



Happy Holidays

Heading into the holidays, we've wrapped up some helpful tips and clarifications for eFile Submissions.

- If considering an **ARO submission**, please check page 6 of the [ARO Planned Features Detailer](#) to ensure your APS meets the current eligibility criteria.
- **ARO submissions:** Any APS with ≤ 2 pages of new content and ≤ 5 references is eligible for ARO 2. Submissions containing ≤ 10 pages of new content are eligible for the remaining levels of ARO. However, due to the nature of the review, RMTs, DTC, and patient information have often been excluded from the limit of 10 pages of new content. Consult with a PAAB file coordinator prior to submitting ARO patient information, DTC, or RMTs that exceed 10 pages of new content. Please indicate in your cover letter how your APS qualifies for ARO.
- Although we will accept layout alone for straight renewals (English and French), a copy deck is still required for website and video **renewals**. This is an update to the latest Submissions Guidance document as it has proved challenging to review videos and websites without a copy deck. Please see s. 2.1.3 of the [Guidance On Submission Process and Format Requirements](#) for details. Note that 'renewal' file types must show 100% direct pickup from the previous file. However, FYI changes such as version codes, trademark/logo changes, resizing and French grammar are not counted as new content.
- Reminder: **Series submissions** must show at least 60% common copy with the parent file, shaded in light blue. Please indicate in your cover letter that your submission is a series and submit the parent file first. Series submissions need to be submitted on the same day as the corresponding parent file. Please see s.2.2.1c of [Guidance On Submission Process and Format Requirements](#) for details.
- **Iterative submissions** include one layout in the base fee. Enter the number of additional iterations in the submissions form (e.g., a submission for desktop, mobile and tablet in one iterative submission would be 2 iterations). Please see page 7, s.4.2 of the [ARO Planned Features Detailer](#) and page 14, s.2.2.1 of the [Guidance On Submission Process and Format Requirements](#) for details. Please indicate that your submission is iterative in your cover letter.
- **"Time sensitive"** announcements per page 6 of the ARO Detailer [ARO Planned Features Detailer](#) are brief announcements (≤ 2 pages) that focus on a time sensitive issue. While we know there are many news-worthy developments in the pharmaceutical industry, what ultimately renders a piece a 'time sensitive announcement' is the need to be disseminated



in an urgent manner (e.g., safety concerns, indication authorizations). Please refer to the most recent [ARO Q&A #8 Time Sensitive Announcements](#) for examples of time sensitive announcements.

- Please note that a “**minor update**” file will replace the previous version of the original file and maintain the previous file’s approval period. Prior to submitting as a minor update, please ensure that the previous file's approval is still valid, and you are comfortable with maintaining that expiry date. Please refer to page 12 of the [ARO Planned Features Detailer](#) for details and examples. Indicate the previous file in your cover letter along with details of the updates. For minor updates which require only the removal of a claim or content, a final copy-correct layout will be accepted for review. If updates to copy are more complex or require referencing, a copy deck is required.

Reminder: As per the [ARO Planner Features Detailer](#) originally published in Nov of 2021 and the website [fee schedule](#), the PAAB is adjusting fees annually to account for inflation. **As of April 2023, the fees will be increased by 5%.** These adjustments will impact all files submitted as of April 3rd. All fees are exclusive of HST.

We encourage all clients to connect with the PAAB Forum for real time updates and answers to commonly asked questions by [completing your registration](#). You may select to follow specific categories and receive updates as they are posted.

Happy Holidays from the Team at PAAB