Pharmaceutical Advertising Advisory Board **July 2003**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
SECOND QUARTER OF 2003

Year 2003 marks the 27th operating 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 6, 2003 – Executive Committee

November 29, 2003 – Directors 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. Most violations of the regulations occur because companies are compiling "hybrid" pieces that combine two different regulatory categories e.g. a help-seeking ad and a consumer brochure.

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.

Strategic Planning Update

On June 23, 2003, the PAAB Executive Committee reviewed the reports from the four task groups that were created during the strategic planning initiative. See next page for an update.

LOOK INSIDE

Task Group #1 - Health Canada Relationship

This group had directed Commissioner Chepesiuk to join with Advertising Standards Canada to request that the two organizations meet together with Health Canada officials on a regular basis to discuss issues related to drug advertising. Assistant Deputy Minister Diane Gorman has responded by inviting the two organizations to submit agenda items for a meeting later in 2003. These meetings are seen as a good mechanism to improve communications between the PAAB and Health Canada.

Task Group #2 - Review Consistency

During PAAB client focus group discussions in October 2002, one of the topics identified as important was PAAB review inconsistencies. This group had asked AMAA members to send written examples of PAAB review inconsistencies to the task group. The goal was to analyze the examples and to look for patterns of inconsistency that could be addressed by the PAAB commissioner. Two written examples were received after an extended deadline. The task group also reviewed the quality assurance procedures for reviewers that have been in place since 1999. The Executive Committee decided that no immediate action was necessary and directed the Commissioner to be vigilant about identifying and handling examples related to review inconsistency. The Executive Committee would revisit this issue at the November 6, 2003 Executive Committee meeting.

Task Groups # 3 - Communications Plan

This group had made progress in identifying important PAAB stakeholder groups and a need to help influence the political process regarding drug advertising issues. There was emphasis on a need for making the meaning of the PAAB logo more apparent to healthcare professionals, especially physicians. The group suggested creation of a process to make the PAAB logo recognized as a "trustmark". Research had been carried out on non-profit organizations that had successfully created branding of their organization or programs developed by that organization. The group also suggested a need for a review of the PAAB members to ensure consistency in the PAAB mandate and an ability to reach its goals without internal conflict. The group suggested a targeted marketing plan aimed at stakeholders. The group also suggested that PAAB support the Board delegates so that they could represent the work of the PAAB to their constituents.

Task Group #4 –Stakeholder Relations

This group is looking at ways to engage greater stakeholder support in efforts to strengthen the PAAB, both in ongoing operations and for future issues such as emerging advertising. The group suggested in the short term to: developing a new professional message as to PAAB's role that would be flexible for various audiences; development of a communications plan; development of a polling mechanism to get feedback from stakeholders; develop a databank of important stakeholders. The group suggested in the long term to: develop a brochure about the PAAB for distribution to physicians by pharmaceutical company representatives during their visits to physicians; develop industry training workshops; evaluate the need and costs for re-vamping the PAAB web-site to provide more interactivity.

Executive Committee Summary

The Executive Committee was pleased with progress made to date by the task groups. It was decided that task groups #3 and #4 would be merged at least on a temporary basis to discuss several overlapping issues.

New PAAB Training Initiative

The PAAB Executive Committee has accepted a proposal from Pharmahorizons to partner in the creation of several mechanisms to provide pharmaceutical industry personnel with training regarding the PAAB Code of Advertising Acceptance. The goal is to teach the application of the PAAB code 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 anticipated: PAAB workshops, Internet interactive learning and PAAB staff participation in other Pharmahorizons training courses for new marketing personnel. The first offering of this workshop is expected to be in early 2004. You can contact the PAAB Commissioner or Pharmahorizons (1-888-514-5858) for more information.

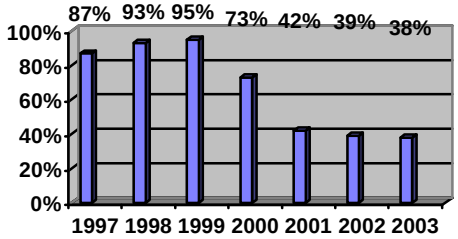
Review Activity

During the period of April 1 to June 30, 2003, the total number of first review submissions reviewed was 894. This compared to 786 during the same period of 2002.

