PHARMACEUTICAL ADVERTISING ADVISORY BOARD JANUARY 2005

PAAB REVIEW

Year 2005 marks the 29th 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

January 27, 2005 – Executive Committee

April 22, 2005 – Annual/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 link to a pharma company sponsor and the appearance that it is promoting the sale of the sponsor's product(s).

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 REVISION

On December 3, 2004 the PAAB approved revisions to the PAAB Code of Advertising Acceptance. **Implementation of the new revisions will be April 1, 2005.**

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 received and analyzed by the Code Review Committee.

Two task forces were created to review two outstanding issues. One task force will look at the format and content requirements in the Code for prescribing information and fair

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balance. The other task force will look at the PAAB Code scope particularly with respect to nonprescription drugs and natural healthcare products.

The Code is available on the PAAB web-site www.paab.ca.

PROMOTION VS SAFETY INFO

Our goal is to provide advice on when healthcare product companies should send their material to the PAAB for review or whether they should consult Health Canada directly. If you believe that your company has to send a message about product safety to either health professionals or the general public, you should send the letter, print message or broadcast message to Health Canada. They will assist you in putting out a clear and meaningful safety message. All other product-focussed messages would be promotional in nature and they should be sent to the PAAB for review.

We have seen examples of companies distributing promotional messages that they called safety messages, and they consulted neither Health Canada nor the PAAB. I consider that to be deceptive and unethical. Health Canada intervened in a prescription product promotional campaign in a national newspaper and the PAAB could have prevented that intervention had we been given the chance to review that advertisement. The result is more distrust of that company and the pharmaceutical industry as a whole. One company argued that they didn't have time to wait for the PAAB review. Companies shouldn't be in such a hurry to break the law. In fact, we have expedited reviews of messages that we believed were in the best interest of the target audience to get them sooner rather than later. All we are saying, is give PAAB a chance.

COMMUNICATION PROJECT

As mentioned in the October 2005 PAAB Review 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 continue to appear in most Canadian medical journals during 2005. Also, the PAAB is seeking the help of publishers to carry articles about the PAAB and the Code of Advertising Acceptance.

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

PAAB TRAINING INITIATIVE 2005

The PAAB is partnering with Pharmahorizons to continue a training project 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. We will be adding content regarding the April 1 revisions to the PAAB Code. The next offering of this workshop will be in Montreal and Toronto in April or May 2005, dates to set. 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 October 1to December 31, 2004, the total number of first review submissions reviewed was 1116. This compared to 1078 during the same period of 2003, a 3.5% increase. From January 1 to December 31, 2004 there were 3915 first reviews compared to 3756 during the same period in 2003, a 4% increase. To handle the steady workload, the PAAB added a Reviewer in April 2004.

During the third quarter of 2004, 22% of the submissions were given a first review response in five days or less and 78% were given a first review response in 10 days or less. Year to date shows 28% in five days or less, 64% in ten days or less and 7% have exceeded ten working days.

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 December 31, 2004

During the period of October 1 to December 31, 2004, the PAAB Commissioner processed 2 **Stage 2 complaints**. PAAB reviewed 1116 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 fourth quarter. Four cases were sent directly to Health Canada because they involved allegations regarding Direct-to-Consumer drug advertising and 1 case for noncompliance with the PAAB Code.

STAGE TWO DECISIONS

Update on Complaints c04-11 & 17

In the October *PAAB Review* we reported on two complaints versus Apotex Apo-omeprazole APS. Subsequent to the PAAB sending the complaints to Health Canada, we received correspondence from Health Canada indicating that they had notified AstraZeneca and Apotex that both companies should stop advertising their products stating bioequivalence of Losec tablets to Losec capsules and the bioequivalence of Apo-omeprazole capsules to Losec.

1.

ADVERTISER: GlaxoSmithKline

COMPLAINANT: AstraZeneca

SUBJECT: Advertorial "Taking Control: A Continuing Series on Issues in Asthma #1 Is symptom-free asthma a realistic goal?

PRECLEARANCE: Yes JAE49835

ALLEGATIONS: Alleges misleading conclusion "It means the goal of total control of asthma symptoms may be within reach for many." Also alleges "Total Control is a defined term in the study. It is not a proven treatment strategy." and other allegations relating to use of data.

PAAB DECISION: Rejected. We note that none of the data cited by AstraZeneca actually appeared in the advertorial. The term "total control" is defined and is not used in the context of a product claim. The advertorial's objective was to increase physicians' awareness about the current status of asthma management in Canada and to raise awareness regarding the standard care of patients. The advertorial informs readers that following asthma guidelines could provide better overall disease control.

PENALTY: $500 fee assessed to AstraZeneca.

OUTCOME: No action required of GSK.

2.

ADVERTISER: GlaxoSmithKline

COMPLAINANT: AstraZeneca

SUBJECT: Invitation to Meeting

PRECLEARANCE: No

ALLEGATIONS: Invitation to CHE meeting makes promotional claims and was not precleared by the PAAB.

PAAB DECISION: Rejected. The PAAB Code of Advertising Acceptance does not have a requirement to preclear promotional meetings and the invitations are deemed to be part of the meeting. The Commissioner remarked that GSK was remiss in that the meeting was called a CHE event and yet it was not accredited CHE. This complaint should be directed to Rx&D as the activity may be in violation of the Rx&D Code of Conduct.

CONTACT INFORMATION

For information or if you have comments:

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