Pharmaceutical Advertising Advisory Board **April 2003**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
FIRST QUARTER OF 2003

Year 2003 marks the 27th 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

June 23, 2003 – Executive Committee
November 14, 2003 – General Meeting

What is drug "advertising" ?

This is a reminder that 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.

Pre-Launch Review Policy

Check the PAAB web-site for a revised administrative policy regarding review of APS prior to a product launch.

PAAB CODE REVISION

On January 17, 2003 the PAAB members approved the following PAAB Code revisions, effective immediately.

Code Section 5.9 Analysis of data
To be considered as evidence, results must achieve the statistical significance level of $p<0.05$, which can also be stated in terms of 95% confidence intervals. Failure of study results to demonstrate a statistically significant difference in the measured effect is not sufficient to support a claim of equivalence between the treatments studied.

9.4.5 Options facing complainant
When the complainant receives a response from the advertiser, the complainant may wish to assess whether to: continue discussion with the advertiser, possibly by writing another letter narrowing the points of dispute; accept the advertiser's response and therefore not pursue the complaint; or conclude that further intercompany dialogue will not be productive and therefore seek review by the PAAB Commissioner in Stage 2. The complainant should send a letter of intent to proceed to stage two. The letter should be received by the Commissioner within 10 working days of the date of receipt of the advertiser's Stage

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1 response by the complainant. The Stage 2 allegations should be clearly stated. Failure to comply with this section will result in the Commissioner voiding the complaint. If the complainant requests action after the ten working day deadline, they may file a new Stage 1 complaint.

9.5.4 Registration of complaint
In order for a complaint to pass to Stage 2, the complaint must be registered. Under Section 9.5, complainants other than from pharmaceutical companies are not liable to pay registration fees. If the advertiser does not respond by 10 working days after receipt of the complaint, registration is deemed to occur on the subsequent working day. If the advertiser does respond within 10 working days, the complainant may request registration by notifying the Commissioner. The complainant should send a letter of intent to proceed to stage two. The letter should be received by the Commissioner within 10 working days of the date of receipt of the advertiser's Stage 1 response by the complainant. The Stage 2 allegations should be clearly stated. Failure to comply with this section will result in the Commissioner voiding the complaint. If the complainant requests action after the ten working day deadline, they may file a new Stage 1 complaint.

Get DTCRx 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 January 1 to March 31, 2003, the total number of first review submissions reviewed was 914. This compared to 793 during the same period of 2002, a 15% increase.

During the first quarter of 2003, 37% of the submissions were given a first review response in five days or less and 97% were given a first review response in 10 days or less. The Reviewers faced a workload more weighted towards detail material at 46%. Next highest was service vehicles, including patient information, at 18%.

Challenge Offers Web-based Learning Opportunity for Industry Marketers and Managers

The Pharmahorizons Case Study Challenge offers an exciting development opportunity for life science professionals in the pharmaceutical, biotechnology, healthcare, medical device, and pharmaceutical sectors. In the Challenge, participants compete by analyzing realistic business cases and solving difficult workplace situations. Check out the Pharmahorizons site at www.pharmahorizons.com

In the innovation web-based Challenge, life science professionals work together on realistic business cases in marketing, business development, regulatory affairs, human resources, sales, and sales management. Participants compete against Challenge teams from other companies and with teams within their own company. A case will include PAAB Code issues.

Last year, a number of Challenge teams, representing 11 major pharmaceutical companies, competed and learned together. This year, the Challenge includes two streams, a Challenge for life science managers, and a Challenge for sales representatives in the life sciences. The Challenge cases are also available in French and English.

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, 2003

During the period of January 1 to March 31, 2003, the PAAB Commissioner processed 2 **Stage 2 complaints** and **1 Stage 3 complaint**. PAAB reviewed 842 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 12 notice of violation letters in the first quarter. Three cases were sent to Health Canada.

STAGE THREE DECISIONS

1.

