



REVIEW

Year 2008 marks the 32nd year of the PAAB since its incorporation in 1976. You can get this document in French from the PAAB office or see it on the PAAB Web-site. To see the current edition of the PAAB Code, visit the PAAB Web-site.

www.paab.ca

Ce document est également disponible en français au bureau du CCPP ou sur notre site web.

PAAB MEETINGS

April 25, 2008 - Annual / General Meeting

May 14, 2008 - Training Workshop Toronto

May 22, 2008 - Training Workshop Montreal

E-FILE LAUNCH

As of January 1, 2008 all clients must use the web-based electronic file submission software system to submit new APS files for review by the PAAB. The goal is to facilitate communication with clients regarding their submissions. Foreseen benefits include: universal communication tool for PAAB clients, efficient storage and handling of PAAB submission files, and better tracking data for PAAB and the clients. We have notified thousands of individuals by email that the eFile procedure is available for use. We have also sent a letter by mail to all PAAB clients. There is an eTutorial on the PAAB web-site www.paab.ca to explain how to use the eFile process. You can access the web portal directly at <http://efiles.paab.ca>. We expect all clients to use the electronic filing process. For more information call Glenn Golaz at the PAAB office 905-509-2275 x29.

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 order to continuously improve our level of service, the PAAB has engaged in a number of activities in the past year to obtain feedback from our clients.

In late 2006, the PAAB worked with Pharmahorizons to survey all of our clients to identify general service issues and perceptions. The PAAB followed that up in 2007 with focus groups involving over 50 clients speaking face to face with PAAB management about those issues and perceptions in more detail. The 4 events were organized and facilitated by Pharmahorizons. PAAB management introduced some of the service improvement suggestions through knowledge transfer and staff training.

The focus group attendees told us that we should strive for continuous improvement. We are at the next phase in our service improvement initiative.

With the help of Pharmahorizons, we are introducing 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 the commitment of the PAAB to improve our customer service. Please keep in mind we will still say "No" if that is the correct answer.

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PI CODE REVISION REMINDER

Effective November 23, 2007, **Section 7.3** of the PAAB Code of Advertising Acceptance has been revised to read: **"The Prescribing Summary must be a minimum of 8.5 point font with 10 point leading for text and 8 point font with 10 point leading for bold headings."**

We understand from publishers that some clients have not learned to apply the code guideline for the new format in the proper manner. The commissioner reminds advertising sponsors to take advantage of the opportunity to edit the content from a style and grammar point of view and eliminating extraneous commentary in the product monograph. The new format is designed to provide the important efficacy and safety content of the product monograph in a manner that is concise and easy to read as a reference tool. Health Canada has reviewed and stated no objection to the new format.

Please refer to the PI FAQs on the PAAB web-site www.paab.ca. Please call the PAAB office for answers to additional questions.

Product monographs vary considerably. Depending on the complexity of product claims and safety information, the length of the P.I. required may change. Most pharma company sponsors can reduce P.I. wording to leave the essential message of the Product Monograph. Choice of font style can further reduce the overall length.

PAAB reviewers can provide guidance in interpreting the code requirements. They will not edit the P.I. for you. **The Code, FAQs, and examples of the new ad format are available on the PAAB web-site www.paab.ca. Booklets are available for purchase at \$4 each (includes shipping) from the PAAB office.**

DIRECT-TO-CONSUMER

Ads 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.

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 John Wong at the PAAB office 905-509-2275.

PAAB reviews include branded ads, help-seeking ads and consumer brochures on all media. 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.

HEALTH CANADA MEETING

On April 8, 2008, Health Canada is hosting a meeting in Ottawa with officials from the PAAB, ASC and BCA to discuss advertising issues and exchange information. Agenda topics include regulatory framework, communication processes, Natural Health Product advertising issues, and DTCA among others. This meeting is a continuation of previous meetings involving the PAAB, ASC and HC.

PAAB CLIENT TRAINING

The PAAB is partnering with Pharmahorizons to continue a training project regarding the PAAB Code of Advertising Acceptance. The goal is to teach the application of the PAAB Code primarily to new pharmaceutical industry employees. Pharmahorizons will provide professional logistical support while the PAAB staff will provide and maintain control of all content. The next sessions will be in May 2008. You can contact Pharmahorizons (1-888-514-5858) for information about the workshops.

REVIEW ACTIVITY

During the period of January 1 to March 31, 2008, the total number of first review submissions was 1,168. This compared to 1,287 during the same period of 2007. During the first quarter of 2008, 100% of submissions were given a first review response in 10 days or less. During the first quarter of 2007, 100% of first reviews were completed in ten days or less.

PAAB COMPLAINT REPORT

Period: January 1 to March 31, 2008

During the period of January 1 to March 31, 2008, the PAAB Commissioner processed 3 Stage 2 complaints. PAAB reviewed 1,168 advertising pieces during the same period. Two were regarding files not reviewed by the PAAB and were upheld. One complaint about a previously reviewed file was upheld.

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. During the first quarter the PAAB sent one accredited CME program to Health Canada for assessment and HC determined it was advertising. After PAAB notice the company ceased distribution of the off label promotion.

STAGE TWO DECISIONS

1. ADVERTISER: Amgen
COMPLAINANT: Schering-Plough
SUBJECT: c08-01 Enbrel multiple APS
PRECLEARANCE: Yes, originally in April 2005
ALLEGATIONS: The tagline "A Clear Choice" is a unsubstantiated superlative claim in violation of PAAB Code section 5.16.
PAAB DECISION: The double entendre tagline was originally accepted because there were no competitors in the marketplace, thus there was no comparative context. The marketplace has changed and choices similar to Enbrel are available. Thus, the superlative nature of "a clear choice" is not substantiated.
PENALTY: PAAB withdraws acceptance and distribution of APS containing this claim should be stopped.
OUTCOME: Amgen agreed with ruling and offered an APS withdrawal plan that was acceptable to the PAAB.

2. ADVERTISER: Apotex
COMPLAINANT: Wyeth
SUBJECT: c08-02

PRECLEARANCE: No

ALLEGATIONS:

- a) No PAAB preclearance, code s1
- b) No Fair Balance safety information code s2.4, 7.3
- c) Imitation of competitor advertising and packaging s2.7
- d) Copy in price comparison implies therapeutic equivalence that has not been established.

PAAB DECISION: PAAB agrees with Wyeth on allegations 1, 2 and 4.

PENALTY: Apotex to cease and desist distribution of the subject material and make corrections prior to future dissemination. Advertising sent to Health Canada with respect to fair balance safety allegations and similar packaging issue.

OUTCOME: Apotex agreed to stop distribution of material. The PAAB is not aware of any Health Canada action at this time.

3. ADVERTISER: Novo Nordisk
COMPLAINANT: Eli Lilly
SUBJECT: c08-04 Novomix 30 BC
 Formulary letter

PRECLEARANCE: No

ALLEGATIONS: Violations of PAAB Code s6.2 (pre-clearance review) and s7.2 (no prescribing information).

PAAB DECISION: Agreed with complainant. Because the APS had not been sent to the PAAB for review and there were fair balance safety allegations, the file was sent to Health Canada for investigation and enforcement.

PENALTY: Cease distribution and request Health Canada to enforce if necessary.

OUTCOME: PAAB has not heard outcome of Health Canada investigation.

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Ann Sztuke- Fournier	Health Canada
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For information or if you have comments:

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