



REVIEW

Year 2009 marks the 33rd 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

April 23, 2010 - Annual/General Meeting

June 21, 2010 - Executive Committee

November 19, 2010 - General Meeting

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

We remind you that the door to the commissioner's office is open to receive comments about PAAB staff performance. He 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. Our Customer Experience surveys have not revealed negative comments that we were able to act on. We would like to document and investigate specific cases and take appropriate action. You can contact the commissioner at 905-509-2275 x28 and by email at commish@paab.ca.

HEALTH CANADA MEETING

PAAB representatives will meet with Health Canada at a bilateral meeting between Health Canada and all of the sanctioned self-regulatory agencies on April 20, 2010 in Ottawa. Topics are identified by mutual discussion and are marked for information, update, direction, or action. The PAAB directors have identified 4 issues for discussion.

HEALTH CANADA INTERIM GUIDANCE ON DTC VACCINE ADS

On December 8, 2009 Health Canada issued "Interim Guidance on Fair Balance in Direct-to-Consumer Advertising of Vaccines". This came about because Health Canada received several complaints about the lack of Fair Balance safety information in DTC television ads for Schedule D vaccine products. This was perceived to be a violation of section 9(1) of the Food & Drugs Act. Health Canada has confirmed that none of the ads that required change and that led to the HC intervention guideline had been reviewed and approved by the PAAB. We have posted the guidance on the PAAB web-site www.paab.ca and it is available on the Health Canada web-site http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_dtca-pdac_vaccine-vaccins-eng.php It is similar in intent to s2.4 of the PAAB Code of Advertising Acceptance.

The PAAB can assist you to meet the regulations of DTC TV advertising. We have been doing it since 1990. The PAAB allows advertisers to include the PAAB logo on DTC material reviewed by the PAAB and that reach a "no further comment" stage. Prescription-requiring drug ads including drugs, biologics and vaccines directed to consumer television require a Telecaster number available from the Television Bureau of Canada. Telecaster will accept a letter from the PAAB as proof of valid review prior to authorizing a number. The PAAB provides a seamless review of advertising campaigns that include health professionals, patients and consumers.

Written opinions regarding Direct-to-Consumer Advertising of Prescription Drugs and opinions regarding whether an activity is advertising subject to the PAAB Code will be given to the client within 4 business days. Please use the PAAB eFile submission system available at www.paab.ca and clearly indicate your request for an opinion. If you have any questions please call Glenn Golaz or Patrick Massad at the PAAB office 905-509-2275.

PAAB reviews include branded ads, help-seeking ads, web-sites and consumer brochures on all media including television and internet. Reviews are based on the Health Canada document "The Distinction between Advertising and Other Activities". PAAB will charge a review fee for written opinions, including e-mail (see Fee schedule on web-site). Advertisers should note that the PAAB members have agreed to the Health Canada request that it be copied on final versions of DTCARx material reviewed by the PAAB.

PRODUCT INFORMATION (PI) COMMITTEE

The PAAB Directors have struck a code committee of various industry stakeholders to review how product information (PI) is delivered to the target audience in various media. Options will be reviewed and a suggestion to the board is expected to follow. Any changes will have to be within the current federal regulatory framework and the opinion of Health Canada will be sought.

TRAINING WORKSHOPS

The PAAB will be conducting training workshops in May 2010 to help clients understand the application of the PAAB Code and Direct-to-Consumer advertising of prescription drugs. Social media marketing guidance will be covered. Montreal May 17 and Toronto May 19. Check the PAAB web-site for details and registration information.

STRATEGIC PLANNING SESSION

The PAAB conducted a strategic planning session on January 28 and 29, 2010. The board will develop and approve an action plan on April 23, 2010.

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 20009 indicated 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 COMMISSIONER SPEAKS

The PAAB Commissioner, Ray Chepesiuk, will give two presentations in April. One is to the Industry Advisory Committee of the American College of Chest Physicians regarding promotion of health products in Canada and a second to the Association of Corporate Counsel, Quebec Chapter about self-regulation in the promotion of health care products.

PAAB BUILDING NEW OFFICES

The PAAB has purchased land at 113 Old Kingston Road in Ajax, Ontario and will build new offices by the end of 2010.

In the last ten years, due to compliance support from industry in response to PAAB leadership and training, the volume of PAAB reviews have been much higher than anticipated. Also, the PAAB has managed to control its expenses through prudent management. This resulted in the following:

- A challenge to ensure an adequate size of review staff and facilities to meet the growing demand for reviews to meet the performance targets expected from PAAB. PAAB human resources have grown significantly in the last decade, as has its office, and PAAB has continued to deliver a high performance.
- Excess revenues over expenses over the decade allowing PAAB to build a reserve fund for its ongoing operations. Prior to this period of growth, PAAB did not have an adequate operational reserve fund.
- Only one increase in PAAB review fees over this ten year period.
- Growth in a reserve fund much higher than necessary for the purpose of ongoing operations and warnings by our financial auditors that our non-profit status could be threatened if the excess funds were not put to use for the benefit of the PAAB non-profit organization.

At our last strategic planning meeting, this information was considered and the construction of a building was proposed and agreed to by the PAAB Board. The reasons for this decision were three fold:

- Our success and growth - we have funds available for use to improve the PAAB organization.
- The current rental facilities of PAAB were not considered adequate for a national organization.

PAAB is currently renting facilities in a strip shopping mall above a grocery store. We have endured comments about the aesthetic and professional nature of this location. The rent could be converted to financing.

- The PAAB Board wanted to provide PAAB employees a more favorable working environment through control over our operational environment with respect to technology and ergonomic conditions.

The decision to build a modest 6,500 sq. ft. office was not taken lightly and the reasons for the decision were several. The money in reserve funds was invested in GIC's and thus was not affected by the financial downturn in 2008-9. This prudence resulted in almost no interest from the money in 2009. It was argued that the money would receive a better return if invested in a building that was recommended by the board at our 2008 strategic planning session. The building will help to improve the image and recognition of PAAB as a national organization, be a great place to work for its employees, and help maintain a very low turnover in staff. Also, the possibility of our non-profit status being questioned should be minimized as we are utilizing excess revenues to better the PAAB to achieve its goals.

REVIEW ACTIVITY

During the period of January 1 to March 1, 2010, the total number of first review submissions was 1535. This compared to 1182 during the same period of 2009. 99% of submissions were given a first review response in 10 days or less.

PAAB COMPLAINT REPORT

During the period of January 1 to March 31, 2010, the PAAB Commissioner processed 0 Stage 2 complaints, a first.

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.

For information or if you have comments:

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