PAAB FORUM

QUARTERLY REVIEW

A review of the last quarter on the PAAB Forum: April - June 2025

Announcements

- **PAAB AI Model Testing Launched May 1, 2025:**
  We are thrilled to announce that the Pharmaceutical Advertising Advisory Board (PAAB) has started testing its regulatory review model on live files, starting with patient pieces. PAAB is grateful to all clients who opted-in and look forward to providing updates on the testing along the way.

  This initiative marks a major milestone in enhancing the efficiency, consistency, and effectiveness of advertising review processes for our industry, ensuring that preclearance keeps pace with the speed and quantity of specialization afforded through AI adoption across the industry.

- **Monitoring Incidents:** PAAB has reported 29 marketing incidents to Health Canada so far in 2025. This is in addition to 7 monitoring incidents in which we directly reached out to the manufacturer as the incidents were related to materials which were closely related to precleared APS. Keep an eye on the PAAB website for the publication of a reporting table.

- **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.

- **PAAB National Workshops:** Early Bird tickets for PAAB National Workshops are now live for the November 4th Toronto session and November 6th Montreal session. Don't miss this day of diving into cases on RWE and Creative. Hear from colleagues in the industry and PAAB on best practices for streamlining submissions and evaluating studies.

New Documents

- **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

17 Forum questions across 8 agencies and 1 manufacture from 13 different users. Topics covered:

- International guidelines
- Exempt formulary messages
- Comparative adverse events outcomes
- FB weblink destinations
- Patient reported outcomes (PROs) from RWE
- Ungated websites and HCP advertising

- Reformatting approved APS
- RMT submissions
- Patients on multiple products

In the Works for 2025

RWE Guidance Continuous Evaluation of Approach – 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.

In 2025, we'll continue this approach by entering early-stage consultations with multiple stakeholders to explore different aspects of RWE studies and additional study types. While it's too early to know whether changes will result, we're committed to keeping stakeholders informed as these discussions develop.

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.

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. We've delayed this launch to Q3 to be rolled out with updates to the EFiles system. In Q3, PAAB will be revising the submission form to an "optional" field that can still be completed if required for internal compliance but will not be required by PAAB. Additional details will be provided upon revision of the submission form.

eFiles Tag and CEI Reports

- Q2 tag and CEI report will be coming shortly. Stay tuned to see 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.