PHARMACEUTICAL ADVERTISING ADVISORY BOARD January 20

PAAB REVIEW

Year 2004 marks the 28th 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

February 12, 2004 – Executive Committee

April 23, 2004 – Annual/General Meeting

RECORD YEAR FOR REVIEWS

The PAAB staff had their hands full during all of 2003 as they handled a record number of submission reviews. The PAAB performed 3745 new reviews and reviewed 10,849 files including all the resubmissions. Add in French translation files and the total becomes around 14,000. It was a mega year! And the staff deserved a well-earned seasonal break after performing a record number 381 first reviews during December. There was good reason for the turnaround time to be hovering near ten days for most of the month. Of the new reviews only 172 were renewals of previously approved Advertising/promotional systems (APS) whose clearance approval had expired. Detail Aids comprised 1691 APS or 45% of the total. PAAB reviewed 57 Direct-to-Consumer pieces, not including patient information pieces.

ARE YOU A PAAB REVIEWER?

The PAAB is seeking a bilingual person to be a PAAB Reviewer. You should have a good knowledge of pharmacology and therapeutics as a starting point. Formal training will take care of the rest. Contact Commissioner Ray Chepesiuk at commish@paab.ca.

STRATEGIC PLAN RESULTS

At the November General meeting the PAAB directors reviewed, edited and approved the recommendations of the four task force committees that were struck at the initiation of the strategic planning exercise held during 2002-2003. Nine recommendations were approved by the Directors (actions that have already occurred follow in brackets):

1. Develop improved communications with senior Health Canada officials to address issues of mutual interest. (PAAB met with Health Canada senior officials in December 2003.)

2. *Investigate the allegations from the client focus group regarding the inconsistency of PAAB reviews*. (The Association of Medical Advertising Agencies had solicited examples from its members and two were received. The Commissioner is keeping a watchful eye on this issue and ensuring quality control procedures are in place for the review process.)

3. *Engage outside counsel to develop stakeholder and government consultation strategies and seek external recommendation on need for in-house capability.* (The Commissioner had contracted a consultant regarding government consultations and workshops in the Fall of 2003. In-house capability at this time was not seen as needed.)

LOOK INSIDE

4. *Approve and communicate an updated description of the scope of PAAB's core business.* (The Directors agreed on the following wording "pre-clearance of communications for Rx medications to all audiences, and non-prescription drugs to healthcare professionals".)

5. *Authorize PAAB staff to lead a selection process for additional marketing-oriented suppliers*. (A budget was approved and the Commissioner will create a request for proposal in January 2004).

6. *Key Stakeholders: PAAB should focus resources mainly on healthcare professionals and the related industry, as the key PAAB stakeholders. (A marketing campaign will commence in 2004)*

7. *Board Configuration (a) PAAB should approach one or more "group of disease-specific groups" to reinforce Board balance. (b) PAAB should explore additional medical organizations who could provide enhanced healthcare expertise. (c) PAAB should formulate a specific policy on organization criteria for Board membership.*

8. *Data-bank: PAAB should develop and maintain a formal, comprehensive, database of specific stakeholder targets.* (The Commissioner has received names of organizations from Executive committee members)

9. *Input: PAAB should capture and retain for future review all the Task Group #4 input, recognizing much of the original work ended in overlap with, and transfer to, Task Group #3.*

The PAAB thanks Carolyn Everson for her outstanding work in guiding and facilitating the strategic planning process. We also thank everyone who responded to our request for input into this process. We look forward to moving confidently into 2004.

FEE POLICY NEWS

All Advertising/Promotional System (APS) should be approved by the sponsor before they are sent to the PAAB. When an Advertising/Promotional System (APS) is received it is PAAB's understanding this is the version that the sponsor wants to go to publication. The fee schedule is based on that assumption. The following policy will come into effect January 1, 2004:

All APS review files which have not received any response for over 180-days will be closed and any revisions following the 180-days period will be assigned a new file number and subject to a new fee.

All APS reviews that are not completed within a period of twelve months will be assigned a new file number and subject to a new fee.

Once an acceptance number is issued, the file is considered completed and further revisions to the APS would require a new submission and subject to the usual fee.

PAAB TRAINING INITIATIVE - 2004

The PAAB is partnering with Pharmahorizons to create a training initiative 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. Three approaches are: PAAB workshops, Internet interactive learning and PAAB staff participation in other Pharmahorizons training courses for new marketing personnel. The first offering of this workshop will be January 27, 2004 in Montreal and January 29 in Toronto. And it is sold out. You can contact Pharmahorizons (1-888-514-5858) for information about the March and October workshops.

GET DTCARX ADVICE

We remind you that PAAB will give an advisory opinion on specific projects that involve advertising or information directed at the general public. Currently, companies cannot advertise prescription drugs except for name, price, and

quantity, or treatments of Schedule A diseases to the general public. We can assist you in interpreting Health Canada guidelines on what is advertising and what is not considered to be advertising. 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 ultimate legal regulatory authority regarding drug advertising.

