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*"All labor that uplifts humanity has dignity and importance and should be undertaken with painstaking excellence."*

Martin Luther King, Jr.

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](http://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

## 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:

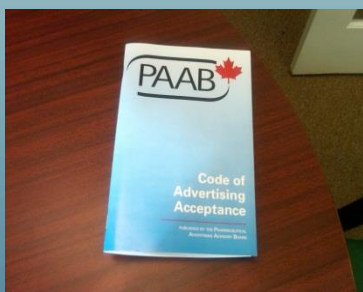
- National workshops
- In-house company-specific workshops
- Webinars
- Newsletters
- External guidance documents and advisories on the PAAB website
- Email blasts
- "Ask PAAB" on the PMCQ website
- Individual telephone conversations with staff

## 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:

## Training Committee Recommendations

- 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.



## “Consistency” Review

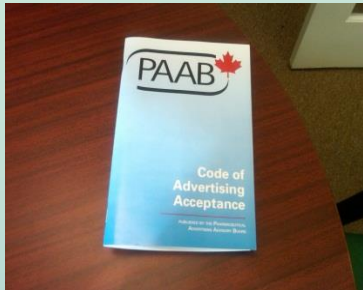
### COMMITTEE ON REVIEW CONSISTENCY

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 will be committee members. Commissioner Ray Chepesiuk will chair the committee. The first meeting is scheduled in October and the committee will decide on a schedule of activities at that time. 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. After this session 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. The second meeting saw the members identify action steps that could be taken by the PAAB commissioner to help improve the review consistency. The committee members were then asked to prioritize the six recommendations to the PAAB Directors. See below.



### *“Consistency” Review*

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.

***The PAAB reviewed a record number of first submissions in 2013 at an on-time completion rate of 99.86%***

## **REVIEW ACTIVITY**

During the period of January 1 to December 31, 2013, the total number of first review submissions was 7,251, with 10 files going more than 10 days on first review. In the same period of 2012 the PAAB reviewed 7,042 new submissions. For all reviewers, the average of turnaround for first review was 7.04 days. 83.7% 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 4.1 days vs. the client holding it 13.6 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](http://www.paabtraining.com) for registration info.

The agenda is based on research conducted by Jon Gwillim with 250 pharma industry and suppliers executives. PAAB is responding to what they have asked for. Come out and learn how to create advertising that is compliant with the PAAB Code of Advertising Acceptance.

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 the Fall Commissioner Chepesiuk spoke in Toronto at the EyeforPharma Digital Marketing Conference and acted as a judge for the 2013 Digital Marketing Awards. The open PAAB workshops in Montreal and Toronto were a success, attracting 240 delegates. In late November Commissioner spoke in London, England at the PharmaCreates session "Deliver value beyond the pill to Payers, Physicians and Patients to create a customer centric business." Commissioner Chepesiuk presented a lecture at the Pangaea Marketing course in October and CRO Massad presented a lecture on applied statistics to a graduate class at the University of Toronto.

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](http://www.paab.ca) for fee info.

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

## NEW PAAB ELECTRONIC FILES 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 February, 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." See [www.paab.ca](http://www.paab.ca) for more info.

***"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 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.*

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

## PAAB STRATEGIC PLANNING

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.

## PAAB COMPLAINT REPORT

During the period of October 1 to December 31, 2013, the PAAB Commissioner processed 1 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.

### STAGE TWO DECISION

ADVERTISER: Octapharma

COMPLAINANT: Grifols

SUBJECT: Multiple APS

PRECLEARANCE: No

ALLEGATIONS: misleading claims, no indication statement, comparative, DTC violations.

DECISION: Send the alleged DTC violations to Health Canada. Multiple violations required shutdown of web-site and cease distribution of letters and posters. Submit for PAAB review.

OUTCOME: Octapharma agreed with the PAAB ruling.

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

Total of 2 stage two decisions in 2013. lowest ever!

**For information or if you have comments:**

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