PHARMACEUTICAL ADVERTISING ADVISORY BOARD January 2006

PAAB REVIEW

JULY 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

July 6, 2006 - Executive Committee Meeting

November 24, 2006 – General Meeting

30 YEARS!

PAAB celebrated its inception 30 years ago in 1976 by holding an invitational golf tournament for 100 well-wishers at Copper Creek Golf Club on May 29. It was a hot day enjoyed by all. Paul Hickey took home the low gross trophy with a score of 71 (don't play him for money). Kevin Bell took home the trophy for low net.

FAIR BALANCE CODE CHANGE

This summer, the PAAB will be conducting a consultation survey of over 400 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 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. The Board chose Vice Chair Gloria Bowes to provide leadership of the committee that will bring the proposed wording to the Board for a vote in November 2006, with planned implementation during 2007.

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

Look Inside

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 & 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.

We are looking forward to the help of the PAAB stakeholders to refine the revision.

PAAB TRAINING INITIATIVE 2006

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 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.

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 April 1 to June 30, 2006, the total number of first review submissions reviewed was 1,328. This compared to 996

during the same period of 2005, a 33% increase.

During the first half of 2006, PAAB reviewed 2607 new submissions compared to 1988 in 2005 an increase of 609 or 31%. 15% of the submissions were given a first review response in five days or less and 88% were given a first review response in 10 days or less. Detail material comprised 39% of the volume followed by service oriented material (including patient information) at 21%.

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: April1 to June 30, 2006

During the period of April 1 to June 30, 2006, the PAAB Commissioner processed 5 Stage 2 complaints. Three complaints involved an APS with current approval by the PAAB and two of the complaints were rejected. The other two complaints that did not have PAAB approval were sustained. PAAB reviewed 1328 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 2 notices of violation in the second quarter, Health Canada was notified of one potential violation of the Food & Drugs Act regarding a public web-site.

STAGE TWO DECISIONS

Update on the Outcome of c06-09 Genpharm Euthyrox (levothyroxin) registered by Abbott reported in the April 2006 PAAB Review. Genpharm agreed to cease distribution and make revisions to the claim to be reviewed and accepted by the PAAB prior to distribution to health professionals.

1.

ADVERTISER: Novartis

COMPLAINANT: Bristol Myers Squibb

SUBJECT: c06-13 Gleevec (imatinib) promotional tool to health professionals with a BRC option for doctors to give to patients to get direct access to the magazine, namely "Source" magazine vol 1, *News and*

Information about CML and associated web-site *www.cmlsource.ca*

PRECLEARANCE: No

ALLEGATIONS: Single-sponsored and promotional in nature that serves "to promote the sale of that product (imatinib) either directly or indirectly. Requires PAAB review. Various treatment options are not discussed in an objective manner. There are: emphasis on the use of Gleevec, references to unauthorized Gleevec dosage, and reference to availability of Gleevec in an unauthorized dosage through a phase III clinical trial.

PAAB DECISION: It was single-sponsored by Novartis and distributed to health professionals for further distribution to patients. Gleevec is mentioned on all but two pages and there is no objectivity in presenting other treatment options. A Novartis employee is listed on the advisory board shown in the magazine. Violations of PAAB Code sections 1, 2.4, 3.1, 3.2, 3.5, 6.4.

PENALTY: Cease and desist unsolicited distribution of this magazine. Notice of violation of s2 of the Rx&D Code of Conduct for their consideration of penalties.

OUTCOME: Novartis ceased distribution of *Source* magazine Vol 1 and associated web-site.

2.

