PHARMACEUTICAL ADVERTISING ADVISORY BOARD April 2011

PAAB REVIEW

Year 2011 marks the 35th 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

April 15, 2011 – Annual/General Meeting

June 7, 2011 - Executive Committee Meeting

November 2011 – General Meeting

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

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.

PRODUCT INFORMATION (PI)

The PAAB Directors have approved in principle the possibility to change the PAAB Code requirement for Product Information that accompanies advertising. The change would allow a link to the PI in the ad. The PAAB will examine how the code can be changed to accommodate this new format. Any changes will have to be within the current federal regulatory framework and the opinion of Health Canada will be sought.

RESEARCH FUNDING

The PAAB will be funding two research projects in 2011. One project deals with Code section 3.1 and the standard for evidence that supports claims. The researcher will be looking at current standards for evidence as recognized by the medical community and evaluating whether or not the PAAB code should be amended. The other project deals with a measurement of online advertising sponsored by Canadian pharmaceutical companies.

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. www.paab.ca

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.

WHAT IS AN FYI?

An FYI for the PAAB submission review process means an informative email sent to review@paab.ca to make PAAB aware of post approval changes to an approved APS within its clearance period for the following reasons only,

- corporate, logo, trademark changes
- some French language grammar correction
- resize of APS that results in NO layout changes

If your FYI falls into one of the three categories listed above, email review@paab.ca to include the reason for sending the FYI and attach final layouts which highlight the changes. Please include the previously approved eFile # and your telephone contact information.

Your email will be processed and if cleared as an FYI, the email and final layouts will be uploaded to the originally approved eFile. You will be telephoned to advise that the FYI has been cleared.

Written confirmations in letter form or by email are not provided. The original PAAB acceptance letter will cover the FYI changes for the originally approved acceptance timeframe.

Please Note: All other post approval changes to previously approved APS, i.e. any copy or layout changes, visual changes and layout changes as a result of resizing are subject to further review and should be submitted in the form of new eFiles.

SOCIAL MEDIA MARKETING

Commissioner Chepesiuk appeared as a faculty member at the E-Pharma Summit in New York City in February 2011 as well as a speaker at the E-Marketing Europe 2011 conference in Munich Germany in March 2011. Commissioner Chepesiuk also appeared as a speaker in a Canadian E-Marketing meeting to be held in Toronto March 21-23, 2011. In future Commissioner Chepesiuk has been invited to speak about the PAAB in a global webinar and he was interviewed for a global online forum for thought leaders in pharmaceutical marketing.

REVIEW ACTIVITY

During the period of January 1 to March 31, 2011, the total number of first review submissions was 1696 with 9 files going more than 10 days on first review. This compared to 1535 during the same period of 2010. The reviewers averaged 5.5 days for 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 the first quarter of 2011, on average the PAAB has held the file 2.3 days vs. the client holding it 5.9 days.

The average number of total revisions per submission for a file was 2.1 in the first quarter of 2011 (2.6 in 2010). 15% of accepted files took more than 3 revisions to complete in 2011 versus 24% in 2010.

Ask CRO Patrick Massad how your agency or company performed.

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 January 1 to March 31, 2011, the PAAB Commissioner processed 4 Stage 2 complaints. Two were sent to Health Canada for investigation.

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. In the first quarter of 2011 the PAAB sent 6 monitoring notices regarding DTC advertising.

STAGE TWO DECISIONS

1. **ADVERTISER**: Astellas

COMPLAINANT: Pfizer

SUBJECT: c10-24 Vesicare comparison chart in various APS

PRECLEARANCE: Yes dating several years back.

ALLEGATIONS: see decision below.

DECISION:

1. Pfizer states "It is important that when physicians look at the APS, their conclusion should align with the primary endpoint of the study, which is similar efficacy for tolterodine SR and Vesicare in reducing micturition/24 hours." We agree with that position. Code S2.3 states "APS must be presented in a manner that accurately interprets valid and representative research findings." Astellas can do this in a number of ways using sequence, emphasis and proximity. It should be easy for the reader to identify what the primary endpoint was in this study. PAAB reviewers will be reminded of this interpretation of the code.
2. Pfizer also states that the omission of a comparison of two common side effects shown in the study is a violation of s 3.5. I cite s2.3 as well in thinking that physicians would want to know that information. Pfizer has shown that the author agrees with their position. Astellas should note that the letter to the editor was signed by the author of the study and therefore has some weight, in my opinion. Also, if I applied the Astellas logic to the decision regarding the pooled analysis to both side effects and efficacy then no data should be used in advertising. The data was pooled in the same manner for the efficacy and side effects.
3. The author states that the reader of the study should be able to draw their own conclusions. Regarding the APS, the reader would be able to do this if sufficient information is presented. It is apparent that Astellas has left out important information.

PENALTY: Astellas should discontinue the APS relevant to this ruling immediately. Astellas should submit a written action plan by February 7, 2011 indicating the list of the material and when they will be out of the marketplace.

OUTCOME: Astellas complied with the ruling.

2. ADVERTISER: BioK-Plus International

COMPLAINANT: Health Canada Quebec Region

SUBJECT: c11-05 4 page Dear Doctor Letter

PRECLEARANCE: No

ALLEGATIONS: Alleged Off label therapeutic use and dosage; alleged omission of fair balance safety info; alleged deceptive presentation

DECISION: Cease distribution and have sales people return all copies to head office.

OUTCOME: BioK+ president agreed to comply with the PAAB decision. Health Canada was informed of that decision.

3. ADVERTISER: Tercica

COMPLAINANT: Quebec Physician

SUBJECT: c11-08 Somatuline Autogel Product Monograph

PRECLEARANCE: No

ALLEGATIONS: deep subcutaneous dosage and needle size is questioned

DECISION: Refer to Health Canada because of potential patient safety issue

OUTCOME: received by Health Canada.

4. ADVERTISER: Nycomed

COMPLAINANT: GSK

SUBJECT: C11-02 Journal ad and detailer

PRECLEARANCE: Yes several years back

ALLEGATIONS: 1. Disclaimer that was previously used was omitted from the APS subject of the complaint.

2. Comparative data presentation does not appear in the PM. The study is mentioned in the Pharmacodynamics section, not the clinical section. Therefore, comparative clinical relevance is questioned.

DECISION: Agreed with complainant.

PENALTY: Cease distribution and revise copy where appropriate in future APS.

OUTCOME: Nycomed complied with the ruling.

UPDATE. Regarding File # c10 - Pfizer Champix complaint, Pfizer did comply with the PAAB decision.

For information or if you have comments:

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