Pharmaceutical Advertising in Canada

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Agenda

• Part 1: Scope of Regulatory Framework
• Part 2: Role of the Regulators
• Part 3: Advertising to Health Professionals
• Part 4: Direct to Consumer Advertising
Part 1: Scope of Regulatory Framework
Part 1: Scope

Regulation of Drug Advertising

- Health Canada
- Food and Drugs Act
- Regulations to the Food and Drugs Act
  - Food and Drug Regulation
  - Medical Devices Regulation
  - Natural Health Products Regulation
Food and Drugs Act

- Sets basic criteria for acceptable advertising of drugs and medical devices
- General Restriction
  - Advertising of drugs must not be false, misleading or deceptive in any way
Food and Drugs Act

- Prohibited Advertising: those geared towards treatment of diseases listed in Schedule A of the Act
- Restricted Advertising: drugs manufactured, sold or represented for use in prevention of conception
Food and Drugs Act

- Definition of Advertising
  - “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”
Definition of Advertising

- Health Canada: if a message is not considered to promote the sale or disposal of a drug it is not considered advertising.
- Example: if information is targeted to health professionals it might include items such as
  - Patient Information
  - Educational Letters
Part 1: Scope

Definition of Advertising

• Basic Rule: includes any message with a primary purpose to influence the audience that it is geared toward
Part 1: Scope

Regulation of Internet Advertising

- Federal Competition Bureau Guidelines
  - Application of the *Competition Act* to Representations on the Internet
- All regular advertising regulations and guidelines also apply - but only within Canadian jurisdiction
- The need for special rules
Other Regulation of Advertising

- *Competition Act*
  - e.g., misleading advertising

- *Trade-marks Act*
  - e.g., unfair competition, depreciation of goodwill and trade-mark infringement
Other Regulation of Advertising

- *Copyright Act*
  - e.g., infringement

- *Common Law*
  - e.g., torts of passing off, injurious falsehood and wrongful interference with economic relations
Part 2: Role of the Regulators
Part 2: Role

Self-regulatory Bodies/Associations

- Advertising Standards Canada (ASC)
- Pharmaceutical Advertising Advisory Board (PAAB)
- Canada’s Research-Based Pharmaceutical Companies (Rx&D)
Part 2: Role

An Overview of ASC

- National industry body
- Members
- Governance
Part 2: Role

What ASC Provides

- Mechanisms for effective self-regulation of advertising through the *Canadian Code of Advertising Standards*
- Objective and independent advertising copy review service through ASC Clearance Services
Canadian Code of Advertising Standards

- Principal instrument of advertising self-regulation
  - 14 clauses set standards for acceptable advertising
  - Basis for evaluating consumer & trade complaints
- Supplemented by *Interpretation Guidelines* and *Comparative Advertising Guidelines*
Part 2: Role

Canadian Code of Advertising Standards

Definition of Advertising:

“any message (the content of which is controlled directly or indirectly by the advertiser) expressed in any language and communicated in any medium...to Canadians with the intent to influence their choice, opinion or behaviour”
Part 2: Role

**PAAB**

- An independent review agency whose primary role is to ensure that advertising of prescription drugs, geared towards healthcare professionals, is accurate, balanced and evidence-based.
Part 2: Role

PAAB

- All advertising to healthcare professionals must comply with the *PAAB Code of Advertising Acceptance*
Part 2: Role

PAAB Code of Advertising Acceptance

- **Scope**
  - Applies to Advertising/Promotion Systems (APS) and institutional messages directed to healthcare professionals

- **Preclearance Requirement**
  - All copies and illustrations of APS intended for distribution to health professionals must be submitted for PAAB review and clearance prior to use
Part 2: Role

Rx&D

- Rx&D is an association representing Canadian research-based pharmaceutical companies
- Members must adhere to the *Rx&D Code of Conduct*
- The PAAB *Code of Advertising Acceptance* and the CAMP *Guidelines for General Advertising, Supplied Advertising Inserts, & Journal Supplements* apply to all its members
Part 2: Role

