PHARMACEUTICAL ADVERTISING ADVISORY BOARD OCTOBER 2010

PAAB REVIEW

Year 2010 marks the 34th year of the PAAB since its incorporation in 1976. To see the current edition of the PAAB Code, visit the PAAB Web-site.

www.paab.ca

Ce document est également disponible en français sur notre site web.

PAAB MEETINGS

November 19, 2010 – General Meeting

December 13, 2010 – Executive Committee

MISSION, VISION, VALUES

MISSION: To provide a preclearance review that fosters trustworthy healthcare communications within the regulatory framework.

VISION: Trusted healthcare product communication that promotes optimal health.

VALUES: Integrity, Competency, Credibility, Independence, Excellence, Transparency

EDITORIAL ADVERTISING

Several sources have brought a marketing activity to the attention of the PAAB commissioner. It is sponsored editorials. This type of advertising is covered in section 7.6 Editorial Advertising of the "PAAB Code of Advertising Acceptance"

One such publication states something similar to: As such, we are pleased to offer article sponsorship rates for our online version journal, in addition to the print and online rates! Sponsoring an article in the journal will have two major outcomes for your clients. First, it will showcase their [therapeutic area] products and their role within a published article of the journal. Secondly, it will demonstrate to the Canadian medical community the ongoing commitment of your clients company to the education of Canadian physicians, particularly those in the [therapeutic] area. Another benefit of sponsoring an article is fast publishing. We will place a priority on your submitted articles to ensure a quick turnaround and flexible publishing dates."

Just a reminder that "editorial advertising" sponsored by pharma companies should be reviewed by the PAAB. Call CRO Patrick Massad if you have any questions.

CLIENTS INVITATION

The PAAB commissioner is proud of the high level of customer service shown by the PAAB staff. We strive for continuous quality improvement. We remind you that the door to the commissioner's office is open to receive comments about PAAB activities or review issues. We would like to receive specific examples that caused satisfaction or dissatisfaction for the client to help identify trends for areas of improvement of the PAAB review service. Our Customer Experience surveys have not revealed negative comments that we were able to act on. We would like to document and investigate specific cases and take appropriate action. You can contact the commissioner at 905-509-2275 x28 and by email at commish@paab.ca.

GUIDANCE ON DTC VACCINE ADS

We have posted the guidance on the PAAB web-site www.paab.ca and it is available on the Health Canada web-site http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_dtca-pdac_vaccine-vaccins-eng.php It is similar in intent to s2.4 of the PAAB Code of Advertising Acceptance.

PRODUCT INFORMATION (PI) COMMITTEE

The PAAB Directors have struck a code committee of various industry stakeholders to review how product information (PI) is delivered to the target audience in various media. Options will be reviewed and a suggestion to the board is expected to follow. Any changes will have to be within the current federal regulatory framework and the opinion of Health Canada will be sought.

TRAINING WORKSHOPS

The PAAB conducts ad hoc training sessions at the request of pharma/biotech companies, agencies and suppliers. Check the PAAB web-site for details.

The next national open workshops will be held December 6, 2010 in Montreal and December 8, 2010 in Toronto. Check the PAAB web-site under "What's New" for details.

CUSTOMER EXPERIENCE INDEX

The PAAB's primary role is to ensure that advertising of prescription drugs is accurate, balanced and evidence based. The PAAB staff strives to provide service that is accurate, transparent and prompt, demonstrating a high level of scientific and regulatory expertise in its reviews.

In late May, 2008, we introduced a Customer Experience Index Survey (CEI). This will provide the PAAB with a systematic and ongoing tool for client feedback, measuring administration, reviewers, management, general process and technology.

Clients who have had an APS accepted will be randomly selected to receive a survey involving 14 questions. If you get one, please complete it and send it back to us promptly. It is important to answer the questions regarding the referenced review file. It is the commitment of the PAAB to improve our customer service. Results for 2010 indicate a continuance of an 80% satisfaction level with the individual file that the client commented on. The PAAB commissioner is pleased with the results and is encouraging the staff to keep up the good work.

SOCIAL MEDIA MARKETING

Keep an eye out for the EyeforPharma "Pharma E-Marketing Canada" conference November 1 and 2, 2010. See "The PAAB" LinkedIn group for additional information or http://www.eyeforpharma.com/emarketingcanada

Commissioner Ray Chepesiuk and Chief Review Officer Patrick Massad are included in the faculty for this event.

Commissioner Chepesiuk has accepted an invitation to be a faculty member at the E-Pharma Summit in New York City in February 2010.

REVIEW ACTIVITY

During the period of July 1 to September 30, 2010, the total number of first review submissions was 1,372 with 6 files going more than 10 days on first review. This compared to 1,199 during the same period of 2009. The total for the year to date is 4,427 with 19 files going more than 10 days on first review compared to 3,413 in 2009. Some reviewers are averaging 6 day turnaround to first review.

To address industry perception, the PAAB can now generate a report to show how long the client holds a file vs. the PAAB during the review process to acceptance. In 2010, on average the PAAB has held the file 3.2 days vs. the client holding it 10.8 days. In 2009 the PAAB held it for 4.2 days on average of all accepted files vs. 15 days by the client.

