Regulatory Oversight of Health Product Advertising in Canada – Focus on Social Media

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Alain Musende, PhD
Manager, Regulatory Advertising Section
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada

Canada

Purpose

- **To provide an overview of the regulatory oversight of health product advertising in Canada.**

- **To discuss the applicability of the current health product advertising regulatory framework on Social Media (SM) Advertising.**

- **To present practical cases and best practices of health product advertising using SM.**

- **To share some Health Canada advertising related initiatives.**

Context

Regulator

Regulatory Oversight & Guidance Provider

Advertising Preclearance Agencies

Review & Preclearance Service Provider

Industry Associations

Guidance Tool Provider for Members

Market Authorization Holders

Compliance Procedure Developer

Healthcare Professionals

Advisor & Information Provider

General Public

Information Gatherer

Health Canada's Roles

- **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 to effectively regulate marketed health products.**
- **Provides guidelines for the interpretation of the regulations.**

Health Products and Food Branch (HPFB)'s Roles

- **HPFB intervenes 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., prescription drug advertising to the general public beyond name, price, and quantity, advertising of unauthorized products, off-label promotion, etc.).

- **Contraventions of the legislation and regulations, and non-compliance with advertising guidelines are subject to compliance verification.**

- **Appropriate compliance & enforcement actions are taken when required (risk-based approach).**

Marketed Health Products Directorate (MHPD)'s Roles

- **Responsible for overseeing the regulatory activities of health product advertising.**

- **Point of contact with advertising preclearance agencies (APAs) and *Ex-officio* representative on boards of APAs.**

- **Coordinates requests for clarifications relating to health product advertising received from various stakeholders.**

Marketed Health Products Directorate (MHPD)'s Roles *(Continued)*

- **Conducts regulatory assessments of certain types of advertising complaints.**

- **Chair of HPFB Advertising Working Group.**

- **Liaises with licensing directorates and the Health Products and Food Branch Inspectorate (HPFBI).**

Where are we Situated Within Health Canada?

Health Canada

Health Products & Food Branch

Health Product Licensing

- **Therapeutic Products Directorate**
- **Biologics and Genetic Therapies Directorate**
- **Natural Health Products Directorate**

Post Market Surveillance

- **Marketed Health Products Directorate**
  - Therapeutic Effectiveness & Policy Bureau
    - Regulatory Advertising Section
- **Compliance & Enforcement** ↔ **Health Products & Food Branch Inspectorate**

Review and Preclearance of Health Product Advertising

- **Complete information in the Guidance Document entitled *"Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising"* (http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/role_apa-pca-eng.php).**

- **Advertising material for all health products directed to healthcare 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).**

Review and Preclearance of Health Product Advertising *(Continued)*

- **The preclearance of advertising of marketed health products is:**
  - **A self-regulatory system**
  - **A voluntary system**
  - **Required by some industry associations for their members**
  - **Strongly recommended by Health Canada**

Roles of Advertising Preclearance Agencies (APAs)

- **APAs perform the following:**
  - **Offer independent mechanisms to resolve complaints**
  - **Provide the first route of adjudication of complaints for authorized health products.**
  - **Review and preclear health product advertisements to verify that:**
    - **Advertising is compliant with the legislative and regulatory advertising provisions and the various codes of advertising.**
    - **Advertising is accurate, balanced and evidence-based.**

Review and Preclearance of Health Product Advertising *(Continued)*

- **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)**
  - **MIJO (www.mijo.com).**

Additional services provided by the PAAB and ASC

- **Provide advisory opinions on messages directed to consumers which may relate to prescription drugs or vaccines, as well as on educational material discussing a medical condition/disease.**

- **Assist industry and other stakeholders (including physicians) in meeting the applicable regulatory requirements when required.**

Roles of Industry and Other Stakeholders

Industry and other stakeholders, such as physicians, are responsible for:

- **Meeting the federally legislated requirements for advertising of health products.**

Current Regulatory Requirements for Advertising

- **Section 2 – *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.

