April 2014

PAAB VIEWS

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

INSIDE THIS ISSUE

" A foolish consistency is the hobgoblin of little minds, adored by little statesmen and philosophers and divines."

- Ralph Waldo Emerson

Year 2014 marks the 38th 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 for the benefit of all stakeholders.

VISION: Evidence-based healthcare product communication that promotes optimal health.

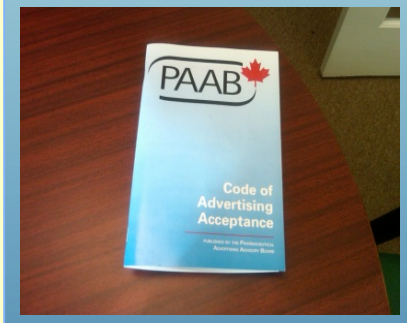
VALUES: Integrity, Competency, Credibility, Independence, Excellence, Transparency

NEW PAAB EFILES SOFTWARE ROLLOUT

The PAAB is pleased to announce the arrival of its newly upgraded EFiles Submission Review Software. The launch is projected for April 14, 2014.

The PAAB has engaged the services of Innovasium Inc.(Dan Hageman) to build a new electronic files file 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, surveys and hands-on tests have been conducted with clients to identify areas of improvement. Four client webinars have been conducted to help clients in the transition to the new system. 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." See www.paab.ca for more info.

Training Committee Recommendations



Health Canada Directive

COMMITTEE ON PAAB TRAINING

At the November 15, 2013 General Meeting the PAAB Directors struck a committee to review current PAAB client training methods and make recommendations on new methods.
The group discussed the following ways industry currently receives information about PAAB:

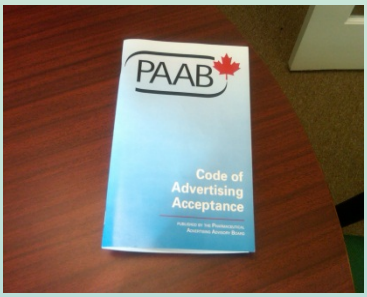
- National workshops
- In-house company-specific workshops
- Webinars
- Newsletters
- External guidance documents and advisories on the PAAB website
- Email blasts
- "Ask PAAB" on the PMCQ website
- Individual telephone conversations with staff

Summary Report
After discussion, the group agreed that the information channels currently used by PAAB are quite robust, and that the diversity helps account for different learning styles. The group also concluded that the PAAB should not proceed with a certification program at this time as there is unknown board and client interest and need to offset the significant costs associated with this initiative. Instead, the PAAB commissioner should:

- Continue smaller scale live national workshops geared toward people who are new to the industry. The PAAB could consider a morning for basic PAAB information and review process (e.g. history, systems, processes, and basic code review) followed by more intricate (advanced) code application in the afternoon (with a focus on cases and group work).
- Add a new feature to the website for presentation of cases on specific issues related to the code to support continued self-directed learning incorporating some of the questions asked in the PMCQ "Ask PAAB" web feature.

LINKING TO CORPORATE WEBSITES FROM THE PRE-GATE PORTION OF WEBSITES

Based on direction from Health Canada, the product branded pre-gate portions of prescription drug websites must not contain a hyperlink or URL to a corporate website containing product monographs. This is true even though, when taken separately, the pre-gate section of the branded site (reminder ad) and the corporate Web site (corporate message) are compliant. Health Canada considers the link between the two to exceed the restriction set out in Section C.01.044 of the Food & Drug Regulations.
Note that the same principle applies to non-prescription products which are indicated for the treatment of a schedule A disease (per the restrictions set out in Section 3 of the Food and Drugs Act).



"Consistency" Review

COMMITTEE ON REVIEW CONSISTENCY

The PAAB directors have struck a committee to review and analyze consistency during the PAAB review process. One representative from each of the four trade association members of the PAAB and Chief Review Officer Patrick Massad were committee members. Commissioner Ray Chepesiuk chaired the committee. Terms of Reference are:

1. Define Consistency for the purpose of this review.
2. Devise a study with methodology agreed on by all committee members to measure PAAB reviewer "consistency".
3. Analyze the results.
4. Make recommendations to the PAAB commissioner.

