Health Canada Santé Canada

RECORD OF DISCUSSIONS

CANADIAN ADVERTISING PRECLEARANCE AGENCIES
and
HEALTH CANADA

Health Protection Building, 200 Tunney's Pasture Driveway, Ottawa, Room 0218
Tuesday April 13, 2016 – 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):
Linda Nagel, 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
Christophe Roy, Regulatory Advertising Officer, Regulatory Advertising Section
Judy Allaire, Regulatory Advertising Officer, Regulatory Advertising Section

Aline Labaki, Regulatory Advertising Officer, Regulatory Advertising Section
Arshia Bhatti, Regulatory Policy and Risk Management Officer, Regulatory Advertising Section

Natural and Non-prescription Health Products Directorate (NNHPD):
Sarah Skuce, Manager, Risk Management Division
Deidre Pollard-Bussey, Manager, Policy

Regulatory Operations and Regions Branch (formerly Health Products and Food Branch Inspectorate):
Collin Pinto, Manager, Medical Devices Compliance and Enforcement
Mimi Lin, Senior Corporate Regulatory Compliance & Enforcement Advisor, Health Product Compliance and Enforcement Unit

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1. Opening Remarks & Self-Introductions

The Chair introduced himself, welcomed attendees and thanked advertising preclearance agencies for the outstanding collaboration they have with Health Canada. He mentioned that we have a new Minister of Health, Dr. Jane Philpott and we are working towards implementing her vision. The chair noted that the Regulatory Advertising Section (RAS) has been leading approximately 30% of all transparency initiatives of the Branch. This led to RAS staff being awarded the Assistant Deputy Minister award for contribution to increased transparency and openness.

2. Performance Report and Key Advertising Issues

Issue:

- Health Canada and the advertising preclearance agencies provided an annual statistical report of advertising complaints activities.

Discussion Highlights:

Health Canada:

- The performance report of advertising activities presented was for MHPD only and not all of Health Canada. Moving forward, we hope to present data for all of Health Canada. In the meantime, the posting of advertising complaints table allows for a comprehensive view of all advertising complaints received by Health Canada on health products.
- It is important to note that MHPD lost a significant amount of electronic data during the transition from the Information Tracking System (ITS) to the Information Management System (IMS).
- The Annual Statistical Report (complaints and requests for information), including tables of Advertising Complaints Assessed by MHPD for the last 10 Fiscal Years, and All Advertising Actions for the 2015-2016 Fiscal Year were shared with participants.
- For this fiscal year the performance standard for complaints is 87%, which is an improvement from last fiscal year's performance standard of 79%.

- For this fiscal year the performance standard for requests for information is 81%, which is also an improvement from last fiscal year's performance standard of 72%.
- Advertising issues of interest, such as the Homeopathic Nosodes, Ms. Kim Kardashian Instagram post regarding Diclegis, Medical Device advertising guidelines and Cold-fX lawsuit, were also discussed.

Pharmaceutical Advertising Advisory Board:

- The PAAB presented an overview of their accomplishments of the previous year along with historical data.
- First reviews: reviewers handled 7718 first reviews in the year 2015
- Average time to first response for reviews in 2015 was 6.8 days.
- For resubmissions, the performance standard is 3 days, for 2015 the average number of days was 1.9.
- For complaints, there is a 3 stage complaint system:
    - Stage 1: both parties have 10 days to respond once a complaint has been received. The PAAB is copied but there is no obligation to intervene.
    - Stage 2: if the complainant is not content, they can file a stage 2 complaint where the commissioner has to make a ruling.
    - Stage 3: If neither party is content with the commissioners ruling, they can file a stage 3 complaint which is an appeal panel of 3 independent people that are agreed upon by all 3 parties. Since 1999 there has been 1 stage 3 appeal.
    - Advertising trends include low number of complaints but a high compliance rate and a record high number of submissions for preclearance reviews.

Advertising Standards Canada

- ASC receives more than 1,700 complaints a year under the Canadian Code of Advertising Standards
- ASC's complaints report focussed solely on complaints handled by ASC Clearance Services regarding therapeutic claims in consumer drug advertising for authorized products
- The report highlighted the number of consumer drug complaints handled by ASC between 2011 and 2016.
- ASC presented a breakdown of the number of complaints received from Health Canada, healthcare professionals, trade and consumers.
- ASC reported that the majority of complaints received in the past 5 years related to claims that exceeded Terms of Market Authorization on websites for Natural Health Products
- The majority of complaints were reported to be resolved within 4-8 weeks.

