Complementing the Standard Preclearance Pathway with Accelerated Review Options (AROs)

Planned Features Document

January 2022

Edit from Nov 2021 version: Series submissions have been removed from the list of exceptions for the supplemental page fee. This exception was originally included in error as it does not reflect current practices

CONTENT

IMPORTANT: This is a planned feature document for a set of expedited preclearance timelines we expect to launch on July 1, 2022. Specified features may change prior to, during, or after the pilot.

Section 1

What are "Accelerated Review Options" **(AROs)?**

The AROs are a set of expedited preclearance timelines that cover four urgency levels and a wide range of budgets while maintaining the same rigour and quality of review as the existing standard preclearance pathway.

While we assess the demand for these new urgency levels, the PAAB will continue to offer the existing standard pathway. For Advertising/Promotion Systems (APS) submitted through the standard pathway, the PAAB will continue to provide the first response in ten or fewer business days, while responses for revisions will continue to be provided within three or fewer business days. Although response times can be shorter than these standard timeline targets, this outcome is typically unpredictable as it is the result of many dynamic factors impacting submission volume and review capacity. By contrast, agencies or manufacturers submitting APS through the ARO-2, ARO-4, or ARO-7, can be assured that they will receive their initial response within two, four, or seven (or fewer) business days respectively, while responses for revisions will be received within two business days. APS submitted through the ARO-10 will follow the initial response timeline of the standard pathway; however, all other benefits of the AROs will be provided, namely receipt of revision responses within two business days, and availability of the messenger functionality. A detailed explanation of the ways the AROs can reduce time to approval is outlined in **Section 2.**

During the July 2022 pilot launch, the AROs will initially be available for a subset of submission types that are outlined in the list in **Section 3.** This list will increase over time as PAAB optimizes staff levels, technologies, policies, and procedures to ensure that we continue to deliver excellent service quality.

Every reviewer will deliver the standard and accelerated review pathways. Submissions will continue to be assigned to the reviewer based on our existing therapeutic team specializations for optimal efficiency and consistency. Choosing one of the AROs for some APS and the standard review pathway for others will not typically lead to reviews for a single brand being split across multiple reviewers at a time.

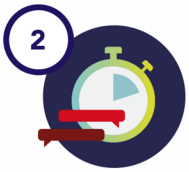
Section 2

How can **AROs** reduce time to approval?

2.1 Shorter response time for initial review

For a shorter time to first response, you can choose from two, four, or seven business days depending on your budget and urgency. See ARO-2, ARO-4, and ARO-7 respectively in **Annex 1.**

The ARO-10 is an urgency level that was added in response to client requests. Although it does not shorten response time for initial review, it can shorten time to approval through the other mechanisms listed below (i.e., 2.2 and 2.3).



2.2 Shorter response time for review of revisions

Due to the complexity of advertising directed to healthcare professionals, most submissions are not approved during the initial review. Client revisions based on PAAB's review letters will be assessed within two business days (as opposed to three business days in the standard preclearance pathways).

2.3 Reduce the number of resubmissions to approval by using the messenger functionality to obtain timely review decisions on pivotal segments of the APS before resubmitting the complete revised copydeck/layout

The messenger functionality is a feature exclusive to the AROs. It is intended to be used selectively to help move key elements of the APS forward. It enables agencies and manufacturers to receive PAAB review decisions on pivotal segments of the submission before resubmitting the entire copydeck/layout. This feature may reduce time to approval for the following reasons:

- The ability to obtain review decisions before resubmitting the revised APS should reduce the number of resubmissions of the complete copydeck/layout required for approval
- Time savings from not having to wait until all revisions requested throughout the copydeck/layout are performed, and vetted through the manufacturer, prior to obtaining review decisions on pivotal parts of the copydeck/layout.
- APS may contain pivotal segments that set the direction/context for the piece and, thus, have an impact on the remainder of the APS. Having the ability to decouple those pivotal segments, and receive timely review decisions relating to them, allows the marketer to determine how to proceed with the remainder of the copydeck/layout prior to resubmitting it for review.

