Marketed Health Products Directorate

Role in Regulatory Oversight of Health Product Advertising

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Canada

Topics

- Health Canada's role
- Role of the advertising preclearance agencies
- Role of Industry
- Regulatory requirements for advertising
- Policies & guidelines
- Distinction between advertising and other activities
- Recent changes to the consumer advertising preclearance system

Health Canada's Role

- Health Canada (HC) is the national regulatory authority for health product advertising
- Sets the parameters under which health products are marketed in Canada (e.g., Product Monograph)
- Puts in place regulations and policies to effectively regulate marketed health products
- Provides guidelines for the interpretation of the regulations

Health Canada's Role (cont'd)

- Within HPFB, the Marketed Health Products Directorate (MHPD) is responsible for overseeing the regulatory activities related to health product advertising
- Chair of the Branch Advertising Working Group
- MHPD liases with pre-market areas and the HPFB Inspectorate
- MHPD is the HPFB point of contact with advertising preclearance agencies

Health Canada's Role (cont'd)

- MHPD coordinates requests to clarify interpretations of the terms of market authorization (e.g., Product Monograph) in advertising
- MHPD conducts regulatory assessments of advertising complaints
- Ex-officio representative on boards of advertising preclearance agencies

Health Canada's Role (cont'd)

- Health Canada intervenes in advertising complaints when advertising:
  - Contravenes regulatory requirements and poses a significant risk to health
  - Preclearance agencies are unable to obtain wilful compliance
  - Relates to incidents of illegal promotion (i.e., unauthorized product)
  - Of a prescription drug to the general public is illegal

- Violations of the regulations and advertising standards are subject to investigation. Appropriate compliance & enforcement actions are taken when required.

Role of the Advertising Preclearance Agencies

- The preclearance of advertising of marketed health products is governed by a self-regulatory and voluntary system.
- Drug advertisements are reviewed and precleared by independent advertising preclearance agencies in order to determine compliance with the regulatory provisions of the *Food and Drugs Act* and Regulations and the various codes of advertising.
- The agencies verify that advertising is accurate, balanced and evidence-based.
- The agencies also offer independent mechanisms to resolve complaints and provide the first route of adjudication of complaints for authorized health products.

Role of Industry

- Preclearance of advertising by the agencies is voluntary for industry but is strongly recommended by HC
  - Required by Rx&D code

- Industry is responsible to meet the federally legislated requirements for advertising of health products

Advertising to health professionals

- 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 HC since the mid-seventies
  - www.paab.ca

Advertising to consumers

- Advertising material for nonprescription drugs and natural health products (NHPs) directed to consumers:
  - Is reviewed and precleared by the independent agencies that have publicly self-attested to meeting HC's recommended attestation criteria
  - Two agencies are currently listed for this service:
    - Advertising Standards Canada (ASC), www.adstandards.com
    - Broadcast Clearance Advisory (a division of MIJO Corporation) (BCA), www.bcacanada.com

Advisory opinions – consumer messages for prescription drugs

- Advisory opinions on messages direct to consumers for prescription drugs and on education material discussing a medical condition/disease:

  – PAAB and 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 regulatory requirements

Regulatory Requirements for Advertising

- Only health products that Health Canada has authorized for sale in Canada may be advertised, i.e., only products for which the Terms of Market Authorization (TMA) have been established can be advertised in Canada (e.g., Product Monograph)
- Section C.08.002 requires that the Terms of Market Authorization of a new drug be established prior to sale or advertising
- The advertising must not exceed the TMA

Food and Drugs Act

- “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

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)]
- No person shall distribute or cause to be distributed any drug as a sample, except under the prescribed conditions [Section 14]
- No person shall advertise any drug to the general public as a treatment, preventative or cure for any of the diseases listed in Schedule A [Subsection 3(1)]

Proposed Regulatory Amendment – Schedule A Revision and Claims

- Proposes to:
  - (i) revise the list of Schedule A diseases
  - (ii) exempt NHPs and certain drugs (nonprescription drugs) from the prohibition on preventative claims for the remaining diseases listed in Schedule A of the *Food and Drugs Act*
- Published in Canada Gazette, Part I on June 16, 2007 (Project 1539) with a 75-day comment period

Regulatory Requirements for Advertising (cont'd)

- Section C.01.044 limits the advertising of prescription drugs to the general public to name, price and quantity
  - Information on a specific prescription drug and a particular disease cannot be combined in an advertisement directed to consumers
- Advertising of narcotic and controlled drugs to consumers is prohibited

HC Policies & Guidance Documents on Advertising

- Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)
- Therapeutic Comparative Advertising: Directive and Guidance Document
- The Distinction Between Advertising and Other Activities
- Advertising Campaigns of Branded and Unbranded Messages
- Principles for Claims Relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products
- Advertising Standards Canada and HC's Roles and Consultation Related to Advertising Review and Complaint Adjudication (currently under review)
- PAAB and HC's Roles and Consultation Related to Advertising Review (currently under review)

Are All Health Product Messages Considered to be Advertising?

