PAAB REVIEW

OCTOBER 2006

Year 2006 marks the 30th 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 / EVENTS

October 24 PAAB Workshop Montreal
October 25 PAAB Workshop Toronto
October 27, 2006 - Executive Committee Meeting
November 24, 2006 - General Meeting

FAIR BALANCE CODE CHANGE

The PAAB sent a consultation survey to over 440 organizations and individuals regarding a proposal to change section 7 and some other sections regarding the prescribing information and fair balance requirements in the PAAB Code of Advertising Acceptance. The deadline for responses was September 15, 2006. What follows is a repeat of a message we put in the July PAAB Review and I thought it would be useful to PAAB stakeholders to see the whole process again and where we are heading. The PAAB board members have chosen a new format for the provision of fair balance information and prescribing information that accompanies healthcare product advertising to health professionals. Committee Chair Gloria Bowes will bring the proposed wording to the Board for a vote on November 24, 2006, with planned implementation during 2007, TBD.

And now a little bit of history. Impetus for this initiative came from a few industry and advertising executives who told Commissioner Chepesiuk that there should be a better way to provide fair balance information in advertising. As chair of the Code Revision committee he included the topic as part of the broad stakeholder consultation to determine what in the code required revision.

In May 2004, when it became apparent that the Code Committee required a lot more work to be done on this topic, the PAAB struck a task force to study the fair balance/prescribing information requirements of the PAAB Code of Advertising Acceptance. PAAB chose Paul Hickey as the chair and he was "... charged with the task of improving the quality of pharmaceutical communication (both content and format) across all major types of media, starting with the most high profile medium, medical journal advertising."

Stage one consisted of defining the problem and identifying a definition of medical journal advertising. This was done by committee members Praveen Chawla (NDMAC), Ron Weingust (CGPA), Elgin Cameron (Rx&D), Gloria Bowes (CAMP), Dr. Jeff Blackmer (CMA) and Paul Hickey (AMAA). It was agreed that it was very difficult to do a one page journal advertisement that included all of the fair balance information the PAAB Code required, and that the current format of the PI was almost useless. During this period, the Canadian Association of Medical Publishers conducted research involving 48 physicians in 6 centers across Canada to assess what was important to physicians regarding the prescribing information. They ranked the different sections for importance to them. An important finding was that physicians said they "referred" to the PI rather than "reading" it. So, the committee agreed that revising it to be a better reference document would be a good thing.

A group consisting of two PAAB Directors, Paul Hickey and Gloria Bowes and two creative consultants, Gord Schwab and Rob Vosburgh developed format options. These options were assessed and narrowed down to one. The next step was consultation and refinement through a group consisting of Paul, Gloria, Gord joined by Ray Chepesiuk and John Wong of the PAAB staff. To refine the chosen format, they sought stakeholder input through CAMP, AMAA, Procter &

LOOK INSIDE

Gamble Pharmaceuticals Regulatory department, Bristol-Myers Squibb Regulatory department and the Allergan Pharmaceuticals Regulatory department.

Then, a committee of Paul Hickey and Ray Chepesiuk evaluated RFP bids from 3 market research firms and chose Ipsos Camelford Graham because of the unique approach they offered to reach 100 physicians within the approved budget.

The survey results were convincing in that 93% of physicians surveyed thought the new format should be the standard. 98% thought it was much improved or slightly improved. In April 2006 the PAAB Directors commissioned Gloria Bowes to bring a proposal for a code revision to the Board for a November vote.

The PAAB stakeholders have helped refine the Code wording through the consultation. A clear majority (75-90%) thought the change was an improvement, provided clarity as to what was required of advertisers and presented the safety information in a useful manner.

NEW STAFF

The PAAB welcomes two new permanent full time staff members.Ellen Fan as the latest addition to the PAAB Reviewer staff. Ellen is a licensed pharmacist and has experience in community pharmacy and in a provincial drug information centre. She is also an accomplished author and has had numerous articles published.

Sabrina Hack has joined us full time as an assistant submissions coordinator. Sabrina is experienced in office administrative work and has been at the PAAB office in a part-time position since last year.

The two new positions have been created to help handle the growing volume the PAAB has faced for six consecutive years. Chief Review Officer John Wong supervises 8 reviewers and Office Manager Glenn Golaz supervises 3 administrative staff.

