

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

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 <a href="www.paab.ca">www.paab.ca</a>

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

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## 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 LOCATION

The PAAB office is located at 1305 Pickering Parkway, Suite 300 in Pickering, Ontario.

The office can be reached by the 401 and the Pickering GO train station is a five minute walk away.

### TRAINING WORKSHOPS

Watch the PAAB web-site for news about the October PAAB 101 basic course to learn how to apply the PAAB code like the reviewers do. We have some exciting additions to the course to help you market your drugs within the rules. The PAAB also 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 35 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

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



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# **CODE REVISION PROJECT UPDATE**

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 have provided 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 April 30, 2012. The input was collated and where there was disagreement with the recommendations, the expert committees reviewed that input and the basis for the disagreement and made a decision. Health Canada was part of the consultation. The second draft of the code went to the PAAB members for review and consultation. We anticipate a positive vote by the Board on November 23, 2012 with implementation starting July 1, 2013. After a transition, full implementation will occur January 1, 2015. Extensive training sessions for clients will be offered in the first half of 2013. This should help educate PAAB 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 2012 indicate a continuance of an average 80%-plus 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.

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### 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, New Jersey in June, on an international regulatory panel at the DIA Annual meeting in Philadelphia in June, Digital Marketing Conference in Istanbul Turkey in September. Upcoming are presentations at the Digital Health Coalition in Philadelphia in October, a Patient Social Media 2012 international webinar sponsored by Kakushin Group in November and the EFP Canada Digital Summit. CRO Patrick Massad has spoken at many client workshops this year.

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

### **REVIEW ACTIVITY**

During the period of January 1 to September 30, 2012, the total number of <u>first review</u> submissions was 5,227 files with 40 files going more than 10 days on first review. In the same period in 2011 the PAAB reviewed 5,070 new submissions. Turnaround for first review was 50% in 7 days or less. The reviewers averaged 2.45 days for turnaround on revision.

In 2012, on average the PAAB has held the file 3.6 days after first review to acceptance, vs. the client holding it 10.4 days on average.

### PAAB COMPLAINT REPORT

During the period of July 1 2012 to September 30, 2012, the PAAB Commissioner processed 0 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 1 monitoring notice.

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

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5,227 files is the highest three quarters volume in the 36 years history of the PAAB.

There were 0 stage two complaints in the third quarter of 2012.