PAAB FORUM

QUARTERLY REVIEW

A review of the last quarter on the PAAB Forum: October - December 2025

Announcements

- **Attention Icon Formatting** – After feedback and consultation with various stakeholders, PAAB worked collaboratively with a number of agencies to generate a revised Attention Icon Formatting Guidance. Learn more in the New Documents section below.

- **Expansions for Rare Diseases** – Based on consultation with various stakeholders and experts, PAAB is expanding our approach to advertising for rare diseases, to accommodate presentations from post-hoc studies (See Section 3).

- **Protecting the Integrity of PAAB Resources** – PAAB resources have been transitioned to a secured platform. Login can be done with your eFiles account access information. In the event that you do not have an eFiles account, a resource account can be set up. The account should be set up with a work email. If the email domain has not been approved, please reach out to info@paab.ca for assistance.

- **AI Assisted Submission Process** – PAAB has now started mapping AI augmented services for eFile 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 January**.

- **Monitoring Incidents:** The year ended with a total of 46 monitoring incidents reported to Health Canada or dealt with through PAABs channels.

- **ARO EXPANSION HAS ARRIVED:** 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 – Free with ARO through end of Q1 – In celebration of PAAB's 50th anniversary 🎉**

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

- **Reminder: 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 or starting the PAAB review prior to the MLR process, 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.

- **Reminder: 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.

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New Documents

- **Creative Imagery Document** – This document, created in collaboration with industry, provides new approaches to reviewing creatives that balance utility and credibility. If you'd like to partner to build out more cases and examples, please reach out to review@paab.ca
- **Attention Icon Formatting Guidance** – This document outlines the revised approach to formatting for the Attention Icon. The new icon and formatting captures feedback from HCPs while maintaining the integrity of separation and clear disclosure of non-gold standard data. Ongoing files can update the formatting immediately if they wish. Straight renewals will be considered without revision to formatting. If the client wishes to make revisions, the new formatting will be required starting at the beginning of Q2, 2026.
- **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:

- RMT and MSL
- Controlled drug websites
- Prognosis as BoD
- Annotated product monographs
- DTC URL
- Short of stock messages
- Study design comparisons
- Secondary endpoints
- Scrollable fair balance
- RWE studies and application
- Google responsive ads

In the Works for 2026

Introducing NEW Consulting Services:

PAAB is pleased to introduce a set of enhanced consultation services designed to make it easier for clients to engage with us early and often throughout the development and review process. These services provide flexible, timely access to PAAB expertise, helping clients anticipate issues, reduce rework, and move forward with confidence.

Rapid Access Consults
Rapid Access Consults offer fast-turnaround feedback on targeted questions or materials. This service is designed for situations where speed is critical and focused regulatory insight is needed quickly.

Intra Review Consults
Intra Review Consults allow clients to engage with PAAB while a submission or review is already underway. These consults help address questions, clarify expectations, and resolve issues before they escalate**.** Move beyond traditional back-and-forth communication to live virtual discussions and presentations.

PM Consults
PM (Product Monograph) Consults support proactive project management by aligning

regulatory considerations with timelines and deliverables. This service helps teams integrate PAAB guidance into broader planning and execution.

Together, these services are designed to support ongoing dialogue with PAAB, helping clients engage earlier, consult more often, and navigate the review process more effectively. To learn more, please visit the resource section on www.paab.ca.

Anonymous Advertising Reporting System – PAAB will be launching an anonymous reporting portal on the PAAB.ca website. This system creates a space for all stakeholders to report advertising anonymously (optional) and confidentially. This system is designed to reduce the barriers to reporting advertising which is perceived to be in violation of the advertising regulations and PAAB Code.

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.