Reviewers will continue to be available for live phone discussion to provide clarification on revision requests. However, review decisions are NOT provided over the phone. Only written correspondences, including the messenger functionality, provide the opportunity for reviewers to perform the level of due diligence that a review decision necessitates. PAAB responses through the messenger functionality:

- will be provided within 24 hours *(excluding weekends, holidays, and other PAAB office closures)*
- carry the weight of review decisions that are provisional only on the final context established by the remainder of the revised copydeck/layout

In addition to providing a timely mechanism for potential revisions to be considered, the messenger functionality provides the opportunity for a question to be answered without requiring all parties to be available for a live discussion. As an added benefit, the eFiles system will enable the agency account supervisor to add relevant staff from the manufacturer into an ongoing messenger discussion (e.g., individuals from the medical department, marketing department, regulatory department, etc.).

As indicated in the fee schedule in **Annex 2,** limits and/or fees associated with the number of messages per round of review will be established, if necessary, based on utilization patterns observed during the pilot. This is unprecedented territory for PAAB and our clients, so we will make data-driven decisions based on real-world experience.

Section 3

For which **APS** types will the **AROs** initially be available?

Although the list of APS types will grow over time, the AROs will initially be available for the following (as of the planned pilot launch in July 2022):

- Time-sensitive announcements (e.g., formulary coverage changes, guideline updates, product shortages, availability announcements, and so on)
- Updates to the information approved in prior APS ("minor updates" and "APS with little new content" as defined in section 7 and section 6 respectively)
- Launch materials for products approved via Health Canada's "Interim Order" or their "Accelerated/Priority Review"
- Print pieces that are re-purposed to digital media (or vice versa) where the criteria for exemption from preclearance, outlined in the PAAB Guidance "Clarification regarding digitization of APS", are not met.
- Risk Management Tools (RMTs)
- Patient information APS

This list was designed to balance BOTH of the following critical but potentially conflicting objectives of the pilot's initial phase:

1. Allow for the volume and heterogeneity of accelerated preclearance submissions to be sufficient to pressure-test our policies, practices, procedures, and technology to generate data that will guide fine-tuning.
2. Ensure that our resources are not overburdened during the initial growing stages in a manner that could compromise either review quality or success of the pilot.

We will be monitoring implementation carefully during the pilot rollout to make data-driven decisions on the timing of additions to the list of APS types.

Section 4

What new features introduced in the **AROs** pilot will be offered in the standard preclearance pathway?

4.1 Modular submissions:

As of the July 2022 pilot launch, manufacturers and agencies (whether working through the standard pathway or the AROs), will have ability to make modular submissions. Manufacturers or agencies begin by building a module library or database. PAAB will then assess the modules independently from each other to ensure that their content is accurate and not misleading. The library/database then acts as a reference from which future submissions are built by selecting and sequencing a subset of the modules from the library/database. Because the content in each module has already been reviewed, the review is focused on ensuring that the flow and context adheres to the applicable standards of the Code (including disclosure requirements). This should generally result in fewer back-and-forths to approval. **Section 8** discusses the fee structure for modular submissions.

4.2 Iterative submissions:

Our clients occasionally need to submit several versions or iterations of an APS concurrently. The PAAB has invested in upgrades to the eFiles submission system that will enable manufacturers and agencies to submit different iterations of an APS in the same docket, or even the same copydeck, while still assigning the appropriate number of review fees. This will make it easier for agencies and manufacturers to track projects that use variable fields or email subject lines tailored to audience demographics or valuegraphics. It will also benefit projects that contain the same content but with different layouts configured for different platforms (e.g., PC, tablet, smartphone), as well as app store descriptions for different stores. **Section 9** discusses the fee structure for iterative submissions.

Section 5

Fees

The PAAB fee schedules effective July 2022 are annexed as follows:

- **Annex 1: Base fees for PAAB reviews**

  Includes the planned fees for assessment of healthcare professional (HCP) advertising, patient information, direct to consumer advertising or information (DTCA/I), risk management tools (RMTs), and requests for written opinion.

