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 9, 2013 – 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

MIJO:
Anna Haine, Director, Clearance and Verification Services

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

Health Canada Participants

Marketed Health Products Directorate (MHPD):
Dr. Supriya Sharma, Interim Director General
Robert Liteplo, Acting Director, Therapeutic Effectiveness and Policy Bureau (Chair)
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
Lorraine Van Loon, Regulatory Advertising Officer, Regulatory Advertising Section

Therapeutic Products Directorate (TPD):
Mark Bustard, A/Manager, Bureau of Pharmaceutical Sciences

Biologics and Genetic Therapies Directorate (BGTD):
Dr. Wendy Mooney, Medical Officer, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics

Natural Health Products Directorate (NHPD):
Stephanie Reid, Manager, Bureau of Program Policy, Risk Management and Stakeholder Engagement

Health Products and Food Branch Inspectorate (HPFBI):
Christopher Rose, Manager, Drug Compliance Verification and Investigation Unit

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1. Opening Remarks & Self-Introductions

The Chair welcomed attendees and noted that the meeting is an opportunity to exchange information and to have thoughtful discussions on health product advertising, but is not a decision-making forum.

2. Brief Update on Outstanding Items from the 2012 Bilateral Meeting

A) Nonprescription Drug Label Approval Process

Issue:

- Following confirmation, at the 2011 bilateral meeting, that TPD has always reviewed draft labels for Category IV monograph or Labeling Standard submissions, ASC questioned whether the final marketed labels are also reviewed and if they could be accessible to the general public via the external Drug Product Database (DPD).

Discussion Highlights:

- TPD confirmed that final labels are not reviewed.
- Health Canada had previously explored the possibility of making the final marketed labels available via the external DPD and thus accessible to the general public.
- It was decided, however, that this initiative is not currently a priority for the Health Products and Food Branch.
- ASC stated that these labels are often vital to understanding Health Canada's approval of the claims for a given product. Access to such information facilitates effective and efficient advertising preclearance and complaint adjudication. ASC thus sees this as information that should be shared by Health Canada with advertising preclearance agencies (APAs).

Action:

- Health Canada will provide an update at future bilateral meetings with the APAs.

B) Symbols Used in Food and NHP Ads that Depict Off-Label Indications

Issue:

- PAAB raised the issue that health product advertising that include graphics such as a heart logo need to have an accompanying claim for efficacy approved by Health Canada. They cited examples for foods and natural health products such as cheerios and Vitamin E respectively that were showing hearts in their advertising without a claim approved by Health Canada.

Discussion Highlights:

- The Food Directorate explained last year that at the present time, health claims related to heart disease can be made on food under certain conditions.
- MHPD is proposing the addition of an example to the *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)* (CAG) that logos or pictures in health product advertising must be consistent with the product's Terms of Market Authorization.
- Health Canada continues to work on developing a position with regard to the rest of the product lines.

Action:

- MHPD will provide an update on the progress of this initiative by September 2013.

3. Performance Report and Key Advertising Issues

Issue:

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

Discussion Highlights:

- The Annual Statistical Report of Regulatory Advertising Activities (complaints and requests for clarification) for Fiscal Year 2012-2013 was shared with participants.
- MHPD is working on the performance standard for the adjudication of advertising complaints it receives. The new standard is expected to be adopted by September, 2013.
- Key advertising issues were also discussed.
- PAAB requested clarification on whether MHPD had timelines for responses to advertising complaints related to health product safety issues.
- MHPD confirmed that there is a specific protocol followed to determine the health risk of an ad and that subsequent processes are followed accordingly. A health product advertising posing a medium or high health risk is handled as top priority; there is no

other specific timeline for handling this type of complaint.

Action:

- None

4. Updates to:

A) The *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)*(CAG)

Issue:

- ASC requested a clear timeframe for publication of the revised CAG in order to facilitate planning.

Discussion Highlights:

- MHPD continues to consult internally as the transfer of medical device advertising oversight lead to MHPD has identified a number of considerations with respect to the preclearance and complaint resolution.
- MHPD will resume its work on the update of the CAG with the possible inclusion of medical devices, and the APAs will be consulted again.
- ASC is concerned that, in their opinion, the document is becoming large and unwieldy and believes that the CAG should be a lean document that gives users practical advice on complying with important concerns relating to *Section 9.1* of the *Food and Drugs Act*.
- ASC clarified that they did not object to the addition of other product categories (ie. vaccines and medical devices) to the CAG.
- MHPD is exploring ways of making the CAG more useful and practical.

Action:

- MHPD will resume the update of this document following the completion of the medical device advertising internal consultation.
- The anticipated timeframe for an updated CAG ready for consultation is fall 2013.

B) Ongoing Advertising Related Initiatives at Health Canada

Issue:

- MHPD wanted to provide the APAs with an update regarding ongoing advertising initiatives at Health Canada.

