



PAAB 300-1305 Pickering Parkway, Pickering, Ontario L1V 2P3
www.paab.ca info@paab.ca 905-509-2275

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"We've Moved!"

Year 2012 marks the 36th 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.

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

PAAB OFFICE RELOCATION

As of December 5, 2011, the PAAB office will be located at 1305 Pickering Parkway, Suite 300 in Pickering, Ontario. The phone numbers and fax number will remain the same.

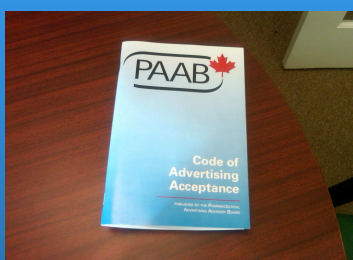
The staff is getting accustomed to the new office which is considerably larger than the previous location. The office can be reached by the 401 and the Pickering GO train station is a five minute walk away.

Look for a message about an open house soon. Come visit us!

NEW STAFF ADDITIONS

The PAAB has recently hired a new reviewer. Ms. Danielle Newman comes to the PAAB with a M.Sc. and experience in hospital sales in the pharmaceutical industry, and in a leading advertising agency. This addition brings the reviewer total to twelve and a total staff of seventeen.

"... a goal of revising the PAAB Code of Advertising Acceptance.."



"To be clear, we are seeking collective, organizational opinion and not individual opinion."

CODE REVISION PROJECT

The PAAB board has approved a project with a goal of revising the PAAB Code of Advertising Acceptance. We are using a new project management technique for the code revision process. The project is lead by Commissioner Chepesiuk assisted by PAAB staff, four committees and a consultant. The commissioner has struck four expert committees in the area of: a) evidence basis for claims; b) prescribing information/ fair balance; c) electronic media; d) specific nonprescription issues.

The four committees and PAAB staff will provide recommendations to revise the PAAB code. Those recommendations will be part of a survey to all PAAB stakeholders. We want one answer from one company or organization. To be clear, we are seeking collective, organizational opinion and not individual opinion.

The survey will be conducted by the consultant to the PAAB to ensure that it is objective and reaches a wide audience. The input will be collated and if there is disagreement with the recommendations, the expert committees will review that input and the basis for the disagreement and make a decision. Health Canada will be part of the consultation. The final draft of the code will go to the PAAB members for a vote of approval. We hope to do that in August to allow a 2013 implementation.

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 2011 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.

PAAB SPEAKS

The PAAB is recognized as a world leader in pharma advertising regulation and guidance. As in the past, Commissioner Chepesiuk has been invited to speak at several venues. He will be giving two presentations, at the E-Pharma Summit in New York City in February 2012. In March, he will be presenting at a Health Canada staff educational workshop in Ottawa and at an E-Marketing conference in Barcelona, Spain.

The Commissioner and Chief Review Officer Patrick Massad are available for workshops on the PAAB Code for companies by invitation.

PAAB staff can conduct learning sessions about the PAAB and the Code of Advertising Acceptance or Direct-to-Consumer advertising of Rx or biological health products on-site at your workplace. Sessions are usually 2-3 hours long and the content can be tailored to your needs. Q&A about your confidential marketing situations can be discussed. There is a fee and travel expenses charge.

Contact Commissioner Ray Chepesiuk for details and fee information 905-509-2275 x28.

TRAINING WORKSHOPS

The PAAB conducts ad hoc training sessions at the request of pharma/biotech companies, agencies and suppliers. The PAAB office now has a training room that can handle 36 people seated. We plan on having more frequent workshops with diverse specialty topics e.g. social media, DTC, evidence, how to submit etc. Check the PAAB web-site for details. www.paab.ca

REVIEW ACTIVITY

During the period of January 1 to December 31, 2011, the total number of first review submissions was 6,901 files with 41 files going more than 10 days on first review. In 2010 the PAAB reviewed 6,132 new submissions. The average turnaround for first review was 6.3 days. The reviewers averaged 2.0 days for turnaround on revision.

To address industry perception, the PAAB can generate a report to show how long the client holds a file vs. the PAAB during the review process to acceptance. In 2011, on average the PAAB has held the file 3.3 days vs. the client holding it 11.5 days.

The average number of total revisions per submission for a file was 2.4 in 2011. 12% of accepted files took more than 3 revisions to complete in 2011 versus 16% in 2010. Ask CRO Patrick Massad how your agency or company performed.



6,901 files is the highest one year volume in the 36 years history of the PAAB.

PAAB COMPLAINT REPORT

During the period of January 1 to December 31, 2011, the PAAB Commissioner processed 8 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. In 2011 the PAAB sent 8 monitoring notices.

The 8 stage two complaints in 2011 was the lowest for one year in 36 years.

STAGE TWO DECISIONS

1. ADVERTISER: Sanofi

COMPLAINANT: Hospira

SUBJECT: c11-20 Taxotere (docetaxel) "Vial" study reprint.

PRECLEARANCE: No

ALLEGATIONS: 1. Distribution of a study reprint to a formulary committee was advertising and should be reviewed by the PAAB.

2. If it is advertising there are 9 alleged violations of the PAAB code.

The nature of the study was a comparison to products that are not available on the Canadian market and it implied a comparison to the Hospira product.

DECISION: Sanofi asserted that the reprint was requested by the formulary committee during negotiations and the Hospira product was not available on the market at the time. Hospira did not provide sufficient evidence to make it clear that Sanofi distributed the material in an unsolicited manner which would make it "advertising". Therefore, the complaint was rejected.

OUTCOME: Both parties accepted the ruling.

For information or if you have comments:
Pharmaceutical Advertising Advisory Board
300 -1305 Pickering Parkway
Pickering, Ontario Canada L1V 2P3

Tel: (905) 509-2275 fax: (905) 509-2486
e-mail: info@paab.ca

www.paab.ca