PHARMACEUTICAL ADVERTISING ADVISORY BOARD

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

November 4, 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**.

CODE REVIEW PROGRESS

On September 2, 2004, the PAAB Commissioner sent a draft revision based on the cover-to-cover review of the PAAB Code of Advertising Acceptance by the PAAB Code Review Committee. 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 draft was written based on the results of a e-survey that 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

LOOK INSIDE

received by the deadline of May 14, 2004.

The revisions focussed on areas that have come to the attention of the PAAB for review e.g scope, CME exemption, evidence, internet, DTCARx, and others. The Code Committee reviewed and analyzed the responses and agreed on recommendations for a revised Code. The deadline for the Board member organizations to respond is October 20, 2004 to allow time for analysis of the comments by the Code review committee. The Commissioner is hoping that a final draft will be ready for approval at the December 3 General Meeting.

COMMUNICATIONS PROJECT

Based on a recommendation resulting from the strategic planning initiative during 2003, the PAAB has engaged Healthworld and Hill and Knowlton to conduct an advertising and public relations campaign directed at physicians to create more awareness of the value-added service that the PAAB provides to pharmaceutical advertisers. The goal is to help physicians become aware of the PAAB and appreciate pharmaceutical advertising that bears the PAAB logo.

Advertisements telling doctors about the PAAB preclearance review service will appear in most Canadian medical journals during October to November. Also, the PAAB is endeavoring to help publishers carry articles about the PAAB and the ongoing review of the Code of Advertising Acceptance.

If you see components of the campaign, please share your opinion with the PAAB Commissioner at commish@paab.ca.

The Board will decide if they want to continue the campaign into 2005 at the December 3, 2004 General Meeting.

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 future 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.

REVIEW ACTIVITY

During the period of July 1to September 30, 2004, the total number of first review submissions reviewed was 915. This compared to 866 during the same period of 2003, a 6%

increase. From January 1 to September 30, 2004 there were 2799 first reviews compared to 2678 during the same period in 2003.

During the third quarter of 2004, 26% of the submissions were given a first review response in five days or less and 74% were given a first review response in 10 days or less. Year to date shows 31% in five days or less, 59% in ten days or less and 10% have exceeded ten working days.

PRE-NOC REVIEWS

The Commissioner reminds some companies not to abuse the pre-NOC policy that is designed to help advertisers at launch time. Please ensure that the company's medical regulatory has signed off on materials that are sent for review. You can see the PAAB pre-NOC review policy on the PAAB web-site www.paab.ca.

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: July 1 to September30, 2004

During the period of July 1 to September 30, 2004, the PAAB Commissioner processed 3 **Stage 2 complaints**. PAAB reviewed 915 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 6 notices of violation in the third quarter. One case was sent directly to Health Canada because they involved allegations regarding Direct-to-Consumer drug advertising.

STAGE TWO DECISIONS

1.

ADVERTISER: Apotex Inc.

COMPLAINANT: AstraZeneca Canada

SUBJECT: c04-11 Apo-Omeprazole letter and price comparison chart sent to pharmacists

PRECLEARANCE: No

ALLEGATIONS: Misleading comparative information because "… these promotional pieces clearly (and erroneously) state the Apo-Omeprazole can be used as an 'equivalent' to Losec tablets" and "Health Canada has not deemed Apo-Omeprazole bioequivalent to any formulation of Losec, or any other specific product on the Canadian market." and "… a review of the approved product monograph for Apo-Omeprazole, appears to confirm that Health Canada has not declared bioequivalence for this product with any form of Losec …".

PAAB DECISION: PAAB received confirmation from Health Canada that there was no established bioequivalence between Apo-Omeprazole capsules and Losec tablets. Agreed with AstraZeneca that the material violated PAAB Code sections 6.2 (requirement for PAAB review), 2.1 (inaccurate and misleading), 5.13 (no established equivalence.

PENALTY: Correction letter to the same audience as the original mailing signed by President Jack Kay.

OUTCOME: Apotex did not respond to the PAAB request. In accordance with Health Canada policy, the PAAB Commissioner filed a formal complaint with Health Canada on July 16, 2004 asking them to conduct an investigation regarding the alleged misleading claims and unfair attack on a competitor. At the time of publishing no notice of action by Health Canada has been received by the PAAB.

2.

ADVERTISER: Apotex Inc.

COMPLAINANT: AstraZeneca Canada

SUBJECT: c04-17 Apo-Omeprazole Journal ad in March 2004 *Pharmacy Practice*

PRECLEARANCE: No

ALLEGATIONS: See #1 c04-11 above and allegations of unfair attack against AstraZeneca.

PAAB DECISION: PAAB received confirmation from Health Canada that there was no established bioequivalence between Apo-Omeprazole capsules and Losec tablets. Agreed with AstraZeneca that the material violated PAAB Code sections 6.2 (requirement for PAAB review), 2.1 (inaccurate and misleading), 5.13 (no established equivalence.

PENALTY: See #1 above.

OUTCOME: Apotex did not respond to the PAAB request. In accordance with Health Canada policy, the PAAB Commissioner filed a formal complaint with Health Canada on July 16, 2004 asking them to conduct an investigation regarding the alleged misleading claims and unfair attack on a competitor. At the time of publishing no notice of action by Health Canada has been received by the PAAB.

3.

ADVERTISER: Wyeth

COMPLAINANT: Janssen-Ortho

SUBJECT: c04-36 Alesse Brochure "Birth Control Your Up-to-date Guide to the Variety of Options" with information directed to patients along with physician counseling.

PRECLEARANCE: Yes

ALLEGATIONS: 1. Misleading Chart – absolute percentages and ranges are used for various options and have a potential to mislead, the order implies rank and the graphic depiction is

misleading because the visual depiction and ordering is arbitrary and false. Efficacy data is not consistent with the product monograph

2. Graphics in this patient counseling brochure are the same as those for Alesse promotion. This item was approved as objective "editorial" in nature and not promotion for Alesse.

3. Misleading and Derogatory Statement – "if used correctly, each patch needs to be replaced on a weekly basis". A similar statement could apply to all of the stated options and it only appears in the section re the patch.

PAAB DECISION:

Agree with JOI that the visual depiction suggested a ranking system that was not valid and, thus, potentially misleading. Efficacy data was derived from a well-recognized consensus document and the data were not inconsistent with the respective product monographs.

Agree with JOI that the editorial consumer/health professional brochure should not contain promotional elements such as colours, graphics and icons used in product promotional pieces.

Agree that in this context the statement "if used correctly …" appears to be singling out problematic use issues for the patch when the statement should apply to all options.

PENALTY: PAAB withdraws acceptance of the clearance of this APS. Cease distribution and notify the field representatives to stop distributing the brochures and send back retrieved copies. Existing stock should be destroyed.

OUTCOME: Wyeth complied with 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.

For information or if you have comments:

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