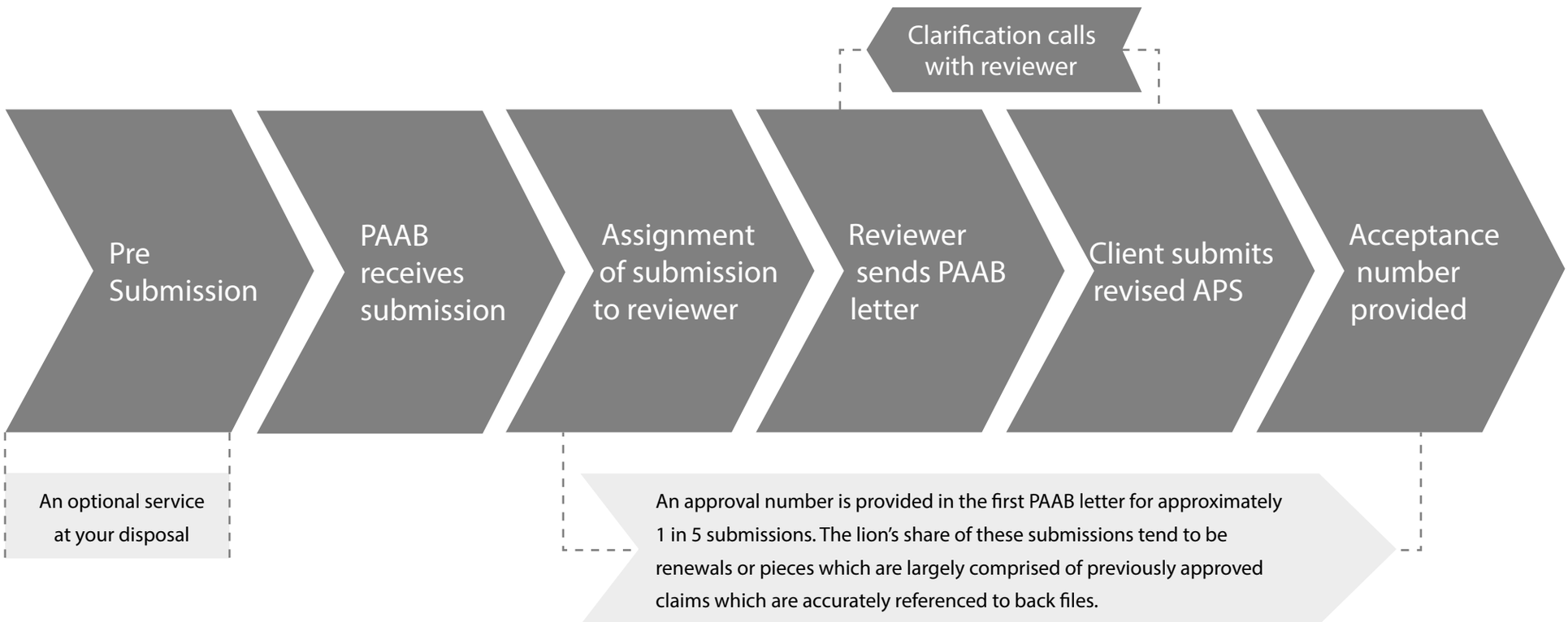
Key Steps in PAAB Approval Process

Click through the steps of the PAAB Approval Process for more detail...



Click here for more information on the submission process and requirements.

Click here for more information on the PAAB.

PAAB

Pre Submission

Important Note:

Reviews are only performed through official written correspondences with appropriate turnaround time for rigorous consideration.

Reviewers will not perform reviews over the telephone.

For example, we frequently get phone calls about whether a particular concept, message, study, or project is 'doable'.

Reviewers have been instructed not to answer such questions over the telephone. This is both in the best interest of PAAB and the client. Guidance on specific tactics is more robust when the context is known and there is adequate time for contemplation and/or consultation.

Back to process

General Questions:

A reviewer can return your call about questions which relate to the PAAB Code or PAAB guidance documents in a general way. These calls should take no more than 5 to 10 minutes and should require no PAAB preparation time.

