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

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

PAAB MEETINGS

October 26, 2007 - Executive Committee Meeting

November 23, 2007 - General Meeting

CODE REVISION

On November 24, 2006 the PAAB approved revisions to the PAAB Code of Advertising Acceptance.

Implementation of the new revisions is July 1, 2007.

Key Change Elements Include:

1.Harmonization with Health Canada terminology throughout the Code.

2.Section 2.4 and explanatory notes Fair Balance requirements - a modest change designed to redistribute minor information and study parameters from the body copy with a shift to the Prescribing Summary Box (s7.3). Major safety information and necessary qualifying information (e.g. dosing adjustments in certain patient populations or indication limitations) are still required to be shown. The goal is to redistribute the mass of small-type footnotes on the main display area of the advertising. The reviewers will work with advertisers to adjust to the new code requirement. The end result in each ad will be dependant on the product monograph.

3. Section 2.9 - The requirement for a specific contact person from the sponsor's Medical or Regulatory departments to sign off on the advertising prior to sending it to the PAAB. it is the sponsor's corporate responsibility to designate an accountable person. We want to review market ready material from the sponsor's viewpoint. The PAAB does not review and approve marketing objectives. The PAAB review is a scientific/clinical /regulatory/ ethics review and therefore we want to know that qualified people from the sponsor agree with the material we are reviewing.

4. Sections 3.2.2 and 3.2.3 - revised wording to strengthen the message that statements should be consistent with the Terms of Market Authorization and no literature supporting off label claims will be acceptable.

5. Section 5.10.1 - some claims may be supported by peer reviewed, published meta-analysis. Use caution in interpreting this section because not all meta-analyses are of high enough quality to be accepted as support for advertising. The PAAB will reject sub-standard studies.

6. Section 5.11 Disclosure of Study parameters - it will be acceptable to put certain study parameters in the Prescribing Summary Box. The reviewers can help you during the review process.

7. Sections 5.13 and 5.14 - new wording regarding equivalence claims and formulation studies

8. Section 6.1 - a requirement for the use of a new icon in journal ads to link to the indexed Prescribing Information

LOOK INSIDE

9. Section 7 - a major shift including extensive changes in the Prescribing Information format and content requirements. Larger type requirement for "Prescribing Summary Box" information. Deletion of Full and Condensed Disclosure and replacement by requirements for "Advertising With Product Claim Prescribing Information". This resulted from research with doctors performed by CAMP and the PAAB. Health Canada was consulted early and late in the revision process. The approved format was rated high by physicians in readability and usefulness to clinical practice.

10. Section 11 Definitions - a few changes there.

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. Booklets are available for purchase at $4 each (includes shipping) from the PAAB office.

DTCARX 4-DAY TURNAROUND

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 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.

Activities include branded ads, help-seeking ads and consumer brochures. 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.

E-FILE 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 has been delayed and we are nearing the testing phase. In coordination with the launch of e-Files expected in September 2007, the PAAB will be unveiling a new web-site look and format. For more information call Glenn Golaz at the PAAB office 905-509-2275.

PRESCRIBING INFORMATION

The major change in the code is to the prescribing format for advertising purposes. See PAAB Code section 7 for details. The change has been accepted by PAAB stakeholder organizations and Health Canada officials. The Full Disclosure and Condensed Disclosure requirements have been replaced by one format "Advertising with Product Claim Prescribing Information (APCPI)" for the lifetime of the product.

Along with APCPI, Reminder, Editorial and Institutional categories still exist and the requirements for prescribing information of those categories have not changed. The new format is designed to be used for all media, however, it is mandatory for Journal Ads. In other media, to allow some flexibility and cost control, the code sets a minimum standard for prescribing information and companies can set their own policy to exceed that standard. For example, with detail aids, mailers or exhibit advertising, a company can still accompany the advertising by a full product monograph or equivalent that will meet federal legal requirements.

New material entering the marketplace after July 1, 2007 should include the new PI format. There is a grandfathering opportunity to allow companies to use the existing PI format for journal ads until the ads expire and need to be renewed. PAAB grants a 12 month clearance period and thus, the new format should be in place for all journal advertising by July 2008.

We have had questions about placing the message "Refer to Page x for Prescribing Information". This is not a new activity and publishers have been doing this for a long time. Some publishers may have a problem if they do not use page numbers for prescribing information. Those are very few and we are working out alternatives with them.

An example of the new format can be seen at www.paab.ca.

PAAB CLIENT SURVEY UPDATE

We followed up our survey findings with a series of focus groups during the month of June. We did two sessions involving 12-15 people each in Montreal and Toronto in mid-June. We thank Pharmahorizons for their great assistance in making these activities happen.

We are in the midst of looking through the 38 page report and determining the short, medium and long term activity that the PAAB should undertake to address the comments. We appreciate all of the input we have had from the PAAB clients through the survey and focus groups. We also appreciate the help to do this that we received from Pharmahorizons.

COMMUNICATION PROJECT

The PAAB has engaged Ogilvy 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 pre-clearance 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 Ray Chepesiuk at 905-509-2275 x28 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.

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 2007.

We will be including content regarding the July 1, 2007 revisions to the PAAB Code. You can contact Pharmahorizons (1-888-514-5858) for information about the workshops.

REVIEW ACTIVITY

The commissioner commends the PAAB office staff for their continued dedication and exemplary work during 2007. During the period of April 1 to June 30, 2007, the total number of first review submissions reviewed was1,387. This compared to 1,329 during the same period of 2006. Detail aids were 36% of the volume followed by service vehicle APS at 21%. For the first half total new pieces reviewed was 2,682 compared to 2,610 during the same period last year.

During the second quarter of 2007, 60% 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 10% of first reviews were completed in five days or less, 78% in ten days or less.

This is the record of ratio of files and how many days it took to first review of 2,682 new submission files in the first half of 2007:

10-days: 3%
9-days: 8%
8-days: 6%
7-days: 9.4%
6-days: 14.6%
5-days: 59%

The PAAB staff will strive to keep the current excellent record.

PAAB COMPLAINT REPORT
Period: April 1 to June 30, 2007

During the period of April 1 to June 30, 2007, the PAAB Commissioner processed 1 Stage 2 complaint. PAAB reviewed 1387 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 1 notice in the second quarter.

STAGE TWO DECISIONS

1. ADVERTISER: Ferring

COMPLAINANT: Health Canada

SUBJECT: Norprolac (Quinagolide) doctor letter

PRECLEARANCE: No

ALLEGATIONS: Off-label (3.1), lack of evidence (3.1) and unfair comparisons (5)

PAAB DECISION: Multiple violations of the PAAB Code of Advertising Acceptance.

PENALTY: Correction should be reviewed by the PAAB and then sent to the same target audience as the original.

OUTCOME: Ferring submitted a correction letter that was approved by the PAAB. It was to be mailed to the original target audience

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 www.paab.ca