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 14, 2015 – 10:00 a.m. - 1:00 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

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

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

Health Canada Participants

Marketed Health Products Directorate (MHPD):
John Patrick Stewart, Interim Director General (Chair)
Lisa Lange, Director, Therapeutic Effectiveness and Policy Bureau
Matthew Bown, Associate Director, Therapeutic Effectiveness and Policy Bureau
Co Pham, Senior Scientific Advisor
Alain Musende, Manager, Regulatory Advertising Section
Christophe Roy, Regulatory Advertising Officer, Regulatory Advertising Section

Judy Allaire, Regulatory Advertising Officer, Regulatory Advertising Section
Lorraine Van Loon, Regulatory Advertising Officer, Regulatory Advertising Section
Stephanie Schmidt, Regulatory Advertising Officer, Regulatory Advertising Section
Aline Labaki, Regulatory Advertising Officer, Regulatory Advertising Section
Arshia Bhatti, Junior Policy Analyst, Regulatory Advertising Section

Biologics and Genetic Therapies Directorate (BGTD):
Agnes Klein, Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics

Therapeutic Products Directorate (TPD):
Kelly Robinson, Director, Bureau of Metabolism, Oncology and Reproductive Sciences
Robyn Blom, Senior Regulatory Project Manager, Bureau of Gastroenterology Infection & Viral Diseases
Bruce Boulton, Product Information Officer, Bureau of Gastroenterology Infection & Viral Diseases

Natural and Non-prescription Health Products Directorate (NNHPD):
Sarah Wiles, Manager of Policy Development, Bureau of Program Policy, Risk Management and Stakeholder Engagement

Health Products and Food Branch Inspectorate (HPFBI):
Jenny McLaughlin, Regulatory Policy and Risk Management Specialist, Drug Compliance Verification and Investigation Unit

Healthy Environments and Consumer Safety Branch (HECSB):
Mathew Cook, Manager, Scientific Regulations Division

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1. Opening Remarks & Self-Introductions

The Chair introduced himself, welcomed attendees, and highlighted the passage of Vanessa's Law as a key contribution for greater transparency and improved working relationships with external stakeholders. Health Canada foresees even more collaboration with the advertising preclearance agencies (APAs) in the sharing of information on new developments and emerging trends in advertising.

2. Performance Report and Key Advertising Issues

Issue:

- Health Canada provided an annual statistical report of advertising activities.

Discussion Highlights:

- The Annual Statistical Report of Regulatory Advertising Activities (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 2014-2015 Fiscal Year

were shared with participants.

- Compared to the previous fiscal year, the Regulatory Advertising Section (RAS) received more than triple the number of advertising complaints while simultaneously taking on new responsibilities, but performance targets were still largely met.
- MHPD also implemented a new performance standard of 15 business days to respond to requests for information 90% of the time in the new fiscal year.
- It was noted that complaints from the Regions and HPFBI are not reflected in these numbers but that we are striving for a more streamlined single window approach. The APAs supported this idea and commented that it would serve to improve the coordination of complaints and to allow for more comprehensive statistics.
- Key advertising issues, such as the increase in complaints against the promotion of human chorionic gonadotropin and Botox® by private clinics, were also discussed.

Action:

- None

3. Ongoing Advertising Related Initiatives at Health Canada

3.1 Consumer Advertising Guidelines

Issue:

- There is an ongoing project to update the 2006 Health Canada guidance document entitled “Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)”.

Discussion Highlights:

- ASC is now leading the project to update the Consumer Advertising Guidelines. There are plans to incorporate guidelines on the advertising of vaccines and medical devices in these guidelines.

Action:

- Health Canada will continue to work with ASC on this project as required.

3.2 Transparency Initiative - Posting of Advertising Complaint Decisions on Health Canada’s Web Site

Issue:

- Health Canada has been working on an initiative to post information on health product advertising complaints received and addressed by the Department onto its Web site.

Discussion Highlights:

- A notice announcing the implementation of this initiative, as well as a sample summary

table, was posted and circulated to stakeholders on March 31, 2015.

