

Providing a preclearance review that fosters trustworthy healthcare communications within a regulatory framework for the benefit of all stakeholders.

Note From the Commissioner

Welcome to the new format of PAAB Views! We have refreshed our newsletter format with mobile viewers in mind, and hope you find it user-friendly and useful. This new look is actually part of a larger revisit of PAAB's assets and communication channels that we have undertaken to ensure that we are communicating with our important stakeholders in a timely and effective manner. We will be introducing our other refreshed assets over the coming months so stay tuned!

You will find highlights of recent meetings and training initiatives in this newsletter, as well as updates and clarifications on the advertising regulatory environment in Canada. We have prepared a content calendar for PAAB Views and other communication channels for the remainder of 2015 that is based on requests for additional information we have received from you throughout the years. Your feedback matters to us.

We are especially grateful to those of you who took the time to complete the agency and industry online survey circulated in February, 2015. In addition to this survey, as PAAB understands that consistency in reviews has been expressed by some as a concern, PAAB has also implemented an independent audit commissioned by the PAAB Board of Directors to assess the overall operational performance and the level of consistency within the PAAB preclearance review system. The results of both the survey and audit are currently being considered, and opportunities are being identified to leverage the strengths and develop solutions to address the challenges presented. We will share more information as results are finalized and next steps confirmed.

Thank you for your interest in PAAB Views – we welcome your thoughts on our new look and any content you would like to see covered in upcoming editions.

Sincerely,

Ray Chepesiuk
PAAB Commissioner

PAAB Stats

January 1 through April 30, 2015

✓	Number of submissions: 2,560
✓	Time to first response: average of 6.68 days; zero files beyond day 10
✓	Time to revision response: average 2.2 days



Updates

PAAB Welcomes Jehan Lalani

PAAB welcomes Jehan Lalani as its newest reviewer. Jehan received her MPharm degree at the University of London's School of Pharmacy in London, UK. She is a registered pharmacist, licenced in British Columbia and Ontario. In addition to patient care experience in the community setting, she has teaching experience and joins us most recently from the pharmaceutical industry.

Clarification: Materials Only Intended to be Provided in Response to Unsolicited Requests do not Require PAAB Review

As per the Health Canada policy document [The Distinction Between Advertising and Other Activities](#), "Information provided to an individual about a drug treatment(s) by a pharmaceutical manufacturer in response to a request for information that has not been solicited in any way (by the manufacturer of the drug) is not considered to be advertising for the sale of a drug." As such, material of this kind does not require PAAB review.

Note that the response, however, should be limited to the information that is required to respond to the specific request. It is advisable for the company's medical department to document the details regarding the request (eg, date, name of requester, nature of request, content provided, etc).

Please call the PAAB if you have any further questions about this.

Reminder of PAAB's role in DTC communications

Legal jurisdiction over direct-to-consumer prescription (DTCRx) product advertising lies with Health Canada, which has recognized the PAAB as an authorized DTC preclearance agency. The PAAB provides a user fee advisory service on:

- Messages directed to consumers for prescription drugs (eg, reminder ads)
- Material discussing a medical condition or disease (eg, help-seeking messages, consumer brochures)
- Schedule D drug (biologics, including vaccines) advertisements
- Other messages or materials (eg, clinical trial recruitment announcements, press releases, institutional messages, etc.).

The PAAB's assessment for such materials is not based on the PAAB Code. Advisory opinions are assessments as to whether materials, based on Health Canada's policy [The Distinction Between Advertising and Other Activities](#), are promotional, in which case they must be in accordance with the Food and Drugs Act and Regulations, Controlled Drugs and Substances Act (CDSA), and associated policy and guidance documents.

Manufacturers and/or agencies may elect to submit such materials to PAAB for an opinion on whether the materials meet the relevant Health Canada provisions. Materials which have been granted "no objection" status are authorized to bear the PAAB logo as a symbol of that approval. The first response turnaround time for DTC content is four business days. The PAAB advisory review service is recognized by Health Canada.

Visit the Health Canada guidance document [Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising](#) document and the [PAAB website](#) for more information.

