Health Canada Santé Canada

RECORD OF DISCUSSION

**HEALTH CANADA**
**and**
**CANADIAN ADVERTISING PRECLEARANCE AGENCIES**

Jeanne Mance Building, 200 Eglantine Driveway, Ottawa, Ontario, Room 836 D
Wednesday April 04, 2018 – 10:00 a.m. – 12:30 p.m.

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

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

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**Canadian Advertising Preclearance Agencies Participants**

**Ad Standards (AS):**
Jani Yates, CEO & President
Nicole Bellam, Vice-President, AS Clearance Services
Ruta Rozentals, Senior Analyst, AS Clearance Services

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

**Pharmaceutical Advertising Advisory Board (PAAB):**
Ray Chepesiuk, Commissioner
Patrick Massad, Deputy Commissioner

**Health Canada Participants**

**Marketed Health Products Directorate (MHPD):**
Lisa Lange, Director, Office of Policy, Risk Advisory and Advertising (OPRAA) (Co-Chair)
Alain Musende, Manager, Section of Transparency & Advertising Regulatory Surveillance

(STARS) (Co-Chair)
Christophe Roy, Senior Regulatory Policy and Risk Management Advisor, STARS
Aline Labaki, Senior Regulatory Policy and Risk Management Advisor, STARS
Rim Lejmi-Mrad, Senior Regulatory Policy and Risk Management Advisor, STARS
Ruth Nara, Regulatory Policy and Risk Management Officer, STARS
Dejana Vukic, Regulatory Policy and Risk Management Officer, STARS
Shelley Wagner, Regulatory Policy and Risk Management Officer, STARS
Angela Tonary, Scientific Evaluator, Marketed Biologicals, Biotechnology and Natural Health Products Bureau (MBBNHPB)

**Natural and Non-prescription Health Products Directorate (NNHPD):**
Amanda Moir, Director, CHPM, NNHPD
Alysyn Smith, Manager, NNHPD
Heather Gilmer, Senior Policy Advisor, CHPM, NNHPD
Polina Ostrovsky, Policy Analyst, NNHPD
Adenike Orimoloye, Head, PSCU, NNHPD

**Regulatory Operations and Regions Branch (RORB):**
Matthew Ryan, Manager, RORB
Celina Bak, A/Manager, RORB
Kira Kaminsky, Corporate Regulatory Compliance & Enforcement Advisor, RORB
Jenny Lee Choon, Corporate Regulatory Compliance and Enforcement Advisor, RORB

**Office of Medical Cannabis (OMC):**
Corinne Guenette, Director, OMC
Benoit Séguin, Associate Director, Compliance and Enforcement, OMC
Marie-Claude Vachon, Supervisor, OMC
Karine Paré, Senior Corporate Regulatory Compliance and Enforcement Advisor, OMC
Dominique Bourassa, Senior Corporate Regulatory Compliance and Enforcement Advisor, OMC
Mahdi Hassan, Senior Regulatory Affairs Officer, OMC

**Healthy Environments and Consumer Safety Branch** (**HECSB**):
Matthew Cook, Manager, TPRO, HECSB

**Medical Devices Bureau (MDB):**
Yen Luc, Senior Regulatory Affairs Officer, MDB, TPD
Peggy Seely, Senior Regulatory Affairs Officer, MDB, TPD
Kamran Fazli, Regulatory Affairs Officer, MDB, TPD

**Foods Directorate (FD):**
Cecilia Van Egmond, Manager, Bureau of Policy, Intergovernmental and International Affairs, FD

Eunice Chao, Nutrition Labelling and Health Claims, FD

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## 1. Opening Remarks & Welcome

The Co-Chair, Lisa Lange, opened the meeting by welcoming Health Canada participants and the Advertising Preclearance Agencies representatives (APAs) representatives. The Co-Chair congratulated the APAs and Health Canada representatives for their ongoing collaboration and outlined the meeting purpose, namely to discuss current initiatives under development at Health Canada (Self Care Framework, Cannabis Act, Tobacco and Vaping Products Act) and their potential impact on regulatory advertising as well as observed trends in the regulatory advertising of health products.

The Co-Chair introduced the rebranded Office of Policy, Risk Advisory and Advertising (OPRAA), formerly the Therapeutic Effectiveness and Policy Bureau (TEPB) to the audience as well as the Section of Transparency and Advertising Regulatory Surveillance (STARS), formerly the Regulatory Advertising Section (RAS). She provided updates on the new Minister of Health, Ms. Ginette Petitpas Taylor, notified participants that the Marketed Health Products Directorate (MHPD) has a new Director General, Ms. Rhonda Kropp, who sent her regrets as she was unable to attend the meeting. The Co-Chair also mentioned that Health Canada is considering mandatory preclearance of opioid materials directed to healthcare professionals (HCPs).

Alain Musende, the Manager of STARS kindly undertook Co-Chairing responsibilities.