ADVERTISER: Abbott

COMPLAINANT:Hoffmann LaRoche

SUBJECT: Meridia (sibutramine) journal ad

PRECLEARANCE: Yes as JAC55261 in December 2005

ALLEGATIONS: Use of the study "Comparison of efficacy of sibutramine or orlistat versus their combination in obese women" by Sari et al in Endocr Res 2004; 30(2):159-67 to support the claim "*Meridia patients lost almost twice as much weight as those on orlistat (10.1 kg vs. 5.5 kg, p=0.003*" is misleading in violation of PAAB Code s 3.2 and 5.5.i. because it is not representative of the literature and the Xenical (orlistat) product monograph. It is an open-label trial; sufficient details are not provided on compliance to diet especially percent fat content a critical factor given the mechanism of action of orlistat; study has a small sample size; results of this study were not reproduced; study is not placebo-controlled; statistical analysis is not presented in enough detail in the article to conclude whether the study was designed appropriately to support the implied superiority claim.

PAAB DECISION: Disagreed on 5 points with Roche that the Sari study did not meet the evidence requirements of the PAAB Code. Agree with Roche regarding unstated s3.1 and s5.5 that the results were not consistent with the data shown in the Xenical product monograph and that, in stage one, Abbott had not supported the case that the Sari results were representative of the available literature regarding the comparative weight loss of these two products.

PENALTY: Cease distribution of the ad immediately.

OUTCOME: Abbott voiced a verbal appeal to the commissioner pending agreement on a replacement claim. Discussion ongoing at the time of printing.

3.

ADVERTISER: GlaxoSmithKline

COMPLAINANT: Merck Frosst

SUBJECT: Avodart (dutasteride)

PRECLEARANCE: Yes JAF55950 in January 2006

ALLEGATIONS: 1. Misleading creative concept (s2.1, 4.2, 4.3, 5.7, 5.10, 5.12) in that the title "Updating the BPH Story" is misleading because it implies Avodart is clinically better because of its DHT suppression versus finasteride.

2. Misleading claims about dual inhibition (s2.1, 3.1, 4.2, 4.3, 5.5, 5.7, 5.10, 5.12)

PAAB DECISION: 1. Agree with GSK that the term "update" does not mean exclusively "new" or "better". Allegation rejected .

2. The claims in the advertisement are consistent or verbatim from the Health Canada approved product monograph and therefore have clinical relevance to the use of Avodart. A disclaimer could be presented in a better context in future versions. Allegation rejected.

PENALTY: $500 registration fee assessed to GSK.

OUTCOME: No appeal.

4.

ADVERTISER: Solvay

COMPLAINANT: Private Physician

SUBJECT: Androgel (testosterone) journal ad accepted by the PAAB as JAF56237 in December 2005.

PRECLEARANCE: Yes. JAF56237 in December 2005.

ALLEGATIONS: Violation of s4.2 "without stating in the advertising if the improvements are of clinical significance the statistics are not presented in a manner that reflects their "level of significance". The advertisement also violates s4.2.3 by not providing information to determine whether the changes seen represent relative or absolute risk reductions."

PAAB DECISION: All of the claims and data presentation are directly from the Health Canada approved product monograph. On several occasions, Health Canada has confirmed to the PAAB that the information included in the product monograph is clinically relevant and significant. The source is cited in the ad. Physicians should read the product monograph for complete information before prescribing.

PENALTY: None.

OUTCOME: No appeal.

5.

ADVERTISER: Genpharm

COMPLAINANT: Abbott

SUBJECT: c06-10 Euthyrox (levothyroxin) detail aid "Euthyrox Bioequivalence with Synthroid"

PRECLEARANCE: No

ALLEGATIONS:

1. makes unsupported bioequivalence claims s5.13.1
2. is inaccurate and misleading s2.1
3. is not expressed in terms, language, graphics that can be understood by the intended audience s5.6
4. failed to adjoin or reference prescribing information s6.1
5. failed to present a balanced treatment of the various features of the drug s2.1.2
6. needs preclearance review s1

PAAB DECISION: Based on resolution of c06-09 Genpharm agreed to cease distribution and submit future APS to the PAAB for review.

PENALTY: Destroy current material and correction of future material.

OUTCOME: Genpharm agreed to work within the scope of the PAAB Code of Advertising Acceptance.

CONTACT INFORMATION

For information or if you have comments:

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