Discussion Highlights:

- MHPD provided an update on the transparency initiative (posting of advertising complaint decisions on Health Canada's Web site), potential guidance document on

social media, and also a possible update to the Health Canada policy *The Distinction Between Advertising and Other Activities* (The Distinction document).
- PAAB requested to be included in the updating process for The Distinction document and ASC suggested that a meeting among Health Canada, ASC and PAAB could be useful.

Action:

- MHPD agreed to seek input from the APAs prior to going ahead with revisions to any of the guidance documents.

5. Presentation on the Impact of the Repeal of NHP-UPLAR on Compliance and Advertising

Issue:

- Health Canada wished to present the new approach for reviewing natural health products (NHPs), as well as the impact of the repeal of the *Natural Health Products (Unprocessed Product Licence Applications) Regulations* (NHP-UPLAR) on compliance & enforcement and advertising of NHPs.

Discussion Highlights:

- NHPD explained the new three-class system for reviewing NHPs as well as the changes following the ending of NHP-UPLAR.
- HPFBI described the compliance and enforcement plan during the 18 month transition period for NHPs that formerly had exemption numbers (EN).
- MHPD provided details on the advertising of NHPs following the repeal of NHP-UPLAR.

Action:

- None

6. APAs Expectations of HC When Receiving Referred Advertising Complaints

Issue:

- Health Canada wanted to clarify the APA's interpretation of "summary of findings" referred to in Section 3.5.2.3 of Health Canada's guidance document *Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising* when referring advertising complaints to them.

Discussion Highlights:

- Health Canada explained that prior to referring complaints to APAs, a preliminary assessment of the complaint is performed.
- Although the guidance requires that a "summary of findings" is provided to the APAs, details of what is included in the "summary of findings" are not clear.

- It is Health Canada's interpretation that a "summary of findings" would be limited to verification of the status of the product and whether the ad presents no or a low level of health risk.
- ASC confirmed that they don't require a "summary of findings", from Health Canada but requested Health Canada, in advance of forwarding complaints, have a mechanism to ensure that the review is within the scope of the APA (i.e. product is authorised for sale in Canada and does not include Schedule A claims, and that contact information for the advertiser is included).
- MIJO added that specific information such as a copy of the ad, or contact information of the complainant is sometimes missing from complaints referred by Health Canada and the information being provided to the APAs should be more consistent.
- Health Canada is working towards a better complaint coordination process and will remind all employees to follow internal policies regarding the referral of complaints to APAs.

Action:

- Going forward, when referring complaints to the APAs, Health Canada's "summary of findings" will be limited to the status of the product and the level of health risk.

7. Health Canada Issued Advertising Policy Clarification

Issue:

- ASC requested that Health Canada share with APAs any policy issues that arise from advisories to companies regarding direct-to-consumer advertising of prescription drugs and direct-to-consumer information messages.

Discussion Highlights:

- Health Canada will inform the APAs when advice is provided to companies regarding direct-to-consumer advertising of prescription drugs and direct-to-consumer information messages.
- In order to avoid redundancy, information will only be provided if it is precedent setting.

Action:

- None

8.

A) Generic Health Product Advertising that Includes Comparisons to Reference Brands

Issue:

- The PAAB requested clarification from Health Canada regarding the advertising of generic products with the claim "same as" in a general or overall sense as well as claims

such as “generic product A has the same efficacy and safety as reference product B”.

Discussion Highlights:

- The PAAB interprets “same as” as “identical”, while Health Canada interprets “same as” as being different from “identical” and thus would not authorize claims with the term “identical”.
- Health Canada would authorize a “same as” claim providing it is used with a qualifier such as “Product A has the same safety and/or efficacy as Product B”.

Action:

- None

B) Biosimilar Health Product Advertising

Issue:

- The PAAB wanted confirmation from Health Canada (as in item 8A) regarding the advertising of biosimilars and the use of “same as” or “identical” when used in a general sense only with no qualifier e.g. same bioavailability, same efficacy etc.

Discussion Highlights:

- Health Canada explained that a “biosimilar” is referred to by Health Canada as a Subsequent Entry Biologic (SEB) and that there are no so-called ‘generic biologics’: biologic drugs are not interchangeable.
- The terms “same as”, and “identical” are considered false and misleading and would not be permitted for Subsequent Entry Biologics.

Action:

- None

9. Web site Gating Requirements

Issue:

- Health Canada is requesting confirmation from PAAB that a gating system requiring a healthcare professional licence number alone to grant access would qualify as a “well-controlled entry system” according to the newly revised PAAB Code.

Discussion Highlights:

- PAAB explained that they have determined multiple ways of properly gating Web sites and that companies would be able to choose from these options.
- PAAB confirmed that a gating system requiring a healthcare professional’s licence number alone to grant access would qualify as a “well-controlled entry system”.

Action:

- None.

10. Closing Remarks

Health Canada thanked participants for the valuable discussion and input.

Dr. Supriya Sharma, Interim Director General
Marketed Health Products Directorate