## 2. Regulatory Advertising Oversight – Highlights of Key Activities, Trends, and Issues

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

Discussion Highlights:

- Health Canada discussed:
    - Advertising complaints and advertising actions 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
- Key trends and issues of interest involved:
    - Medical device advertising guidance update may affect the number and types of advertising complaints in the future.
    - Between January and December 2017, Health Canada received 141 complaints,

the majority of which were natural health products and prescription drugs. Complaints involving Web sites and Social Media Platforms comprised 70%.
    - Vaccine advertising complaints of radio commercials were deemed compliant and were previously precleared by APAs.
    - The number of complaints on Botox advertising by clinics remains consistent compared to last year.
    - Biosimilar advertising complaints have increased and sometimes target drug formulary/pharmacy benefit managers and health insurers. Health Canada used these actual complaints as illustrative examples for educational purposes at the PAAB training workshops in 2017.
    - Health Canada's commitment to addressing the opioid crisis includes a proposal to have mandatory preclearance of opioid-related materials targeted to healthcare professionals by APAs.
    - Meeting attendees heard about Transfer of Values (TOV), which are payments from industry to Health Care Professionals (HCPs) and Health Care Organizations (HCOs) i.e., grants, gifts, etc. The Ontario Provincial Government enacted legislation that will compel pharmaceutical companies to publicly disclose how they compensate HCPs and HCOs. The Federal Minister of Health's 2017 mandate letter included direction to consult with provinces, territories, and professional regulatory bodies to increase transparency in the marketing and promotion of opioid therapies. Health Canada is exploring federal options to increase transparency on this issue as it believes it would be beneficial to start engaging in proactive monitoring of health product advertising. This would enable identification and anticipation of high risk/profile advertising issues such as opioid promotion.
    - Policy developments:
        - Collaboration with AS for the development and launch of the updated Guidelines for Consumer Advertising of Health Products (GCAHP)
        - Health Canada initiated consultation to update the policy - 'The Distinction between Advertising and Other Activities'.

<u>Advertising Preclearance Agencies</u>

**Ad Standards**:

- Administers the Canadian Code of Advertising Standards, engages in advertising preclearance in 5 regulated areas and educates industry on how to advertise in a truthful, fair and accurate manner.
- In 2017, AS received a total of 1808 Consumer advertising complaints with the majority associated with television advertisement. Sixteen complaints involved Health Products, 10 NHPs and 6 OTCs.
- Key Consumer Concern: accuracy and clarity.

- Presented the new interpretation guideline Clause 7 of Testimonials, Endorsements and Reviews, which requires clear and prominent disclosure of the nature of the connection between the endorser and the sponsor.
- Launched the GCAHP in Toronto and Montreal in early 2018. Starting January 1, 2018, AS began issuing approval numbers for medical devices and telecasters will require approval numbers prior to airing commercials starting July 1, 2018.

**Pharmaceutical Advertising Advisory Board**:

- The PAAB board is comprised of:
  - Pharmaceutical trade associations, healthcare professional organizations, patient groups, medical publishers and medical advertisers
- In 2017, PAAB carried out:
  - 7408 first preclearance reviews, average response time of 5.6 days, the majority of the ads is intended to healthcare professionals
- The PAAB handled a total of 5 stage II complaints (reassessment by PAAB Commissioner). One of the Commissioner's rulings was appealed to stage 3. That appeal was rejected by the Complaint Resolution Review Panel.
- PAAB proposes HC enforces egregious cases, codify mandatory preclearance in the *Food and Drug Regulations*, finalize Cannabis Regulations, require mandatory preclearance of opioid advertising and continue the excellent collaboration with APAs.

**Extreme Reach**:

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

Extreme Reach observed the following trends:

- Clients are more informed on regulatory requirements for advertising
- Less infomercials
- Increase in sponsorship ads

## 3. Modernizing the Regulation of Self-Care Products: Presented by NNHPD

- Self-care products (SCPs) 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 that:
  - SCPs be regulated according to the level of risk they pose to consumers categorized by low, medium and high risk (Category I, II and III)
  - Consistent labelling of SCPs is ensured
  - Products making similar claims would require similar evidence
  - Health Canada have appropriate powers to address safety concerns and non-compliance
- Health Canada has scheduled a new series of consultations with Canadians across the country.

- Health Canada proposes a phased approach to amend the following Regulatory Frameworks to enable this regulatory approach to address self-care products:
  - Phase I – Fall 2018: Introduce, for consultation, targeted amendments to the *Natural Health Products Regulations* (NHPR) to improve labelling of natural health products.
  - Phase II – Early 2019; Introduce, for consultation, targeted amendments to the *Food and Drug Regulations* (FDR) to introduce a risk-based approach to regulatory oversight for non-prescription drugs.
  - Phase III – 2020: Introduce, for consultation, regulatory amendments to address: evidence standards for similar health claims, extending risk-based regulatory oversight and seek additional powers for Health Canada, such as the ability to require a recall or label change for all self-care products.