PAAB WORKSHOPS

The PAAB will continue its training project regarding the PAAB Code of Advertising Acceptance with the assistance of Pharmahorizons. The goal is to teach the application of the PAAB Code primarily to new pharmaceutical industry employees and provide a refresher for experienced personnel.
Pharmahorizons will provide professional logistical support while the PAAB staff will provide and maintain control of all content. The next offering of this case-study approach workshop will be in Montreal October 24 and in Toronto October 25, 2006. You can contact Pharmahorizons (1-888-514-5858) for registration and information about future workshops.

ADVISORY NOTICE

On July 29, 2006 the commissioner sent the following written notice:

NOTICE OF PAAB POLICY TO:
President and Marketing Director of: Wyeth, Amgen, Astellas, BMS, Roche, Schering, Abbott, Serono

The PAAB has given a ruling on a complaint (#C06-20) to the PAAB from Serono on a Wyeth/Amgen Enbrel (etanercept) advertising/promotion system (APS). PAAB agrees with Serono that the PAAB should not accept claims of "excellent safety profile" in Enbrel advertising. After some research with a PAAB member and physician experts in this therapeutic area, with respect to s2.4 (note of caution) and s2.1 (trust, credibility) of the PAAB Code of Advertising Acceptance, I have decided that the PAAB should not accept claims of "excellent safety profile" in advertising for similar biological products in related therapeutic areas (competitive products to Enbrel). This would include but not exclusive to: Serono Raptiva (efalizumab), Wyeth/Amgen Enbrel (etanercept), Schering Remicade (infliximab), Abbott Humira (adalimumab), Astellas Amevive (alefacept), Roche Rituxan (rituximab) and BMS Orencia (abatacept).

I respectfully ask that you notify company personnel and your agencies of record of this decision.

Please note that we have extended a transition period to allow companies that have advertising with the claim of "excellent safety profile" to modify their advertising. You may see this claim in the near future. I am asking affected companies to modify their advertising pieces by the end of October 2006.

The PAAB reviewers will assist companies to get to acceptable safety claims through the regular submission review process. We are doing this policy announcement to help all companies provide credible, trustworthy advertising and to provide some order in the marketplace. If you have any questions, please call me.

Post-notes
The commissioner received full cooperation from Amgen/Wyeth and Serono and has agreed to advertising phase out schedules with those two companies.

The Health Canada liaison has supported the PAAB in their action and made a recommendation that this decision apply to all healthcare products. The commissioner advises advertisers of all health care products to refrain from using the promotional statement "excellent safety profile" unless the product monograph and a strong body of published evidence and opinion can be shown as support.

GET DTCARX ADVICE

We remind you that the PAAB will give an advisory opinion on specific projects that involve advertising or information directed at the general public. Currently, companies cannot advertise treatments of Schedule A diseases to the general public or advertise prescription drugs except for name, price, and quantity. We can assist you in interpreting Health Canada guidelines on what is advertising and what is not considered to be advertising. The 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. Health Canada has endorsed both the PAAB and Advertising Standards Canada to perform the review service based on the Health Canada guidelines. Advertisers are not required to send a particular submission to both the PAAB and ASC.

REVIEW ACTIVITY

During the period of July 1 to September 30, 2006, the total number of first review submissions reviewed was 1262. This compared to 1202 during the same period of 2005, a 5% increase.

During the first three quarters of 2006, PAAB reviewed 3870 new submissions compared to 3190 in 2005 an increase of 680 or 17.6 %. In 2006, 15 % (29% in 2005) of the submissions were given a first review response in five days or less and 85 % (92% in 2005) were given a first review response in 10 days or less. Detail material comprised 38% of the volume followed by service oriented material (including patient information) at 22%.

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 September 30, 2006

During the period of April 1 to June 30, 2006, the PAAB Commissioner processed 3 Stage 2 complaints. One complaint involved an APS with current approval by the PAAB and all three of the complaints were sustained. PAAB reviewed 1259 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 advertiser's trade association and/or Health Canada for their assessment of additional penalties. PAAB sent 7 advisory notices in the third quarter.

