PHARMACEUTICAL ADVERTISING ADVISORY BOARD April 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

April 5 – Executive Committee

April 23 – Annual/General Meeting

AVOID DECEPTION

The definition of *advertising* in the Food & Drugs Act is "any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device". Therefore, most product-focussed messages would be considered *advertising*. Keep that definition in mind when you are creating communications to health professionals or to the public. That includes items that are called "patient information" or "educational" letters or reports and distribution of third-party communications by drug manufacturers. Accredited CME material may be exempt from PAAB review but could be considered "advertising", and subject to PAAB Code provisions, depending on the content and manner of distribution, if linked to a sponsor.

Manufacturers should look to improving the overall image of the pharmaceutical industry by providing promotional material that meets all of the legal and ethical requirements. The PAAB can you help you do that through the preclearance review process.

PUT SAFETY FIRST

Agencies and advertisers should understand the basis for the requirement of PAAB Code section 2.4. Section 2.4 states "APS must reflect an attitude of caution with respect to drug usage, with emphasis on rational drug therapy. The advertising copy should provide sufficient information to permit assessment of risk and benefit." If you see a need for prominence and frequency of a benefit message, then there is the same need for prominence and frequency of the risk information.

PAAB Reviewers have sufficient training in health care to appreciate the concern that patients and health care professionals have about this information. Please build the requirements of section 2.4 into the planning and creative phase.

DON'T USE SMALL PRINT

We have received a complaint from a physician who has noted a trend toward smaller print in the safety information, references and footnote qualifiers that clarify primary copy. The PAAB reviewers will be reminding you of the requirement for legible copy. They do not necessarily see the final print size that ends up in the distributed material. We will send notices of violation of the PAAB Code s2.4 to companies who appear to want to perpetuate this activity after the normal ad

LOOK INSIDE

expiry date. We also remind you that improper shading behind the safety information is not acceptable.

CAVALRY COMING

Commissioner Ray Chepesiuk welcomes Karen Rizwan to the PAAB staff as the 7th PAAB Reviewer, beginning April 12, 2004. Karen is a licensed pharmacist and a graduate of the University of Toronto. She brings a sound knowledge of therapeutics and pharmacology to the PAAB. She is bilingual English / French. Karen will be trained by Deputy Commissioner /Senior Reviewer John Wong.

WERE YOU THERE?

The PAAB has partnered with Pharmahorizons to provide industry personnel training regarding the PAAB Code of Advertising Acceptance. The goal is to teach the application of the PAAB code to new pharmaceutical industry employees. Pharma-horizons has provided professional logistical support while the PAAB staff will provide and maintain control of all content. Successful workshops were conducted in Montreal and Toronto in January and March. The next workshops are scheduled for October 2004. You can contact Pharmahorizons (1-888-514-5858) for more information and registration.

GET DTCARX ADVICE

We remind you that PAAB will give an advisory opinion on specific broadcast and print projects that involve advertising or information directed at the general public e.g. help-seeking ads, consumer brochures, Reminder ads. 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.

HAVE YOUR SAY

On April 2, 2004, the PAAB mailed 421 invitations to participate in the cover-to-cover review of the PAAB Code of Advertising Acceptance. Although sections of the Code have been revised since 1992, this is the first complete review. Commissioner Ray Chepesiuk is chairing the Code Committee that has 7 members appointed by PAAB voting member organizations and 1 member from the University of Toronto Faculty of Medicine CME division.

The request for participation in an e-survey was sent to PAAB board members, pharmaceutical companies, agencies, federal and provincial governments, healthcare associations, patient advocacy associations, medical publishers, CME providers, e-business suppliers and interested individuals. The deadline for responses is May 14, 2004.

The survey focussed on areas that have come to the attention of the PAAB for review e.g CME exemption, evidence, internet, DTCARx, fair balance and others. The Code Committee will review and analyze the responses and make recommendations for a revised Code that will be sent to the PAAB Board members for review and approval at the December General Meeting.

Questions about the process can be directed to Commissioner Ray Chepesiuk.

REVIEW ACTIVITY

During the period of January 1 to March 31, 2004, the total number of first review submissions reviewed was 851. This compared to 916 during the same period of 2003, a 7% decrease.

During the first quarter of 2004, 32% of the submissions were given a first review response in five days or less and 56% were given a first review response in 10 days or less. The increased delay was due to the high volume, reviewers' carryover vacation time and preparation time need for the PAAB workshops. The Reviewers faced a workload

more weighted towards detail material at 37%. Next highest was service vehicles at 22%. and journal ads at 18%.

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: January 1 to March 31 2004

During the period of January 1 to March 31, 2004, the PAAB Commissioner processed 1 **Stage 2 complaint**. The complaint was rejected. This is the lowest number for a quarter in recent memory. PAAB reviewed 851 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 advertisers trade association and/or Health Canada for their assessment of additional penalties. PAAB sent 1 notice of violation letter in the third quarter, with Health Canada being notified.

STAGE TWO DECISIONS

1. ADVERTISER: Teva Neuroscience

COMPLAINANT: Biogen Idec

SUBJECT: Copaxone (glatiramer acetate) detail aid booklet DAF45741 approved August 2003

PRECLEARANCE: Yes

ALLEGATIONS: There were 4 allegations:

1. Biogen questioned a number of statements made in the guide to suggest that Copaxone reduces disability progression.
2. An important limitation on data interpretation has been omitted re Bornstein trial and a claim of 78% reduction in relapse rate was not confirmed by the Johnson study and 60% fewer patients progressed in disability not confirmed by Johnson and significance of Kurtzke score 0-2 stratum should be clarified.
3. Other problematic statements in the guide about the Johnson trial e.g. 38% more Copaxone-treated patients improved in EDS scores and 27% fewer Copaxone-treated patients worsened in EDSS scores and 123% reduction in mean EDSS scores was seen in Copaxone treated patients over 2 years in comparison to the placebo group.
4. Laboratory and warnings comparison chart compares Copaxone to interferons. Biogen argues that the warning related to depression and suicide in the Biogen Avonex product

monograph is not represented in a fair manner. Other laboratory data was not fairly compared.

PAAB DECISION:

1. The data presentation is based on and consistent with the Copaxone product monograph that was approved by Health Canada.
2. The Bornstein data is consistent with data shown in the Copaxone product monograph, both data sets are shown in the APS, the presentation does not appear to mislead and the target audience of physicians have sufficient information to decide the meaning of these data as presented.
3. The Johnson data were statistically analyzed and were considered to be secondary endpoints and the claim was consistent with a statement in the results section of the study. The EDSS data including the p-value is part of the product monograph.
4. The chart appears to be complete, fair and not misleading.

A discussion with Biogen Idec ensued regarding the validity and relevance of the data presented in the Copaxone product monograph approved by Health Canada in a division different from the one that approved the Avonex product monograph.

PENALTY: The complaint was rejected and Biogen Idec assessed a registration fee of $500.

OUTCOME: Biogen Idec accepted the decision.

VOTING ORGANIZATIONS

Canadian Medical Association (CMA)

Canadian Pharmacists Association (CPhA)

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

Canadian Generic Pharmaceutical Association

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.

Look for this logo

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