ADVERTISER: Amgen

COMPLAINANT: Janssen-Ortho

SUBJECT: Letter to Physicians

PRECLEARANCE: No

PAAB STAGE TWO DECISION THAT WAS APPEALED:

Amgen sent a letter to Canadian physicians with comparative information about Eprex (epoetin alfa) and Aranesp re Pure Red Cell Aplasia. In the opinion of the PAAB Commissioner, statements about Aranesp were not consistent with the Product Monograph and the letter had elements of an unfair comparison to Eprex. The letter was promotional and should have been precleared by the PAAB.

INDEPENDENT PANEL DECISION:

Amgen should send a correction letter prior to January 31, 2003 to the same target audience as the original message. The letter should mention that the original letter was deemed to be promotional in nature by Health Canada and the PAAB. The letter should also address the alleged misleading statements that were stated in the Health Canada letter to Amgen. Health Canada should approve the letter prior to distribution and the PAAB should be copied. Therefore, Health Canada would be responsible for enforcing the correction letter penalty. The panel assessed costs of the hearing and a $2,500 fine to Amgen. Amgen should also provide the PAAB Commissioner with a copy of their standard operating procedure (SOP) that deals with advertising and the PAAB Commissioner should be satisfied with the content of the SOP.

OUTCOME: As of March 31, 2003, the PAAB had not received a copy of the correction letter. The fine was paid and PAAB approved of the Amgen SOP for advertising review.

STAGE TWO DECISIONS

1.

ADVERTISER: Sanofi-Synthelabo

COMPLAINANT: Private Physician

SUBJECT: Medi-View Express Report "Evolving Concepts in the Treatment and Management of Benign Prostatic Hyperplasia"

PRECLEARANCE: No

ALLEGATIONS: The physician alleged the piece was "advertising" because it was not objective and balanced and it appeared to promote the sale of

the single sponsor Sanofi-Synthelabo's product Xatral (alfuzosin). Thus, it should have been precleared by the PAAB and be presented as advertising.

PAAB DECISION: Agree with complainant. A high proportion of the commentary was about alfuzosin and the Summary section spoke only about alfuzosin by name.

PENALTY: Cease distribution of this APS and if future distribution is desired the company should clearly mark the item as "advertising" and send it to the PAAB for preclearance review.

OUTCOME: Sanofi-Synthelabo agreed to comply with the PAAB decision.

2.

ADVERTISER: Bristol-Myers Squibb

COMPLAINANT: Novartis

SUBJECT: Detail Aid using a clinical reprint as a reference (*Mancia et al, Blood Pressure Monitoring 2002; 7:135-142*) comparing Novartis Diovan (valsartan) with Bristol-Myers Squibb Avapro irbesartan)

PRECLEARANCE: Yes

ALLEGATIONS:

1. The graphics and headline "a recent major study … sheds new light on an important clinical issue" convey the thought that the Mancia study represented a "breakthrough" in therapeutic knowledge and no other studies exist to support that degree of importance.
2. Similar to the first allegation.
3. The partial results from Mancia et al that support this claim should be balanced with prominent copy.
4. The Mancia et al study is in direct violation of PAAB Code sections 5.4, 5.7, 5.8, and 5.9 because differences in blood pressure measurements between Avapro and Diovan did not fall within the requirements for statistical significance specified in the study design. Novartis provided a commissioned statistical analysis.
5. Sample sizes were misrepresented violating s4.1.

PAAB DECISION:

Although the nature of the complaint was not perceived to be overtly misleading, the PAAB agreed with allegations 1 and 2. Calling the Mancia et al study a "major" study in advertising was an overstatement although the topic was an important clinical issue. Agreed with allegation 5 and that was a printing error. Disagreed with allegation 3 that the APS required further balancing and disagreed with allegation 4 in that the study was peer reviewed and published and appeared to be adequately controlled, blinded and randomized.

PENALTY: BMS should cease distribution of this APS and others of similar nature and retrieve where possible any previously distributed copies.

OUTCOME: BMS agreed to destroy remaining inventory and to send a letter to the sales force to destroy all remaining copies and not to distribute it in the future.

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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