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 and 21, 2008 - General Meeting and Mission Review

E-FILE SUBMISSIONS

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. 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 . For more information or assistance call Laurie Johns at the PAAB office 905-509-2275.

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 with reference to the referenced review file.

It is the commitment of the PAAB to improve our customer service.

APRIL BOARD MEETING UPDATE

The PAAB Directors last met on April 25, 2008. The following are highlights of the meeting:

1.The Directors agreed to meet in the evening of November 20, 2008 for the next General Meeting and to conduct a planning day on November 21 to discuss the Mission, Vision, Values, Scope and Mandate of the PAAB.

2.A vote on the By-laws revision proposal to refer the vote to the next General Meeting was carried.

3.NDMAC will bring forward a proposal at the next General Meeting to change

4.several sections of the code relevant to nonprescription drug advertising.

5.The DTCA/I Task Force were directed to prepare guidelines relevant to Direct-to-Patient materials already reviewed by the PAAB under Code section 6.4. The Task Force is made up of representatives from PAAB member organizations and several external experts.

6.The PAAB Research Task Force has been looking at options to fund research related to biopharmaceuti-

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cal advertising. No specific grants have been made.

7.The CMA proposed wording to make section 2.5 (no compromise of healthcare professionals ethics in advertising) more specific to encourage advertisers to promote public safety through the use of safety equipment in depictions of activities such as boating, bicycle riding or other activities in advertising. The motion was rejected because a majority thought the wording was overly restrictive. However, the CMA delegate was encouraged by many to revisit this proposal because they agreed with the spirit of the proposal in the interest of promotion of public safety being part of health care professionals' ethical values.

NEW REVIEWER

We are pleased to inform you that Susan Hoy has joined the PAAB staff as a Reviewer. Susan has a B.Sc.Life Sciences and an MBA from Queens University. Susan has over 20 years experience in the pharmaceutical industry in product management, agency account management and marketing compliance management. She has worked on communications involving prescription drugs, nonprescription drugs, biologicals, DTCARx, DTCI, CME and the PAAB Code of Advertising Acceptance. She has worked with patient groups, government, hospitals, and health professionals to develop communication programs.

PI CODE REQUIREMENT UPDATE

PAAB clients are reminded that all product claims advertising should be accompanied by prescribing information that complies with Code section 7.3. 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. Code 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, 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.

HEALTH CANADA MEETING

On April 8, 2008, Health Canada hosted a meeting in Ottawa with officials from the PAAB, ASC and BCA to discuss advertising issues and exchange information. Agenda topics included 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. The summary of the meeting should be made available on the HC web-site.

HEALTH CANADA PM ADVISORY

"This letter is to confirm that Health Canada has no objection with respect to the concept of public online availability of Product Monographs since this document is a factual, scientific document on a drug that, devoid of promotional material, describes the properties, claims, indications, and conditions of use of the drug product and which contains other information that may be required for optimal, safe and effective use of the drug. A method currently being used by Market Authorization Holders (MAHs) is to post the exact, most updated version of Health

Canada's authorized Product Monographs on their corporate websites in order to provide accurate non-promotional information about their products. This practice is deemed acceptable by Health Canada as long as the website does not contain any advertising / promotional claims with respect to drug products. The intent of the dissemination of a Product Monograph is to provide information and must not be used as a complement to promote a drug product.

Posting of partial or selective information, emphasis on specific claims and strategies to highlight particular aspects of the Product Monograph are activities that would not be acceptable in most circumstances. As well, the listing of products with the sole mention of the respective therapeutic uses is not acceptable either. It should also be noted that providing access to Product Monographs through other means, such as giving access to a Product Monograph by clicking on an online reminder type ad banner, is not acceptable, as such a practice would exceed the restrictions set out in Section C.01.044 of the Food and Drug Regulations. The link to the Product Monograph becomes part of the branded promotional banner, and, as a whole, the material goes beyond the regulatory requirements in place. It is important to note that the posting of such online branded banners (i.e. online reminder type ad banners linking to Product Monographs) on various websites directed to the health professional community will be deemed acceptable if the access to the Product Monograph is limited to health professionals (e.g. through a gated portal or by making sure that by clicking on the banner, only health professionals have access to the Product Monograph)."

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 April 1 to June 30, 2008, the total number of first review submissions was 1,220. This compared to 1,387 during the same period of 2007. During the first half of 2008, 100% of submissions were given a first review response in 10 days or less. During the first half of 2007, 100% of first reviews were completed in ten days or less. During the first half of 2008 the total number of first submissions was 2388 compared to 2678 in 2007.

PAAB COMPLAINT REPORT

Period: April 1 to June 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 second quarter the PAAB sent no notices.

STAGE TWO DECISIONS

ADVERTISER: Schering-Plough
COMPLAINANT: Amgen
SUBJECT: c08-11 Remicade APS and Editorial APS
PRECLEARANCE: Yes
ALLEGATIONS: The two ads appeared side-by-side in the Journal of Rheumatology and appears to promote an off-label use for Remicade. The subject of the editorial was not in the Remicade Terms of Marketing Authorization. Allege a s3.1 violation.
PAAB DECISION: Violation of section 3.1 of the PAAB Code of Advertising Acceptance. With reference to a Health Canada guideline on linking advertising to non-advertising, the two ads should not appear side-by-side in a medical journal.
PENALTY: Cease distribution and complaint sent to Rx&D for assessment of penalty re breach of Rx&D Code of Conduct s2.2.
OUTCOME: Schering-Plough agreed to cease distribution. Of the two ads in the previous manner that caused the violation.

BOARD OF DIRECTORS -2008

Walter Rosser, MD	Chair
Gloria Bowes	Vice Chair
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Ann Leblanc	Canadian Association of Medical Publishers (CAMP)
Ivan Silver, MD	Association of Faculties of Medicine of Canada
Carol Repchinsky	Canadian Pharmacists Association (CPhA)
Ken Stallman	Non-Prescription Drug Manufacturers Association of Canada
Julie Tam	Canadian Generic Pharmaceutical Association (CGPA)
James Dunsmuir	Canada's Association for the Fifty Plus (CARP)
Denis Morrice	Best Medicines Coalition
Gilles Hudon, MD	Fédération des médecins spécialistes du Québec
Jeff Blackmer MD	Canadian Medical Association (CMA)
Ed Dybka	Canada's Research-Based Pharmaceutical Companies (Rx & D)

Ex-Officio Member:

Ann Sztuke- Fournier	Health Canada

For information or if you have comments:

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