- Answer: No! Some messages, depending upon content and context in which they are disseminated may be considered non-promotional
- No one factor alone determines whether or not a message is advertising
- The purpose, content and context must be examined to determine if the intent is to promote the sale of the health product or provide information
- See HC Policy The Distinction Between Advertising and Other Activities

Policy - Distinction Between Advertising and Other Activities

- Its purpose:
  - To clarify if material is deemed promotional (i.e., to promote the sale of a health product) versus activities that are not primarily intended to promote the sale (e.g., education, scientific exchange, labelling)
  - Not intended for use in determining whether or not the provisions of the *Food and Drugs Act* and its Regulations are observed
  - Messages that are deemed non-promotional are not subject to the advertising provisions of the Act or its related Regulations

Criteria to determine if advertising:

- Content and context (audience, influence of sponsor, frequency)
  - Context in which this information is disseminated must be taken into consideration
- Purpose of message very significant
- Lack of clarity and evidence poses difficulties
- If HC determines that the primary purpose of a message is advertising, an assessment is then made regarding compliance with the regulations
- Dissemination of factual information in the media is not subject to the advertising provisions of the *Food and Drugs Act* and Regulations
- Examples of message types given in the policy

Reminder Ads and Help-Seeking Messages

- Two types of prescription drug messages directed to consumers have been permitted:
  - Reminder ads
  - Help-seeking messages
- Advertising campaigns directed to consumers including simultaneous branded and unbranded messages would exceed restrictions in C.01.044

Reminder Ads

- Only mentions the name of a prescription drug without making any reference to a disease or medical condition
- Generally not considered to exceed the restrictions set out in section C.01.044 of the Food and Drug Regulations as long as there are no representations that allude to the therapeutic use of a prescription drug
- Pack shot representations (e.g., blister pack of oral contraceptives), pictures, reference to medical specialists are all factors considered to allude to therapeutic use

Help-seeking Messages

- Generally considered non-promotional information, not advertising
- Discusses a disease or medical condition and invites patients to contact a health professional or to call a toll-free number for additional information
- Does not make reference to any specific prescription drug product

Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)

- Final version came into effect on October 18, 2006
- Designed to help advertisers develop ads that meet all the relevant provisions of the *Food and Drugs Act*, and Regulations, Natural Health Products Regulations and other related HC policies and guidelines
- Form the basis upon which advertising preclearance agencies review and approve advertising for nonprescription drugs, including NHPs
- Replaced the 1990 Consumer Drug Advertising Guidelines

Section 2.21 of the Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)

- Deals with risk/safety information communication
- Consumers should be provided with fair and balanced info about the benefits and risks associated with the use of the advertised product
- Consumers should be advised to read the label and where there are known risks, be provided with a general cautionary statement
- Came into effect on April 1, 2007 to allow industry to adjust their advertising materials

Section 2.21 of the Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products) (cont'd)

- Divergence of opinion as to how the general cautionary statement in TV ads ought to be conveyed: super vs. verbal communication
- General cautionary statement, when needed, informs that the advertised product may pose risks and may not be suitable for everyone (or similar wording)

Section 2.21 of the Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products) (cont'd)

- In the meantime, HC still recommends the general cautionary statement in TV ads be communicated verbally
- But the use of visual disclosures ("supers") will be permitted as long as they are clear, visible and of sufficient duration to be effectively read and understood by consumers

The New Consumer Advertising Preclearance System for Nonprescription Drugs and NHPs

- From 1997 until 2006, the role of reviewing and preclearing consumer ads for nonprescription and NHPs was carried out by one preclearance agency, namely ASC which was endorsed by HC

- Advent of additional consumer advertising preclearance agencies since that time

- In order to achieve a workable system, HC no longer endorses specific agencies providing these services

The New Consumer Advertising Preclearance System for Nonprescription Drugs and NHPs (cont'd)

- HC has established attestation criteria for agencies in Canada

- Agencies in Canada who wish to provide review and preclearance services for nonprescription drug and NHP advertisements direct to consumers are requested to publicly attest to the criteria

- See document posted on the HC website: *Health Canada's Recommended Public Attestation Criteria for Advertising Preclearance Agencies in Canada who Provide Review and Preclearance Services of Nonprescription Drugs and NHPs Advertising Material Directed to Consumers* (Dec. 2006)

The New Consumer Advertising Preclearance System for Nonprescription Drugs and NHPs (cont'd)

- Note that this new system does not affect the advertising preclearance function for material directed to health professionals or for material related to prescription drugs or vaccines directed to consumers

Conclusion

- Health Canada is committed to protecting the health and safety of Canadians by maintaining regulatory standards for the advertising of health products
- Continues to work with advertising preclearance agencies to accomplish this goal

Contact Information

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Regulatory Requirements for Advertising – HC Website:
http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/index_e.html