  Note: Health Canada uses the policy "**The Distinction Between Advertising and Other Activities**" to distinguish promotional campaigns from information.

- **Section 9(1) – *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.*

  Objective: To protect Canadians against false and misleading advertisements and encourage advertising that is accurate and truthful, which will help them make informed decisions about their health.

Current Regulatory Requirements for Advertising *(continued)*

- **Section 3(1) – *Food and Drugs Act*:**
  *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*.

  Note:
  Diseases listed in *Schedule A* to the *Food and Drugs Act*, such as cancer, diabetes and depression, all require medical intervention.

  Objective:
  To discourage self-diagnosis, self-medication and self-treatment of serious diseases.

- **Section C.08.002 – *Food and Drug Regulations*:**
  *No person shall sell or **advertise** a drug unless it has received a notice of compliance.*

  Objective: To avoid:
  - Health risks that may be caused by products with unknown benefit/risk profile and quality.
  - Promotion of unauthorized claims (off-label promotion).

Current Regulatory Requirements for Advertising *(continued)*

- **Section C.01.044 – *Food and Drug Regulations*:**
  *Where a person **advertises** to the general public a prescription drug, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.*

Note:
Prescription drugs generally possess a high level of risk relative to expected benefits, have a narrow margin of safety between the therapeutic and toxic doses, may require individualized instructions and/or direct practitioner supervision, and may not have been on the market long enough (to establish a safety profile).

Objective:

- To encourage patients to obtain information about prescription drugs from their healthcare professionals.
- To allow consumers to compare prescription drug prices.

No Exception for Social Media…

- **The current regulatory framework pertaining to health product advertising in Canada apply to all advertisements, irrespective of the advertising medium (television, radio, print, and digital).**

- **There is no reason for applying a different set of rules for social media platforms.**

However…

- **Since there are unique features to social media, it may be pertinent to provide industry with specific guidelines.**

- **Health Canada is monitoring the situation closely in the US and other countries in terms of research, development, and issuance of social media-specific guidance.**

- **Any potential guidance issued in Canada would have to be flexible and adaptable to various situations as this is a rapidly evolving platform.**

Unique Features of Social Media

- **User-Generated Content (UGC):**
  - **The main driving force of social media**
  - **The main drawback of social media**
  - **May contribute to provide inaccurate, false and potentially misleading information**
- **Reporting of adverse reactions**
- **Space limitations**
- **Lack of clarity on how health regulators may view certain social media activities.**

Actual Case: "Off-Label" Promotion on YouTube…

- **A Stroke Prevention YouTube Channel featured experts discussing an off-label indication for a product authorized for sale in Canada.**

Actual Case: "Off-Label" Promotion on YouTube… (Continued)

- **The video included a disclaimer: "*Content was intended for viewers outside the United States.*"**
- **Viewers could believe that the messages were appropriate for a Canadian audience, which was not the case.**
- **Considered in contravention of:**
  - **Section C.08.002 of the *Food and Drug Regulations***
  - **Section 9(1) of the *Food and Drugs Act***