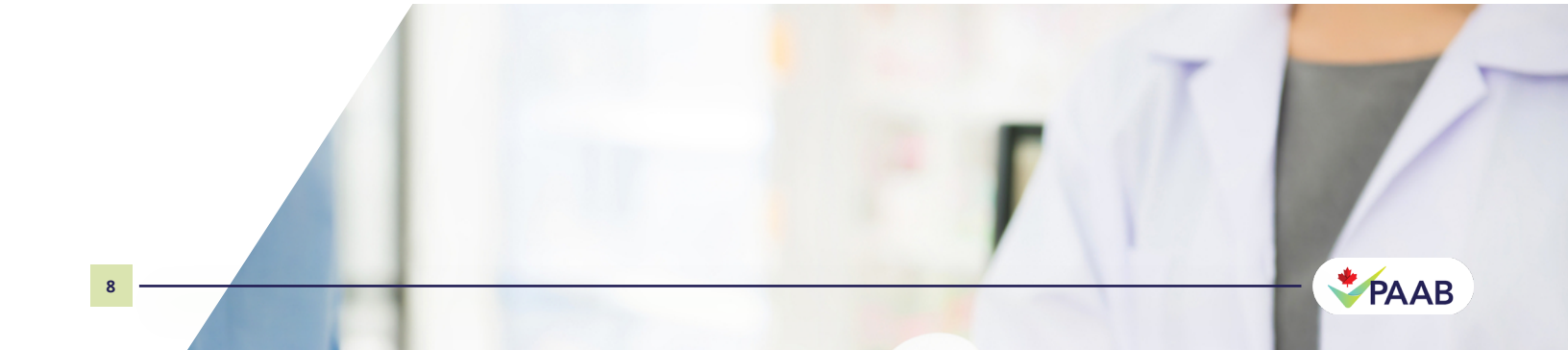
- **Annex 2: Supplementary fees for PAAB reviews**

  Includes the supplemental length/reference fee and the supplemental resubmission fee.

- **Annex 3: PAAB meeting and training fees**

  Includes the fees for in-house training sessions and for virtual consultative meetings.

To assist in planning future submissions, a fee calculator will be added to the eFiles system.



Section 6

"New content pages" - **a new parameter in the fee schedules**

The number of pages of new content in a submission is an important factor in the resource intensiveness of a PAAB review. For submissions with little new content (i.e., two or fewer pages of new content), the review fees for the AROs in section "a" of Annex 1 are reduced. Please see the annex for details.

Section "a" of Annex 1 also outlines how the number of new content pages potentially impact availability of ARO-2 for submissions of higher complexity.

Finally, the number of new content pages impacts the size of the supplemental fee assigned to longer APS as outlined in Section 7 and Annex 2.

How are the number of "new content pages" determined?

APS content that are accurately identified as being extracted verbatim from previously approved materials do not contribute to the count of new content pages. These sections of the copydeck must cite the PAAB file number corresponding to the previously approved materials in accordance with the instructions in the upcoming version of the Submission Guide.

The eFiles submission system will automatically calculate the number of new content pages from the following client inputs on the submission form:

- "% pickup" field (i.e., approximate percent of APS which is extracted verbatim from prior APS)
- "# of pages" field (i.e., the total number of pages of the copydeck)

The calculation is done automatically for the client based on the following function:

# of new content pages = [100 - (proportion of APS which is extracted verbatim from prior APS)] x (total number of pages of the copydeck)

The number of new content pages is any number between zero (e.g., for a straight renewal) and the number of pages of the APS (for an APS in which no content had been extracted from previously approved APS for that brand – e.g., a launch tool).

CAVEAT: Incorrect entries in the "% pickup" field and/or "# of pages" field will cause substantial delays in submission processing. The submission will not be accepted for distribution to a reviewer until the field is corrected and the client acknowledges any corresponding changes to review cost. Accuracy in these fields is important for billing purposes, internal workload tracking, and future modelling.

Note: As of July 2022, all initial submissions will be required to include a copydeck EXCEPT for straight renewals and minor updates of previously accepted submissions wherein the final layout provided was copy-correct

Section 7

Which fee changes will impact the standard preclearance pathway?

In planning for the AROs, the PAAB re-visited its fee schedule for the first time in several decades. This presented an opportunity to improve alignment of fees with the level of resources used to conduct a review. The following aspects of the July 2022 fees presented in Annex 1 and Annex 2 represent changes from the status quo for APS submitted through the standard preclearance pathway:

i. Reduced fee for minor updates

A new fee level will be created for submissions meeting the criteria for minor updates to previously approved APS. A minor update fee will be assigned in instances where the client has the ability and desire to maintain the expiry date from the most recently approved version of that APS. This new option is intended to facilitate keeping APS up to date in order to optimize value to the intended audience. See Annex 1 for "minor update" pricing.

