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 22, 2014 – 10:00 a.m. - 12:15 p.m.

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

No policy decision is 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
Charlotte Wurz, Senior ASC Drug Clearance Analyst

MIJO:
Anna Haine, Director, Clearance and Verification Services
Jacquelin Blakey, Senior Clearance Analyst

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):
Scott Sawler, Director General (Chair)
Lisa Lange, Director, Therapeutic Effectiveness and Policy Bureau
Reem Mahmoud, A/Advisor, Director General's Office
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

Therapeutic Products Directorate (TPD):
Bruce Boulton, Product Information Officer, Bureau of Gastroenterology Infection & Viral Diseases

Natural Health Products Directorate (NHPD):
Benjamin Mahon, A/Senior Advisor, Director General's Office
Anik Michelle Chartrand, A/Manager, Bureau of Licensing Services and Systems

Health Products and Food Branch Inspectorate (HPFBI):
Stephanie DiTrapani, A/Manager, Drug Compliance Verification and Investigation Unit

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1. Opening Remarks & Self-Introductions

The Chair welcomed attendees and announced that as a result of Bill C-17, transparency will be one of Health Canada's priorities. Because Health Canada expects to be collaborating more with the advertising preclearance agencies (APAs), it was suggested that there could potentially be additional meetings with the APAs in the future.

2. Brief Update on Outstanding Items from the 2013 Bilateral Meeting

Symbols Used in Advertisements that Depict Off-Label Indications

Issue:

- The PAAB tabled this item at the 2012 Bilateral Meeting with the APAs and expressed concerns that there were inconsistencies with the use of graphics in advertising between product lines.

Discussion Highlights:

- Prescription drug manufacturers were complaining that the PAAB was being too strict in their rulings since certain foods and NHPs such as cheerios and Vitamin E were showing hearts in their advertising despite no supporting claims having been approved by Health Canada.
- The Food Directorate explained at that meeting that they do not object to the use of graphics in advertising provided the graphic doesn't change the nature of the claim.
- MHPD had proposed the addition of an example to Section 2.11 of the "Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)", which discusses graphics.
- The example would clarify that for nonprescription drugs and NHPs, logos or pictures must not be included when they extend beyond or are too specific compared to the product's Terms of Market Authorization (TMA).

Action:

- Health Canada continues to explore the best approach in developing a branch position for the other product lines regarding the unique nature of each product line and the claims that would be accepted for these products.

Nonprescription Drug Label Approval Process

Issue:

- Participants were reminded of this item from the 2013 bilateral meeting regarding the nonprescription drug label approval process.

Discussion Highlights:

- This was not added to the 2014 agenda since there is nothing new to update on.

Action:

- This item will not be included on future agendas unless there are new developments.

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 information) for Fiscal Year 2013-2014 was shared with participants.
- Over the last fiscal year, the Marketed Health Products Directorate (MHPD) established a new performance standard of 45 business days to issue a regulatory letter 90% of the time for advertising complaints.
- 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.
- Key advertising issues were also discussed.
- When the APAs were asked if the statistics MHPD was providing were helpful for them, the PAAB commented that they would prefer to see a better breakdown of the types of products in the complaints (prescription vs non-prescription). ASC suggested that statistics alone do not provide great value to an APA, and that it would be helpful to understand more about outcomes and the nature of concerns.

Action:

- MHPD will look at the information that is disseminated to the APAs to see if we can better capture the impact of our actions with respect to advertising activities.

4. Ongoing Advertising Related Initiatives at Health Canada

1. Posting of Advertising Complaint Decisions on Health Canada's Web Site

Issue:

- In an effort to provide Canadians with information that will matter to them the most and level the playing field, Health Canada has been working on an initiative to post advertising complaint decisions taken by the Department on its Web site.

Discussion Highlights:

- An update was provided that Health Canada is now looking at posting advertising complaint decisions involving higher risk issues and that work is ongoing.

Action:

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

2. Interpretation of Section C.01.044 of the *Food and Drug Regulations* (DTCA)

Issue:

- MHPD wanted to inform the APAs that preliminary work has started towards clarifying our interpretation of Section C.01.044 of the *Food and Drug Regulations*.

Discussion Highlights:

- It was explained that additional clarifications with respect to the restriction on direct-to-consumer advertising of prescription drugs would provide clearer guidance to the APAs when providing advisory opinions to industry.
- Although a formal consultation with the APAs and key stakeholders will occur if this initiative moves forward, MHPD solicited the APAs for examples and suggestions that could be added to this guidance.

Action:

- MHPD will keep the APAs informed, should this initiative move forward.

5. Compliance Promotion

Issue:

- The Natural Health Products Directorate (NHPD) wanted to inform the APAs of developing initiatives around opportunities for compliance promotion.

Discussion Highlights:

- Although there is an assumption amongst Canadians that if a product is available for purchase it means that it has been approved for sale by Health Canada, this is not always the case, especially with respect to natural health products.
- NHPD explained that they want to increase awareness to consumers and are looking to incentivize supply chain retailers into carrying only products that Canadians are looking for.
- It was suggested that we can look at logos and that any advertising that was precleared by the APAs would have a corresponding logo. There are logos for approved products and logos for approved advertising, however, and what seems to be important for companies and consumers are claims indicating a product has been authorized for sale by Health Canada.

Action:

- Health Canada will continue to explore ways for companies to comply and will consult with the APAs and possibly consumer groups (such as CARP) as well.

