



# 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](http://www.paab.ca)**

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

## PAAB MEETINGS

January 11, 2010 - Executive Committee Meeting

January 28 & 29 - Strategic Planning Session

April 23, 2010 - Annual/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

## NEW 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](http://www.paab.ca) and it should be available on the Health Canada web-site. It is similar in intent to s2.4 of the PAAB Code of Advertising Acceptance.

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](http://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. The committee surveyed Rx&D clients to measure the understanding of and the impact of the PI code changes of 2007. The committee decided that more work needs to be done and the PI Committee has funding from the PAAB for more extensive research involving direct interviews with senior marketing officials representing PAAB clients. 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. Check the PAAB web-site for details.

## STRATEGIC PLANNING SESSION

The PAAB will be conducting a strategic planning session, by invitation, on January 28 and 29, 2010. The board is proud to report that the previous plan was implemented successfully. Scrub your crystal ball.

## 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.

## 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.

## 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 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. In the past three months one company has come forward to discuss examples and we developed an action plan that required involvement from both sides. You can contact the commissioner at 905-509-2275 x28 and by email at [commish@paab.ca](mailto:commish@paab.ca).

## REVIEW ACTIVITY

During the period of October 1 to December 31, 2009, the total number of first review submissions was 1,451. This compared to 1,445 during the same period of 2008 and it is a record breaking quarter. The total for 2009 was 5168 compared to 4993 in 2008. 99% of submissions were given a first review response in 10 days or less.

## PAAB COMPLAINT REPORT

### Period: October 1 to December 31 2009

During the period of October 1 to December 31, 2009, the PAAB Commissioner processed 3 Stage 2 complaints, all upheld. Two nonprescription product files were sent to Health Canada for investigation. PAAB reviewed 1,451 advertising pieces during the same period. The total number of stage two complaints for 2009 is 13.

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: Hill Dermaceuticals

**COMPLAINANT:** Leo Pharma

**SUBJECT:** c09-34 Two APS for patients

**PRECLEARANCE:** No

**ALLEGATIONS:** 1. Patient Handout with Comic Strip: absolute claims without substantiation (2.6) such as "eliminates the crust", "a crust-free normal scalp", "you will be very pleased with your results as well as the cost of this product"; no references (s3.1); no fair balance (s2.4).

2. Double-folded Product Information Pamphlet: similar violations of s2.6, 3.1 and 2.4.

**DECISION:** Commissioner agrees with Leo that there are multiple code violations. Because Hill did not choose to send their material to the PAAB for preclearance review, a copy of complaint was sent to Health Canada to encourage compliance with the PAAB ruling.

**OUTCOME:** Hill agreed to cease distribution of the APS.

### 2. ADVERTISER: Pendopharm

**COMPLAINANT:** Nycomed

**SUBJECT:** c09-37 ZAP Head Lice Treatment

**PRECLEARANCE:** No

**ALLEGATIONS:** Despite not having Terms of Market Authorization as a Natural Health Product, Pendopharm had an extensive advertising campaign for ZAP.

**DECISION:** With respect to Health Canada policy, the commissioner requested formal investigation by Health Canada.

**OUTCOME:** HC indicated they will investigate.

### 3. ADVERTISER: Pendopharm

**COMPLAINANT:** Schering-Plough

**SUBJECT:** c09-38 Lax-A-Day promotion through Alberta Health Services

**PRECLEARANCE:** No

**ALLEGATIONS:** Safety allegations related to Off-label promotion of dosage for pediatric use. Terms of Market Authorization states "Pediatrics: LAX-A-DAY is not indicated for use in children under 18 years of age unless recommended by a physician" and **Warnings** section states "Pediatrics (<18 years of age): Safety and effectiveness of LAX-A-DAY in pediatric patients has not been established."

**DECISION:** Commissioner sent the complaint to health Canada because of HC policy regarding safety allegations in complaints.

**OUTCOME:** Health Canada agreed to do a formal investigation.

### For information or if you have comments:

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