# PAAB 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

**November 12, 2008** - Training Workshop Montreal
**November 19, 2008** - Training Workshop Toronto
**November 20, 2008** - General Meeting (evening)
**November 21, 2008** - Mission Review (all day)

## 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.

## 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, web-sites 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.

## FAREWELL CRO

We said goodbye to Chief Review Officer John Wong. on September 30, 2008. After ten years at the PAAB, John has decided to pursue a career as an account director in an advertising agency. The PAAB will miss him. We are grateful for all that John did for the PAAB and we wish him well in the future. At the time of publication, a successor had not been appointed.

## *LOOK INSIDE*

# 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 November 2008. You can contact Pharmahorizons (1-888-514-5858) for information about the workshops.

# REVIEW ACTIVITY

During the period of July 1 to September 30, 2008, the total number of first review submissions was 1,119. This compared to 1,109 during the same period of 2007. During the first three-quarters of 2008, 100% of submissions were given a first review response in 10 days or less. During the first three-quarters of 2007, 100% of first reviews were completed in ten days or less except for 12 files in the last week of September. Year-to-date in 2008, the total number of first submissions was 3,539 compared to 3,746 in 2007.

# PAAB COMPLAINT REPORT

## Period: July 1 to September 30, 2008

During the period of April 1 to June 30, 2008, the PAAB Commissioner processed 1 Stage 2 complaint. PAAB reviewed 1,220 advertising pieces during the same period. One complaint about a previously reviewed file was upheld although the infraction was related to the placement of the ad, not the content that was reviewed.

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 third quarter the PAAB sent one notice.

# STAGE TWO DECISIONS

**1. ADVERTISER:** Schering-Plough

**COMPLAINANT:** Amgen

**SUBJECT:** c08-11 a combination of a product ad and an editorial ad promoting Remicade (infliximab), both approved by the PAAB as stand alone ads, put in close proximity in the April and May issue of Journal of Rheumatology.

**PRECLEARANCE:** yes for stand alone ads, no for the combination placement

**ALLEGATIONS:**

1. Proximity - the two ads were positioned by Schering-Plough to be in close proximity
2. Creative -common font, colour and creative elements were used in both ads
3. Remission - Remicade does not have an indication for the subject of the editorial, remission. This appears to be an attempt to current medical thinking and an off-label use.

**PAAB DECISION:** The PAAB approved the two ads independently of each other and did not approve "linkage" i.e. placement in close proximity. Amgen makes a strong case related to proximity, creative and remission linkage. When advertising and information pieces are linked in some manner, the combination becomes advertising. In this case the combination appears to promote an off-label use for Remicade. When asked for proof that the publisher was responsible for the placement, Schering-Plough did not respond with proof.

**PENALTY:** Cease distribution in that manner. Complaint forwarded to Rx&D for consideration of violation of Rx&D Code of Conduct.

**OUTCOME:** Schering-Plough ceased distribution of the unbranded ad in a linked manner. We are not aware of the Rx&D decision.

**2. ADVERTISER:** Schering-Plough

**COMPLAINANT:** GSK

**SUBJECT:** c08-13 a combination of branded and unbranded ads used in a public elevator to promote Nasonex (mometasone furoate monohydrate)

**PRECLEARANCE:** No

**ALLEGATIONS:** Direct-to-Consumer promotion that involved linkage of a branded Nasonex ad and an unbranded information ad to promote the therapeutic use of Nasonex.

**PAAB DECISION:** DTC ad. Therefore forward to Health Canada with respect to Health Canada directive.

**PENALTY:** TBD by Health Canada

**OUTCOME:** Marketed Health Products Directorate informed the PAAB that this Nasonex advertising campaign did not meet the intent of section C.01.044(1) of the Food and Drug Regulations. Complaint was sent to HPFB Inspectorate for compliance and enforcement action.

**3. ADVERTISER:** Shire

**COMPLAINANT:** Procter & Gamble

**SUBJECT:** c08-15 Mezavant (mesalamine) regarding several APS approved by the PAAB in 2007.

**PRECLEARANCE:** Yes

**ALLEGATIONS:** Four allegations:
1. Claim "a once daily route to remission" implies absolute efficacy (s2.6).
2. Claim "Simple once daily dosing" employs superlative language where clinical relevance has not been demonstrated (s5.16).
3. Claim "The simplest route to remission is here" employs superlative language where clinical relevance has not been demonstrated (s5.16).
4. Company-generated comparison table fails to accurately represent the compared entities and their respective indications (s5.10.2 and 5.6.iii).