Extreme Reach:

- Extreme Reach presented numbers from April 2013 – April 2016.
- 97 TV requests in 2013-2014
- 7 radio requests in 2013-2014
- 100 TV requests in 2014-2015
- 15 radio requests in 2014-2015

- 90 TV requests in 2015-2016
- 10 radio requests in 2015-2016
- These numbers are for reviews only where consumers wanted to ensure their scripts were in compliance with the regulations.
- Natural Health Products advertising comprised only 7% of Extreme Reach's compliance department.
- Trends discussed included an increase in submissions for pain relief and digestive supplements and skin care products.

Action:

- None

3. Ongoing Advertising Related Initiatives at Health Canada

3.1 Transparency Initiative – Posting of Advertising Complaints on Health Canada's Web site

Issue:

- As part of Health Canada's Regulatory Transparency and Openness Initiative, The Department is now posting advertising complaints it receives and addresses on Health Canada's Web site.

Discussion Highlights:

- The summary table providing details about the complaints (company, product, source, issues and actions taken) was first posted in July 2015 and is now updated on a quarterly basis. The last posting was for the quarter ending in December 2015 and the next posting will cover the January 1 – March 31, 2016 quarter.
- This is an ongoing activity where both the Marketed Health Products Directorate (MHPD) and the Regulatory Operations and Regions Branch (RORB) collate the complaints they received and addressed in order to capture all health product advertising complaints handled by the Department.

Action:

- Health Canada will continue to provide updates at future bilateral meetings with APAs.

3.2 Consumer Advertising Guidelines

Issue:

- The Consumer Advertising Guidelines are in the process of being updated.

Discussion Highlights:

- As of February 9, 2016, the responsibility for the update and publication of the

Consumer Advertising Guidelines for Marketed Health Products (CAG) was transferred from MHPD to Advertising Standards Canada.

- Advertising Standards Canada has provided a proposed revised version and is expecting Health Canada's comments/feedback.
- The revised guidelines will now include guidance for vaccines and medical devices advertised to the general public.
- Once Health Canada has provided its feedback ASC will take the necessary steps to organize a formal consultation where all external stakeholders will be invited to provide their feedback.
- MHPD will be holding WebEx sessions starting on April 21, 2016, to inform the Medical Device Industry of the upcoming inclusion of medical device advertising guidance development and procedures for preclearance.

Action:

- Health Canada and ASC will continue to provide updates at future bilateral meetings with APAs.

3.3 Consumer Health Products Canada – Social Media Guidelines

Issue:

- Consumer Health Products Canada is in the process of developing a Voluntary Guide on Social Media Engagement for the Consumer Health Product Industry.

Discussion Highlights:

- MHPD has been consulted and met with Consumer Health Products Canada (CHP Canada) regarding the development of the Voluntary Guide.
- Health Canada has provided input and suggestions to ensure the document was consistent with the position of the Department.
- The document is in the process of being finalized and Health Canada will be consulted again before it is made public.

Action:

- Health Canada will provide an update at the next bilateral meeting with the APAs.

3.4 International Comparative Legal Guide (IGLG) to Pharmaceutical Advertising

Issue:

- Bill Hearn, a Toronto lawyer responsible for writing the Canada Chapter on Pharmaceutical Advertising in the annual ICLG publication is currently working on the 2016 edition.

Discussion Highlights:

- This is a document that is used by legal counsel, private law firms and government agencies around the world to get information on various legal topics.
- One of the chapters focuses on pharmaceutical advertising and he sought our input on the current state of the regulations and guidelines as well as upcoming projects from Health Canada.
- The chapter provides information about the *Food and Drugs Act*, Health Canada's advertising guidelines and guidance documents, the advertising preclearance system, off-label promotion, advertising to healthcare professionals, gifts and financial incentives, hospitality and related payments, Direct-to-Consumer Advertising, transparency, Internet, and recent developments.

4. Status of Revision to the policy *The Distinction Between Advertising and Other Activities* to Encompass Guidance for Social Media

Issue:

- At the 2015 bilateral meeting, MHPD stated that work would resume in the fall on the update to the policy document entitled *The Distinction Between Advertising and Other Activities* to encompass guidance for social media.

Discussion Highlights:

- In summer 2014, MHPD met with the PAAB and ASC to discuss a potential revision to the policy document "*The Distinction Between Advertising and Other Activities*".
- It was Health Canada's intent to resume work on this file this year but due to the implementation of the Transparency Initiative (posting of advertising complaints), many competing priorities and a decrease in available staff working on advertising issues/projects, no further progress has been made to date.
- Health Canada does intend on resuming work on the file in the coming fall/winter.
- Also, as previously discussed, a section on social media will be considered in the revised policy.