USE OF PAAB LOGO

We encourage you to show the PAAB logo on all material reviewed to acceptance (HP) or to no objection (DTC). The new DTC codes are CA for advertising and CI for information. The clearance period is for 12 months and please submit a renewal request if you wish to use the advertising for longer than 12 months. Two month extensions for exceptional circumstances can be granted by the commissioner.

PAAB COMPLAINT REPORT

During the period of July 11 to September 30, 2010, the PAAB Commissioner processed 4 Stage 2 complaints.

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.

STAGE TWO DECISIONS

1. **ADVERTISER**: Odan

COMPLAINANT: Ferring

SUBJECT: c10-14 Purg-Odan "Sample Express" APS

PRECLEARANCE: No

ALLEGATIONS: 4 allegations (see decision).

1. **DECISION**: "Now #1 Choice in more than 750 Canadian Hospitals" can be supported by buying group data. However, Odan should reference this claim properly and make the reference available on request. A PAAB review would validate the accuracy of the claim after review of the data and help Odan to reference it properly.
2. "The Easy Way to Purge Away" contravenes code s5:10.2.ii. Also, the claim violates s2.4 because it does not provide an attitude of caution. The special status conveyed by this wording has not been supported by evidence.
3. Trademark acknowledgement. Odan has indicated in previous correspondence that they will revise their advertising to include this.
4. Use of the word "new" in this ad is seen to be misleading because there is no mention of a sample offer program in the ad. A PAAB review would have prevented this misleading advertising.

OUTCOME: Odan complied with the ruling and agreed to send future APS for PAAB review.

2. **ADVERTISER**: GlaxoSmithKline

COMPLAINANT: Merck

SUBJECT: c10-14 Cervarix Detail Aid

PRECLEARANCE: Yes

ALLEGATIONS: **"...** the bullet in the body copy, in conjunction with the headline and layout, provide the appearance that there is an indication for types 31 and 45. As such, we believe that the APS is in violation of sections 2.1, 2.3, 2.4, and 3.1 of the Code."

DECISION: The statements appearing in the APS are consistent with statements in the product monograph and reflect a similar degree of emphasis as the PM. The disclaimers are appropriate and well-placed and are similar in nature to advertising for other products in this class. I agree with the PAAB reviewer and the well written argument of GSK in the defense of the PAAB approval. The ad is neither false nor misleading.

OUTCOME: No action required of GSK. $500 registration fee assessed of Merck.

3. **ADVERTISER**: Sanofi Aventis

COMPLAINANT: Dr. Joel Lexchin

SUBJECT: c10-17 Multaq (dronedarone) journal ad in NEJM August 5, 2010

PRECLEARANCE: Yes

ALLEGATIONS: Doctors do not consider harms and benefits of medications in isolation but need to be presented with all of the relevant characteristics of a medication in order to make an informed choice. The fact that there is no difference in mortality rates is not

a negative finding in the sense that dronedarone causes more harm than placebo but it certainly is a very relevant result from the ATHENA trial and one that clinicians would want to know about before prescribing dronedarone. While avoiding hospitalizations for patients in atrial fibrillation is certainly one outcome that doctors would want to avoid, improving overall mortality for their patients is definitely a more important outcome. If doctors are presented with the knowledge that dronedarone does not improve mortality then they would definitely take that finding into consideration in their decision as to whether or not to prescribe the medication especially if they had evidence that other medications might lower mortality.

Therefore, I stand by my original complaint that the absence of the information about overall mortality rates is a violation of both sections 2.3 and 2.4 of the Code as doctors would consider this essential information in making a decision about whether or not to prescribe dronedarone."

DECISION: In my opinion, while the ad was submitted in good faith by Sanofi-Aventis in accordance with the PAAB Code of Advertising Acceptance, it could be improved from a clinical perspective by Dr. Lexchin's suggestion of informing physicians of the secondary outcome overall mortality to provide information that may be relevant to clinical choice. The PAAB appreciates feedback from stakeholders on how to improve advertising. Sanofi-Aventis should add the statement from page 21 of the PM to the fair balance section of the ad at the time of renewal of the ad. (All APS approved by the PAAB have a 12 month clearance period.) This would apply to other relevant APS into the future. If Sanofi-Aventis agrees to that, I see no further action that is necessary.

OUTCOME: Sanofi-Aventis complied with the ruling and revised the ad.

4. **ADVERTISER**: Amgen

COMPLAINANT: Novartis

SUBJECT: c10-18 Prolia (denosumab) Web-site

PRECLEARANCE: No

ALLEGATIONS: DTC web-site contents exceed name, price quantity restriction and no PAAB review.

DECISION: Send complaint to Health Canada as per HC policy.

OUTCOME: No response from Health Canada at time of publishing.

For information or if you have comments:

Pharmaceutical Advertising Advisory Board
375 Kingston Road, Suite 200
Pickering, Ont. L1V 1A3
Tel: (905) 509-2275 fax: (905) 509-2486
e-mail: info@paab.ca www.paab.ca