Guidance on Submission Process and Format Requirements

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Chapter 1: Using eFiles (tips & system requirements)

All PAAB submissions must be sent through the eFile system. This is a document management system which allows for file access and file transfer between PAAB and clients.

1.1 System requirements

Consider the following system requirements:

- video file formats accepted must be in .mov, .wmv, .swf, .udf, .mp4
- **New:** .gif, .jpg, .png, svg
- **New:** there is no maximum size for uploaded documents

PAAB responses are emailed with letter attachments; please ensure PAAB is on the "white list" to receive emails and attachments. You must be registered as an eFile User in order to access the system or receive PAAB communications.

1.2 Registering your company and users in the eFile system

When registering a company and user:

- A Senior employee of the company must email to Review@paab.ca:
    - legal company name, mailing address, and phone number
    - user's email addresses, full name, and phone number
    - name and email address for company's billing contact

PAAB Administrators will complete the set-up process and email individual users with a temporary password to access the system. Your email address is your Login, or you can set a login name to use when logging into eFiles.

New users to the eFile system should promptly access the system using the temporary password and their login and then proceed to the "My Profile" link to change the temporary password to one of their choosing.

1.3 Submission form requirements

To help minimize delays in processing your eFiles and eliminate rework, please help facilitate the process by doing the following:

a. “Intended Date of Use” field

Please remember to indicate the “Intended Date of Use” on every submission.

In doing so, please keep in mind:

- the month in which a previously approved submission is due to expire
- the actual date that the advertising piece will be produced for distribution
- renewal submissions should be submitted 6 weeks prior to expiry
- the 12-month acceptance period may be granted up to a maximum of three months after the date of the approval notification.
- a 3-month forward dating option is available for the acceptance period, however if this option is chosen, please note that the option to request a 2 month extension period at the end of the acceptance period will not be available.
- all submissions are processed to ensure that they are accurate and complete before they are assigned to a reviewer.
- any new eFiles that do not indicate an “Intended Date of Use”, will be returned to the sender as incomplete.

b. Mandatory PO numbers

If your company has a policy requiring a valid PO # for each eFile submission, please remember to include a valid PO # on your eFile submission at the time of the submission or it will be returned as incomplete.

All submissions are processed to ensure that they are accurate and complete before they are assigned to a reviewer.

If you wish to have a contact name listed on an invoice, please add this name to the PO field at the time of a new submission.

c. Uploading

Please ensure that documents are uploaded to the correct fields in eFiles. We invite you to call our Submission Coordinators if you have any questions.

1.4. Frequently asked questions:

Question: I’m going on vacation. How can my co-employee work my files in my absence?

Answer: Access each file to select your co-employee from the drop-down listing found within each of the 2 backup fields. Backup fields are found on the Submissions Details Page in the

Contact Information section. Your co-employee will receive PAAB responses and have access to your eFiles to submit revisions on your behalf. As the main contact, you will continue to receive the PAAB responses while away from your files.

Question: My submission now has the status "Revision Required". How do I see the details behind this status? When I click on my submission, I only see the original submission and documents and no indication of what revisions or additional documents are required.

Answer: If your file status has been changed to "Revision Required", you should have received an email with the Reviewer's comments attached. If you did not receive the email, please check your spam folder or speak to your IT department to ensure the PAAB is on your whitelist. Please call the PAAB if you require further assistance regarding your electronic submission.

Chapter 2: Putting together your submission/response

2.1. General requirements

2.1.1 Cover letter and letters of response

a. Every new submission should be accompanied by a cover letter. The cover letter should identify any special considerations such as:
   - intended audience
   - placement of the ad
   - relevant backfiles
   - if the ad is part of a series or is a minor update, and if so, the associated eFile numbers should be provided. Please see *Appendix A* for the definition of a minor update.
   - for minor updates, cover letters must include
     - the file number of the previously approved submission
     - a clear description of the update from the previously approved submission
     - confirmation that the remainder of the *advertising/promotions system* (APS) remains unchanged
     - the approval expiry date for the previously approved submission along with confirmation of the understanding that this expiry date carries over to the updated submission. **A new expiry date is not provided for APS submitted as a minor update.**
   - if the submission is a modular, iterative, or other series submission. Please see *Appendix A* for definitions for modular, iterative, or other series submissions.