If the call is likely to take more than 5 to 10 minutes, it's probably not a general question and there are more appropriate/rigorous avenues to address that inquiry. Consider submitting the query as a written opinion or consider booking a billable meeting with the PAAB.

What is a General Question about the code?:

General Questions...

"What kind of data is required in order to make a comparative claim about drug efficacy?"

The question relates neither to a particular product nor to a particular measure of efficacy.

"PAAB code section 5.7 makes reference to open-label studies, what does open-label mean?"

Not General Questions...

"What kind of data do I need in order to make the claim "Androidal increased overall survival vs Appledal?"

Various factors which are particular to those drug products or the endpoint (or any combination thereof) could render the claim unacceptable and these factors cannot possibly all be anticipated in a short call.

"Would PAAB accept the Frank study as support for a safety claim?"

This question is about a particular study, it would require PAAB to perform a review activity. A 5-10 minute phone call is not the forum for reviewing activities. PAAB could address this query in the context of a written opinion request.

Billable Meeting:

This is an opportunity to share information with reviewers who work within the relevant therapeutic area and then obtain preliminary feedback on your planned messaging. See the Fee Schedule on PAAB website.

Opinion Request:

See the Fee Schedule and the Policy Clarification sections on the PAAB website.

PAAB receives submission

Initial Submission:

Clients format the submission in accordance with the PAAB document: Guidance on Submission Process.

The countdown to receipt of PAAB's first response begins only once the submission is deemed to be complete by the PAAB file coordinators. At this time, the project will have the status "First" on your eFile dashboard.

Create a complete submission on your first attempt:

Ensure all references are included and that these are the most recent versions of those references. For the sake of PAAB efficiency, significant product monograph updates provided during the course of a review may incur a new file number and new fee.

Reference naming convention must coincide with the convention used for reference support copy in the APS.

Ensure that the referencing format used throughout the piece for supporting references and previous file numbers follows the format requested in the submissions guidance document. Note that claims or presentations which are similar to what has been previously approved should be accompanied by identification of the relevant backfile number(s). This information should appear in close proximity to (and should be in a different colour from) the advertising copy and reference support copy.

Do not submit separate projects within the same eFile. These will be returned for division into separate files.

Ensure that a cover letter is included to provide background related to the piece (e.g. context of use, target audience...)

Either copydeck or layout may be submitted for content review. The PAAB prefers copydecks. The format used for the initial submission should be maintained for the duration of content review.

If a copydeck was initially submitted for content review, subsequent resubmissions should be in copydeck format. After content review is completed, a layout matching the copy and flow of the copydeck will be requested for review of positioning, visuals, etc. Likewise, if a layout was initially submitted for content review, subsequent resubmissions should be in layout format. If a layout is submitted for content review, please provide both an annotated version (see referencing, left) and a non-annotated version. In cases where a copydeck and a layout are submitted together, the copydeck will be reviewed for content and the layout will be reviewed for positioning and formatting only.

Provide an annotated PM with each new submission for the first 3 months after notifying PAAB of the change. Also, when submitting renewals, please provide an annotated PM if the PM has been updated since the APS was last accepted. If the PM has undergone multiple updates since the APS was last accepted, the submission must include an outline of all PM changes throughout that period.

Renewal submissions should include both copydeck and layout formats if the initially approved submission included both copydeck and layout.

Ensure all references, letters, copydecks, and layouts are legible and saved in a searchable format. They should open right side up.

Assignment of submission to reviewer

Submission assignment is based on specialized therapeutic teams.

This is invaluable both in terms of review efficiency and review quality as it provides the reviewer valuable insight about the competitive landscape.

Reviewer sends PAAB letter

The first PAAB letter is provided within 10 business days of receipt of a complete submission.

The subsequent PAAB letters (i.e. for revisions) are generally provided within 3 business days.

Keep in mind that the PAAB is not resourced for research. Where needed, we will request additional evidence/support rather than seek it out ourselves.

Back to process

Clarification calls with reviewer

Clarification Calls:

A client may feel that he/she does not understand a PAAB review comment sufficiently to provide a productive response to PAAB. In such cases, the client may request a call with the reviewer in order to obtain clarification about that comment. This can be beneficial both to the client and to PAAB as it may result in fewer PAAB correspondences.