- A summary table with details (complainant, product, manufacturer, issue, action taken) about the complaints will be posted this spring and will be updated on a quarterly basis.
- ASC suggested providing statistics on complaints that were deemed invalid, as opposed to reporting details of those cases on the Web site.
- PAAB noted that many complainants are not participating in the preclearance process. PAAB also suggested that Health Canada target specific advertising trends in its enforcement activities.

Action:

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

3.3 The Distinction between Advertising and Other Activities / Social Media Guidelines

Issue:

- Health Canada met with PAAB and ASC last year to discuss revising the 2005 policy "The Distinction between Advertising and Other Activities".

Discussion Highlights:

- Other initiatives over the past year have taken priority over the planned revisions but Health Canada expects to resume the work on the project this fall. The incorporation of a section on social media is being considered.

Action:

- Health Canada will keep the APAs informed if any additional input/feedback is required.

4. Unauthorized NHP Advertising / "Authorized by Health Canada" Claim

Issue:

- ASC continues to be concerned about the advertising of unauthorized natural health products and is looking for a mechanism that allows compliant manufacturers/advertisers to clearly communicate that their products are authorized.

Discussion Highlights:

- Health Canada considers a neutral factual statement such as "Product X is authorized for sale by Health Canada" to be acceptable in advertising as long as it does not make reference to the legislation or imply endorsement or recommendation by Health Canada.
- The HPFBI takes a risk-based compliance and enforcement approach to unauthorized health products and will be involved in promoting the use of compliant products through initiatives such as the posting of advertising complaints addressed by the Department.

Action:

- None.

5. General Overview of the proposed Consumer Health Products (CHP) Framework

Issue:

- Health Canada provided the APAs with an overview of the proposed CHP Framework.

Discussion Highlights:

- Natural health products are currently regulated under the *Natural Health Products Regulations*, non-prescription drugs are regulated under the *Food and Drug Regulations*, and cosmetics are regulated under the *Cosmetics Regulations*
- The proposed CHP Framework would apply to all of these products; it would thus be an aligned and modernized approach that is proportional to product risk, benefit, and uncertainty. The *Natural Health Products Regulations* and the *Cosmetics Regulations* would remain intact but non-prescription drugs will fall under a new set of regulations once they are removed from the existing *Food and Drug Regulations*.
- In response to PAAB's question, Health Canada indicated that the intended timeframe for this project is about 2 years; it is a key priority in our legislative renewal work.

Action:

- Health Canada is continuing internal consultations and MHPD is examining the impact of the new framework on advertising. The APAs will be consulted in this process.

6. Electronic Smoking Product Advertising

Issue:

- ASC requested an update on Health Canada's current position on electronic smoking products as well as guidance on the advertising of these products.

Discussion Highlights:

- Electronic smoking products which contain nicotine and/or have health claims require market authorization under the *Food and Drugs Act*. No such products have been authorized, thus it is prohibited to advertise, sell and import them. Advertising complaints regarding these products should be directed to the HPFBI.
- Electronic smoking products which do not contain nicotine and do not have health claims are subject to the *Canada Consumer Product Safety Act*. Advertising complaints or questions pertaining to these products should be directed to the Consumer Product Safety Directorate within HECSB.
- The Standing Committee on Health published a report in March 2015 with 14 recommendations including significant restrictions on the advertising of these products. There is a strong theme of youth protection within the recommendations. A response to

this report is expected to be tabled in early July 2015.

Action:

- None.

7. *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law)

Issue:

- Health Canada provided the APAs with an overview of the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law).

Discussion Highlights:

- This new law amends the *Food and Drugs Act* and came into effect in November 2014. It strengthens the regulation of drugs and medical devices and increases patient safety by allowing Health Canada to take tougher measures (eg: recalls, fines, penalties, injunctions, etc.) more quickly against serious health risks.
- The most significant impacts on advertising would be the new provisions on statutory injunction and increased fines and penalties.
- APAs are very pleased with the new legislations. PAAB offered to provide examples of contraventions that Health Canada could use to exercise new powers under the Law.