- cover letter requirements for series submission types
  - for modular submissions, cover letters must include:
    - whether this is a submission of the module library or a subsequent modular APS based on the pre-assessed modules from the module library.
    - when submitting a modular APS, please provide the eFile number of the module library for reference
    - please also see *Section 2.1a* for further information on modular APS requirements and *Appendix D* formatting examples.
  - for iterative submissions, cover letters must include:
    - which file is considered the parent file
    - the 'iterative' elements for review (e.g. variable subject lines, mobile vs desktop layout, etc.)
    - please also see *Section 2.1b* for further information on iterative submission requirements, and *Appendix E* for submission format examples
  - for other series submissions, cover letters must include:
    - which file is considered the parent file and associated eFile number. Please see *Appendix A* for a definition of parent file.
    - which other files are being requested for consideration as a series (i.e. child submissions).
    - confirmation that the child files submitted as a series are at least 60% duplication of content from the parent files. Please also see *Section 2.2.1* for other submission requirements for series APS and *Appendix G* for formatting examples.

b. Every resubmission should be accompanied by a letter of response. This letter should include an itemized list of actions taken in response to PAAB comments. Please ensure the numbers used to itemize your responses match the numbers used in the PAAB response letter. Any unsolicited changes should be noted in the letter of response and highlighted in a different colour from the requested changes within the copydeck. In your letter of response, please include the page number(s) on which the change(s) occurred, as well as a brief description of the changes. Please note that significant unsolicited changes may result in your file being returned and a request to submit a new eFile which will incur a new fee.

2.1.2 Regulatory field

a. The Health Canada approval letter (e.g. Notice of Compliance [NOC], No Objection Letter [NOL]) and the most current version of the Product Monograph (PM) or Product License (PL)

must be uploaded into the regulatory field. The submission control number on the Health Canada approval letter must match that which appears on the PM. In cases where these elements do not match, the client should provide a signed letter from the manufacturer's regulatory department confirming that Health Canada approval is not required for the PM change (e.g. level III or IV change).

b. If a product does not have a PM or PL, an alternate document (e.g. prescribing information, product label, category IV monograph) may be provided. In this case, written confirmation from Regulatory Affairs indicating that this document is the current Terms of Market Authorization (TMA), should be included as part of the initial submission.

2.1.3 Submission format

In a change to our previous procedures, we ask that all submissions include a copydeck for content review, except in the case of renewals and minor updates of previously accepted submissions wherein the final layout provided was copy-correct. Layouts may also be submitted in the initial submission; however, the PAAB only reviews layouts for positioning, visuals, etc. Please see *Appendix A* for the definition and examples of a minor update, and renewal. Please note that we do not require submission of a French layout, as layout is reviewed for position only. We will review the French version of the APS in copydeck format. All copy content must be finalized prior to initial PAAB submission. Works in progress (i.e. any to-be-determined elements) will be returned as incomplete.

All documents should be searchable for text and the search function should remain available throughout the review process.

As fee calculations now consider the amount of previously approved, aka "picked up", content, please clearly identify the previously approved content by highlighting the duplicated content in light yellow and ensuring the previous eFile number is clearly identified next to the claim. This assists our admin team in calculating the accurate percent pick up.

Please note: For content to be considered as part of the "percent pick up" calculation, it needs to be identical (i.e. verbatim and the same visual treatment and placement) to what was previously approved

Please see the checklist below to help ensure your first submission is complete:

Item #	Checklist Item	√
1	Internally approved by manufacturer's medical, regulatory, or compliance department	
2	Complete and final	
3	Legible and meets minimum formatting requirements as per *Appendix B*	
4	Searchable	
5	If submission is iterative, clearly identify and label documents	
6	Submission implications (copydeck submitted for content review, considerations for modular, iterative, series, and other submission types as per this document)	
7	Ad content text appears in the manner and flow intended in the layout	
8	Appropriate highlighting and identification of backfiles/modules: • Backfiles text or appropriate modules quoted? • Picked up content highlighted in light yellow? • Series content highlighted in light blue? • Only revisions pertaining to the current round highlighted?	
9	Referenced support copy (e.g. clinical trials, med/reg letters, etc)	
10	Art and functionality notes are visually distinct from copy to be reviewed	
11	Functionality copy (i.e. Information Architecture (IA))	
12	Meta-data copy (i.e. websites)	
13	Orientation	
14	Submission letter that meets the standards in *Section 2.1.1*	

2.1.4 Referencing

Please see *Appendix C* for Referencing examples.

a. Supporting references

Each claim or presentation should be accompanied by clear identification of the supporting reference and the relevant page number and section of the page (e.g. ref 1A, p. 151). This referencing copy should appear in a different colour from the advertising copy. The corresponding section of the reference paper should be highlighted and labeled.

