PHARMACEUTICAL ADVERTISING ADVISORY BOARD July 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

September 24, 2004 – Executive Committee

December 3, 2004 – General Meeting

PAAB CAN HELP YOU

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**.

FOOTNOTES FOLLIES

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 and the appropriate qualifying information regarding study parameters. Avoid small-type footnotes.

NEW PAAB STAFF

We are pleased to have Karen Rizwan as an addition to the PAAB staff as of April 12, 2004. Karen is a licensed pharmacist with patient care experience in various community pharmacy settings. The addition of Karen will help address the increased workload pressure that the PAAB Reviewers have faced in the past few years. Client service regarding review turnaround is an important factor to the PAAB.

We are also pleased to have added Laurie Johns as a part-time administrative assistant to help address the increased workload pressure that Carol and Estelle have encountered due to volume increases.

LOOK INSIDE

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 next offering of this workshop will be October 12, 2004 in Montreal and October 14 in Toronto. You can contact Pharmahorizons (1-888-514-5858) for information about the 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.

NATURAL HEALTH PRODUCTS

Yes, the PAAB Code covers Natural Health Product advertising to health professionals if the product falls into the Code s11.3 definition of "pharmaceutical product". We acknowledge that very few NHPs have labeling approved by Health Canada and therefore approval of specific therapeutic claims may not be accepted by the PAAB unless proof of labeling acceptance by Health Canada is shown to the PAAB. The PAAB Commissioner will continue to send to Health Canada examples of false and misleading NHP advertising to the public as they come to his attention.

CODE REVIEW PROGRESS

On April 2, 2004, the PAAB mailed 427 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. Over 70 written responses were received by the deadline of 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.

REVIEW ACTIVITY

During the period of April 1 to June 30, 2004, the total number of first review submissions reviewed was 1015. This compared to 896 during the same period of 2003, a 13% increase. From January 1 to June 30, 2004 there were 1871 first reviews compared to 1812 during the same period in 2002, a 3% increase.

During the first half of 2004, 21% of the submissions were given a first review response in five days or less and 84% were given a first review response in 10 days or less. The increased delay compared to the previous year was due to the high

volume and vacation time. The Reviewers faced a workload more weighted towards detail material at 40%.

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: April 1 to June 30, 2004

During the period of April 1 to June 30, 2004, the PAAB Commissioner processed 4 **Stage 2 complaints**. PAAB reviewed 1015 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 8 notice of violation in the third quarter. Six cases were sent directly to Health Canada because they involved allegations regarding Direct-to-Consumer drug and Natural Health Product advertising.

STAGE TWO DECISIONS

1. ADVERTISER: AstraZeneca

COMPLAINANT: Novartis

SUBJECT: c04-08 Atacand (candesartan) editorial APS

PRECLEARANCE: Yes December 2003

ALLEGATIONS: 1. Product sticker promoting Atacand was attached to a non-advertising editorial piece.

2. A non-advertising editorial piece regarding indications not approved by Health Canada for Atacand included branding elements e.g. colours, images.

PAAB DECISION: PAAB did not uphold allegation one because there was no evidence regarding who applied the branded sticker to the non-advertising APS. PAAB agreed with the complainant that inclusion of the colours and images used in previous Atacand promotion would make this item promotional as well. The link of the brand name to the off-label indications is a violation of PAAB Code s3.1. PAAB reviewers were reminded to ask for coloured layouts and check all images and potential branding elements during the review process.

PENALTY: Immediate withdrawal of PAAB approval. AstraZeneca must show proof of retrieval of all existing stock from representatives and destruction

OUTCOME: AstraZeneca confirmed notification of sales representatives to return all existing copies of this APS. A reconciliation of materials shipped versus the quantity returned and destroyed was conducted.

2. ADVERTISER: Ortho Biotech

COMPLAINANT: Amgen

SUBJECT: c04-15 Eprex (epoetin) Product Monograph on web-site

PRECLEARANCE: No

ALLEGATIONS: Ortho Biotech has displayed an older version of a Product Monograph despite a newer version that included additional safety information which had been approved by Health Canada. Also, several Dear Healthcare Provider letters had been issued about these safety information additions.

PAAB DECISION: This being perceived as both a Direct-to-Consumer issue and a potential patient safety issue the complaint was referred to Health Canada for consideration.

OUTCOME: No response received from Health Canada as yet.

3. ADVERTISER: Stiefel

COMPLAINANT: Dermik

SUBJECT: c04-26 Clindoxyl sample package and detail aids

PRECLEARANCE: No

ALLEGATIONS: Improper labeling on samples regarding storage conditions for Clindoxyl samples. Detail material did not conform to storage conditions in Health Canada approved product monograph.

PAAB DECISION: Labeling issues are not covered by the PAAB Code and thus, no decision made on that allegation. Stiefel had responded prior to the Commissioner's decision indicating that they had addressed the timing of distribution issue raised by Dermik by applying stickers with appropriate "use before" dates.

PENALTY: None because issue was resolved prior to the Commissioner's decision.

OUTCOME: No further action required.

4. ADVERTISER: Merck Frosst

COMPLAINANT: Procter & Gamble

SUBJECT: c04-14 various promotional APS

PRECLEARANCE: Yes in 2003/2004

ALLEGATIONS: Use of a clinical paper in a misleading manner

PAAB DECISION: Material was potentially misleading because use of "superior efficacy" claim in a headline and lack of appropriate disclaimers regarding the studies limitations. Paper could be distributed as a whole.

PENALTY: Immediate withdrawal of PAAB clearance.

OUTCOME: Merck Frosst agreed with the ruling.

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

For information or if you have comments:

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