REVIEW ACTIVITY

During the period of October 1 to December 31, 2003, the total number of first review submissions reviewed was 1069. This compared to 843 during the same period of 2002, a 27% increase. December saw a record review volume of 381 first reviews. From January 1 to December 31, 2003 there were 3745 first reviews compared to 3227 during the same period in 2002, a 16% increase. Overall, the staff handled close to 11,000 files, including all of the revisions. That does not include French copy translations that followed.

During the fourth quarter of 2003, 27% of the submissions were given a first review response in five days or less and 88% were given a first review response in 10 days or less. The increased delay was due to the high volume and a larger number of teleconferences and meetings needed to resolve issues . The Reviewers faced a workload more weighted towards detail material at 47%. Next highest was service vehicles at 19%.

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: October 1 to December 31, 2003

During the period of October 1 to December 31, 2003, the PAAB Commissioner processed 8 **Stage 2 complaints**. PAAB reviewed 1069 advertising pieces during the same period. Two files had been previously approved by the PAAB and one complaint was sustained. All of the six files that had not received PAAB preclearance were sustained.

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 7 notice of violation letters. Three cases were sent directly to Health Canada because they involved allegations regarding Direct-to-Consumer drug advertising.

STAGE TWO DECISIONS

1. ADVERTISER: Teva Novopharm

COMPLAINANT: Merck Frosst

SUBJECT: c03-26 Novo-Alendronate (alendronate) Journal Ad in Pharmacy Practice

PRECLEARANCE: No

ALLEGATIONS: This is a product ad with no preclearance approval (s6.1), no fair balance (s2.4) no prescribing information (7.1)

PAAB DECISION: Agreed with MFCL

PENALTY: Cease Distribution prior to preclearance review and approval by the PAAB. PAAB notified CGPA of violation.

OUTCOME: Teva Novopharm agreed and requested a meeting to clarify PAAB Code issues to facilitate future compliance.

2. ADVERTISER: Janssen-Ortho

COMPLAINANT: Pfizer

SUBJECT: c03-20 Reminyl (galantamine) promotion to one physician through unpublished posters distributed by representatives

PRECLEARANCE: No

ALLEGATIONS: Items were not precleared (s6.3) and author's conclusions and comparative data presentations were misleading causing multiple PAAB code violations. Evidence presented was an affidavit from one private physician and many Fastrak reports indicating extensive rep usage of the material.

PAAB DECISION: Agreed with Pfizer based on the physician affidavit. Fastrak reports are not considered hard evidence because individual occurrences cannot be identified and validated. However Fastrak reports indicate extensive unsolicited distribution.

PENALTY: Evidence of distribution to one physician did not warrant a correction letter. Retrieval of material and evidence of a letter sent to representatives instructing them not to use this material in a promotional manner. PAAB notified Rx&D of the violation.

OUTCOME: JOI complied. A fine was levied by Rx&D.

3. ADVERTISER: Abbott

COMPLAINANT: Janssen-Ortho

SUBJECT: c03-23 Prevacid (lansoprazole) detail aid "How to Continue Prevacid 30 mg usage" created by a representative

PRECLEARANCE: No

ALLEGATIONS: Not precleared (s6.4), incorrect treatment regimen is misleading (s2.1)

PAAB DECISION: Abbott stated that the items were sales training material. Agreed with JOI.

PENALTY: Cease distribution.

OUTCOME: Prior to the decision by the Commissioner, Abbott had sent a letter indicating that the representatives were notified to cease distributing the training material.

4. ADVERTISER: Ortho Biotech

COMPLAINANT: Amgen

SUBJECT: c03-32 Eprex (epoetin alfa) promotional material distributed by a representative at a hospital grand rounds meeting with a Regional sales manager present

PRECLEARANCE: No

ALLEGATIONS: no preclearance for promotional information distributed at renal rounds in one hospital. Material included false and misleading statements with multiple PAAB code violations.

PAAB DECISION: Agreed with Amgen on need for preclearance to prevent false and misleading statements.

PENALTY: The evidence indicated that this was an isolated incident. The presence of the sales manager was not made known to the commissioner

at the time of the decision. Correction letter to be sent to the list of attendees at the meeting required . Ortho Biotech to send PAAB a copy of its standard operating procedure to prevent such occurrences. Rx&D notified of the violation.

OUTCOME: Ortho Biotech complied with the decision and also notified all representatives that similar actions in the future could result in termination of employment.

5. ADVERTISER: Novartis

COMPLAINANT: AstraZeneca

SUBJECT: c03-33 journal ad promoting research study "VALIANT" related to the benefits of Diovan (Valsartan)

PRECLEARANCE: Yes

ALLEGATIONS: Study has been completed and Novartis continues to promote the study hoping to entice physicians to ask for the results. This is off-label promotion (s3.1)

PAAB DECISION: Advertisement to promote research was approved by PAAB in good faith. Agreed with AstraZeneca that any promotion after completion of the study would appear to indirectly promote the off-label claim.