Please see below for our referencing best practices:

Do	Do Not
ensure the reference name and number used in the copydeck matches the name and number of the reference uploaded to the eFiles system	use inconsistent nomenclature that is difficult to link
list your references after each claim	list multiple different references after a paragraph of copy, or next to a large block of copy
highlight specific, relevant sections of the reference for easy cross-referencing	highlight entire pages of the reference with no further instruction on the specific copy intended to support claims.
cross-reference using the page number of the PDF	cross-reference using the page number from the source (i.e. page 426 of the journal but Page 6 on the PDF).
ensure all references are uploaded for all submissions	assume that because a reference was uploaded in another file, that it will not be required in the current submission

As referencing is a crucial aspect of a submission and can significantly contribute to delays if not done properly, PAAB will return your submission if the referencing does not meet requirements.

b. Previous file numbers and Percent Pickup

Within the new fee structure, it is crucial that the appropriate percent pick up from a previously approved eFile is indicated both within the submission form, but also in the copydeck. In addition, please clearly reference which eFile the content is picked up from. Please note that this must be the most recent backfile available with this content. Our admin team will review each copydeck to assess the percent pick up in order to accurately calculate your fee. If the APS contains claims or presentations identical to what has been previously approved, please identify the relevant eFile(s) and highlight the copy in light yellow. The relevant backfile annotation should appear in close proximity and should be in a different colour from the advertising copy and referencing copy. Please see *Appendix F* for an example on how to properly highlight and cite relevant backfiles.

Please note: it is not considered 'picked up' copy unless it is identical to what is previously approved. If your submission information is misleading or the copy is found to not be identical to what was previously approved, it will result in unexpected fee changes or delays for the eFile.

If the content has been previously approved and backfiles are not provided, your fee will reflect 0% pick up and PAAB reviewers will proceed with a complete, full review of the piece as though new. Any code infractions identified during our review will need to be addressed even if the copy is later discovered to have been previously approved.

2.1.5 Revisions and unsolicited changes on resubmission

All revisions and unsolicited changes should be highlighted on the copydeck. Requested revisions should be highlighted in a different colour from unsolicited changes. Only revisions and changes from the previous copydeck should be highlighted; please ensure that any residual highlights from previous versions of the copydeck are removed.

a. Within the cover letter:
   - Include an itemized list of actions taken corresponding to the PAAB response comments.
   - For unsolicited revisions, please provide a brief description of the change, the associated page number and how it has been identified on that page.

b. Within the copydeck:
   - Highlight solicited revisions in one colour, and any unsolicited revisions in a different colour
     - Only revisions and changes from the previous copydeck should be highlighted
     - NOTE: Please ensure highlight colours chosen do not render the copy difficult to read (i.e. dark colours such as red, dark greys, purples, blues, etc. should be avoided)

Please note: If the contrast would not meet accessibility standards, it should not be used for highlighting in your PAAB submission

How clear is this message to you. Could you read this without additional effort

- If complete sections have been moved, please clearly indicate where the section has moved from and where it is now located.

- In the case of unsolicited changes where copy is removed, please indicate by using strikethroughs and highlighting.

Please note: If significant unsolicited changes are made, the reviewer may return your file for resubmission under a new eFile, with a new fee associated, at their discretion.

Please see below for the resubmission checklist:

Item #	Checklist Item	√
1	Letter as per standards outlined in *Section 2.1.5*	
2	Highlighted revisions and removed previous highlights	
3	Format	
4	Declaration of any unsolicited changes	

2.1.6 AROs Messenger Functionality

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 and enables agencies and manufacturers to receive PAAB review decisions on pivotal segments of the submission before resubmitting the entire copydeck/layout.

Please see the following considerations for use of the AROs messenger functionality:

- Message responses sent prior to the end of PAAB's business hours will be returned the next business day. For messages sent after the end of business hours, they will be considered as being sent the following business day, as that is when the reviewer can be expected to see it, and the response will be received within one business day after that.
- In instances where more than one message is sent prior to a response being received, you will receive a response to all messages within one business day of the most recent message.
- The number of acceptable messages per round of revision may change pending results of the AROs pilot.

