PHARMACEUTICAL ADVERTISING ADVISORY BOARD

# PAAB REVIEW

Year 2006 marks the 30th 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 / EVENTS

January 19, 2006 – Executive Committee

April 21, 2006 – General Board Meeting

May 16, 2006 – Open Workshop in Toronto

May 18, 2006 – Open Workshop in Montreal

## PAAB CODE SECTION REVISION

The following paragraph has been added to section **6.6.a** of the PAAB Code of Advertising Acceptance. It replaced a similarly worded paragraph. "*Meeting Reports of sections of accredited Health Professional Meetings or Continuing Education (CE) events/activities (see s **11.10**) organized independently of the sponsor of the materials and that are not focused on, or provide emphasis on, the sponsor's product(s) i.e. do not promote the sale of the sponsor's product(s).*" Also sections **11.11** and **11.12** definitions have been removed. You can see the Code at www.paab.ca. The initiative to make the change came from the Canadian Association of Medical publishers. That was the impetus for this recommendation as well as the Commissioner having experienced many comments about potential confusion in the application of these code sections. The current wording reflects the Health Canada interpretation of advertising with respect to meeting reports. You can see that in the Health Canada guideline "The Distinction Between Advertising and Other Activities" available on the Health Canada web-site.

## FEE SCHEDULE REVISION

The 2006 PAAB Fee schedule has been revised. You can see the complete fee schedule at www.paab.ca. The increase in the primary fees represents the first major increase in six years. During that time, the PAAB has increased its staff complement, increased the office space, has engaged in strategic planning, a major code review and a communications program that was designed to increase the awareness of the PAAB by physicians. The Board is looking to secure the future of the PAAB to enable it to perform well within its mandate. We are hiring additional staff and have recently renovated the office. We look forward to providing excellent service to our clients.

## LOOK INSIDE

## NEW PAAB STAFF

Two new staff members have joined the PAAB. Ms. Sabrina Hack has joined the PAAB in the Fall of 2005 as a part-time administrative clerk. Mr. Chris Seto has started as a reviewer in January 2006. Chris is a licensed pharmacist who has worked in community pharmacy providing patient care. We welcome them both to the PAAB.

## PAAB TRAINING INITIATIVE 2006

The PAAB will continue its training project regarding the PAAB Code of Advertising Acceptance with the assistance of Pharmahorizons. The goal is to teach the application of the PAAB Code primarily to new pharmaceutical industry employees and provide a refresher for experienced personnel. Pharmahorizons will provide professional logistical support while the PAAB staff will provide and maintain control of all content. The next offering of this workshop will be in Toronto May 16 and in Montreal May 18, 2006. You can contact Pharmahorizons (1-888-514-5858) for registration and information about future workshops.

## DO WE HAVE THE MOST RECENT PRODUCT MONOGRAPH?

That is a question frequently asked by PAAB staff these days. Please send us your product monographs along with the Health Canada NOC approval letter as soon as they get updated because it helps our review efficiency.

The PAAB handles 12-15,000 files per year and you can help us administratively to handle them efficiently. Ways you can help the PAAB review process are:

- Send new submissions or revised copy submissions only once. Do not duplicate by fax, e-mail, courier etc.
- Send layouts by courier or by e-mail in pdf and not by fax..
- If faxing, do not highlight over text because we cannot read it
- Ensure medical/regulatory has approved all submissions before you send it to the PAAB. Check-off the submission form.
- Send the submission form with the submission i.e. not separately.
- Send one submission per e-mail and state the PAAB file number in the subject line.

## GET DTCARX ADVICE

We remind you that the PAAB will give an advisory opinion on specific projects that involve advertising or information directed at the general public. Currently, companies cannot advertise treatments of Schedule A diseases to the general public or advertise prescription drugs except for name, price, and quantity. We can assist you in interpreting Health Canada guidelines on what is advertising and what is not considered to be advertising. The PAAB will charge a review fee for written opinions. Advertisers should note that the PAAB members have agreed to the Health Canada request that it be copied on final versions of submissions reviewed by the PAAB. Health Canada has endorsed both the PAAB and Advertising Standards Canada to perform the review service based on the Health Canada guidelines. Advertisers are not required to send a particular submission to both the PAAB and ASC.