Health Canada Posting Complaints on its Website

The Transparency Initiative "Posting of Advertising Complaint Decisions on Health Canada's Website" is one of the 18 transparency initiatives at Health Canada. Since its beginnings in 2011, Health Canada has been working towards implementing this initiative with the intent of posting information on health product advertising complaints received and addressed. This practice aligns with the Advertising Preclearance Agencies (APA) in Canada, as well as key international counterparts. A notice announcing the implementation of this initiative was posted and circulated to stakeholders on March 31, 2015. The summary table providing details about the complaints (company, product, source, issue, action taken) will be posted this spring. The table would then be updated on a quarterly basis.

For more information on Health Canada's transparency initiatives, visit the [Health Canada's website](#).

eFiles Phase Two Improvements

PAAB is always striving to improve our systems for all users. As such, we are pleased to announce that we are in the process of rolling out various improvements to eFiles as Phase 2, set to launch in Q2 2015.

One noteworthy improvement for our clients is the new feature "Client Copy a Submission," which enables a client to use a previous eFile as a draft (copy) for a new submission. Additional information will follow upon launch.

If you have any improvement ideas for us, we encourage you to send them to efiles-qa@paab.ca.

Review Tips & Cases

Retention & Market Share Claims

Comparative claims/presentations related to market share and retention in advertising must be based on empirical evidence which is limited to that which is directly observable and measurable. [Read more...](#)

PAAB is here to help you with the submissions process, and we have heard your requests for case examples. In response, we have begun adding review tips and cases to the PAAB website. Every month, we'll add at least one new entry formulated specifically to address current submission trends or key issues. If you have any suggestions for future posts, please contact Deputy Commissioner Patrick Massad at patrickm@paab.ca.



Training & Events

Board Meeting Update

The PAAB held its Annual meeting on April 24, 2015. Officers were elected:

- Chair Walter Rosser, MD
- Vice-chair Gloria Bowes
- Treasurer Lorenzo Biondi
- Secretary Ray Chepesiuk

The Annual Meeting was immediately followed by a General Business Meeting of the Directors. Highlights include:

1. A Report from the Health Canada representative on the Health Canada/Preclearance Agencies Bilateral Meeting held on April 14, 2015. The minutes of the meeting will be posted on the PAAB website when they are received from Health Canada. We will advise once the minutes are available.
2. A Progress Report from the Commissioner regarding the Code Gap Advisory Committee. The Board agreed to strike a code committee composed of members appointed by the PAAB member organizations (and coordinated by the commissioner) to apply recommended revisions to the PAAB Code.
3. A Report from the Governance Review Committee with two resolutions approved by the Board. A Handbook of policies was approved, and a stakeholders issues forum to advise on operational matters was created.
4. Preclearance Review System Consistency Audit. The auditor of the independent audit presented the final findings to the whole Board for the first time. The audit results are currently being considered and opportunities are being identified to leverage the strengths and develop solutions to address the challenges presented. We will share more information as results are finalized and next steps confirmed.
5. Progress Report on Communication Plan 2015. Salient Communications gave an update on the plan and the activities related to it. Communications specifically related to PAAB's social media assets are being prepared, with a view to providing timely updates and maintaining ongoing dialogue with PAAB's important clients and stakeholders.
6. The Board will next meet on June 19, 2015.

Health Canada Bilat with Preclearance Agencies

The annual meeting of Health Canada officials and representatives from the three advertising preclearance agencies met on April 14, 2015. Health Canada was represented by 23 officials from seven areas of Health Canada, and they were joined by six representatives from the PAAB, ASC, and Extreme Reach. All parties were able to send in topics for discussion prior to the meeting. There were 12 sections to the agenda and the meeting was chaired by John Patrick Stewart, Interim Director General of the Marketed Health Products Directorate (MHPD). Minutes of the meeting will be posted on the PAAB website when they are received.

Highlights of Webinar: CASL Compliance for Pharma Companies – Where Are We Now?

On April 30, 2015, DLA Piper (Canada) LLP (formerly Davis LLP) hosted a complimentary webinar exclusive to PAAB clients called "CASL Compliance for Pharma Companies – Where Are We Now?"