2.1.7 Updates to the Product Monograph (PM)

a. Please provide an annotated PM with each new submission for the first 3 months after notifying PAAB of the update. Please only include the **final** changes versus the previous version. The inclusion of the clarifax communications render the updates difficult to read

and require more time to review. If there has been more than one PM update in the past year, please provide an annotated PM identifying the net changes across all PM updates for review. If this is not possible, please provide the individual annotated and updated PMs along with a letter from the sponsor's medical/regulatory department that includes an itemized list of changes from each PM update.

When submitting renewals, please provide an annotated PM, if the PM has been updated since the APS was last accepted.

b. Where relevant, please also provide the corresponding Health Canada letter confirming approval of the PM update. Alternatively, provide a signed letter from the manufacturer's regulatory department confirming that Health Canada approval is not required for the PM change (e.g. level III or IV change).

c. **Ongoing reviews:** Note that a PM update during an ongoing review may incur a new file number and the corresponding fee. Changes in the PM will trigger a reassessment of the ongoing APS content. If there is more than one ongoing APS, it is preferable to first re-submit only one (1) of the ongoing APS' containing any applicable revisions to the piece. The reviewer will assess whether a new file number/fee is necessary and communicate the most efficient way to submit the remaining ongoing files. The manufacturer should apply the revisions requested in that file to the remaining ongoing pieces prior to resubmitting them.

d. **Advertising in use:** Note that it is the manufacturer's responsibility to ensure that advertising approved prior to the PM change accurately reflect the revised PM. APS deemed by the manufacturer to require updating to reflect the PM change must be submitted for PAAB review even though the original approval period has not elapsed.

e. **Renewals:** A renewal is a submission that is 100% pickup from the previously approved version. If there are any updates to the piece, please do not submit your file as a renewal as a different fee structure will apply. When submitting renewals, please provide an annotated PM if the PM has been updated since the APS was last accepted.

The following exceptions, if revised, can still be considered a renewal:

- Version code changes
- Trademark changes and corporate logo changes
- French language grammar correction which does not alter the claim
- Directly proportional resize of APS that results in NO layout/flow/content/functionality changes

2.1.8 Submitting written opinions

For information relating to submission of exemption opinion requests, please visit the Policy and Procedure for Exemption Requests document.

The PAAB will enforce its original, and still standing, policy of providing one opinion letter.

2.2. Requirements specific to various submission types

2.2.1 Series Submissions

a. Modular Submissions

There are two parts to modular submissions: a module library and modular APS. The module library contains all of the modules (i.e. claim presentations) that you would like to have reviewed and pre-assessed for use in future APS based on the module library. These APS are the modular APS. The module library will receive a "no further comments" letter when the review of the modules has been completed. No expiry date will be given but, should modules become outdated (e.g. no longer relevant or accurate due to changes in the marketplace), the PAAB will request that the module library be updated and resubmitted. In scenarios where a module is removed completely, the update can be resubmitted as an FYI. French copy should be submitted as part of the modular library upon English completion for dual language files

When creating your module library, please see the following requirements for your submission below:

- include modules for only one product per library
- for products with multiple indications, please create a separate library for each indication. We also suggest that individual libraries are generated for distinct campaigns.
- provide a table of contents with active links to each associated section within the library. This assists with cross-referencing when reviewing future modular APS based on this library. This also eliminates the need to update page numbers across all submissions should the library content change.
- segment library into clinical, non-clinical, and dosing presentations and label appropriately. Further segmentation (i.e. efficacy, safety, MOA, etc.) can be used to further assist in the categorization of modules.
- ensure your modules include all copy that is intended to be presented together (i.e. headline, data, associated footnotes, etc.).

- ensure there is labelling/nomenclature to identify each module in the library that will be used in future modular APS to link back to the library (i.e. D.1 – dosing module 1, FB.1 – Fair balance, etc.). Please see *Appendix D* for examples of modular APS.
- ensure referencing requirements are met as per *Section 2.1.4* and *Appendix C* of this document
- it is the sponsor and agency's responsibility to identify and confirm if changes to the TMA will impact the module library.

Please note: While there is no requirement to renew the library on an annual basis, the library should be resubmitted when updated (e.g. for time-sensitive claims, PM updates, changes in the market, etc.). If a claim is found to be outdated upon review of a modular submission, the PAAB will request that the module library also be updated.