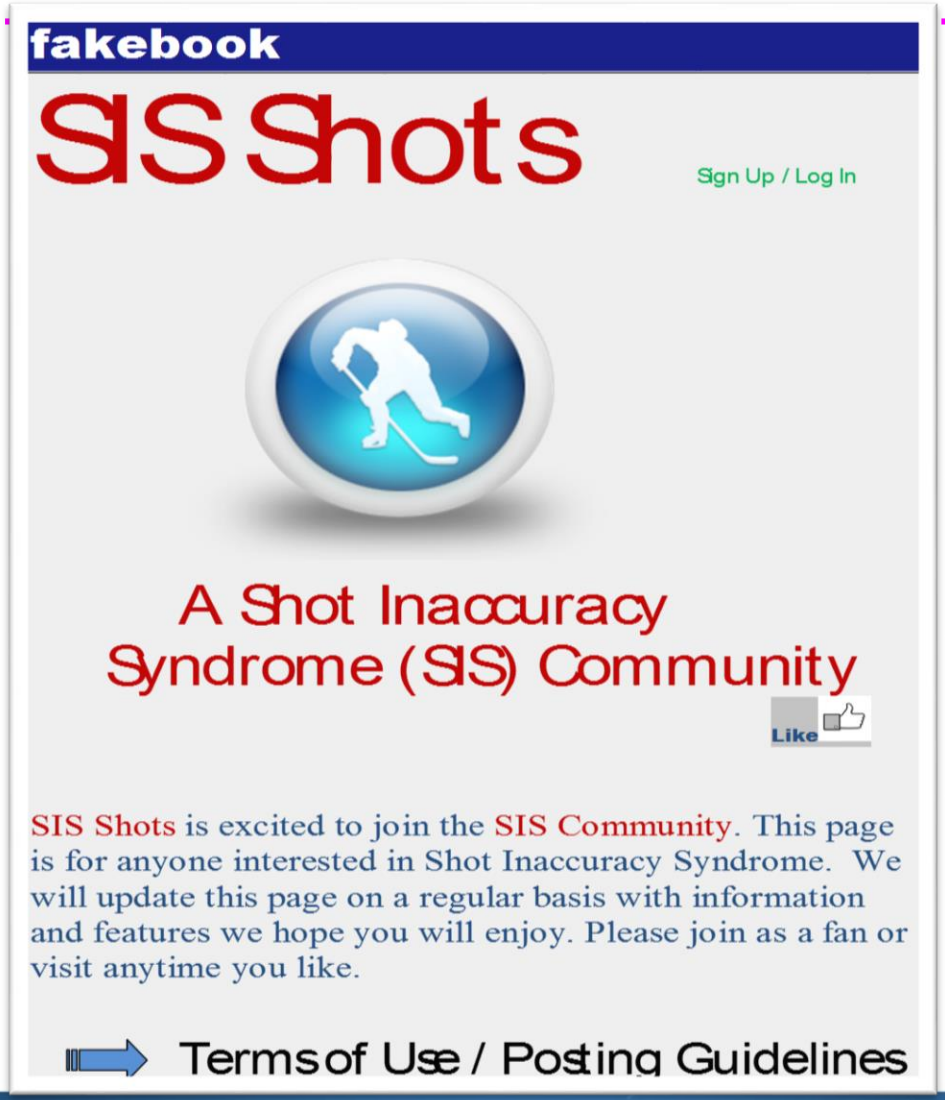
Actual Case: Advertising Via Blogging…

- **A person created a blog to discuss the results of the use of a specific prescription drug.**

Actual Case: Advertising Via Blogging…(Continued)

- **Health Canada determined:**
  - ❑ **The blogger was previously paid by the manufacturer of the product as a speaker/spokesperson.**
  - ❑ **Mention of this material fact was omitted entirely and did not appear in any of the blog entries**
- **Contravention of Section C.01.044 of the *Food and Drug Regulations*.**

Hypothetical Case: Acceptable Fakebook Page…



Hypothetical Case: Acceptable Fakebook Page…*(Continued)*

SIS Shots: Terms of Use / Posting Guidelines

To our fans: Our fakebook page invites you to share your thoughts, comments or questions. Below are a few elements to keep in mind when submitting a comment:

1. The information on this page is owned and monitored by Hockey Pharma Inc. and may be modified at any time without notice.
2. All messages posted will be reviewed and approved by Hockey Pharma Inc. before being posted.
3. Please keep your comments respectful, appropriate, and do not include any health product name or information.
4. Comments about any health product, whether marketed by Hockey Pharma Inc. or other manufacturers will not be posted. Product-specific questions should be directed to the market authorization holder.