In the first six months of 2003, the total number of submissions reviewed was 1810 compared to the 2002 total of 1579 for the same period. This was the highest submission review volume for the first half of a year in the 26 year history of the PAAB.

During the second quarter of 2003, despite the unusually heavy workload, 39% of the submissions were given a first review response in five days or less and 99% were given a first review response in 10 days or less. For the first six months of 2003, the turnaround to first review in five days or less was 38% and 98% in ten days or less. The Reviewers faced a workload more weighted towards detail material (42%). Slowing down the process was the fact that some clients were inconsistent in the submission of material, submitting material that had been previously rejected by the PAAB or that had insufficient regulatory or scientific support. The element of trust from the PAAB reviewers diminishes when this occurs.

Share of ads with first review in 1- 5 days



COMPLAINTS / MONITORING

PROCESS

Complaints against Advertising/Promotion Systems (APS) may be lodged by: health professionals, healthcare 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 from individuals named by national organizations.*

PAAB COMPLAINT REPORT

Period: April 1, 2003 to June 30, 2003

During the period of April 1, 2003 to June 30, 2003 the PAAB Commissioner processed 4 **Stage 2 complaints**. PAAB reviewed 894 advertising pieces during the same period. This number brings the stage two complaint total for 2003 to 6 (1810 product advertising reviews).

Of the 4 complaints, 3 were generated from advertising that had been previously PAAB-reviewed and 1 complaint was sustained. The 1 complaint on advertising that was not PAAB-approved was sustained.

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 13 notice of violation letters in the second quarter bringing the total for the year to 25. Seven cases were sent to Health Canada re Direct-to-Consumer or natural health product advertising.

STAGE TWO DECISIONS

1.
ADVERTISER: Wyeth-Ayerst

COMPLAINANT: GlaxoSmithKline

SUBJECT: textbook and reference card c03-08

PRECLEARANCE: No

ALLEGATIONS: Alleged that both the textbook "The Psychotropic Handbook: Second Edition" and a reference card "CYP 450 Drug Interactions Amongst Newer Antidepressants" were subject to PAAB review with regard to PAAB Code section 1.

PAAB DECISION: The textbook was not considered to be advertising because it was objective information that was created by a third party and the pharma company had no influence on the final version. Rejected. The allegation about the card was sustained because the author was commissioned directly by Wyeth-Ayerst to produce the intended content. It was also seen as potentially misleading because there was no information about "drug interactions" just comparative CYP450 enzyme activity for various drugs and a direct clinical correlation had not been established for the individual listings.

PENALTY: Wyeth-Ayerst was to cease distribution immediately and show an action plan that included recall of the information by the sales representatives where possible. Future use of such a card would require PAAB preclearance review.

OUTCOME: Wyeth-Ayerst complied with the request.

2.
ADVERTISER: Novartis

COMPLAINANT: GlaxoSmithKline

SUBJECT: Famvir (famcyclovir**)**Dose Card c03-12

PRECLEARANCE: yes DAC43578 in December 2002

ALLEGATIONS: Allegation #1

Claim: "As with other drugs of this class, in patients with moderately or severely reduced renal function …"

Allegation #2

Claim: "Demonstrated FAST RELIEF of zoster pain" and Relieve patients' chronic pain (PHN)"

Allegation #3

Dosing Chart: "The lack of cross-referencing to dosage adjustments in renal impairment does not reflect an attitude of caution". The precautionary statement appears in the footnote, in the same paragraph as the adverse event statement and is on a page separate from the dosing chart. We find that the placement of this statement contravenes PAAB Code 2.4 in not reflecting an attitude of caution and not allowing enough prominence for this important safety information."