When creating your modular APS based on the approved module library, please see the following requirements:

- all modules used to create the piece should be clearly identified and use the same labelling/nomenclature used to identify the module within the module library.
- submissions should be comprised entirely of preapproved modules with the exception of administrative/transactional/greeting copy, email subject lines, and email footers that do not contain claims.
- modular submissions may not be submitted until the corresponding modular library has been accepted.
- referencing and providing the original source reference will not be required for submissions entirely based on the pre-assessed module library.

b. Iterative Submissions

An iterative submission can be considered when there is a need to submit different iterations (or versions) of an APS within the same PAAB eFile. This is intended to help make it easier to track projects that use variable fields or email subject lines tailored to specific audiences. Iterative submissions can also be considered for projects that contain the same content but with different layouts configured for different platforms (e.g. PC, tablet, smartphone), or app store descriptions for different stores. Please see *Appendix E* for examples of iterative APS.

When submitting your iterative submissions, please note the following:

- copy that differs between iterations (or child) submissions and the parent file must be highlighted in the iterative files.

c. Other Series

A series submission is a type of submission in which there is a parent file, which is reviewed as a full submission, and subsequent submissions (child submissions) that are at least 60% pickup of identical copy from the parent file. Please ensure within your cover letter that you identify that you are requesting a series fee for the submission, and provide the parent eFile (i.e. the first eFile in the series) and child eFiles that this file should be considered in series with. Additionally, please indicate the duplicated content within the child file by highlighting the common copy in light blue. Please see *Appendix G* for an example on how to highlight the identical copy in series submissions.

Please note: A series submissions must contain at least 60% duplicate content from the parent file and submitted on the same day in order to be considered for the series fee.

If several submissions are submitted as a series, please ensure that the parent file is always resubmitted at the same time as, or prior to, the series submissions, as that is considered the lead file for review. Should the series be broken up mid-review (i.e. you wish to advance a file in the series independent of the parent file), then the file's fee will be adjusted to reflect a regular fee.

2.2.2. Minor updates

A piece may be submitted as a minor update to a previously approved file in instances where the client has the ability or desire to **maintain the expiry date** from the most recently approved version of the APS. Please see *Appendix A* for a detailed definition of a minor update.

When submitting your minor update, please consider the following:

- clearly identify the previously approved eFile number that this piece is an update to
- highlight the updated content only
- provide confirmation that nothing else in the piece has changed

2.3. Requirements specific to various APS types/formats/media

This section of the document is meant to address frequently asked questions. We've therefore targeted key points which have been used to answer those common questions. This section is not meant to be all-encompassing.

2.3.1 Emails/Letters

When submitting emails and letters, please consider the following:

- a layout may not be required, with confirmation that the arrangement and style treatment will be identical to the provided copydeck with no additional graphic elements.
- links/attachments are reviewed as separate APS. The eFile number for all links and attachments should be embedded in the copydeck.
- when a sequence of emails/letters are planned as part of a campaign, each e-mail/letter will be reviewed as a separate APS -- e.g. March e-mail vs April e-mail.
- in the event that an email platform or other 3rd party platform does not allow images in the email body or ad, and therefore the PAAB logo would not be visible, please insert the text "Reviewed by PAAB" to ensure that it is conveyed that the content has been precleared.

Please see *Tips for Email Submissions* for additional pointers on maximizing the accuracy of email submissions.

2.3.2 E-detail aids

As the PAAB review is performed on a static eFile rather than the live program, the submission must clearly/fully describe all electronic functionalities and other considerations such as:

- whether its use is intended to be rep-driven or self-directed
- if there are multiple call flows
- if there are tabs and/or pop-ups and their associated functionality (e.g. for a pop-up, the reviewer should be informed of what triggers its appearance, what is contained within it, and what other elements on the page remain visible).
- if there are options for user annotation like highlighting or drawing, this functionality should be identified and described and whether its use is intended to be representative-driven or self-directed.

Please note: A detailed wireframe/tool map must be included at initial submission.

Like any APS, e-detail aids are reviewed as a whole. They are not approved for selective presentation of content. The PAAB will question functionality which permits the drug representative to tailor the e-detail aid by selecting which pages/segments to include from a more comprehensive PAAB approved piece.