Hypothetical Case: Acceptable Fakebook Page… *(Continued)*

SIS Shots: Terms of Use / Posting Guidelines *(continued)*

5. Hockey Pharma Inc. reserves the right to reject or remove a comment at its discretion. Comments from members of the public do not necessarily reflect the views of Hockey Pharma Inc. and no endorsement of their content should be implied. Comments that contain links to third-party or commercial Web sites may not be posted; please note that any Web site that may appear in comments are not endorsed or supported by Hockey Pharma Inc.
6. If a posting includes possible adverse events associated with a health product, Hockey Pharma Inc. may be required to contact you for further information. You are encouraged to report adverse events of prescription drugs to Health Canada. Visit www.healthcanada.gc.ca/medeffect, or call 1-866-234-2345.
7. The information on this page is intended for Canadian residents only and is not meant to substitute for the advice provided by a healthcare professional. Always consult a healthcare professional if you have health concerns.

Best Practices

- **Monitor User-Generated Content and remove inappropriate content**:
  - Being up front with the posting rules will minimize the need for intervention. Include a statement such as:

    "Online content written by users contributing to provide inaccurate, false and potentially misleading information will be monitored and removed."

- **Report Adverse Drug Reactions mentioned on the site if they meet the 4 minimal criteria: a patient, a drug, an adverse reaction and a reporter.**
  - It is acknowledged that it may be challenging to monitor the information, gather missing pieces, confirm the location of a patient, and avoid duplication of reports.

Best Practices *(Continued)*

- When a site is restricted to healthcare professionals only, discussion of an unauthorized drug or indication for use must include a statement indicating that the drug/indication has not been authorized for marketing in Canada.

- Avoid responding publically to questions that may lead to non-compliant statements. Include a statement such as:
  "May respond directly to individuals who have submitted questions, in private".

Take Home Message

- Social Media advertising meets the definition of Section 2 of the *Food and Drugs Act*. It thus must comply with the health product advertising framework.

- The regulator's objective is to protect the public, patients, and healthcare professionals against false and misleading advertising.

- Industry should take advantage of the advertising preclearance system in Canada to help ensure compliance:
  - ❑ The Pharmaceutical Advertising Advisory Board (PAAB)
  - ❑ Advertising Standards Canada (ASC)

Take Home Message *(Continued)*

- Industry should try to create best practices, such as:
  - Monitoring social media activities that it has set up
  - Being transparent with users and the posting rules
  - Implementing measures to avoid non-compliance (ability to remove comments, use of disclaimers, etc…)
- Recognize that best practices may appear to contradict the interactive, open-dialogue, and active community engagement that are key to success for social media initiatives.
- Therefore, the use of social media for health product advertising may not always be suitable.

Take Home Message *(Continued)*

- The presentation and examples discussed herein reflect Health Canada's current approach in regulating health product advertising.

- A case-by-case analysis is always required.

Updates to Existing Guidance Documents and Policies…

- ***Consumer Advertising Guidelines for Marketed Health Products*** **(Collaborative work between Health Canada and Advertising Standards Canada)**
- ***Distinction Between Advertising and Other Activities***
- **Exploring work to clarify Section C.01.044 of the *Food and Drug Regulations***
- **Transparency Initiative**

….Interested stakeholders will be provided with ample consultation opportunities.

For More Information…

Contact:

- **Alain Musende, PhD**
  Manager, Regulatory Advertising Section
  Marketed Health Products Directorate
  Health Products and Food Branch
  Tel.: (613) 954-6780
  Facsimile: (613) 948-7996
  E-mail: alain.musende@hc-sc.gc.ca

- **Regulatory Advertising Section**
  Tel.: (613) 960-2868
  Facsimile: (613) 948-7996
  E-mail: mhpd_dpsc-advertising_reg_publicite@hc-sc.gc.ca
  Web site – Health Canada's Regulatory Requirements for Advertising:
  http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/index-eng.php