



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

INSIDE THIS ISSUE

- 1 Code Launch
- 1 PAAB Client Research
- 2 Code Revision Update
- 2 PAAB Speaks
- 3 PAAB Workshops
- 3 Review Activity
- 4 Electronic Files Program
- 4 Formulary Ads
- 5 Strategic Planning
- 5 Complaints

Spring has Sprung

Year 2013 marks the 37th 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

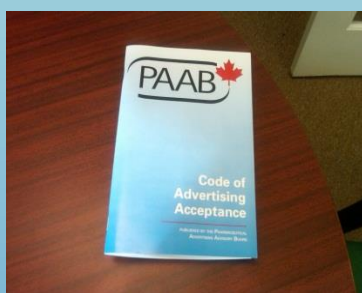
PAAB CODE LAUNCH

The revised PAAB Code of Advertising Acceptance took effect on July 1, 2013. Please get an electronic copy from www.paab.ca at no charge. Print copies are available from the PAAB office at \$5 each. You can get the new PAAB Code app at the Apple Store for iPad and from the PAAB website for web browser. There is no cost for the electronic app. It includes the code, advisories and guidances in English and French.

PAAB RESEARCH WITH CLIENTS

The PAAB thanks all clients who participated in the telephone interviews during December and January to help us improve the PAAB. We have used the information to plan the October workshops and other forms of training and communications coming to you in 2013.

*Implementation
July 1, 2013*



CODE REVISION UPDATE

On November 23, 2012 the PAAB board approved the revision of the PAAB Code of Advertising Acceptance. There were 4 major areas of the code that received extensive stakeholder consultation and comment: a) evidence basis for claims b) prescribing information/ fair balance c) electronic media s6.5 d) specific nonprescription issues. **Implementation is July 1, 2013 with full transition by July 1, 2014.** Health Canada was part of the consultation.

Please note we have made an update in explanatory note 7.3.2.a. The revision will provide clients with more flexibility when deciding on how to present the required link to the full product monograph.

- *The TMA and the risk communication on the Health Canada website. The requirement relating to the TMA can be met by linking to the appropriate database search page (e.g. the Drug Product Database, Licensed Natural Health Products Database). This option may not be available for new products or those having recently undergone TMA revision due to Health Canada delays in posting which are beyond the advertiser's control. The requirement relating to the risk communication can be met by linking to the MedEffect Canada page.*

Staff will answer specific code questions on the phone. Code Books are available from the PAAB office at \$5 each. Code App is available for Ipad at the Apple Store and in PC on the PAAB website (works in browsers at no charge).

PAAB SPEAKS

The PAAB is recognized as a world leader in pharma advertising regulation and guidance. Commissioner Chepesiuk has spoken in Canada, United States and Europe on digital marketing activities. The Commissioner and Chief Review Officer Patrick Massad are available for presentation by invitation.

In April, Commissioner Chepesiuk presented at the EyeForPharma Patient Centricity conference and the EXL Pharma Digital Health Conference. CRO Patrick Massad presented at the EXL Pharma Digital Health Conference and the EyeForPharma Sales Excellence Conference in June.

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 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. See the web-site www.paab.ca for fee info.

Contact Chief Review Officer Patrick Massad for details and fee information 905-509-2275.

PAAB WORKSHOPS

The next training workshop events will be held in Montreal October 22 and in Toronto October 24, 2013. We are planning an interactive learning event to help you understand the application of the new PAAB Code of Advertising Acceptance coming into effect July 1, 2013. Go to www.paabtraining.com for registration info.

The PAAB conducted workshops in Montreal and Toronto in February 2013. They were a huge success with a vast majority stating that objectives were met. Jon Gwillim was in charge of the marketing for the event and has reported the following marketing campaign stats:

Emails:

Roughly 10,000 emails were sent as part of the awareness / content campaign.

