# PILOT: Administrative Guideline for the Review of Pre-NOC Advertising Submissions

The PAAB mandate is to review Advertising and Promotional Systems (APS) for approved pharmaceutical products. However, PAAB acknowledges the need for updated procedures for advertising review before Notice of Compliance (NOC) has been granted. These new procedures recognize the importance of accelerating the preclearance of launch materials to facilitate use in the market as soon as possible. The new procedures are as follows:

1. PAAB will accommodate pre-NOC submissions at the discretion of the PAAB Commissioner with respect to workload at the time of submission and will not be subject to the standard turnaround time.

2. At any stage of Product Monograph (PM) negotiations with the Therapeutic Products Directorate (TPD), the advertiser or its agency may contact the PAAB to arrange a pre-NOC review.

    - **NOTE:** Additional fees may apply if updated drafts of the PM or if other unsolicited changes to the piece (e.g. creative concept, change in flow, etc.) are made. Please see **Appendix A** for further detail on how additional fees will be determined.

3. Any number of APS may be submitted for Pre-NOC review. Acceptance of these submissions remains at the discretion of the PAAB Commissioner as per **Section 1** of this document. We continue to suggest the submission of core APS first to facilitate a more efficient review of subsequent APS, but we will no longer enforce a limit on pre-NOC submissions. All APS require approval by the advertiser's medical/regulatory staff prior to PAAB review. Please also see **Appendix B** for best practices for Pre-NOC submissions to help facilitate the review process.

4. Meetings between the advertiser and PAAB are not required for every product launch. Reasons for a meeting include: first in a new therapeutic class, new indication for existing product, novel marketing methods, competitive environment, complex pharmacology issues, cost-effectiveness issues, and ethical issues. The advertiser may contact PAAB to determine whether a virtual meeting would be appropriate.

5. While waiting for the final approval of the Product Monograph, the company should apply PAAB revision requests to all the submissions that form the launch campaign.

6. When the pharmaceutical company receives its NOC, they should resubmit the final revised APS along with the NOC and final Product Monograph (formal, written PAAB acceptance cannot be provided until the signed NOC and final Product Monograph are received). The advertiser should highlight additional revisions that may have been made to facilitate the review process. After the launch campaign has been reviewed and accepted, any additional APS for the product would be processed within the customary PAAB procedure and timelines.

7. This guideline is effective **December 1, 2023.**

**NOTE:** Advertisers should be aware that under PAAB's mandate, it can only provide acceptances for advertising for use post-NOC. PAAB does not issue acceptances for any branded promotional activities carried on pre-NOC.

*For more information, please speak to the Director of Client Services, Danielle Anthony, or the Director of Preclearance Services, Yin Man.*

**APPENDIX A – Additional Fees**

As this new guidance allows for submission of APS at any stage of Product Monograph negotiations with Health Canada, it is possible that there will be changes to the PM as these negotiations, and our review, proceed.

Please see the table below for fees that may apply in addition to the standard initial submission fee should a PM update be made mid-review of a Pre-NOC APS.

| **Update Type** | **Turnaround Time** | **Additional Fee*** |
|---|---|---|
| The PM or unsolicited APS update **does not impact** the APS (e.g. grammatical changes, the drug receives a name, measurement units change, etc.) | Continues in the same eFile<br><br>3-day standard revision turnaround time | Not applicable. |
| The PM or unsolicited APS update **has a minor impact** on the APS (e.g. bullet added to fair balance, adverse event (AE) is added to an existing AE table, etc.) | Continues in the same eFile<br><br>3-day standard revision turnaround time | +$200.00 (2 languages) or +$147.00 (single language) per round of revision with a PM update or unsolicited change that has a minor impact on the APS. |
| The PM or unsolicited APS update **has a significant impact** on the APS (e.g. indication change, new data, new creative concept, etc.) | Requires resubmission as a new eFile<br><br>10-day turnaround time (instead of 15 day pre-NOC initial turnaround time) to facilitate continuation of the eFile. | +full standard fee for a PM update or unsolicited change with a significant impact on the APS. |

*All fees are subject to change.

**APPENDIX B – Pre-NOC Submissions Requirements**

1. Please ensure that any updates to the Product Monograph are provided at the next resubmission of the file to facilitate our review process against the most current version of the PM.

2. When a **PM update** has occurred during the review, please consider the nature of the PM changes and clearly convey them to PAAB. This includes:
    a. A description of the changes to the PM within the cover letter, including citing page numbers and the nature of the revisions from the last version provided to PAAB forward.
    b. A description of the changes to the APS within the cover letter, including citing page numbers.
    c. Identifying in the cover letter whether (to the best of your knowledge) this is a change that has a **minor impact** or **major impact** on the APS **(See Appendix A).**
    d. Highlighting of the PM update-related changes to the APS in a different colour than the colour used to identify reviewer-requested changes within the copydeck.

3. If multiple PM updates have occurred prior to resubmission of an eFile, please provide **either:**
    a. a consolidated version of the PM that shows the annotations for all updates that have occurred since the prior submission.
    b. a letter from the sponsor's medical/regulatory department that outlines the nature of the changes as they relate to each PM update **and** all annotated versions of the PMs since the last round of revision.

4. When **unsolicited changes** are made that are not a result of PM updates, please clearly convey the nature of the changes to PAAB. This includes:
    a. A description of the unsolicited changes and the page numbers where they appear in the APS within the cover letter.
    b. Highlighting of the unsolicited changes in a different colour than the colour used to identify reviewer-requested changes within the copydeck.