- Health Canada proposes to release a draft guidance concurrently with Phase I and will hold bilateral sessions with interested parties
- Health Canada outlined the requirements for operational readiness for the Self Care Framework, which is focusing on the statement to the effect of (STTEO) project and the IP501 IT System renewal.

- STTEO expected outcomes:
  - Efficiency in regulatory outcomes that benefit Canadians and support adhering to service standards
  - Updated Compendium of Monographs with pre-populated information to support the new electronic product license application (ePLA) and the new IT system
  - Clear and consistent information in all monographs

Questions from participants focused on impact of this new framework on health product advertising.

## 4. Cannabis Framework : Presented by CLRB

- The purpose of the presentation was to discuss the evolution of the legal framework for Cannabis with APAs and Health Canada stakeholders.

Discussion Highlights:

- The Evolution of the legal framework for cannabis was described as follows:
  - Prior to 2001, access to cannabis for medical purposes was granted via a Section 56 exemption to the *Controlled Drugs and Substances Act*.
  - 2001 – *Marihuana Medical Access Regulations* – repealed
  - 2013 – *Marihuana for Medical Purposes Regulations* – repealed
  - 2016 – *Access to Cannabis for Medical Purposes Regulations*

- The proposed control framework for the Cannabis Act, Bill C-45, intends to:
  - Restrict youth access to cannabis
  - Protect youth from inducements to use cannabis
  - Provide for a legal cannabis market to supplant the illegal market
  - Deter criminal activity by imposing hefty criminal penalties
  - Protect public health through strict product safety and quality requirements
  - Reduce the burden on the criminal justice system
  - Enhance public awareness of health risk associated with Cannabis use

- The role of the federal government under C-45:
  - License producers that grow and manufacture cannabis
  - Set industry-wide rules and standards

- Under the proposed Cannabis Act, Bill C-45, to promote means:
  "in respect of a thing or service, to make, for the purpose of selling the thing or service, a representation — other than a representation on a package or label — about the thing or service by any means, whether directly or indirectly, that is likely to influence and shape attitudes, beliefs and behaviours about the thing or service."

  The restrictions regarding promotion will apply to all forms of communications including:

  printed publications, internet publications (website, social media, email, etc.), direct mail, cannabis products, signage (billboards, etc.), broadcasts (radio, television, etc.), health products and cosmetics with cannabis and mobile devices

Promotion prohibitions under the proposed Cannabis Act, Bill C-45, include absolutely no:

> appeal to young persons, lifestyle, sponsorship, testimonials or endorsements, depiction of a celebrity, character or animal, false, misleading or deceptive, ties to games, draws, lotteries or contests that could induce anyone to increase cannabis consumption, publication, broadcasting or dissemination within Canada

Two types of promotions would be allowed under Bill C-45:

- Informational (e.g. cannabinoid content (% THC, CBD); species (*indica, sativa*)
- Brand-preference promotion (e.g. logo, slogan, tradename)
- These promotions cannot be appealing to youth or associating it with a way of life
- Promotional content that is permitted cannot be seen by individuals < 18 years old.

Action:

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

**5. Tobacco and Vaping Products Act**

- The purpose of the presentation was to discuss Bill S-5, a new legislative/regulatory framework to address the potential benefits and risks of vaping products.

Discussion Highlights:

Proposed Bill S-5, an Act to amend the *Tobacco Act*, the *Non-smokers' Health Act* and to make consequential amendments to other Acts, will implement a new legislative/regulatory framework to address the potential benefits and risks of vaping products.

- Vaping products are:
  - Devices that may resemble conventional cigarettes
  - Consist of a device and a liquid solution, or "e-liquid"
  - Produce an aerosol that is inhaled by the user
  - May contain nicotine and/or flavours
  - Refillable or non-refillable – devices and liquids can be sold separately, other similar products (e.g., e-cigars, e-hookahs) also available

- The rationale for a new vaping framework for vaping products could:
  - Bring a public health benefit if they reduce tobacco-related death and disease
  - Bring risks if they entice youth to develop a nicotine addiction or lead to tobacco use
  - A flexible regime is required to maximize the potential benefits and minimize the risks of vaping products as the science evolves

- Principles of proposed new vaping legislative framework is based on the following principles:

    - Protecting youth and other from development of nicotine addiction and inducement to tobacco use
    - Allowing adults to legally access vaping products as less harmful alternatives to tobacco use
    - Preserving a path to market for products with therapeutic claims (i.e., smoking cessation); and
    - Providing a mechanism to address risks to human health and safety for products without a therapeutic claim

- Proposed New Vaping Framework:
    - To ensure coherence of the proposed legislative framework, amendments will be made to the *Tobacco Act* (TA), *Canada Consumer Product Safety Act* (CCPSA), *Food and Drugs Act* (FDA) and the *Non-smokers Health Act* (NSHA).

- Bill S-5 overview – promotion restrictions would include:
    - 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

Action:

- APA's to schedule meeting with HECSB TVPA Team for further discussion.

## 6. Roundtable

- Questions regarding the various presentations were discussed.

## 7. 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