PAAB FORUM

QUARTERLY REVIEW

A review of the last quarter on the PAAB Forum: July - September 2025

Announcements

- **AI Assisted Submission Process** – PAAB has now started mapping AI augmented services for file submissions. If you are an agency who would like to contribute to testing and provide feedback to improve features, please reach out to Info@PAAB.ca Attn: Danielle Anthony **before the end of November**.

- **Monitoring Incidents:** There has been a total of 40 monitoring incidents reported to Health Canada or dealt with through PAABs channels.

- **Medical/Regulatory Sign-Off** – We have received consistent feedback that sequential reviews are a significant time delay for some companies when developing APS. A concurrent review between MLR and PAAB can remove this delay. In Q3, PAAB revised the submission form to an "optional" field that can still be completed if required for internal compliance but **will not be required** by PAAB.

- **PAAB National Workshops:** PAAB National Workshops takes place November 4th in Toronto and November 6th in Montreal. This year PAAB staffers are joined on stage by representatives from Lemieux Bedard, to share a real RWE case example, and bMod, Point05, and Wellworth and Best, to share the new Creative Imagery document. It is a day of engaging and interactive learning.

- **PAAB IP:** Responses, guidance, and advisories provided by the Pharmaceutical Advertising Advisory Board (PAAB), including but not limited to those available through the PAAB Forum, the PAAB website, and any PAAB correspondences, are specifically intended to assist individuals navigating the PAAB preclearance system. Repurposing or reproducing this content requires written consent from the PAAB Commissioner.

- **ARO EXPANSION IS COMING: Watch for the official launch date on Forum and in your email inbox! -** ALL APS will be eligible for ARO, with the following exceptions:
    - APS that include many pages of new content or many references requiring detailed review will have to meet the following thresholds:
        - ARO 2: >10 pages of new content or >5 references requiring detailed assessment
        - ARO 4: >20 pages of new content or >10 references requiring detailed assessment
        - ARO 7: >40 pages of new content or >20 references requiring detailed assessment

      ARO 2 and ARO 4 are also generally not available for APS using data from non–Product Monograph studies unless those studies have been previously approved for use in advertising.

- **Reminder: Client Messenger: 🎉 Available for all Files 🎉** In Q2 we have continued to see use of Messenger to help expedite review of eFiles. This feature is particularly helpful on nuanced topics which may require multiple rounds of discussion, impacting the timeline of the remaining content review.

  Early trends:
    - Most clients have requested Messenger *after initial submission.*
    - Common uses of Messenger include resolving comments on new creative concepts and data, and layout positioning issues between rounds of revision to reduce rounds of review.

  To request Messenger after initial submission, please reach out to review@paab.ca and request that they turn Messenger on for your eFile.

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New Documents

- **Creative Imagery Document** – While technically posted October 3rd, we snuck this one into the quarterly update so it wouldn't be missed. This document, created in collaboration with industry, provides new approaches to creative that balance utility and credibility.
- **Expanded Manufacturer eFiles Permissions** – This document provides a brief summary of the functionalities available to both agencies and manufacturers within eFiles. Knowing what features you have at your disposal can help with tracking, reporting, accountability and overall efficiency. If there are features you'd like to see added, reach out to info@paab.ca.
- If you missed last quarter's review, don't forget to review here to make sure you're up to date on all things new at PAAB and upcoming projects.

Q&A

20 Forum questions across 11 agencies from 13 different users. Topics covered:

- Safety updates to TMA
- RWE dosing and comparators
- Exempt messages
- Patient preference in case studies
- Abstracts and linkages
- Promoting clinics
- RAMQ definitions and notes
- Pre-NOC review
- Schedule II and DTC
- Ongoing trials
- Opioid market research

In the Works for 2025

RWE UPDATED formatting Guidance – The RWE Guidance, launched on February 1, 2024, marked a groundbreaking shift in how clinical data can be shared. In November, a supplement was introduced to address the evaluation and use of single-arm studies—demonstrating PAAB's ongoing commitment to reassessing the evolving market landscape.

Shortly, PAAB will be sharing guidance on updates to the "Attention Icon" and "Grey box". The revisions are based on feedback from HCPs on the perceived emphasis and weight of the RWE data in pieces due to the current formatting. PAAB has worked with a number of agencies over the last few months, to revise the "Attention Icon" to be better aligned with the core disclosure and transparency goals. Please stay tuned for the updated guidance.

New service offerings – PAAB has been collecting feedback from industry through the Customer Experience Index (CEI), trade associations, and informal interactions, on opportunities to increase touch points throughout the review process. Based on the changing and growing need for increased access to PAAB review staff and to facilitate quicker turn around timelines, preplanning processes, and live collaborations, PAAB will be introducing a few new services before the end of the year. Stay tuned to learn more.

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eFiles Tag and CEI Reports

- Q3 tag report and CEI report are now live. Review the most common tags, what PAAB is doing to address them, and the CEI feedback submitted by you and your colleagues.
- As a reminder, the tickets are **completely confidential.** If you want more information on the tagging system, please see Client Tagging System Advisory.
- As a reminder, the CEI captures the **overall experience** with a file and the review process. It helps to impact macro processes and performance. The "tags" help us pinpoint cases where there was an event that could be assessed for learning purposes, checked for consistency, or which could be used to implement change. This specific feedback helps us improve performance on a more granular level.

Is there more information you would like to know and see in the next quarterly update? Let us know on the forum.