Members of the committee are: Crawford Wright of Rx&D, Joseph Chan of CHPC and Maryse Lemieux of CPGA. BioteCanada did not name a person.

The current system is based on 14 years of continuous improvement. There was agreement that the PAAB staff had good systems in place to handle the approximately 20,000 file reviews (including revisions and second language) they handle annually. It was agreed that the external viewpoint of an inadequate system was mostly due to perception and not based on errors due to a weak system or inadequate staff. It was agreed there is always room for improvement. **Action steps**:

1. Document the steps PAAB currently takes to promote consistency in the committee's report for the PAAB board.

2. Hire a management consultant firm to review current activities, systems & policies relating to consistency and to perform an audit of the extent to which those activities, systems & policies are adhered to and make recommendations on their findings. This will require funds and therefore PAAB board approval.

3. Communicate externally which steps PAAB currently takes to promote consistency. E.g. on the PAAB website, articles.

4. Build functionality within the eFiles system specifically designed for creating and sharing (internally and externally where appropriate) documents conveying key review rulings and changes in review/administrative policy. The primary purpose would be two fold. Firstly to simplify the process involved in creating these communications (thus empowering PAAB to create more of them). Secondly, it would simplify client access & awareness as eFiles users will automatically get notifications when new external communications are added to the website through the system. Note that "eFiles users" will include both agencies and manufacturers in the updated version of eFiles.

5. Instruct staff to provide as much information as possible in the review letter when previously approved content needs to be clawed back.

6. Publish changes in PAAB review policy externally as they occur.

REVIEW ACTIVITY

During the period of January 1 to March 31, 2014, the total number of first review submissions was 1,704, with 4 files going more than 10 days on first review. In the same period of 2013 the PAAB reviewed 1,757 first submissions. For all reviewers, the average of turnaround for first review was 7.48 days. 90% of the reviews went to acceptance in three revisions or less.

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 2013, on average the PAAB has held the file 3.5 days vs. the client holding it 8.1 days after the first review date.

PAAB EDUCATION

The next training workshop events will be held in Montreal and Toronto in the Fall of 2014. We are planning an interactive learning event to help you understand the application of the new PAAB Code of Advertising Acceptance. Go to www.paabtraining.com for registration info.

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 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.

PAAB APPROVAL EXTENSION POLICY

Section 8.4.iii of the PAAB code states: Under special circumstances, e.g. adjustment to a new 12 month advertising schedule or a delay in production of new material, the Commissioner may extend the PAAB clearance beyond the 12-month period. Extensions at no fee charge shall be restricted to no longer than two (2) consecutive months. Longer extensions shall be subject to the full fee applicable to the particular type of advertisement. The new PAAB code was implemented on July 1, 2013. During the transition period which followed, the PAAB has been providing, on a case by case basis, extensions beyond the 2 month period to accommodate clients as they transition to the new code. As you know, we are nearing the end of the 1 year transition period. Therefore, effective immediately, extensions at no fee charge shall be restricted to no longer than two (2) consecutive months per PAAB code section 8.4.iii. Note that extensions are only provided under special circumstances.

All extension requests can be emailed to review@paab.ca with a completed Extension Request Form for each product; see attached. If you have any questions, please contact the PAAB office.

Grace Period is Over.

PAAB STRATEGIC PLAN APPROVED

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

- rewording of the Mission statement
- 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.
- The directors approved the plan at the November 15, 2013 General Meeting.

The directors approved the plan at the November 15, 2013 General Meeting.

PAAB COMPLAINT REPORT

During the period of January 1 to March 31, 2014, the PAAB Commissioner processed 0 Stage 2 complaint.
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 0 monitoring notices.

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