnhpd-bdpsnh-eng.php>

⁷ http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/actv_promo_vs_info-eng.php

Are manufacturers or other groups allowed to post Product Monographs for prescription drugs on the Internet?

A drug product's official Health Canada authorized Product Monograph is a factual, scientific document. It describes the properties, claims, indications and conditions of use of the drug product and does not contain any promotional material. Health Canada does not object to the practice of posting authorized Product Monographs on corporate Web sites when those sites are devoid of promotional material. The context in which the Product Monograph is displayed is critical to the determination of whether this practice is in accordance with federal advertising requirements.

Sometimes physicians, clinics or university departments develop Web sites which provide information to the public regarding particular drugs and their uses. Would these be considered advertising?

An educational Web site will not usually meet the definition of advertising. However, Health Canada assesses this on a case-by-case basis using the factors outlined in "The Distinction between Advertising and Other Activities". We consider the purpose, content and context to see whether it is intended solely to educate or if it may also be promotional. In addition to being educational, a Web site developed by a physician, clinic or university department may also promote the sale of a health product, either directly or indirectly. Such a message is more likely to be advertising if it is sponsored by the product manufacturer, and if it places a favourable emphasis on the sponsor's product. If it meets the advertising definition, it must comply with federal advertising prohibitions.

Who enforces the federal advertising regulations?

The Federal Government bears the ultimate responsibility for enforcing the *Food and Drugs Act* and its associated regulations. When Health Canada receives a complaint about a health product message, the message is first assessed to determine whether it meets the definition of advertising. When advertising, it is assessed for compliance with the regulatory framework; compliance and enforcement action is taken as required. The Health Products and Food Branch Inspectorate is the division of Health Canada which conducts compliance and enforcement activities using a risk-based approach.