



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.

PLEASE NOTE THAT THIS NEWSLETTER IS ONLY AVAILABLE ON THE PAAB WEB-SITE AS OF JANUARY 1, 2009

PAAB MEETINGS

September 14, 2009 - PAAB Executive Committee meeting

September 29, 2009 - Social Media Marketing Workshop Montreal

September 30, 2009 - Social Media Marketing Workshop Toronto

November 27, 2009 - General Meeting

MISSION, VISION, VALUES

At the April Annual meeting the PAAB Directors and Members approved the following:

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

SOCIAL MEDIA MARKETING

Due to requests from our clients, the PAAB will be conducting a training workshop on Social Media Marketing "What Works in Canada" on September 29, 2009 in Montreal and September 30 in Toronto. We have assembled a panel of experts from Industry, Health Canada and the PAAB to interact with our clients to learn best practices in Canada. Pharmahorizons is providing logistics support. It will be a full morning session. Mark your calendars. You can get more info from the PAAB web-site and we will be sending an e-mail blast to clients.

VACCINE DTCA ADVISORY

We remind you that when distributing Direct-to-Consumer vaccine advertising with claims including television broadcast advertising to consumers, they must comply with Food & Drugs Act section 9.1. For the past number of years, the PAAB has asked clients to add fair balance risk information in a manner similar to the requirement in section 2.4 of the PAAB Code of Advertising Acceptance. Despite being on Schedule D of the FDA, vaccines are considered to be similar to prescription-requiring drugs. The PAAB recommends that advertising should include cautionary statements and inclusion of safety information in vaccine advertisements directed to consumers.

Look Inside

Page 2 -	Product Information Committee Research Committee DTCARx Customer Experience Index
Page 3	Review Activity Complaints report

PAAB, Health Canada has advised the PAAB that

they are working on a guidance for providing fair balance for vaccine advertising.

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. The committee will survey clients to measure the understanding of and the impact of the PI code changes of 2007. Options will be reviewed and a suggestion to the board is expected for November 2009. Any changes will have to be within the current federal regulatory framework and the opinion of Health Canada will be sought.

RESEARCH COMMITTEE

As part of the strategic plan set in 2007, the PAAB directors have struck a research committee, chaired by Dr. Walter Rosser, to reward grants to researchers in Canadian pharmaceutical drug advertising. The committee is sending out requests for projects to selected researchers and hopes to award the first grants in the Fall of 2009. We are thinking of having golf tournament in 2010 to raise funds for the research grants, so please let the commissioner know if you would support that event.

DIRECT-TO-CONSUMER RX

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 is the only agency with a 32 year history of reviewing prescription drug advertising and 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.

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.

REVIEW ACTIVITY

During the period of April 1 to June 30, 2009, the total number of first review submissions was 1,335.

This compared to 1,220 during the same period of 2008. During the first half of 2009, 99% of 2,517 submissions were given a first review response in 10 days or less compared to 100% of 2,448 in 2008.

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PAAB COMPLAINT REPORT

Period: April 1 to June 30 2009

During the period of April 1 to June 30, 2009, the PAAB Commissioner processed 1 Stage 2 complaint. PAAB reviewed advertising pieces during the same period. One complaint about a previously reviewed file was upheld in one of the four allegations.

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.

STAGE TWO DECISIONS

1. ADVERTISER: Afexa Life Sciences

COMPLAINANT: Health Canada

SUBJECT: Health professional web-site

PRECLEARANCE: No

ALLEGATIONS: Violations of Food & Drugs Act section c01.007 in reference to Health Canada approval and some fair balance safety information was required.

DECISION: Sustained. The PAAB requested changes promptly.

PENALTY: Web-site correction.

OUTCOME: Company stated web-site was in transition and agreed to make the requested changes promptly.

For information or if you have comments: