PHARMACEUTICAL ADVERTISING ADVISORY BOARD

January 2009

PAAB REVIEW

Year 2009 marks the 33rd 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.

PLEASE NOTE THAT THIS NEWSLETTER WILL ONLY BE AVAILABLE ON THE PAAB WEB-SITE AS OF JANUARY 1, 2009

PAAB MEETINGS

March 9, 2009 – Executive Committee Meeting

April 17, 2009 - Annual General Meeting

April 28, 2009 – Training Workshop Montreal

April 30, 2009 – Training Workshop Toronto

GENERAL MEETING HIGHLIGHTS

Activities from the board meeting of November 20/21, 2008.

1. The by-laws were extensively revised and modernized.
2. Two PAAB Code revisions were passed.
3. A governance review that will bring clarity of accountability of the director role and how the board acts.
4. A conflict of interest policy was passed.
5. the 2009 budget was passed.
6. Drafts of mission, vision, value statements were created and not yet finalized.
7. Committees were struck and charged with evaluating potential changes in PAAB membership and the code prescribing information requirements.

CODE REVISIONS APRIL 1, 2009

At the PAAB General Meeting of November 20, 2008, the PAAB Members approved the following revisions to the Explanatory Notes section of the PAAB Code of Advertising Acceptance. ***These revisions will come into effect on April 1, 2009***.

Section 2.4.3

With respect to advertising of nonprescription drugs and natural health products, the fair balance requirement can be met by inserting the following statements into the APS.

For products with a Product Monograph: "See Prescribing Summary on page XX for information to assist in benefit-risk assessment. Always direct the patient to read the label."

For products without a Product Monograph: "See Warnings, Cautions and Directions of Use on page XX for information to assist in benefit-risk assessment. Always direct the patient to read the label." (Note: also see s7.2.1).

Section 3.1.7

With respect to advertising of nonprescription drugs without a Product Monograph, a Senior Regulatory official of the Market Authorization Holder (MAH) may provide an attestation to PAAB to confirm that a claim has been approved by Health Canada. "Name of the Market Authorization Holder hereby attests that the

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claim (specific expanded claim) has been authorized by Health Canada for (complete product Brand name)." The MAH may be asked to provide further information.
Editorial Note: The change to code s3.1.7 would affect only non-prescription DIN products. It would not affect NHP products. The rationale was that, for non-prescription DIN products, "no reply" from Health Canada for minor changes to the TMA may be taken as acceptance. This lack of paper trail does not occur in the NHP category and PAAB reviewers should ask for the product license claims approved by Health Canada.

Section 6.4.3
Company controlled or prepared branded patient information is information that contains non-promotional material that is consistent with, and in addition to, the consumer information section of the product monograph. The information should focus on educating patients about particular diseases/conditions and optimal use of the product by the patient for whom it has been prescribed.

This information should address patients' expectations through encouraging meaningful dialogue between patient and healthcare professional and supplementing this dialogue with the best available evidence-based statements.
All health product information must be consistent with the Terms of Market Authorization, and should not contain promotional claims.
The Advertising/Promotional System (APS) could contain additional sources of health information from standard setting organizations. It should be written in clear, understandable and legible language.

Principles for education on optimal use of the product and diseases/conditions:
Principle 1: Clarity of message
Principle 2: Manage expectations
Principle 3: Evidence-based information
Principle 4: Un-biased sources of information

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.

NEW REVIEWER

Jennifer Carroll has joined the PAAB team as of January 5, 2009. Jennifer is a graduate of McMaster University in the biopharmacology program. She is bilingual and has worked in pharmaceutical companies in Medical Information and Pricing. She has found time to have been a super volunteer fundraiser.

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 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. 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.

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 April 2009. You can contact Pharmahorizons (1-888-514-5858) for information about the workshops.

E-FILES USABILITY STUDY

The PAAB and Klick conducted two focus groups of AMAA member company personnel to learn about possible improvements in the E-Files submission software that will benefit clients. The suggestions have been evaluated and some of them will be included in the next version of E-Files to be actioned in 2009.

2009 FEE SCHEDULE

Please see the full PAAB fee schedule for 2009 on the PAAB web-site. For the third year in a row, there is no review fee increase. The PAAB has had one fee increase since 1999. Please note that the PAAB does charge a fee for various types of review meetings as listed in the fee schedule.

REVIEW ACTIVITY

During the period of October 1 to December 31, 2008, the total number of first review submissions was 1,446. This compared to 1,336 during the same period of 2007. During 2008, 99% of submissions were given a first review response in 10 days or less. During 2007, 100% of first reviews were completed in ten days or less. In 2008, the total number of first submissions was 4,993 compared to 5,082 in 2007.

PAAB COMPLAINT REPORT

Period: October 1 to December 31 2008

During the period of October 1 to December 31, 2008, the PAAB Commissioner processed 2 Stage 2 complaints. PAAB reviewed 1,446 advertising pieces during the same period. 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.

STAGE TWO DECISIONS

1. ADVERTISER: Biovail

COMPLAINANT: Paladin

SUBJECT: multiple Ralivia (Tramadol HCl extended release tablets) sales material

PRECLEARANCE: No.

ALLEGATIONS: 18 allegations of which 14 were upheld. Seven safety allegations were referred to Health Canada in accordance with Health Canada policy. No response from HC was received at time of publication.

PENALTY: Cease distribution of violative material and send message to representatives to return unused material.

OUTCOME: Biovail agreed to cease distribution, recall material. Biovail reviewed their advertising regulation compliance protocols and invited commissioner to give a PAAB presentation on the code and federal regulations. Revised APS were sent to PAAB for review. No formal response from Health Canada at time of publication.

2. ADVERTISER: Novartis

COMPLAINANT: Boehringer Ingleheim

SUBJECT: Diovan (valsartan) journal ad

PRECLEARANCE: Yes in 2007

ALLEGATIONS: BOE stated the APS did not present the limitations on the indication in a clear manner because the limitations appeared as a footnote that was not contiguous with the indication and in much smaller type. Although the limitation wording was present as a footnote, the commissioner ruled that the presentation of the indication in a headline could have been of a higher standard because sponsors cite poor examples in their efforts to get the PAAB to approve APS.

PENALTY: Cease distribution and revise journal ad.

OUTCOME: Novartis complied with PAAB request.

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Denis Morrice - Best Medicines Coalition

Julie Tam - Canadian Generic Pharmaceutical Association (CGPA)

Ex-Officio Observer:

Ann Sztuke- Fournier - Health Canada

For information or if you have comments:

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