Allegation #4

Claim: Dosing Chart: 'Cold sores and GH in HIV patients"

PAAB DECISION: #1. This wording was approved by the PAAB as far back as April 2000 in a Famvir APS (JAC35925) sent by SmithKineBeecham to the PAAB for preclearance review. It was not deemed to be misleading by SKB then and I see no reason why it is misleading now. The Product Monograph for both Valtrex and Zovirax note dosage adjustment is required for renal dysfunction. Allegation of violation of s5.5, 5.6, 5.10 rejected.

#2. We believe that the Famvir product monograph statement "Early treatment resulted in decreased duration of Post Herpetic Neuralgia" implies relief and that the time period relative to the claim "fast" is clearly stated. We do not see this claim as misleading. Allegation of violation of s2.1 and 3.1 is rejected.

#3. The precaution is clearly stated in the APS n a manner similar to most APS approved by the PAAB. Therefore, I do not find it to be misleading. The safety balance could be improved by the addition of a precautionary statement in close proximity to the dosing chart. We encourage Novartis to do that in future APS and I will inform the PAAB reviewers.

#4. We believe that a cold sore can be due to a mucotaneous herpes simplex infection and therefore would fall under the Health Canada approved

indication. The clinical trials in the product monograph included patients with orogenital or orolabial lesions and that would fall under Genital Herpes and cold sores respectively. Allegation of violation of s3.1 rejected.

PENALTY: rejected 3 of the 4 allegations and agreed that a minor revision in future APS could improve the clarity of the dosing chart with respect to safety balance. Therefore, no further action from Novartis regarding this detail aid is required. Administration fee of $500 assessed to GlaxoSmithKline.

OUTCOME: Agreement by all parties.

3.
ADVERTISER: AstraZeneca

COMPLAINANT: Janssen-Ortho

SUBJECT: Nexium (esomeprazole) journal ad

PRECLEARANCE: Yes c03-13

ALLEGATIONS: #1. The claims "Nexium has demonstrated superior acid suppression beyond all PPIs" and "Nexium demonstrated superior intragastric pH control" are no longer valid because a new agent Pariet (rabeprazole) has entered the market and has not been tested against.

#2. The statement "Current clinical guidelines recommend that patients be managed empirically using the most effective acid suppression first. Nexium 40 mg o.d. is superior in acid suppression to Nexium 20 mg o.d." Presenting clinical data in this manner is misleading and ambiguous and out of context with the conclusions of the authors.

PAAB DECISION: #1. Sustained. The statement was valid when the advertisement was approved by the PAAB. However, the marketplace has changed and the claim has not been proven versus all available agents.

#2. Rejected. When used together the two statements are valid and are not misleading.

PENALTY: Cease distribution of any material that contain the potentially misleading comparison.

OUTCOME: AstraZeneca agreed with the ruling and revised the journal ad.

4.
ADVERTISER: Solvay

COMPLAINANT: Janssen-Ortho

SUBJECT: Pantoloc (pantoprazole**)** Detail Aid c03-14

PRECLEARANCE: Yes

ALLEGATIONS: #1. "Solvay Pharma has presented Pantoloc data that is misleading and out of context with what the authors intended …"

#2. "A PPI price comparison table presented in this APS is misleading as it does not accurately reflect the common alternatives, and does not represent common practice in the Canadian market place. Therefore, the APS is not thorough and complete."

#3 "Page 10 of the Pantoloc APS states that Pantoloc still has no known metabolic drug interactions." What is the source for making this claim? No data source is provided."

PAAB DECISION: #1. Rejected. The data in this presentation have been used in Pantoloc APS since 2001. The presentation format has evolved and this presentation, while not overtly misleading, could be improved for future APS. No immediate action required.

#2. Sustained. The Pariet (rabeprazole) 2x10 mg dose is recognized by provincial formularies and therefore is relevant to prescribers and should be included in the price comparison.

#3. Rejected. The statement is valid and based on the current product monograph and Solvay ADR reporting system.

PENALTY: Immediately cease distribution of material that omits the price for the 2x10 mg dose option. Future APS with price comparisons should include mention of the Pariet 2x10 mg dose option.

OUTCOME: Agreed. Solvay added a sticker showing the Pariet 2x10 mg dose option on existing material.

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

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*

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