6. Mechanism for Managing Complaints about Consumer Directed Advertising of Marketed Health Products

Issue:

- ASC requested from Health Canada a streamlined approach to managing advertising complaints.

Discussion Highlights:

- ASC explained that they receive complaints from MHPD, the Health Products and Food Branch Inspectorate (HPFBI), and directly from the general public. As well, because there are many complaints for natural health products, there is a big educational component with companies and a lot of work goes into adjudicating these complaints.
- ASC asked if it was possible to have one contact point and a more streamlined process for complaints so that they wouldn't need to contact people across Canada if clarification about a complaint is required.
- HPFBI confirmed that the Regional Offices of the HPFBI are the best contact for complaints and that they have procedures that should be followed. To determine whether it would be beneficial to improve current processes, HPFBI asked ASC for the volume of complaints.
- HPFBI committed to bringing this issue up at their bi-weekly subcommittee meeting where this will be shared with the group to ensure proper processes are followed. MHPD requested to be included in these subcommittee meetings if advertising issues are brought up because of our relationship and ongoing discussions with the APAs.

Action:

- HPFBI will make their contact information available to the APAs and will work to ensure a better relationship with MHPD.

7. Update to "The Distinction Between Advertising and Other Activities"

Issue:

- The PAAB asked for an update on the revision to the Health Canada policy "The Distinction Between Advertising and Other Activities*"* as well as the expected timeline for consultation and completion.

Discussion Highlights:

- It was explained that MHPD is exploring ways to update specific sections of the policy along with the inclusion of other media.
- The APAs were informed that they would be consulted as part of the process.
- PAAB mentioned that since they were referring companies to this document often, the sooner the document is updated and the more complete it is, the better.

Action:

- Health Canada is looking to complete the revision of this policy in a timely fashion and the APAs and key stakeholders will be consulted in due time.

8. Permissibility of "Authorized by Health Canada" Claims for NHPs in Advertising Communications

Issue:

- ASC requested an update on possible changes to the interpretation of Section 92 of the *Natural Health Products Regulations*.

Discussion Highlights:

- ASC explained that consumers want to know when a product is authorized by Health Canada and that they don't understand a number (DIN or NPN) as showing this.
- MHPD responded that since the regulations say that you can't make a direct or indirect reference, "approved by Health Canada" claims may be interpreted as Health Canada endorsing the product.
- MHPD is of the opinion that having a DIN, NPN or a DIN-HM on a product is analogous to a claim like "authorized by Health Canada".
- It was raised that we need to be consistent with Health Canada guidance such as the "Labelling of Pharmaceutical Drugs for Human Use" since there are several examples in there of claims that are unacceptable.

Action:

- Health Canada will explore this issue further since all participants were in agreement that a DIN/NPN/DIN-HM is insufficient to show that a product is authorized for sale by Health Canada.

9. Live Discussions Between the PAAB & TPD Reviewers and/or Department Heads

Issue:

- The PAAB explained that it was possible in the past to have live discussions with review department heads from the Therapeutic Products Directorate (TPD) for clarifications relating to nuances within/between specific product monographs (PM). Since this is no longer possible, PAAB has asked for the creation of a mechanism to have live discussions with Health Canada review staff.

Discussion Highlights:

- TPD explained that they previously allowed for live discussions with the PAAB since section C.08.002 (2) (k) of the Regulations required "a statement of all the representations to be made for the promotion of the new drug" which was interpreted to mean the first advertising proposed for the new drug. Division Chiefs were expected to review this first promotional material before the product went on the market.
- Because the PAAB became better at reviewing health product advertising, however, there was no longer a need for Health Canada to do a review of this first advertising, and as such, it was determined that Health Canada no longer needed to perform this function.
- Although section C.08.002 (2) (k) of the Regulations is still there, this provision is not being enforced and Health Canada does not believe it is necessary to reinstate this function.
- Processes have changed, the PM is longer and more complicated thus making it difficult for Health Canada reviewers to discuss nuances of the PM over the phone, and making written responses required for accuracy.
- Concerns with the PM should continue to go to MHPD where they can be re-directed to the appropriate TPD Bureau for a written response and if the PAAB receives a written response that they find unsatisfactory, they can contact TPD directly.
- As well, the PAAB can contact TPD directly for general questions and guidance.

Action:

- None.

10. Licences for NHPD PCI Amendments

Issue:

- NHPD wanted to provide the APAs with an update on changes to the Product Licence

(PL) for products attesting to precleared information (PCI) through Class 1.

Discussion Highlights:

- As per NHPD's new Application Management Policy which outlines the class system, products reviewed through Class 1 will now receive a Product Licence (PL) which will read "as per monograph" rather than listing out the authorized claims on the monograph.
- This approach will decrease administrative burden as NHPD will no longer need to review amendments to PLs licensed in this manner, since all elements that are part of the monograph would be permitted.
- Furthermore, NHPD will no longer need to review amendments as a result of PCI updates because the blanket statement "as per monograph" would already address them.
- This new process will also apply to products seeking an amendment but that were previously licensed using PCI.
- These changes apply to the APAs since, in these instances, the APAs would be expected to check the monographs for the authorized claims rather than the PL.

Action:

- An information webinar is planned for the near future and will further explain this change.

11. 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 with their members since this is no longer posted on the Health Canada Web site.

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