PAAB FORUM QUARTERLY REVIEW –

A review of the last quarter on the PAAB Forum: July – September 2023

Announcements

- Real World Evidence (RWE) Update: A draft of the RWE document has been sent to Health Canada for consultation. Access to the draft document can be found <u>here</u>. PAAB will continue to provide updates on the process. If approved by Health Canada, there will be a three-month window to allow all companies to assess and integrate changes should they choose. Updates will be posted to the PAAB Forum thread <u>RWE Committee Updates</u>. Please follow for timely updates.
- **Burden of Disease Draft Guidance:** PAAB is in the process of finalizing the guidance document and the addition of examples in collaboration with industry. We are hopeful for a fall launch with a one month implementation period.
- **Creative Imagery Committee:** The committee has met twice and will continue to meet as we discuss the state of creative concepts and areas for improved clarity and broadening of scope. <u>Learn more</u>.

New Documents

- Draft Code Change Currently Undergoing Health Canada Review
 - <u>This document</u> provides the summary of proposed changes to the PAAB Code in order to create alignment with proposed changes to the review of real-world evidence. In addition to some background information, you'll also see a proposed implementation timeline.

Q&A

18 Forum questions from industry answered on topics such as:

- PSPs for multiple products
- Biosimilars in patient material
- EAP Listings
- RAMQ
- Website submissions
- Corporate site
- Linked resources
- International conferences
- DTC surveys

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 <u>Myths</u> page today.

Let us know if there are any myths you want clarification on, or for PAAB to help dispel for

the industry.

eFiles Tag and CEI Reports

The Q3 <u>PAAB Tag Report 2023</u> has been posted. Thank you to everyone who completed a tag. 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 throughout 2023. If you want more information on the tagging system, please see <u>Client Tagging System Advisory</u>.

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• 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.