STAGE TWO DECISIONS

1. ADVERTISER: Biovail

COMPLAINANT: Lundbeck

SUBJECT: c06-18 Wellbutrin XL (bupropion hcl) Detail Aid

PRECLEARANCE: No

ALLEGATIONS: 9 allegations of which the commissioner agreed with Lundbeck on 5. See decision for details.

PAAB DECISION: the detail aid required PAAB review (s6.2)

Zimmerman reprint did not support a claim of "low incidence of side effects of greatest concern to patients" (s3.1, 5.5)

Use of pooled analysis to support comparative efficacy claims was not acceptable despite the fact Biovail stated they had sent the data to health Canada. There was no direct mention in the product monograph of the data. (s3.1, 5.5)

Safety comparison was not acceptable (s3.1, s2.4)

Quote from Zimmerman paper was unacceptable because there is more to consider about first-line therapy than two side effects. (s3.1, 5.5)

PENALTY: Cease and desist dissemination of the detail aid and similar materials using the Zimmerman paper. Notice of violation sent to Health Canada for investigation of safety issues.

OUTCOME: Biovail agreed to cease and desist distribution. The commissioner met with senior Biovail marketing officials to explain the violations, explore advertising potential and encourage their acceptance of the PAAB preclearance review mechanism.

2. ADVERTISER: Amgen/Wyeth

COMPLAINANT: Serono

SUBJECT: Enbrel (etanercept) Journal ad in May/June issue of Dermatology Times.

PRECLEARANCE: Yes in January 2006 as JAF55596

ALLEGATIONS: 1. Headline "an excellent combination of safety experience and efficacy to help unlock their lives" is unclear and potentially disparaging.

2. "Excellent safety profile" subheading and section is misleading (s.2.1).

3. Claim of "up to 15 months clinical experience in 1,261 patients with plaque psoriasis is not supported by the approved product monograph and is misleading (s3.1,s4.2)

PAAB DECISION: 1. Rejected. Claim is well supported by the product monographand and QOL data

Sustained. Agree that "excellent safety profile" would not apply to any of the new biologics in the RA and severe psoriasis categories. S2.4 requires a note of caution and this statement exceeds that. It was noted during the commissioner's investigation that Serono had made a similar claim for their product Raptiva. The commissioner received input from experts in the therapeutic area that this claim should not be accepted by the PAAB.

Rejected. The statement is accurate, complete and clear and consistent with the product monograph.

PENALTY: Both Amgen/Wyeth and Serono were instructed to phase out promotional material accepted by the PAAB that included the claim "excellent safety profile" Reviewers were instructed to not accept this claim in this therapeutic area and give close scrutiny in all therapeutic areas. Exceptions are perceived to be rare.

OUTCOME: Amgen/Wyeth and Serono sent action plans and schedules to remove affected promotional material from the market place by the end of 2006. The commissioner sent a letter to seven company presidents and marketing directors of biologics notifying them of this ruling (see page two of this newsletter). The PAAB Executive Committee and Health Canada indicated approval of the commissioner's action in this exceptional circumstance.

3. ADVERTISER: Boehringer-Ingelheim

COMPLAINANT: Bristol -Myers Squibb & Solvay

SUBJECT: exhibit hall poster promoting distri bution of ESPRIT trial (Aggrenox) at a promotional booth

PRECLEARANCE: No

ALLEGATIONS: 1. requires PAAB review (s6.2)

2. off label promotion because approved dose of Aggrenox (dipyridamole- ASA) was used by only 8% of patients and ASA alone arm was not within Health Canada approved dosage.

PAAB DECISION: Agreed that the poster was "advertising" promoting the sale of Aggrenox. Agreed that the dosage used in the study was primarily off label and the ESPRIT study was not contained in the Health Canada approved Terms of Market Authorization.

PENALTY: Cease and desist distribution of this paper.

OUTCOME: Boehringer Ingelheim agreed to cease and desist distribution and registered a stage 3 appeal. Vs the "off-label "decision. The commissioner engaged BOE and the complainants in an alternative dispute resolution mechanism. There was agreement to send a query to Health Canada for an opinion regarding the off label allegation and a query as to how BOE could use the ESPRIT trial paper in future advertising activities. A reply from Health Canada was not received at the time of publication of this newsletter.

CONTACT INFORMATION

For information or if you have comments:

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