Rx&D Code of Conduct

- Provides guidelines to its members about interaction with healthcare professionals when disseminating information about drugs
- Sets out requirements and procedures for organizing educational activities for healthcare professionals
Part 3: Advertising to Health Professionals
Part 3: Health Professionals

Rules/Requirements

- Requirement to include certain mandatory information
- Rules related to comparative advertisements
- Prohibition against gifts, donations, hospitality and other financial incentives
Part 3: Health Professionals

Mandatory Information

- Advertising copy should provide sufficient information to permit assessment of the risks and benefits of the product being advertised in a prominent manner.
- Prescription information must be included.
- A balanced treatment of the various features of the drug must be presented.
  - e.g., indications, limitations, alternate recommendations, dosage regimens, and safety profile.
Part 3: Health Professionals

Comparative Advertisements

- Consistent with section 9(1) of the *Food and Drugs Act*
- Follow Health Canada *Principles for Comparative Claims Related to the Therapeutic Aspects of Drugs*, such as
  - Comparison is drawn only between drugs under the same conditions of use
  - Evidence generated to substantiate the comparison claim is conclusive and based on accurate scientific data
- General Criteria: All direct and indirect comparisons must not mislead, and must be supported by reliable current data
Part 3: Health Professionals

Financial Incentives

- Gifts and Donations - Rx&D Code
  - “companies must never provide a donation, directly or indirectly, in order to have access to a health care professional”
  - “member companies must not offer to any healthcare professional...any gift, in cash or in kind...”
Part 3: Health Professionals

Financial Incentives

- Hospitality - Rx&D Code
  - There are acceptable offers of hospitality
  - Payment/reimbursement related to attending scientific conferences is allowed
  - Payment for services is allowed
Part 3: Health Professionals

Financial Incentives

- Manner of Sale of Medicinal Products
  - Volume-related discounts for institutional purchases
    - *Competition Act* prohibition
  - Addition of “extra” medical/technical services upon purchase as incentives
    - Restrictions against “tied selling”
    - Equal benefits to consumers
Part 4: Direct to Consumer Advertising

The cabby impatiently waits ... 

... for the couple to emerge ... 

... smiling and ... 

... the message is driven home.
Part 4: Direct to Consumer

Sample Canadian Ads
ASC Clearance Services

- Objective and independent advertising copy review service for specific regulated categories
- Provided at the request of industry on a fee basis
- Helps advertisers to comply with pertinent laws and regulations
- Signifies to media that advertising is compliant
DTCA/DTCI

At Health Canada’s request, ASC reviews:

- Direct-to-Consumer ADVERTISING of prescription drugs (DTCA)
- Direct-to-Consumer INFORMATION about a disease state and its treatments (DTCI)
Part 4: Direct to Consumer

DTCA - Name, Quantity, Price

- Prior to 1978 complete prohibition of prescription drug advertising
- In 1978 the Act was amended to add the following clause:
  - Section C.01.044 of Food and Drug Regulation limits advertising of prescription drugs to general public to:
    
    “name, price and quantity”

    e.g. “Obecalp, 30 tablets, $19.99”
Part 4: Direct to Consumer

Schedule A Prohibition

“No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A”

- Section 3(1) of the Food and Drugs Act
Schedule D

- Section C.01.044 of the *Regulations* only applies to Schedule F drugs
- Schedule D drugs, such as vaccines and insulin are not subject to the “name, price and quantity” restriction
DTCA

HC Policy: “The Distinction Between Advertising and Other Activities”

- Describes criteria for “nonpromotional activities”
- The policy helps users differentiate between “advertising”, and other nonpromotional activities (e.g. scientific exchange, education)
DTCI - Types

- “Help-Seeking” Announcements
- Toll-free information lines
- Brochures (unbranded)
- Clinical Trial Recruitment ads
Part 4: Direct to Consumer

