PAAB FORUM

QUARTERLY REVIEW -

A review of the last quarter on the PAAB Forum: October – December 2023

Announcements

- **CODE UPDATE:** Effective February 1st, 2024. An update to the PAAB Code has been approved by the Board. The change to the Code allows for an expansion of permissible presentations in advertising through the use of the Attention Icon and appropriate formatting. The presentation standards around the inclusion of data under the updated framework can be found in the <u>Guidance on Real-World Evidence/Data</u> document and <u>Guidance on When the Attention Icon is Required and Its Presentation</u>.
- Burden of Disease Guidance: PAAB has finalized Guidance on the Presentation
 of Burden of Disease in Advertising and an examples document which was
 prepared with support from bMod, CORE Health Communications, FCB Health
 Canada and GSW. Submissions using the new guidance can be considered as of
 February 19th, 2024.
- Pre-NOC submission window and quantity expansion: PAAB no longer requires that the TMA be at final draft stage and no longer has a 2-piece cap on pre-NOC submissions. Approval will continue to be pending NOC and updates to the PM mid review may incur additional costs. Full details can be found in the link in the documents section below.
- **Creative Imagery Committee:** The committee continues to work through creative examples to create alignment. The committee's next meeting is January 17th. Learn more.
- CEI Celebrating our 2023 Top Contributors: PAAB has <u>published</u> our top CEI contributors and would like to thank everyone who contributed in 2023. We hope to see the contributions continue into 2024 as we collect feedback to continuously improve client interactions.

New Documents

- Draft Code Change APPROVED by the Board
 - This document provides the summary of proposed changes to the PAAB Code in order to create alignment with the implementation of new guidance on RWE. In addition to some background information, you'll also see a proposed implementation timeline.
- Administrative Guidelines for the Review of Pre-NOC Advertising Submissions
 - <u>This document</u> covers PAAB's revised approach to the review of pre-NOC pieces which now no longer requires waiting until draft stage TMA. The document outlines expected timelines costs associated with TMA changes, and removes the limitation of only 2 pieces pre-NOC. Approval will continue to be pending NOC. Questions and comments can be left on the Forum thread at the base of the document page.
- Guidance on the Presentation of Burden of Disease in Advertising
 - <u>This document</u> describes PAAB's expanded approach to disease burden presentations in advertising materials.
- Guidance Regarding Duration of Clinical Trials Used as Reference Support in Advertising
 - This document is an update to our previous approach to study duration. For 6
 months we will keep an annotated version on the site to assist in seeing the
 changes from the past guidance. We hope that you find this useful.

Q&A

22 Forum questions from industry answered on topics such as:

- Help-seeking messages
- "#1 dispensed" claims
- Interim analysis
- Other languages
- Specific comorbidities
- Middle level fair balance links

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- Gating requirements
- Email sign-off 1:1
- Reprints on HCP websites

In the Works for 2024

Renewals – Big changes are coming to the renewals process to help streamline the process, cut down on costs and help manage timelines. Stay tuned for more to come soon.

Al Assisted Submission Process - PAAB has started the process to build out Al powered systems that will assist clients during the preparation of submissions to know when elements are missing that could result in a delay in the acceptance for review, with aspirations of eventually assisting with referencing and annotating things like previously approved copy in past files. We will be looking for clients who are well versed in Al to be part of a committee which shapes this development, so stay tuned.

Messenger system – Messenger functionality in files has been undergoing testing since the late part of in Q4 of 2023. We hope to have this additional service offering to ARO submissions up and running in Q1 of 2024. Make sure you're registered for the Forum to be the first to know when this service goes live.

External Training – PAAB continues to build out our <u>on-demand training</u> offering the PAAB 1.0 and PAAB 2.0 online training services. Moving into 2024, let us know what training you would like available and areas of interest with this <u>quick survey</u>.

Monitoring – Reminder that the <u>Guidance on GATING of websites</u> which was produced in collaboration with Health Canada has been live for almost one year. As was outlined at the time, manufacturers controlling websites that do not appear to meet the minimum gating standards will be contacted through our monitoring activities.

eFiles Tag and CEI Reports

- The Q4 PAAB Tag report will be posted soon. We would like to take another opportunity to thank everyone who contributed to the tagging system this year. We've been able to identify inconsistencies and improve training and internal processes as a result of their use. Similarly, the CEI surveys have provided immensely positive and constructive feedback. We'd like to thank all those who participated, especially our TOP 10 responders! We hope to continue this momentum into 2024 as we strive to provide the best customer service possible.
- As a reminder, the tickets are completely confidential. If you want more information on the tagging system, please see the <u>Client Tagging System Advisory</u>.
- 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 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.