



# PAAB REVIEW

Year 2007 marks the 31st 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](http://www.paab.ca)**

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

## PAAB MEETINGS

April 11, 2007 – Revised Code Info Day, Toronto

April 12, 2007 – Revised Code Info Day, Montreal

April 20, 2007 – Annual/General Meeting

May 2, 2007 – Revised Code Info Day, Toronto

May 3, 2007 – Revised Code Info Day, Montreal

June 25, 2007 – Executive Committee Meeting

November 23 – General Meeting

## CODE REVISION

On November 24, 2006 the PAAB approved revisions to the PAAB Code of Advertising Acceptance. **Implementation of the new revisions will be July 1, 2007.**

The Code, an advisory letter detailing the changes and examples of the new ad format are available on the PAAB web-site [www.paab.ca](http://www.paab.ca). Booklets are available for purchase at \$4 each (includes shipping) from the PAAB office.

## DTCARX 4-DAY TURNAROUND

Please see page 4 for an ADVISORY of a PAAB policy change.

## PAAB CAN HELP YOU

The definition of *advertising* in the Food & Drugs Act is “any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device”. Therefore, most product-focused messages would be considered *advertising*. Keep that definition in mind when you are creating communications to health professionals or to the public. That includes items that are called “patient information” or “educational” letters or reports and distribution of third-party communications by drug manufacturers. Accredited CME material may be exempt from PAAB review but could be considered “advertising”, and subject to PAAB Code provisions, depending on the link to a pharma company sponsor and the appearance that it is promoting the sale of the sponsor’s product(s).

Manufacturers should look to improving the overall image of the pharmaceutical industry by providing promotional material that meets all of the legal and ethical requirements. The PAAB can help you do that through **the preclearance review process and the advisory opinion service.**

## PAAB SURVEY UPDATE

Commissioner Chepesiuk has sent a letter to all of the survey respondents thanking them for their

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4-day Turnaround Policy for DTCARx

participation in the operations survey of December 2006 and January 2007. An action plan written by the commissioner and based on a summary of comments compiled by Mark Gregory of Pharmahorizons was given to the PAAB Board. We are looking to follow up with a series of focus groups and mini-surveys during 2007. Possibly selected one-on-one sessions with the commissioner may also occur. We thank Mark Gregory for his great assistance in making these activities happen.

If you wish to be part of these ongoing activities, please contact Mark Gregory at Pharmahorizons for his consideration of your request. PAAB staff will not be involved in the selection process other than helping construct the criteria for selection.

## COMMUNICATION PROJECT

The PAAB has engaged Healthworld and Hill and Knowlton to conduct an advertising and public relations campaign directed at physicians to create more awareness of the value-added service that the PAAB provides to pharmaceutical advertisers. The goal is to help physicians become aware of the PAAB and appreciate pharmaceutical advertising that bears the PAAB logo. The recent prescribing information requirements will be a focus of the campaign message.

Advertisements telling doctors about the PAAB preclearance review service will appear in selected Canadian medical journals during 2007. Also, the PAAB is seeking the help of publishers to carry articles about the PAAB and the Code of Advertising Acceptance. Call Commissioner Chepesiuk to tell us about your opportunity to help the PAAB.

If you see components of the campaign, please share your opinion with the PAAB Commissioner at [commish@paab.ca](mailto:commish@paab.ca).

## PAAB TRAINING INITIATIVE 2007

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. We will be presenting content regarding the July 1, 2007 revisions to the PAAB Code. The next offering of this workshop will be in Toronto on April 11 and May 2, and in Montreal April 12 and May 3. You can contact Pharmahorizons (1-888-514-5858) for information about the workshops.

## EFILE PROJECT

The PAAB has contracted Klick communications to provide a web-based electronic file submission software system. 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. Stay tuned for more information. Implementation is expected July 1, 2007 depending on the outcome of testing. For more information call Glenn Golaz at the PAAB office 905-509-2275.

## REVIEW ACTIVITY

The commissioner commends the PAAB office staff for their continued dedication and exemplary work during 2007. During the period of January 1 to March 31, 2007, the total number of first review submissions reviewed was 1,288. This compared to 1,281 during the same period of 2006. Detail aids were 35% of the volume followed by service vehicle APS at 22%.

During the first quarter of 2007, 58% of the submissions were given a first review response in five days or less and 100% were given a first review response in 10 days or less. During the same period in 2006 21% of first reviews were completed in five days or less, 100% in ten days or less.

## COMPLAINTS / MONITORING

### PAAB COMPLAINT REPORT

Period: January 1 to March 31, 2007

During the period of January 1 to March 31, 2007, the PAAB Commissioner processed 1 **Stage 2 complaint**. PAAB reviewed 1288 advertising pieces during the same period.

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. PAAB sent 3 notices of violation in the fourth quarter.

## STAGE TWO DECISIONS

1.

ADVERTISER: Novartis

COMPLAINANT: Pfizer

**SUBJECT:** *The Medical Post* articles "Understanding the TARGET trial" on November 14, and December 11 2006. promotion for Prexige (lumiracoxib)

PRECLEARANCE: No

**ALLEGATIONS:** Pfizer alleged that the articles were single-sponsored by Novartis and were advertising and not education as stated in the article. It should have been submitted to the PAAB for review as a journal ad (s6.1). There are off-label claims shown with some emphasis (s3.1).

**PAAB DECISION:** Agreed with Pfizer that there were at least two violations of the PAAB Code of Advertising Acceptance.

**PENALTY:** Cease and Desist distribution of the article by any means prior to formal PAAB review. Notice sent to Rx&D for consideration of penalty for violation of the Rx&D Code. Health Canada notified of the violation.

**OUTCOME:** Novartis agreed with the PAAB to cease distribution of the articles and to send future advertising of this nature to the PAAB.

### CONTACT INFORMATION

**For information or if you have comments:**

Pharmaceutical Advertising Advisory Board  
375 Kingston Road, Suite 200  
Pickering, Ont. L1V 1A3  
Tel: (905) 509-2275 fax: (905) 509-2486  
e-mail: [info@paab.ca](mailto:info@paab.ca) [www.paab.ca](http://www.paab.ca)



## **PAAB ADVISORY**

### **4-DAY TURNAROUND**

#### **For Written DTCARx and Opinion Advisories**

We are pleased to announce that, effective April 1, 2007, the PAAB has changed its policy for providing written opinions. 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 submission form 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 John Wong at the PAAB office 905-509-2275.

The PAAB will give an advisory opinion on specific projects that involve advertising or information directed at the general public. Currently, companies cannot advertise prescription drugs except for name, price, and quantity or treatments of Schedule A diseases to the general public. We can assist you in interpreting Health Canada guidelines on what is advertising and what is not considered to be advertising. Activities include branded ads, help-seeking ads and consumer brochures and 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. 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.

Please note that the PAAB will continue its policy of not charging fees for verbal answers on the telephone.

Ray Chepesiuk

PAAB Commissioner