Website: www.paabtraining.com

17,458 visits

40,268 page views

Banner ad campaign

4,765 impressions

964 clicks

Paying delegates:

168 in Montreal

293 in Toronto

In early March the PAAB conducted five free webinars covering all aspects of the code changes. Questions were answered. I thank Patrick Massad, Jennifer Carroll, Karen Rizwan, Maxine Armstrong, Laurie Johns and Glenn Golaz for their participation. Big thanks to Dan Hageman and Al Burkin for technical assistance.

REVIEW ACTIVITY

During the period of January 1 to June 30, 2013, the total number of first review submissions was 3,694 files with 25 files going more than 10 days on first review. In the same half of 2012 the PAAB reviewed 3,593 new submissions. For all reviewers, the average of turnaround for first review was 6.8 days. The reviewers averaged 2.2 revisions to acceptance.

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 2012, on average the PAAB has held the file 3.3 days vs. the client holding it 9 days.

11% of accepted files took more than 3 revisions to complete in 2013 versus 14% in 2012.

"I felt that all of the topics noted on the agenda were addressed effectively"

- TO participant

"Great use of examples and case studies, very helpful in understanding changes."

- TO participant

PAAB continues to be busy, effective and efficient handling submissions files.

NEW PAAB ELECTRONIC FILES PROJECT UPDATE

The PAAB has engaged the services of Innovasium Inc. (Dan Hageman) to build a new electronic files submission and review system. The previous system was in place from 2007 and has served the PAAB well. Being a leader in the area of electronic applications, the PAAB is looking to improve on the system. Several focus groups and surveys have been conducted with clients to identify areas of improvement. A staff committee is assisting Innovasium in the design of the program at the early stages, an innovative procedure not used with the previous system. The launch is projected for January 1, 2014. Commissioner Chepesiuk states “Innovasium will bring more effectiveness and efficiencies to the PAAB electronic file system on both the client and PAAB interfaces. We are very excited about this project.”

“Innovasium will bring more effectiveness and efficiencies to the PAAB electronic file system on both the client and PAAB interfaces.”

STATEMENTS INVOLVING FORMULARY CHANGES

Only submissions which include one of the following references will be considered for review:

- Formulary listing (or equivalent provincial document)
- Letter signed by a TMA holder senior official (i.e. director level or higher) stating that the product coverage is expected to be unrestricted OR stating the restriction wording expected to be approved by the province. Final PAAB acceptance will not be provided until the final provincially approved formulary listing has been received and reviewed by the PAAB.

Adding formulary messages to already approved pieces will no longer be accepted as an FYI. This update now needs to be submitted for review. In cases where coverage is restricted (e.g. limited use, exceptional coverage):

The APS presentation must indicate that restrictions exist (in prominent body copy within the claim or proximal to it). While different provincial formularies often use different terminology to refer to their coverage status (e.g. Exception Drug Status, Special Authorization, etc.), it is acceptable to use an accurate blanket statement such as “Covered on provincial formulary (special authorization)”. If the manufacturer elects to include coverage codes within the APS, the codes must be accompanied by the corresponding coverage criteria (e.g. inclusion/exclusion criteria), definitions, and notes where applicable. These elements may be included in a footnote. Check The PAAB web-site for the new advisory and the fee schedule. Please contact the Administration Staff if you have any questions 905-509-

Include the formulary reference(s) at the time of the submission

PAAB STRATEGIC PLANNING

The PAAB directors held a strategic planning session in April 2013.

Highlights include:

- rewording of the Mission statement subject to approval of the members.
- rewording of the vision statement subject to approval by the members.
- Strategic Goal 1: agreed to perform an external consultation and review of the PAAB governance structure and function prior to training of the PAAB directors.
- Strategic Goal 2: PAAB should explore closer alignment to Health Canada.
- Strategic Goal 3: The commissioner should form a committee with representation from the 4 member trade associations to explore the allegations of review inconsistency and report back to the board.

PAAB COMPLAINT REPORT

During the period of April 1 to June 30, 2013, the PAAB Commissioner processed 0 Stage 2 complaints. Total for the year is 1.

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. The PAAB sent 3 monitoring notices.

STAGE TWO DECISIONS

none

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