Before you call, we ask that the client first:

Attempts to read the cited sections of the PAAB code and/or guidance documents. The client may find he/she understands the comment once read in the context of the appropriate code/guidance sections.

Consults with colleagues as appropriate to ensure that a call is indeed necessitated. PAAB is not resourced to replace our clients internal initial and continuous training/ learning responsibilities.

Ensures that all needed questions relating to that PAAB letter are asked within the initial call. You can imagine that serial requests for calls can be disruptive and can prevent the reviewer from delivering on the PAAB's target timelines for your reviews.

IMPORTANT NOTE: Reviews are only performed through official written correspondences with appropriate turnaround time for rigorous consideration. Reviewers will not perform reviews over the telephone.

IMPORTANT NOTE: These calls are intended for clarification purposes. Clients sometimes take this opportunity to argue their point of view with the reviewer or to provide new information to the reviewer. This is not a productive endeavour as review rulings will not be provided over the phone.

Escalation Calls:

There is a formal escalation process for important disagreements between the client and the reviewer. Clients may escalate the review decisions to the Deputy Commissioner upon receiving a PAAB letter about the same issue which was discussed on the phone with the reviewer. Representatives from the manufacturer will be required to participate on an escalation call. This process is outlined in the PAAB code (s8.6.ii) and in the "Guidance Document for the Submission Process" on the PAAB website.

Please note that the formal process to the left relates to escalations for disagreements relating to particular comments within a submission under review. The PAAB is always open to discussing concerns and suggestions about broader issues such as customer service, efficiency, and consistency. As a continually improving organization, we welcome your input. Please contact Deputy Commissioner Patrick Massad.

Back to process

Client submits revised APS

Tips when responding to PAAB letters to help you get through the approval process efficiently:

Ensure a client response letter is included containing an itemized list of actions taken in response to PAAB comments and noting any unsolicited changes.

Ensure that the revised APS is submitted in the same format as the initial submission (i.e. either copydeck or layout as discussed in the initial submission note).

Ensure that unsolicited changes are identified for the reviewer on the piece itself and in the corresponding client letter. The unsolicited changes should be highlighted using a different colour from the requested revisions.

Note that significant unsolicited changes may incur a new file number and a new fee (i.e. all copy content must be finalized prior to initial PAAB submission). Also note that only the revisions in this most recent turnaround should be highlighted.

Reviewer Allocation:

The above tips are particularly important as there is no screening of revisions done by the file coordinators. The eFile system automatically distributes the file back to the reviewer who performed the initial review (unless he/she is on vacation in which case another member from the therapeutic team will be assigned as coverage).

We are sometimes asked why reviewers are covering for the initial reviewer during vacation. Although the covering reviewer may not be as familiar with all messaging and PAAB ruling history relating to that particular brand, he/she can still help move the project forward. This can therefore help the client get the APS to market more quickly than if the submission simply laid dormant waiting for the initial reviewer to return.

Keep in mind that reviewers within any given therapeutic team are very aware of the competitive landscape as they frequently consult with one another. Additionally, they update each other on key review issues which are ongoing (prior to and after vacation coverage).

Back to process

Acceptance number provided

The duration of the acceptance period is 12 months from the intended date of first use on the submission form or the date of approval (whichever of these two dates is later).

Note that the beginning of the approval period must be within 3 months of the approval date.

ONLY IN EXCEPTIONAL CIRCUMSTANCES:
PAAB code 8.4.3 enables PAAB to extend the approval by up to a maximum of 2 months without fee.

More about the PAAB

The PAAB strives to provide high quality reviews in an efficient manner to help clients meet their marketing goals.

The PAAB has internalized the values of integrity, competency, credibility, independence, excellence, transparency.

A recent audit showed that the PAAB review mechanism is complex with many variables.

The PAAB conducts its operations in a manner which aims to address those challenges.

The mechanism is dynamic to meet new challenges arising from advances in technology and marketing practice.

The staff is highly trained to meet client needs.

Fees are designed to cover costs of operating the not-for-profit PAAB.

Back to process