



REVIEW

Year 2011 marks the 35th year of the PAAB since its incorporation in 1976. To see the current edition of the PAAB Code, visit the PAAB Web-site.

www.paab.ca

Ce document est également disponible en français sur notre site web.

PAAB MEETINGS

October 17, 2011 - Executive Committee Meeting

November 18, 2011 – General Meeting

Ongoing – PI Code Committee

MISSION, VISION, VALUES

MISSION: To provide a preclearance review that fosters trustworthy healthcare communications within the regulatory framework.

VISION: Trusted healthcare product communication that promotes optimal health.

VALUES: Integrity, Competency, Credibility, Independence, Excellence, Transparency

CLIENTS INVITATION

The PAAB commissioner is proud of the high level of customer service shown by the PAAB staff. We strive for continuous quality improvement. We remind you that the door to the commissioner's office is open to receive comments about PAAB activities or review issues. We would like to receive specific examples that caused satisfaction or dissatisfaction for the client to help identify trends for areas of improvement of the PAAB review service. You can contact the commissioner at 905-509-2275 x28 and by email at commish@paab.ca.

PRODUCT INFORMATION (PI)

The PAAB Directors have approved in principle the possibility to change the PAAB Code requirement for Product Information that accompanies advertising. The change would allow a link to the PI in the ad. The PAAB will examine how the code can be changed to accommodate this new format. Any changes will have to be within the current federal regulatory framework and the opinion of Health Canada will be sought. A code committee has been struck and will report to the Board with their recommendation.

TRAINING WORKSHOPS

The PAAB conducts ad hoc training sessions at the request of pharma/biotech companies, agencies and suppliers. Check the PAAB web-site for details.

www.paab.ca

STAFF TRAINING DAY

The PAAB will be conducting a staff development day on Friday August 19, 2011. We consider this a non-business day and no review letters will be sent to clients. Please build this into your planning.

CUSTOMER EXPERIENCE INDEX

The PAAB's primary role is to ensure that advertising of prescription drugs is accurate, balanced and evidence based. The PAAB staff strives to provide service that is accurate, transparent and prompt, demonstrating a high level of scientific and regulatory expertise in its reviews.

In late May, 2008, we introduced a Customer Experience Index Survey (CEI). This will provide the PAAB with a systematic and ongoing tool for client feedback, measuring administration, reviewers, management, general process and technology.

Clients who have had an APS accepted will be randomly selected to receive a survey involving 14 questions. If you get one, please complete it and send it back to us promptly. It is important to answer the questions regarding the referenced review file. It is the commitment of the PAAB to improve our customer service. Results for 2011 indicate a continuance of an 80% satisfaction level with the individual file that the client commented on. The PAAB commissioner is pleased with the results and is encouraging the staff to keep up the good work.

PAAB SPEAKS

Commissioner Chepesiuk will appear as faculty at the Pharma IQ Global webinar series and at two digital marketing conferences in the Fall. He will also present to a group on international graduate students studying Public Health in France who will be in Canada for a week.

The Commissioner and Chief Review Officer Patrick Massad will be conducting workshops on the PAAB Code for several companies this summer by invitation.

PAAB staff can conduct learning sessions about the PAAB and the Code of Advertising Acceptance or Direct-to-Consumer advertising of Rx or biological health products on-site at your workplace. Sessions are usually 2-3 hours long and the content can be tailored to your needs. Q&A about your confidential marketing situations can be discussed. There is a fee and travel expenses charge.

Contact Commissioner Ray Chepesiuk for details and fee information 905-509-2275 x28

REVIEW ACTIVITY

During the period of April 1 to June 30, 2011, the total number of first review submissions was 1,689 with 14 files going more than 10 days on first review (11 due to reviewer illness). This compared to 1,457 during the same period of 2010. This period, the

reviewers averaged 1.8 days for turnaround on revision.

To address industry perception, the PAAB can now generate a report to show how long the client holds a file vs. the PAAB during the review process to acceptance. In the first half of 2011, on average the PAAB has held the file 2.9 days vs. the client holding it 8.7 days. In the same period it was 3.6 vs 15.2 days.

The average number of total revisions per submission for a file was 2.3 in the first half of 2011 (2.5 in 2010). 12% of accepted files took more than 3 revisions to complete in 2011 versus 16% in 2010. Ask CRO Patrick Massad how your agency or company performed.

USE OF PAAB LOGO

We encourage you to show the PAAB logo on all material reviewed to acceptance (HP) or to no objection (DTC). The new DTC codes are CA for advertising and CI for information. The clearance period is for 12 months and please submit a renewal request if you wish to use the advertising for longer than 12 months. Two month extensions for exceptional circumstances can be granted by the commissioner.

PAAB COMPLAINT REPORT

During the period of April 1 to June 30, 2011, the PAAB Commissioner processed 3 Stage 2 complaints. 2 were sent to Health Canada for investigation.

In addition, PAAB has continued to regularly monitor journals, the Internet, and receive direct-mail/detail aid materials collected by health professionals as part of its monitoring program. When Code violations are discovered, PAAB sends a letter to the advertiser seeking their cooperation to meet the requirements of the Code. When appropriate, PAAB will notify the advertiser's trade association and/or Health Canada for their assessment of additional penalties. In the second quarter of 2011 the PAAB sent 1 monitoring notice.

STAGE TWO DECISIONS

1. ADVERTISER:

COMPLAINANT:

SUBJECT: Prezista DTC ad in *Xtra!* Magazine

PRECLEARANCE: No

ALLEGATIONS: Help-seeking ad for a prescription drug.

DECISION: Due to Health Canada policy, the complaint was sent to Health Canada.

PENALTY: N/A

OUTCOME: Health Canada ruled that the ad was not "help-seeking" and it was product "reminder" and within the regulations.

2. ADVERTISER: Abbott

COMPLAINANT: Dr. Barbara Mintzes et al

SUBJECT: Help-seeking DTC Journal ad and website for testosterone replacement therapy

PRECLEARANCE: Yes

ALLEGATIONS: Violates Food & Drugs Act because it is promoting Androgel with claims to the public. Inherent safety issue in the promotion.

DECISION: As per policy sent to Health Canada for adjudication.

PENALTY: N/A

OUTCOME: Unknown

3. ADVERTISER: AstraZeneca

COMPLAINANT: Dr. Joel Lexchin

SUBJECT: Onglyza journal ad

PRECLEARANCE: Yes

ALLEGATIONS: Ad is misleading because Onglyza has not been shown to reduce risk of hard clinical outcomes in diabetes and therefore the ad should have a disclaimer saying such.

DECISION: The ad was in line with the product monograph both in indication and fair balance safety information. There was no need for a disclaimer.

PENALTY: None

OUTCOME: No action required.

For information or if you have comments:

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