Action:

- None.

8. Clinical trial results in the pharmacology section of the Product Monograph (PM)

Issue:

- PAAB requested clarification from Health Canada regarding the use of clinical trial results within the Clinical Pharmacology section of the Product Monograph (PM) in advertising.

Discussion Highlights:

- Advertising claims should focus on clinical efficacy and not on clinical pharmacology data. Information from the PM must not be taken out of context.
- Some advertisers are using safety information within the PM to support efficacy claims.
- PAAB is seeking Health Canada's support in asserting to manufacturers that claims are not necessarily permissible just because they are consistent with certain details within the PM, the claim must be in accordance with the efficacy data provided in the PM.
- BGTD suggested that the Summary Basis of Decision (SBD) may be useful as a guide on how to use the data in the PM within the proper context.
- MHPD proposed to draft a paragraph to explain the requirement that advertising be "in accordance with the Terms of Market Authorization". This will be shared with TPD and

BGTD for comments before it is finalized. It will then be provided to PAAB for use in cases where manufacturers attempt to use PM data out of context in advertising.

Action:

- Health Canada will draft a paragraph for PAAB to share with manufacturers/advertisers which elaborates upon the requirement that advertising be "in accordance with the Terms of Market Authorization".

9. Patient Knowledge Platform Proposal

Issue:

- TPD initiated a discussion with PAAB regarding the review process of a web-based platform that would be accessible through a 2D Matrix Code on the product label.

Discussion Highlights:

- TPD is comfortable with electronic links to HC-approved information such as the PM, but has concerns with links to third party sites, even if they are balanced consumer information documents.
- PAAB is very comfortable with reviewing and approving electronic pieces, but would need clarification on what is considered by HC to be an extension of labelling.
- Since HC does not view these types of Web sites to be risk minimization tools or extensions of labelling, having PAAB review the patient information within such platforms would be the most appropriate option.

Action:

- None.

10. Proactive Surveillance and Mandatory Preclearance / Off-label Advertising

Issue:

- Health Canada invites APAs to discuss ideas on proactive marketplace monitoring, mandatory preclearance of advertising, and off-label advertising.

Discussion Highlights:

- PAAB noted that compliance has improved and the number of complaints has decreased. They conduct proactive monitoring through activities such as attending conferences for healthcare professionals, canvassing advertising for compliance with the PAAB Code, and examining promotional materials directed to the licenced healthcare professionals on staff.
- ASC highlighted the need for stronger enforcement activity from Health Canada and suggested focussing on certain problematic areas as opposed to all areas at once. Extreme Reach has concerns with respect to resources, particularly with respect to

balancing their for-profit work such as preclearance, with “good citizen” duties such as proactive surveillance efforts.
- PAAB noted that although Fastrack is useful in highlighting problems such as off-label promotion to physicians, it is not considered to be legal evidence and witnesses are still ultimately required.
- ASC noted that most of its experience with off-label claims is related to the advertising of natural health products.

Action:

- None.

11. Summary and Critical Analysis of an Article in the “International Journal of Risk & Safety in Medicine”

Issue:

- Health Canada is sharing its critical analysis of an article titled “A compromise too far: A review of Canadian cases of direct-to-consumer advertising regulation” published in the International Journal of Risk & Safety in Medicine which discusses Health Canada’s response to advertising complaints.

Discussion Highlights:

- MHPD received a number of inquiries regarding direct-to-consumer advertising (DTCA) of prescription drugs, further to this article which concludes that Health Canada requires stronger regulations and enforcement measures.
- MHPD’s critical analysis of the article reveals that it contains some incorrect information. In addition, contrary to the article, Health Canada achieves voluntary compliance in virtually all cases and has even stronger tools to address contraventions now that Vanessa’s Law has come into effect. In addition, the Regulatory Transparency and Openness Framework is expected to encourage compliance among manufacturers.
- ASC expressed interest in seeing MHPD’s full assessment of this article.

Action:

- Share full assessment report with ASC.

12. 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 the Health Canada Web site.

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