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

January 23, 2008 - Executive Committee Meeting

April 25, 2008 - Annual / General Meeting

May 14, 2008 - Training Workshop Toronto

May 22, 2008 - Training Workshop Montreal

E-FILE LAUNCH

As of January 1, 2008 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. 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. We have notified thousands of individuals by email that the eFile procedure is available for use. We have also sent a letter by mail to all PAAB clients. 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 . We expect all clients to use the electronic filing process.

For more information call Glenn Golaz at the PAAB office 905-509-2275 x29.

PI CODE REVISION

Effective November 23, 2007, Section 7.3 of the PAAB Code of Advertising Acceptance has been revised to read:
"The *Prescribing Summary* must be a minimum of 8.5 point font with 10 point leading for text and 8 point font with 10 point leading for bold headings."

The PAAB members voted on and approved a motion for the change on November 23, 2007. The new size was approved based on a recommendation from an expert typographer sponsored by the Canadian Association of Medical Publishers (CAMP).

All newly created prescribing summaries should be in the new format. Prescribing summaries approved in the new format during 2007 can be revised to the new font size and sent at the advertiser's discretion to the PAAB for approval at no charge.

We understand that some clients have not learned to apply the code guideline for the new format in the proper manner. The commissioner reminds advertising sponsors to take advantage of the opportunity to edit the content from a style and grammar point of view and eliminating extraneous commentary in the product monograph. The new format is designed to provide the important efficacy and safety content of the product monograph in a manner that is concise and easy to read as a reference tool.

LOOK INSIDE

Please refer to the PI FAQs on the PAAB web-site www.paab.ca. Please call the PAAB office for answers to additional questions.

The objective is to reformat the P.I. to improve content while maintaining approximately the same length as the previous version.

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.

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.

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

DIRECT-TO-CONSUMER

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.

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.

HEALTH CANADA ADVISORY

Health Canada has received a number of complaints regarding the inclusion of product package representations within branded DTCARx reminder ads; specifically, campaigns which include ads depicting blister packs of oral contraceptive products. Most of the complaints alleged that such ads were not consistent with the federal regulatory requirements for prescription drug advertising to consumers. Health Canada has approached companies displaying such ads and they are in the process of modifying them. The objective is to obtain a level playing field within industry regarding advertising requirements.
The PAAB will continue to advise market authorization holders (MAHs) to refrain from depicting product package representations that may allude to the therapeutic use in reminder ads.

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.

OFF-LABEL PROMOTION

We note that we have had a few complaints about off-label advertising this year. Is it the tip of the iceberg? Doctors can choose to write prescriptions for off-label use, however biopharma companies cannot promote off-label uses.

There has been a lot of government scrutiny in the U.S. on off-label promotional activities during the recent past. Restrictive laws are going into place in the U.S. Predictions are that the regulatory focus will continue on a variety of marketing activities. A recent article stated the U.S. spend on marketing

activities is almost twice the spend on R&D and some believe the same is true in Canada.

Canadian law allows pharma companies to provide off-label information to health professionals in response to specific requests. I believe most companies do this responsibly. Here are some tips on how to avoid regulatory violations:

1. Comply with PAAB Code section 3.1. Go read it in its entirety at www.paab.ca .
2. Document your specific requests for information. You may have a blockbuster drug trial that is not in your Terms of Marketing Authorization (TMA) and may be getting a lot of requests. This is evidence.
3. Tell your sales reps not to "push" samples or information to doctors who you know write off-label scripts for your drug.
4. Seek Health Canada approval to get TMA for growing off-label use. We know you have the sales data.
5. Re-educate or discharge employees who insist on promoting off-label uses.
6. Avoid "seeding" grants for clinical trials. These are studies whose main purpose is to promote use of an unapproved indication. Everybody wants meaningful science, not marketing.
7. Promote patient safety by avoiding off-label use where there is no standard of care or established safe dosing.
8. Don't fall into the trap of promoting off-label because your competitor is doing it. That is not good citizenship or a wise defense in front of regulatory scrutiny.

REVIEW ACTIVITY

During the period of October 1 to December 31, 2007, the total number of first review submissions was 1348. This compared to 1410 during the same period of 2006. Detail aids were 41% of the volume followed by service vehicle APS at 24%. Journal ads with the new PI format were at 16%. For the year, the total new APS reviewed was 5138 compared to 5283 during the same period last year. That was the first decrease in review volume since 2002.

During the third quarter of 2007, 15% of 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 all of 2007 45% 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 2006, 30% of first reviews were completed in five days or less, 89% in ten days or less. This is the record of how many days it took to first review of 5138 new submission files in 2007 (does not include resubmissions and second language reviews):

10-days:	9%	5-days:	13%
9-days:	12%	4-days:	10%
8-days:	10%	3-days:	10%
7-days:	11%	2-days:	7%
6-days:	12%	1-day or less:	6%

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

PAAB COMPLAINT REPORT

Period: October 1 to December 31, 2007

During the period of October1 to December 31, 2007, the PAAB Commissioner processed 1 Stage 2 complaints. PAAB reviewed 1348 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.

STAGE TWO DECISIONS

1. ADVERTISER: Valeant
COMPLAINANT: Pfizer

SUBJECT: c07-35 - APS "A New Approach for Fibromyalgia, Cannabinoids and Symptom Control".

PRECLEARANCE: No

ALLEGATIONS: OFF-LABEL promotion. S3.1 and deceptive comment "sponsored by an educational grant". Single product focus and promotional use of brand elements.

PENALTY: Sent to Health Canada because of repeat allegation after previous similar violation and another complaint to HC.

OUTCOME: To be determined by Health Canada.

BOARD OF DIRECTORS - 2008

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For information or if you have comments:

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We wish you a Happy 2008!