PENALTY: Withdrawal of PAAB approval effective immediately and Novartis should not promote this study prior to receiving product monograph approval by Health Canada.

OUTCOME: Novartis agreed with the decision.

6. ADVERTISER: Pfizer

COMPLAINANT: Private Physician

SUBJECT: c03-38 ziprasidone meeting report journal ad in "The Medical Post" entitled "New Atypical Antipsychotic Shows Promissing (sic) Results"

PRECLEARANCE: No

ALLEGATIONS: Piece was promotional in nature because it was not objective and balanced (s6.1). It appeared to promote a product that had not received a Notice of Compliance (s3.1)

PAAB DECISION: Pfizer and their creative and placement agent Axon contend that the piece complied with the exemption for educational material stated in s6.6.a and the Health Canada guideline "The Distinction Between Advertising and Other Activities". Pfizer stated they did not see the material prior to distribution to physicians. Agreed with the physician that the piece did not meet all of the exemption requirements and meets the PAAB definition of advertising subject to the PAAB Code in s11.1. Also, promotion of information from an oral presentation is not considered to be good evidence (s3.1)

PENALTY: Health Canada notified of pre-NOC promotion. Request a copy of Pfizer standard operating procedure regarding internal approval of this type of promotional activity.

OUTCOME: Pfizer complied with the decision.

7. ADVERTISER: Wyeth

COMPLAINANT: GlaxoSmithKline

SUBJECT: c03-42 Effexor XR (venlafaxine) detail aid

PRECLEARANCE: Yes

ALLEGATIONS: The Title "Effexor XR in Chronic Anxiety" and subtitle "Indicated for Generalized Anxiety Disorder and now also indicated for Social Anxiety Disorder" is misleading in that Effexor XR does not have product monograph approval for the claim of "chronic anxiety" (s3.1). The product monograph states that effectiveness is not known past six months. There is not sufficient fair balance because the side effects for the generalized anxiety disorder does not appear.

PAAB DECISION: The product monograph states that the anxiety symptoms should be marked and persistent, thus indicating a chronic condition. Also, the six month limitation statement regarding proven effectiveness relates to treatment, not the condition of the patient. The advertising focussed on the SAD indication and did include sufficient fair balance. The complete indication wording for both disorders was stated.

PENALTY: $500 administration fee invoiced to GSK.

OUTCOME: Decision made on December 23, 2003 pending 5 day response period.

8. ADVERTISER: Aventis

COMPLAINANT: Merck Frosst

SUBJECT: C03-43 journal insertion in four Canadian medical journals entitled "Symposia Reporter September 2003 Ace Inhibitors and ARBs for Risk Reduction"

PRECLEARANCE: No

ALLEGATIONS: Item meets definition of advertising in s11.1 and does not meet all of the requirements for an exemption in 6.6.a and the Health Canada policy "The Distinction Between Advertising and Other Activities". This is an attempt to promote Altace (ramipril) in an unfair manner with respect to COZAAR (losartan).

PAAB DECISION: Agreed with MFCL. The frequency of distribution means that one doctor could receive this message several times. That is not the intent of the PAAB meeting report exemption. It does not meet the requirements of the Health Canada exemption policy regarding journal ads. The format of the piece is promotional in nature and includes callouts featuring benefits of Altace to the exclusion of other agents (11.1). There is not a fair and objective mention of all treatments. Also, the piece attacks losartan unfairly by including information that is not based on head-to-head published trials (3.1).

PENALTY: Cease distribution immediately. PAAB will notify Rx&D of the violation.

OUTCOME: Decision made on December 29, 2003 pending 5 day response period.

VOTING ORGANIZATIONS

Canadian Medical Association (CMA)

Canadian Pharmacists Association (CPhA)

Canada's Research-Based Pharmaceutical Companies (Rx&D)

Canadian Generic Pharmaceutical Association (CGPA)

Canada's Association for the Fifty Plus (CARP)

Canadian Association of Medical Publishers (CAMP)

Consumers' Association of Canada (CAC)

Fédération des médecins spécialistes du Québec (FMSQ)

Nonprescription Drug Manufacturers Association of Canada (NDMAC)

Association of Medical Advertising Agencies (AMAA)

Advertising Standards Canada (ASC)

INDIVIDUALS

Chair Dr. R. Perkin
Past Chair Dr. J. Godden
Treasurer Lorenzo Biondi

Health Canada is an ex-officio observer.

PAAB: NEED MORE INFO?

PAAB is an independent review agency whose primary role is to ensure that advertising of prescription drugs is accurate, balanced and evidence-based. The scope of the PAAB Code currently includes advertising of prescription and OTC products to health professionals, in all media.

For information or if you have comments:

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The PAAB Code of Advertising Acceptance and PAAB Supplementary Guidelines are available from the PAAB office or at **www.paab.ca**

You can find these key Health Canada documents at **http://www.hc-sc.gc.ca**

- Distinction Between Advertising and Other Activities
- Overview of Drug Advertising
- PAAB and Therapeutics Products Directorate Roles and Consultation re Advertising Review.