Action:

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

5. Posting of Advertising Complaints addressed by Health Canada

Issue:

- Health Canada is taking a series of measures to be more transparent and open with Canadians about regulatory decisions. As part of Health Canada's Regulatory Transparency and Openness Framework, information on health product advertising complaints handled by the department became available on the Internet in the summer of 2015. The last posting was for the quarter ending in December 2015 and the next

posting is anticipated to take place in early May 2016 and will include advertising complaints received up to March 31, 2016.

Discussion Highlights:

- ASC fully supports the initiative and believes that it provides important information to industry and consumers.
- ASC requested clarification regarding the entries “compliance verification ongoing” and “Health Canada is assessing the issue” under the complaint status column. Health Canada explained that complaints at times include other non-compliance issues beyond advertising, which also need to be verified. In addition, the status can also represent cases where a potential advertising contravention has been identified but the case has not been fully assessed yet. Health Canada is not posting complaints where the complaint was deemed invalid or where non-compliance could not be reasonably determined.

Action:

- Health Canada will continue to provide updates at future bilateral meetings with APAs.

6. Health Canada Procedure for Amending/Withdrawing Product Licenses Based on New Findings

Issue:

APAs use the current Terms of Market Authorization (TMA) to approve advertising claims for inclusion in current advertising.

ASC requested information on what mechanisms Health Canada has in place to amend or withdraw a product license (PL) in cases where the validity of authorized information is disproven and what are the timeframes and procedures to notify stakeholders.

Discussion Highlights:

- There are few ways in which a modification can take place:

    1. Applicant initiated/requested
    2. Health Canada initiated/requested

- These requests can be made due to triggers such as new information coming to light, new scientific evidence, foreign country product alerts or advisories, consumer or trade complaints, etc.
- The type of information that is received determines what tools are used to resolve the issue.
- The non-regulatory route includes requesting the company to voluntarily change their labelling based on new information.
- The regulatory route includes issuing regulatory letters, which would be issued in cases where there is a safety risk to a certain population.

- If there is an imminent risk to health, Health Canada will initiate an immediate suspension of the product license and no one is allowed to sell that product (impacts retail level and normally includes recall).
- Companies are not legally compelled to change their product labels based on a product monograph change. Where there has been an addition of a risk statement, Health Canada has been successful in reaching out to the industry and requesting a voluntary change.
- If under the Natural Health Products Regulations (NHPR) a section 16 notice has been issued, the product license holder has 15 days to respond. If the response is not adequate to address the safety concerns, there is a stop sale notice issued (section 17 of the NHPR) and the license is placed under stop sale until the issue is resolved (product may remain under stop sale indefinitely).

Action:

- None

7. Products at the Cosmetic-Drug Interface

Issue:

ASC requested a status report on the Product Assessment Against Criteria (PAAC) classification process for Products at the Cosmetic-Drug Interface.

Discussion Highlights:

- Health Canada is examining some decisions that were made on certain products such as sunscreens and exploring interim measures to address industry concerns with classifications.
- The expectation is that the longer term concerns will be addressed under the new Consumer Health Products Framework which is in early stages of development.
- Currently on Health Canada's Web site, a "what was heard" document was posted on April 1, 2016, which includes an overview of the consultations in the 2015-2016 timeframe.

Action:

- None

8. Revision of PAAB Code of Advertising Acceptance

Issue:

- In 2016 PAAB is celebrating 40 years of drug advertising preclearance and the board has decided to modernize the PAAB code to provide clarity and ease of use. A client survey was conducted to identify code gaps; a committee was assembled to assess the need and finally a code revision committee was struck. PAAB has hired a professional writer to revamp the format and structure of the code to adapt it to online use, including

hyperlinks to the vast repository of guidelines and advisories that are currently on the PAAB web-site. Content change is minimal at this time. The revision is mainly structural in nature and will include examples and other visual aids to help readers understand the code. In 2016, PAAB will also create an online educational tool to help people learn the application of the code.

Discussion Highlights:

- The PAAB last implemented a code revision in 2015
- The PAAB will not be publishing a printed book; instead an electronic format will be produced that is much more user friendly.
- There is a code committee looking at the best approach to publishing an electronic version.

Action:

- None

12. Closing Remarks

Health Canada thanked participants for the valuable discussion and input. APAs were informed that this will be the last year that the Bilat will take place in the Health Protection Building, we will be moving to Jeanne Mance this summer. Phone numbers will change because of the move but emails will remain the same. The APAs will be informed of any phone number changes.

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 the Health Canada Web site.

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