DTCl - Help Seeking Messages

- “Help-Seeking Announcements” may be nonpromotional if:
  - No specific drug is directly or indirectly identified
  - There is no implication that a drug is the sole treatment for the disease or condition
  - No drug manufacturer’s name is included
Clinical Trial Recruitments may be nonpromotional if:

- The intent of message is clearly identified as recruitment for participants
- Patient profile stated
- Telephone number provided
- No reference is made to the name of the drug under investigation, or the manufacturer
Brochures and websites may be nonpromotional if:

- Content is disease related rather than product related
- The various treatment options (drug and non-drug) and their respective risks and benefits are discussed objectively
- No direct or indirect identification of a specific prescription drug
- No implication that a drug is the sole treatment for the disease or condition
Part 4: Direct to Consumer

DTCA/DTCI Campaigns

Health Canada Policy Statement - “Advertising Campaigns of Branded and Unbranded Messages”

- Independently each advertisement or information message may be in compliance,

BUT...
DTCA/DTCI Campaign

- When the entire campaign is taken into consideration, it may as a whole exceed “name, price and quantity”
- Look at context, style, music and actors when reviewing distinct ads as part of same campaign
Part 4: Direct to Consumer

Current Trends

• Health Canada recent clarification - reference to medical specialists in DTCA exceeds Section C.01.044

• Increase in clinical trial recruitment messages in broadcast

• Health Canada currently evaluating the acceptability of depicting packshots/product in DTCA
Part 4: Direct to Consumer

Sample TV Commercials

- Pfizer - Viagra
- Wyeth - Alesse
Part 4: Direct to Consumer

The US - Sample Ad

STRIVE TO BE YOUR BEST

No other ED treatment is proven to work better the first time* than LEVITRA®

LEVITRA is a treatment for erectile dysfunction (ED) that significantly improves erectile quality for most men:

- LEVITRA works the first time, time and again
- Some men may require additional attempts
- LEVITRA works to improve the quality of erectile function
- LEVITRA improves duration, hardness, and the ability to attain an erection
- LEVITRA works fast

It doesn't matter if the challenge is on the field or off - I always strive to be the best. You'll find something that works for me, LEVITRA®

- Mike Ditka, NFL Hall of Fame player and coach

LEVITRA is a medicine that works the first time. It is not for use in women. It is not known if LEVITRA will work in all men. The most common side effects are headache, flushing, and stuffy nose. These side effects are usually mild and go away on their own. If these side effects continue or are severe or cause you to stop taking the medicine, contact your doctor.

Ask your doctor if a free sample of LEVITRA is right for you.

1-888-LEVITRA
www.LEVITRA.com
Part 4: Direct to Consumer

Canada vs. US

If you suffer from Erectile Dysfunction, a variety of treatments are available. Talk to your doctor.

SOMETIME BETWEEN Friday’s LATE NIGHT DIP AND DINNER ON Sunday...

THE MOMENT MAY BE right REDY AND YOU CAN BE.

If a tender moment turns into the right moment

INTRODUCING CIALIS, THE FIRST TABLET FOR ERECTILE DYSFUNCTION THAT GIVES YOU UP TO 36 HOURS TO CHOOSE THE MOMENT THAT’S RIGHT FOR YOU AND YOUR PARTNER.

36-hour Cialis, WHICH MOMENT WILL BE RIGHT FOR YOU?
The US: Policy Issues

- *Pfizer*- “Wild Thing” controversy
- FDA required *Pfizer* to pull ad
- *Pfizer* complies
The US: Policy Issues

- FDA advertising regulations/guidance
- Streamlined disclosures permitted
- Disclosure of major side effects and contraindications is required
Summary

- Pharmaceutical advertising in Canada is heavily regulated
- Rules for advertising to health professionals differ from rules for advertising to consumers
- General rules in statutes and regulations are informed by numerous codes and guidelines of regulators (such as HC, ASC, PAAB & Rx&D)
Questions?