## REVIEW ACTIVITY

During the period of October 1 to December 31, 2005, the total number of first review submissions reviewed was 1251. This compared to 1119 during the same period of 2004, a 12% increase. For the year the number of first reviews was 4444 compared to 3921 during 2004, a 13% increase.

During the last quarter of 2005, 11% of the submissions were given a first review response in five days or less compared to 22% in 2004; and 93% were given a first review response in 10 days or less this year compared to 100% in 2004. For all of 2005 92% of the first reviews were done in ten days or less compared with 93% in 2004.

## COMPLAINTS / MONITORING

### PROCESS

Complaints against Advertising/Promotion Systems (APS) may be lodged by: health professionals, health care organizations, pharmaceutical companies, federal and provincial regulatory bodies and drug payer organizations. Allegations involving public safety and unapproved products are sent without delay to Health Canada for investigation.

There are three levels of PAAB administrative response. In Stage ONE, the complaint is sent directly to the advertiser by the complainant or to the advertiser via the PAAB Commissioner. The advertiser responds in writing to the complainant. The complainant then has three options: continue discussion with the advertiser, possibly by writing another letter narrowing the points of dispute; accept the advertiser's response; or conclude that further intercompany dialogue will not be productive and therefore seek review by the PAAB Commissioner in Stage TWO. Either the complainant or advertiser has the right to appeal the Commissioner's reassessment ruling to a Stage Three independent Review Panel made up of three qualified individuals selected by the Commissioner with agreement by all parties.

## PAAB COMPLAINT REPORT

**Period: October1 to December31, 2005**

During the period of October 1 to December 31, 2005, the PAAB Commissioner processed 2 Stage 2 complaints. One complaint involved an APS with current approval by the PAAB and the complaint was rejected. The other complaint that did not have PAAB approval was sustained. PAAB reviewed 1251 advertising pieces during the same period. The total number of stage two complaints received during 2005 is 22. PAAB reviewed 4444 APS during 2005.

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 advertisers trade association and/or Health Canada for their assessment of additional penalties. PAAB sent 3 notices of violation in the fourth quarter, involving a press release, a meeting invitation and a public newspaper ad. Health Canada was notified of the potential violations of the Food & Drugs Act regarding a press release, a meeting notice and a public newspaper ad.

## STAGE TWO DECISIONS

1.

ADVERTISER: Altana/Solvay

COMPLAINANT: **AstraZeneca**

SUBJECT:c05-50 Pantoloc Journal ad JAC53247

PRECLEARANCE: **Yes May 2005**

ALLEGATIONS: Issues related to use of the Scholten paper as a reference to support claims alleging violations of PAAB Code s5.2, 5.8, 5.9, 2.3, 3.1,4.1, 4.3

PAAB DECISION: The title of the paper stating "equivalency" was unfortunate because that was not proven in the study. However, the Pantoloc advertising approved by the PAAB contained the reference in support of a claim "2 days faster GERD symptom relief than esomeprazole (day and night) demonstrated … in endoscopically proven GERD patients (grade B&C LA classification) and that appeared to be sufficiently supported by the study. No claims of overall equivalency appeared in the advertising. Cautious use of claims based on this study was recommended. Complaint rejected.

PENALTY: $500 registration fee assessed of AstraZeneca.

OUTCOME: No further action necessary.

2.

ADVERTISER: **Schering**

COMPLAINANT: **Health Canada**

SUBJECT: c05-57 Dear Doctor letter

PRECLEARANCE:**No**

ALLEGATIONS: In a letter to doctors regarding notification of Ontario Drug Benefit coverage, Schering promoted an indication that was not approved by Health Canada in their product monograph. This was an alleged violation of the Food & Drugs Act and a violation of PAAB Code section 3.1. Also, the letter should have been sent to the PAAB for preclearance review.

PAAB DECISION: Violation of s6.2 and s3.1. Company-created provincial formulary letters are neither exempt from the PAAB Code. Health Canada has sent a notice previously to members of the Federal-Provincial subcommittee indicating that provincial laws do not overrule federal laws regarding healthcare product advertising. Distribution of this promotion should cease immediately.

PENALTY: **reprimand**

OUTCOME: Schering complied with the ruling and revised their standard operating procedure to prohibit this type of activity. Health Canada was notified of Schering's response.

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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