**PAAB DECISION:**1. Allegation 1 rejected- This statement is seen as an indication statement equivalent. The indication for Mezavant is for clinical and endoscopic remission and the dosing in the TMA is once daily. The full indication is prominent in the APS.

2. Allegation 2 rejected - The claim is for simple once-daily dosing as a statement of fact and it is not used in a superlative or comparative context. It is well-accepted that once-daily dosing is simple. Most health professionals would not find this claim to be misleading. There is no allusion to superiority to other agents or to compliance. The PAAB has approved this claim many times before for other products when it appeared in the same context. The PAAB has received no complaints about this practice.

3. Allegation 3 sustained - The PAAB did not approve this claim and it appeared in one APS by error, admitted by Shire. Shire discontinued the APS immediately.

4. Allegation 4 sustained - We agree with P&G that the presentation could be improved by adding the indication that is common to all the products listed to show the common denominator clearly and not to imply equivalent indications. This is a minor problem that can be addressed in future APS. The full indication for Mezavant is clearly stated and it is not misleading for Mezavant claims. In this chart the line appears to be appropriate to distinguish the nature of the information i.e. fixed number of doses versus total tablets in divided doses. The Asacol product monograph presents the dosing information in a manner that is different from other products in the class, Therefore, it is a good thing to bring a prescriber's attention to that fact.

**PENALTY:** Allegation 3 was already resolved by Shire in stage one. Shire should adjust the chart in future APS to reflect the PAAB suggestions.

**OUTCOME:** Shire agreed with the ruling and will make adjustments in future APS.

**4. ADVERTISER:** Fresenius

**COMPLAINANT:** Genzyme

**SUBJECT:** c08-17 three Advertising/Promotion systems (APS) for PhosLo (calcium acetate)

**PRECLEARANCE:** No

**ALLEGATIONS:** allegations that many claims violated the PAAB code sections 2.1, 2.3, 3.1, 3.2, 3.7, 4.5

**PAAB DECISION:** The APS did not receive PAAB review and we agree that there are potential violations of the PAAB code. Fresenius was invited to participate in the voluntary rself-regulation system in Canada or the PAAB would forward the complaint to Health Canada for review. During mediation Fresenius offered the fact they were new to Canada and were not aware of the PAAB preclearance review mechanism that is part of the self-regulation system for health product promotion.

**PENALTY:** Fresenius agreed to stop distribution and seek PAAB review in future. They also requested a mini-workshop to learn and understand the PAAB process.

**OUTCOME:** Willful compliance.

**5. ADVERTISER:** Bayer

**COMPLAINANT:** Boehringer-Ingelheim (BOE)

**SUBJECT:** c08-20 Distribution of a published paper "Venous Thromboembolism (VTE Risk Awareness and Prevention with the novel anticoagulant Rivaroxaban", Crowther M., et al, Canadian Orthopaedic Association Bulletin (Supplement) Summer 2008 at the AOA/COA combined meeting in Quebec City 2008

**PRECLEARANCE:** No

**ALLEGATIONS:** Bayer provided a review article to the Canadian Orthopaedic Association (COA) to distribute to its members, potential prescribers of rivaroxaban. The paper was not solicited by the COA. BOE wrote "The development of the publication was supported through an educational grant from Bayer Health Care. The article in question was not a presentation of entire randomized controlled trials but instead represented a review of the rivaroxaban trials and did not provide equal balance to other anticoagulants. By providing the article and acting as the sole sponsor of the article which was a review article, we believe they have shown influence on the content. It is advertising or promotion with respect PAAB code s 11.1. Bayer did not have a Notice of Compliance to market rivaroxaban. (s3.1)

**PAAB DECISION:** Sustained. The review article had emphasis on rivaroxaban as mentioned in the title and appears to promote the future sale of rivaroxaban pre-NOC.

**PENALTY:** Cease distribution. Complaint sent to Health Canada.

**OUTCOME:** Bayer complied with the ruling.

For information or if you have comments:

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