The webinar began with an explanation of the types of messages that fall under the scope of commercial electronic messages (CEMs). This was followed by elaboration on which types of messages are exempt, and a focus on CEM issues that are particularly relevant for pharma companies. There was also discussion of CASL's computer program rules as these may have some implications on pharma-generated apps. The webinar concluded with a segment outlining what we can/should learn from CASL enforcement cases to date.

If you missed this learning opportunity, have no fear. The webinar was recorded. It will be uploaded onto the PAAB website for your viewing pleasure. We will advise once the recording is available.

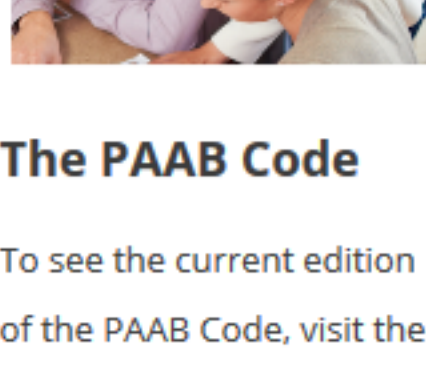
Overview of Brightworks Innovation Day (by Jennifer Carroll, PAAB reviewer)

On March 4th, 2015, four representatives of PAAB attended Brightworks Innovation Day, a day hosted by the Toronto-based advertising agency, Brightworks, designed to inspire those in attendance from multiple industries to think outside of the box in both business and play. By bringing together a diverse group of people with differing backgrounds, the day served to provide collaboration through sharing of previous learnings.

The speakers at this event were captivating as they shared their stories with us on how they seized opportunity, tried new things and got creative to become successful. Some common themes I took away from the day were:

- Content should be timely and timeless if we want it to be impactful
- As a company and employee, you should know what your values are and how you are going to communicate them to various audiences
- Inspiration was another common trend. The speakers elaborated on how they took things that they were passionate about and developed them into the products they are today
- The importance of staying up to date on emerging mobile and digital trends was also stressed
- Many speakers outlined how storytelling was a great way to connect with customers in an authentic and meaningful manner across numerous new platforms. One noted that you can be creative and stay within the rules
- The day ended with the following thought from Nick Parish from Contagious Magazine: **Innovative creativity is still the best way to create an unfair advantage**

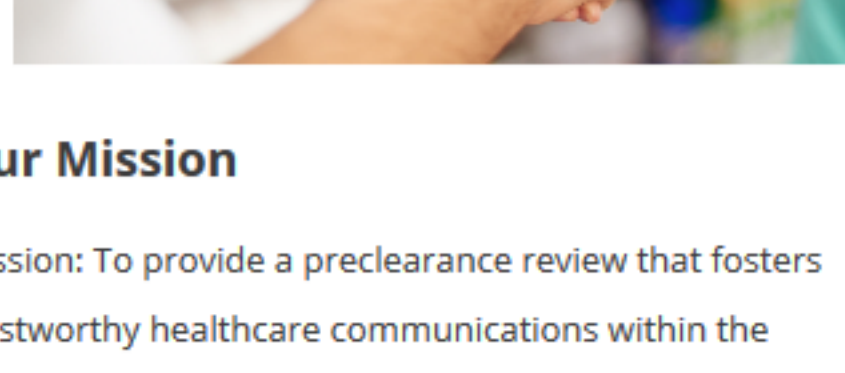
This day gave us great insight into leading-edge technologies that may soon start appearing in submissions, and helped encourage us to think creatively while challenging us to find ways to improve our job through innovation.



The PAAB Code

To see the current edition of the PAAB Code, visit the PAAB website

at www.paab.ca/paab-code.htm.



Our Mission

Mission: To provide a preclearance review that fosters trustworthy healthcare communications within the regulatory framework for the benefit of all stakeholders

Vision: Trusted healthcare product communication that promotes optimal health

Values: Integrity, competency, credibility, independence, excellence, transparency

Social Media

[in](#) [linkedin.com](#) PAAB

Contact us

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