What will qualify as a "minor update"?

An existing presentation in the APS is revised to an updated version of the same presentation. For example:

- An APS containing a place in therapy statement based on a consensus guideline was approved by PAAB. Several months later, that same consensus guideline is updated. An updated version of that APS, with no changes other than the place in therapy statement, is submitted as a minor update.
- A more recent interim analysis updating a single data presentation from an earlier analysis for the same endpoint from the same study.
- Retention data has been updated to reflect more recent data based on the same data source.
- A statement in the APS is revised to reflect an update to the Terms of Market Authorization content on which it is based.
- A formulary claim is updated to reflect a change in that province's coverage criteria.
- A new province has been added to the list of provinces that provide coverage.

Administrative criteria for a minor update:

- The file number for the previously approved submission must be provided (per the upcoming version of the Submission Guide).
- The update from the previously approved submission must be clearly identified (per the upcoming version of the Submission Guide).
- The submission letter must confirm that that the remainder of the APS is unchanged.
- The previously approved submission must still be within its approval period. Note that the approval expiry date of that prior submission will carry over to the updated submission. A new expiry date is NOT provided for APS submitted as a "minor update" (as the PAAB assessment will be limited solely to the updated segment).

Although PAAB reviewers will not be re-assessing unchanged content in a "minor update" submission, any Code infractions we happen to note will be brought to the attention of agency or manufacturer. There are several possible reasons why previously approved content may no longer be approvable. Some common examples include: changes in the marketplace, changes in the Terms of Market Authorization, time-sensitive elements, other review/monitoring/complaint rulings that impact acceptability of the previously approved content, and so on.

ii. Increased supplemental length/reference fee

The existing fee schedule features a $210 supplemental fee for submissions that exceed ten pages and/or fifteen references. This fee does not currently differentiate eleven-page submissions from much longer ones. Assessment of those longer submissions can be much more resource intensive, particularly when the content is largely new. In this digital age, sixty-page submissions are much more common than they were when the current fees schedule was established several decades ago.

In July 2022, as outlined in Annex 2, submissions which are assigned the $210 supplemental fee will also be assigned a fee of $2 for each page of new content in the APS.

How the total length/reference supplemental fee will be calculated

Any APS that exceeds ten pages in length or fifteen references will continue to be assigned the $210 supplemental fee, without regards to whether the content is new or extracted from a prior approval. The amount corresponding to $2 multiplied by the number of new content pages calculated by the eFiles system from client inputs for "% pick up" and "# of pages" fields will be added to the $210. More information relating to calculation of the new content pages can be found in Section 6.

For example:

A 90-page APS submitted through the standard pathway that is 50% "pick-up" will be assigned a supplemental length fee of $210 + $90 = $300 in addition to the base fee.

A 12-page APS submitted though the standard pathway that is 50% "pick-up" will be assigned a supplemental length fee of $210 + $12 = $222

A 90-page APS submitted through the standard pathway that is 0% "pick-up" will be assigned a supplemental length fee of $210 + $180 = $390 in addition to the base fee.

Note that administrative cover pages (e.g., for version or revision tracking), privacy disclosures, and terms of use can be excluded from both the total page count and the new content page count.

Also note that the supplemental length fee is not applicable to straight renewals or minor update submissions. However, it continues to be applicable to APS with "little new content" and series submissions.

Section 8 Fee structure for modular submissions

Modular submissions were introduced conceptually in Section 4. The series fee in Annex 1 will be applicable for APS comprised solely of series of modules that are extracted verbatim from a module library/database approved within the past year. Modular APS submissions must refer to the PAAB eFiles number for the module library/database. The full base fee in Annex 1 will be applicable to the module library/database.

Section 9 Fee structure for iterative submissions

Iterative submissions were introduced conceptually in Section 4. The first APS in the group will be billed at the full base fee, and the remainder will each be assigned a series fee. The base fee and series fee are outlined in Annex 1.

The upcoming version of the Submission Guide will provide guidance on how to determine which variable fields trigger fees and which do not.

Section 10 Questions?

