Health Canada Santé Canada

RECORD OF DISCUSSIONS

CANADIAN ADVERTISING PRECLEARANCE AGENCIES
and
HEALTH CANADA

Jeanne Mance Building, 200 Eglantine Driveway, Ottawa, Room 836 D
Tuesday April 18, 2017 – 10:00 a.m. – 12:30 p.m.

Discussions of Health Product Advertising Issues and Topics of Mutual Interest to Canadian Advertising Preclearance Agencies and Health Canada

No policy decisions are made at these meetings. The following is a summary of the discussions between participants.

Canadian Advertising Preclearance Agencies Participants

Advertising Standards Canada (ASC):
Jani Yates, CEO & President
Nicole Bellam, Vice-President, ASC Clearance Services
Ruta Rozentals, Senior Analyst, ASC Clearance Services

Extreme Reach Canada:
Anna Haine, Director, Clearance and Verification Services

Pharmaceutical Advertising Advisory Board (PAAB):
Ray Chepesiuk, Commissioner
Patrick Massad, Deputy Commissioner
Dr. Walter Rosser, Chair of PAAB Board

Health Canada Participants

Marketed Health Products Directorate (MHPD):
John Patrick Stewart, Director General (Chair)
Lisa Lange, Director, Therapeutic Effectiveness and Policy Bureau
Alain Musende, Manager, Regulatory Advertising Section (RAS)

Christophe Roy, Senior Regulatory Policy and Risk Management Advisor, RAS
Rim Lejmi-Mrad, Senior Regulatory Policy and Risk Management Advisor, RAS
Arshia Bhatti, Regulatory Policy and Risk Management Officer, RAS

Natural and Non-prescription Health Products Directorate (NNHPD):
Manon Bombardier, Director General, NNHPD
Matthew Bown, Senior Analyst, CHPM, NNHPD
Nana Bafi-Yeboa, Manager, BPRA, NNHPD

Regulatory Operations and Regions Branch (RORB):
Collin Pinto, Manager, RORB
Stephanie Di Trapani, Manager, RORB
Mimi Lin, Senior Corporate Regulatory Compliance & Enforcement Advisor, RORB
Kira Kaminsky, Corporate Regulatory Compliance & Enforcement Advisor, RORB

Office of Medical Cannabis (OMC):
David Pellmann, Executive Director, OMC
Chris Rose, Director, OMC
Benoit Seguin, Manager, Compliance and Enforcement, OMC
Sarah Wright-Gilbert, Stakeholder Relations Liaison, OMC

Healthy Environments and Consumer Safety Branch (**HECSB**):
Denis Choiniere, Director, TPRO, HECSB

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1. Opening Remarks & Self-Introductions

The Chair, John Patrick Stewart introduced himself and welcomed Health Canada members and the Advertising Preclearance Agencies (APAs).

He informed the participants that the 2017 bilateral meeting would follow a different format compared to previous years. The new format would focus on sharing trends and issues of interests that Health Canada and the APAs have identified during the year. This year's meeting would also include data on all complaints received and handled by Health Canada and not just MHPD.

2. Performance Report and Key Advertising Issues

Issue:

- Health Canada and APAs presented on trends and issues of interests that they have identified during the year, in addition to statistical report of advertising complaints activities.

Discussion Highlights:

Health Canada:

- Health Canada discussed:
  - Advertising complaints handled by Health Canada
  - MHPD's vigilance & prevention activities
  - Key advertising trends & issues of interest
  - Consistency on regulatory advertising oversight approaches across Health Canada's product types
- Advertising complaints handled by Health Canada: During its previous fiscal year, 63% of the complaints handled by Health Canada involved natural health products while 32% were on prescription drugs, 3% on biologics (including vaccines) and 2% on medical devices. For NHPs, complaints involved Schedule A claims, unauthorized products, as well as authorized NHPs where APAs could not achieve wilful compliance. The majority of complaints involved advertising via Web sites and Social Media.
- MHPD's vigilance & prevention activities: Review of Advertising Advisory Opinions remains the predominant activity carried out by MHPD, accounting for 54% of its actions pertaining to advertising issues.
- Key trends and issues of interest involved:
  - Advertising of Human Chorionic Gonadotropin (hCG) for weight loss use, which is an off-label indication, by clinic Web sites across Canada. Health Canada issued an Information Update and a notice in the Health Product InfoWatch on this issue and informed provincial and territorial colleges of physicians and surgeons; as well as naturopaths and pharmacist associations
  - Opioid Crisis – Health Canada is exploring the option of mandatory preclearance for opioid advertising materials directed to healthcare professionals. Impacted stakeholders will be consulted, should this initiative is to be implemented
  - Advertising of biosimilars – Health Canada has received complaints in relation to advertising of biosimilars. This may be trend-setting as more biosimilar products will be made available in the coming years. Ongoing discussions with APAs and other stakeholders are ongoing to ensure clarity and consistency
  - Medical Device (MD) Advertising – Inclusion of MD guidelines in the Consumer Advertising Guidelines for Marketed Health Products (CAG) in collaboration with ASC. Health Canada and ASC carried out 3 webinars to inform stakeholders and clarify the scope of the initiative (approximately 1,000 stakeholders attended)

- MHPD is leading collaborative work with Health Canada partners to ensure consistency on the regulatory advertising oversight between standard product types and new ones, such as Vaping Products (e-cigarettes) and Medical Cannabis

Advertising Standards Canada:

- Administers the Canadian Code of Advertising Standards and engages in advertising preclearance in 5 regulated areas.
- In 2016, ASC received a total of 1639 complaints with the majority associated with television advertisement.
- In terms of marketed health products:
  - ASC received a total of 9 complaints
  - The majority involved natural health products
  - Eighty percent (80%) of complaints were resolved within 4-8 weeks

Pharmaceutical Advertising Advisory Board:

- The PAAB board is comprised of:
  - Pharmaceutical trade associations
  - Healthcare professional organizations
  - Patient groups
  - Medical publishers
  - Medical advertisers
- In 2016, PAAB carried out:
  - 7535 first preclearance reviews
  - Average response time of 6.4 days
  - The majority of the ads is intended to healthcare professionals and involved Paper-Detail Aid
- The PAAB handled a total of 4 stage II complaints (reassessment by PAAB Commissioner).
- Key upcoming activities of the PAAB are training workshops in Montreal and Toronto.

Extreme Reach:

- Primary Service offerings include:
  - Television & Radio Ad Delivery
  - Broadcast Clearance
  - Digital Ad Serving & Analytics
- Regulated categories include:
  - NHPs
  - Food/Beverages
  - Cosmetics
  - Alcohol

- Extreme Reach observed an increased spending on NHP advertising vs other categories.

Action:

- N/A

3. Modernizing the Regulation of Self-Care Products (SCPs)

Issue:

- Self-care products are comprised of cosmetics, NHPs, and non-prescription drugs.
- Although all SCPs are regulated under *the Food & Drugs Act*, they are subject to:
  - Different rules for how to bring products to market
  - Different levels of evidence required for health claims
  - Different levels of post-market monitoring and compliance enforcement

Discussion Highlights:

- Health Canada is proposing:
  - Self-care products to be regulated according to the level of risk they pose to consumers
  - Products making similar claims would require similar evidence
  - Health Canada to have appropriate powers to address safety concerns and non-compliance
- Health Canada believes this approach would benefit consumers & industry in terms of:
  - Continued access to a wide range of safe & effective SCPs
  - Better information to support informed decision-making
  - More predictable and consistent rules for bringing products to market
  - Risk-based rules that do not impose unnecessary regulatory burden
- Health Canada has scheduled a new series of consultations with Canadians across the country.
- Questions from participants focused on:
  - Impact of this new framework on health product advertising
  - Opportunity for external stakeholders to comment on the framework. Some APAs indicated that they have attended previous consultations on this framework

Action:

- N/A

4. Medical Cannabis Framework

Issue:

- The purpose of the presentation was to discuss access to cannabis for medical purposes with APAs and Health Canada stakeholders.

Discussion Highlights:

- The Access to Cannabis for Medical Purposes Regulations (ACMPR) were introduced on August 24, 2016, to provide Canadians with access to cannabis for medical purposes with the authorization of their healthcare practitioner.
- Patients purchase quality-controlled cannabis from a licensed producer (LP), or register with Health Canada to produce a limited amount for their own medical purposes; or, designate someone to produce it for them. Both dried Marijuana and Cannabis oil are present in the Canadian market.
- Licensed producers may be licensed to produce and sell dried and fresh marijuana, cannabis oil, and starting materials (seeds and plants) to registered patients. Forty two producers have been licensed and their list is on Health Canada's website[1].
- Cannabis is a controlled substance, narcotic, and drug. As such, its advertising is regulated under the *Food and Drugs Act* and the *Narcotic Control Regulations*. Although the NCR prohibits any advertising for cannabis to the public, Licensed Producers are permitted to provide to the public representations of the brand name, proper or common name of the strain, price, cannabinoid content and contact information as it assists patients in making an informed decision.
- However, therapeutic claims and promotional wording have been detected in these ads. Consequently, Warning and Compliance promotion letters are issued to LPs outlining advertising prohibitions.

Action:

- APAs will be kept informed on the progress and will be consulted for comments and feedback.

5. Amendments to the Tobacco Act, Non-Smokers Health Act, and other Acts

Issue:

- The purpose of the presentation was to discuss a new legislative/regulatory framework to address the potential benefits and risks of vaping products.

Discussion Highlights:

[1] https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-use-marijuana/licensed-producers/authorized-licensed-producers-medical-purposes.html

- The discussion focused on the fact that a new legislative framework was needed because the current federal legislative/regulatory framework did not address all of the potential benefits and risks of vaping products. The Government committed to introducing legislation that would include measures to protect youth from nicotine addiction and inducement to tobacco use while allowing adults to legally access vaping products as a likely less harmful alternative to tobacco; and protect Canadians from dangers to health or safety.
- The new Bill contains a number of provisions prohibiting certain types of promotional activities, including:
    - For flavours that could be appealing to young persons
    - Lifestyle advertising and advertising appealing to youth
    - Sponsorship promotion
    - Endorsements
    - Giveaways
    - Pro-tobacco use promotion (e.g., “don’t quit – just switch”)
    - False and misleading promotion
    - Cross branding with tobacco products
- These restrictions would be similar, but not as restrictive as those for tobacco products.

Action:

- N/A.

6. Closing Remarks

Health Canada thanked participants for the valuable discussion and input. Participants were reminded that a record of discussions would be available for comment and the APAs were encouraged to share this document with their members since it is no longer posted on Health Canada’s Web site.

Lisa Lange, Director, Therapeutic Effectiveness and Policy Bureau
Marketed Health Products Directorate