



PAAB 300-1305 Pickering Parkway, Pickering, Ontario L1V 2P3
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New PAABer

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.

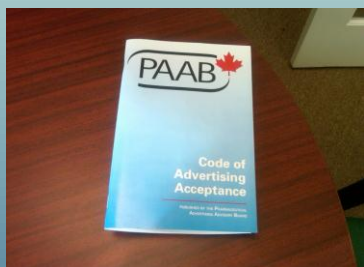
The staff is getting accustomed to the new office which is considerably larger than the previous location. The office can be reached by the 401 and the Pickering GO train station is a five minute walk away.

Thanks to everyone who came to our open house.

NEW STAFF ADDITION

The PAAB has recently hired a new reviewer. Vanessa Coffey is a registered pharmacist who has worked in hospital and community pharmacy. Vanessa started on April 16, 2012.

“... 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 led 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 were part of a survey to all PAAB stakeholders. We asked for one answer from one company or organization. To be clear, we are seeking collective, organizational opinion and not individual opinion.

The survey was conducted by the consultant to the PAAB to ensure that it is objective and reaches a wide audience. The survey ended March 31, 2012. 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.

Extensive training sessions for clients will be offered in the Fall 2012. This should help educate the clients and allay the concerns that a change in the code brings.

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. This year he has presented: at the E-Pharma Summit in New York City in February 2012, at a Health Canada staff educational workshop in Ottawa in March, and at an E-Marketing conference in Barcelona, Spain in March. He has been invited to speak at the DIA Annual meeting in Philadelphia in June and at an international webinar sponsored by a Slovakian company in November.

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

TRAINING WORKSHOPS

The PAAB conducts ad hoc training sessions at the request of pharma/biotech companies, agencies and supplier either at their office or at the PAAB office. 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 Call Patrick Massad if you wish to have PAAB training. 905-509-2275 x125

REVIEW ACTIVITY

During the period of January 1 to March 31, 2012, the total number of first review submissions was 1,955 files with 19 files going more than 10 days on first review. In the same period in 2011 the PAAB reviewed 1,696 new submissions. The average turnaround for first review was 6.3 days. The reviewers averaged 2.0 days for turnaround on revision.

In the first quarter of 2012, on average the PAAB has held the file 2.9 days vs. the client holding it 5.7 days.



1,955 files is the highest one quarter volume in the 36 years history of the PAAB.

PAAB COMPLAINT REPORT

During the period of January 1 to March 31, 2012, the PAAB Commissioner processed 3 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 2 monitoring notices.

There were 4 stage two complaints in the first quarter of 2012.

STAGE TWO DECISIONS

1. ADVERTISER: Pfizer

COMPLAINANT: Sanofi

SUBJECT: c11-24 Fragmin APS first approved in 2009

PRECLEARANCE: Yes

ALLEGATIONS: The claim in question is "the only low molecular weight heparin indicated to treat Cancer-Associated Thrombosis (CAT) in Canada". This claim has been used in Fragmin advertising for several years dating back to 2009. Prior to that, the PAAB accepted a claim "One and only LMWH indicated for the extended treatment of symptomatic venous thromboembolism (VTE) to prevent recurrence of VTE **in patients with cancer**." To PAAB's knowledge, Fragmin is still the only LMWH whose product monograph includes an indication for "extended treatment of symptomatic venous thromboembolism (VTE) to prevent recurrence of VTE in patients with cancer". Sanofi has not provided evidence indicating otherwise.

DECISION: I agree with Sanofi that the current claim is not accurate and thus not acceptable within the PAAB code of Advertising Acceptance. We recommend that Pfizer immediately cease using the claim "the only low molecular weight heparin indicated to treat Cancer-Associated Thrombosis (CAT) in Canada" in all APS where it now exists. We recommend using the wording that was accepted in the past and that appears to be acceptable today. Also, Pfizer may be able to cover over the line in some existing pieces until expiry.

PENALTY: Cease distribution immediately and replace material as necessary.

OUTCOME: Pfizer agreed.

2. ADVERTISER: Neilmed

COMPLAINANT: Private Physician

SUBJECT: c12-02 Neilmed Nasal Spray samples

PRECLEARANCE: No

ALLEGATIONS: Samples distributed illegally

DECISION: Sent to health Canada for investigation

PENALTY: NA

OUTCOME: No response from Health Canada at this time

3. ADVERTISER: Purdue

COMPLAINANT: Two private physicians

SUBJECT: c12-03 Textbook "Managing Pain"

PRECLEARANCE: No

ALLEGATIONS: Misleading statements and patient safety allegations

DECISION: sent to Health Canada for investigation into safety allegations

PENALTY: NA

OUTCOME: Unknown at this time

4. ADVERTISER: Boehringer Ingelheim

COMPLAINANT: Bayer

SUBJECT: c12-04 Pradax journal advertisement

PRECLEARANCE: Yes

ALLEGATIONS: Issue 1 – the claim Pradax reduces the risk of intracranial bleeding by 59% is not an indication and should not be used because it is in violation of s3.1.

Issue 2 - `The journal advertisement focuses on the positive features of the 150 mg dose of Pradax without commenting on the 110 mg dose`. This is seen to be in violation of s3.5 and s2.4.

DECISION: Issue 1 - I agree. BOE should look to using a claim similar to `Demonstrated lower risk of intracranial bleeding vs warfarin`.

Issue 2 - I agree. BOE should add a statement similar to `Please refer to the product monograph for dosing adjustments in special populations`.

PENALTY: BOE should withdraw the journal advertisement and any other APS that have claims similar to the issues of this complaint. I request a written reply including an action plan telling the PAAB the details including timelines of this withdrawal.

OUTCOME: BOE agreed.

For information or if you have comments:
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