PAAB FORUM

QUARTERLY REVIEW

A review of the last quarter on the PAAB Forum: July – September 2022

Announcements

- ARO (Accelerated Review Options) launched July 4th
 - o See the figures on ARO use after 2-months of availability
- We continue to update the ARO resource table with new documents to help with the adoption of ARO and new submission formats. Check back on this handy page from time to time
- Questions posed to PAAB about ARO, will be posted publicly at <u>PAAB Forum</u> <u>Accelerated Review Options (ARO)</u>. Please refer to this page prior to reaching out with questions, and feel free to post your questions directly to this space
- Reminder to those looking to register for the <u>Forum</u>, to use a *professional email* for security purposes. You can select to have your email hidden on your
 profile page after registration. If you do not use a professional email, your
 registration will not be accepted.

New Documents

- Supplementary Guidance on Identifying Pickup Copy
 - These documents elaborate on the submission formatting requirements to provide further clarification on what is considered "direct pickup", as well as examples on how treatment of direct pickup can be addressed.
- Complaints Report for 2022
 - Ruling summaries for all Stage 2 or greater, complaints PAAB ruled on to date in 2022.
- 6 Article Series
 - Article 1: Preclearance is a PAAB Code requirement for advertising that falls within the Code's scope unless it is expressly exempted from preclearance in Section 1.5 of the Code.
 - Article 2: An internal review alone does not satisfy the Code's preclearance requirements. This is true even if consideration of the PAAB Code standards are incorporated into that internal review
 - Article 3: The PAAB Code applies to all manufacturers irrespective of membership status with any trade association
 - Article 4: Recent and imminent improvements to PAAB preclearance: Update on Accelerated Review Options (ARO) and the new submission formats
 - Article 5: PAAB and Health Canada collaboration in HCP advertising monitoring --Exciting update & important process change
 - Article 6: Calling on industry members who have expertise in appraisal of Real-World Evidence (RWE) who want to help shape the future of evidentiary standards in advertising

Q&A

19 Forum questions from industry answered on topics such as:

- Vaccines
- Formulary exempt and exempt messages
- Gating
- Extension studies
- Study footnote placement
- HCP access to patient sites
- Pre-NOC submissions and the use of ARO
- Submissions, ARO, Minor updates
- Post-hoc data
- PM claims with no statistics

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Myths vs. Facts

Keep an eye out for new "Myths vs. Facts" coming later this year and make sure you're familiar with the common ones posted now so that your company isn't falling into the "Myths" trap. Check out PAAB Myths page today.

<u>Let us know</u> if there are any myths you want clarification on, or for PAAB to help dispel for the industry.

eFiles Tag Report

The second quarter <u>PAAB Tag Report 2022</u> has been posted. We continue to
encourage clients to use the tagging system to help PAAB identify areas of
improvement and areas of valued service. As a reminder, the tickets are
completely confidential. We look forward to your continued feedback moving
into the second half of 2022. If you want more information on the tagging
system, please see <u>Client Tagging System Advisory</u>.

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