Post them on the PAAB forum so that everyone can benefit from the question and answer. Alternatively, email info@paab.ca

Annex 1: Base fees for PAAB reviews

a) Preclearance reviews based on the PAAB Code (directed to HCP/Patient)

	Base fee for ALL APS		EXCEPT for "Series" & "Minor update" APS	
	English or French	English & French	English or French	English & French
Standard	$390	$450	$140	$190
ARO-10	$480	$540	$160	$210
ARO-7	$585	$675	$190	$240
ARO-4	$780	$900	$290	$340
ARO-2	$1170	$1,350	$390	$450
	For APS submissions pertaining to these two columns that contain ≤ 2pages of new content, get any urgency level at the price listed in the row directly above it!!			

Please either speak with a PAAB file coordinator or send an email to review@paab.ca if considering ARO-2 for an APS that does not meet BOTH of the following criteria (to ensure that we can deliver the first response within 2 business days):

- 10 or less pages of new content
- 5 or fewer references requiring detailed assessment:

As a general guide, a "detailed assessment" entails needing to read the entire reference to determine its validity (e.g., clinical trials, surveys) and/or to ensure that the promoted elements are not overly selective. Factors that typically determine whether a detailed assessment will be required include whether the reference has been used for similar claims in prior PAAB approved materials, and the nature of the reference (e.g., new studies & surveys generally require a detailed assessment). Additional information will be provided in the upcoming version of the Submission Guide.

b) Direct to Consumer Advertising or Information (DTCA/I) reviews

	Base fee for ALL APS		EXCEPT for "Series" & "Minor update" APS	
	English or French	English & French	English or French	English & French
Standard (4-day)	$390	$450	$140	$190
ARO-4	$450	$510	$160	$210
ARO-2	$585	$675	$190	$240

Annex 1: Base fees for PAAB reviews

c) Assessment of Risk Management Tools (HCP/Patient)

	Base fee for ALL APS		EXCEPT for "Series" & "Minor update" APS	
	English or French	English & French	English or French	English & French
Standard (4-day)	$390	$450	$140	$190
ARO-4	$450	$510	$160	$210
ARO-2	$585	$675	$190	$240

See the guidance document on Risk Management Tools.

d) Request for Written Opinion

4-day response time	$390
2-day response time	$585

e.g., assessment of creative, assessment of a single clinical trial and corresponding claims, assessment of a novel approach/media/platform, determination of whether a piece is advertising or information, and so on

See the following relevant advisories:

- Opinion Policy
- Exemption Opinions

Starting in 2023, all PAAB fees will be adjusted annually by the prior year's change in cost of living. These adjustments will impact all files submitted as of the first working day of each year. All fees are exclusive of HST.

Fees are invoiced after the first review letter has been sent. Fees are for the cost of the review and not for the acceptance of the APS

The series fee is only applicable to:

- A series of modules that are extracted verbatim from a module library/database approved in the past year.
- A series of APS with slight variations, submitted same day.

Submission of multiple APS on the same day alone does NOT qualify them for the series fee.

Annex 2: Supplementary fees for PAAB reviews

	Standard	ARO-10	ARO-7	ARO-4	ARO-2
SUPPLEMENTAL LENGTH/REFERENCE FEE					
APS is more than 10 pages or more than 15 references	$210 + $2 per "new content page"			$210 + $4 per "new content page"	
	Applicable to Annex 1a-d EXCEPT: · Straight renewals · Minor updates				
RESUBMISSIONS TO APPROVAL					
Invoiced upon receipt of the third resubmission	$150 per APS requiring three or more resubmissions The resubmission count will exclude one layout assessment and one translation assessment.				
MESSAGING (DECOUPLED ASSESSMENTS) ¥					
≤ X client messages per resubmission per APS	N/A	No cost Not charged during the pilot. The resources required for delivery of this aspect of the service will be monitored during the pilot. i.e., X will be determined during the pilot.			
> X client messages per resubmission per APS	N/A				

¥ Feature is only available on AROs

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Annex 3: PAAB meeting and training fees

Company-specific training meetings (2-hour maximum) The standard PAAB 101 presentation. Additional costs may be incurred for more tailored or specialized training.	$1,000 + travel expenses and accommodations
Virtual consultative meeting (1-hour maximum) i.e., advertising concepts, advertising review files, distinguishing advertising versus information, pre-launch meetings, etc. NOTE: The manufacturer or agency hosts the web/phone meeting.	$500

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