PAAB-approved print APS which are reformatted onto an electronic platform for further distribution by the sponsor requires separate PAAB review of the electronic format unless all of the following criteria are met:

- the PAAB-approved APS is still within its approval period
- there have been no updates to the TMA (or Health Canada warning letters) since approval of the original piece
- the same content/layout/flow is maintained as in the approved print APS.
- for example:
    - any size changes are directly proportional throughout the APS
        - please note that it is the manufacturer's responsibility to ensure that key disclosure (including, but not limited to, indication and balancing copy) remain legible.
    - content on the page is not repositioned to optimize for landscape/portrait mode
    - no new functionality is added other than zoom-in and zoom-out. e.g. if scrolling functionality is added, the PAAB review is required to ensure it does not cause the Fair Balance prominence to become insufficient i.e. the piece on the electronic platform would essentially be comprised of all scanned pages in same order as the print APS
    - the APS context (e.g. branded vs unbranded) and the target audience are unchanged

In cases where the scanned APS meets these provisions, the APS may be distributed to the intended audience without informing PAAB through an FYI notification. Please note that these APSs should still bear the PAAB logo. Also note that the originally submitted piece is required to be renewed on a yearly basis for the duration of its use (whether the use relates to the print or electronic format, or both).

For more information on e-detail aid submissions, please see the document *e-Detail Aid Submission Best Practices*.

2.3.4 Video APS and animations

Storyboards may be submitted for initial layout reviews. However, a video will be required for review prior to acceptance.

PAAB should be informed of all animation attributes/functionality. For example: Will the animation play automatically when the page is open or is user interaction required to initiate it? What is the duration of each frame? Can the user play/pause/restart the animation? If so, how? A submission might identify, for example, that a finger swipe from left to right on an iPad is used to move the animation forward while a swipe from right to left is often used to rewind it.

See system format/size requirements in *Chapter 1*.

2.3.5 Websites and other web tactics (including social media)

The PAAB cannot review off a live site. Therefore, the submission must clearly/fully describe all electronic functionalities.

The initial submission should include:

- a site map and wireframe
- a layout (if a layout cannot be provided at initial submission, a detailed wireframe must be provided).
- description of the gating mechanism where relevant
- identification of all intra-site links and company/agent-generated external links that direct to and away from the website (e.g. search engine marketing, banner ads, other websites, etc.)
- the site rules and monitoring/moderating policy (if the website offers user-generated content functionality)
- keyword metatags and meta-descriptors for search engine optimization (if the client is setting these).
- alt tags describing images

Please note: Providing a link to a live site will not meet the PAAB submission requirements as PAAB is required to maintain a **persistent** and **immutable** record of what is reviewed and approved.

The layout requirement can generally be addressed by screen shots once the piece is near copy approval.

The following parts of a website are required to be separated into different eFiles:

- segments of a website which are targeted for different regulatory audiences (i.e. HCP vs patient vs consumer). Exception: The landing page on an HCP/patient website is accessible to the general public, but it may be submitted in the same eFile as the HCP/patient website if it does not contain any messaging intended for a consumer audience.
- sections of a website pertaining to different products or indications (depending on the size and nature of the content)

e.g. in a gated portion of company X's corporate site, there is a section for drug ABC advertising, a section for drug DEF advertising, and a section for drug GHI advertising. The sections for ABC, DEF, and GHI should be submitted separately.

- standardized correspondences generated through participation in activities through the site (e.g. email/text messages)
- documents available for download which are created by (or influenced by) the manufacturer/agent e.g. dose cards, product brochures, newsletters

a. Website updates
   - PAAB generally requires that the entire site be submitted for website updates. It is otherwise difficult to keep track of the site content (particularly after multiple updates).

b. Multi-purpose websites
   - If the website is composed of sections intended for different audiences or different users, each section should be submitted as a separate APS.

c. External links/banner ads/e-billboards

   The PAAB should be informed of:

   - all links to and from PAAB-approved APS. The PAAB will assess whether the link requires the PAAB review as a separate piece or documentation of an FYI (the latter would be limited to link content which is exempt from pre-clearance per *PAAB code 1.5*).
   - for rotating frames, the sequence and how much time is spent on each frame and what happens once the last frame is exposed (restart vs. static)
   - any other electronic functionality processed by the APS
   - For more information on small space ads, please see the PAAB Advisory on Small Space Ads

   In campaigns involving multiple banner ads, the individual banner ads should be submitted in separate eFiles except in the following scenarios:

   - they appear on the screen at the same time (e.g. a leaderboard ad paired with a skyscraper ad)
   - they are less than 200 characters in length (in which case up to 10 banners can be submitted in the same eFile e.g. Facebook banner ads

A series fee or an iterative submission may be considered if multiple related files are submitted on the same day and meet the percent pickup requirements as detailed for each submission type.

d. Search Engine Marketing (SEM)
   - unlike search engine optimization (SEO) which is part of the website submission, any SEM activity related to a PAAB-approved site should be submitted for PAAB review under a separate file.
   - a layout may not be required with confirmation that the arrangement and style treatment will be identical to the provided copydeck with no additional graphic elements.
   - the submission should include the URLs, keywords, the meta descriptors they generate, and the PAAB eFile number for the linked website.
     - the submission must convey anytime that broad match keywords are used. Broad search terms are generally impractical for drug advertising as they require the advertiser to set negative keywords for any search term that could potentially create a link between the search and the ad, exceeding consumer advertising regulations. This requirement is generally either difficult or impossible to meet as the factors that determine search results are proprietary and dynamic.
   - a maximum of 10 meta-descriptors can be submitted within a single eFile.
   - a series fee or an iterative submission may be considered if multiple related files are submitted on the same day

e. For responsive search ads, each ad will be considered a separate submission. At the time of this guidance document's creation, Google limits each ad to 15 headlines and 4 descriptions. Within these existing parameters, all components of one ad will be reviewed as a single submission.

   The submission must include

   - the final URL
   - the display URL
   - all headlines
   - all descriptions

PAAB will consider all potential combinations of headlines and descriptions during the review process. While additional ads may be included in the same copydeck, they should be submitted as iterative submissions for billing purposes. For more information on iterative submission requirements please see Sections 2.1.1 Cover letter and letters of response, 2.2.1 Series Submissions, 3.2. Series Files and Splitting files, and Appendix E.

2.3.6 Mobile apps

The general website requirements apply to mobile apps as well (see *Section 2.3.5*). Mobile app submissions must include an explanation of where/how the intended users can obtain the app.

The app description requires review in a separate file (e.g. when available in an app store). The keywords which are tagged to the app must be submitted within the initial submission of the app description eFile. If the app store permits user reviews, the monitoring policy must also be included in the submission. In cases where the sponsor cannot directly remove/alter review comments contravening the regulations, the sponsor must contact the store operator to have the comments removed.

2.3.7 Tele-detailing

The script is required for review. If detailing is performed over a recording, the recording is also required to be submitted (whereas there would be no recording to review in the case of a live session).

2.3.8 Fair Balance Submissions

Clients may submit the 3 levels of Fair Balance for line-by-line review; this is not an opinion review. Submit your Fair Balance as an HCP Detail Aid. Identify in a cover letter that you are requesting review of the 3 levels of Fair Balance; the eFile will be coded accordingly. PAAB will review this Fair Balance in English, French, or both languages and the normal fee schedule applies to these submissions. The PAAB will work toward "no further comments" before the file is complete and there is no acceptance granted, therefore, renewal is not required. Once "no further comments" has been reached, clients may insert the final Fair Balance reviewed into future APS for review.

Chapter 3: Review Fees

3.1. Fees

With the introduction of the AROs, our fee structure has changed. The AROs are a set of four urgency levels designed to expedite the pre-clearance review process. The PAAB also continues to offer the existing standard pathway.

If you wish to change the selected ARO urgency level, your turnaround-time clock will restart, and the appropriate fee adjustment will be made. Please note that if the reviewer has begun review on the file, it may not be possible to change your urgency level.

For detailed information on the AROs and updated fee schedule, please visit the ARO Planned Features Detailer.

3.2. Series Files and Splitting files

There are various options for submitting files as a type of series: modular submissions, iterative submissions, and other series submissions.

a. For modular submissions, please note the following:
- for the initial module library submission, a full fee will be applied as per the information above.
- for subsequent modular APS that are entirely based on pre-assessed modules, a series fee will apply.

b. For iterative submissions, please note the following:
- separate submissions with a small amount of variability may now be submitted within the same eFile. This is intended to help with tracking purposes.
- for billing and reference purposes, please designate one document as the parent file, and the others can be iterations (or child files) to this parent file. This should be specified in the cover letter.
- in the iterative APSs within the same eFile, please highlight the copy that is different than the parent file.
    - Examples of submissions that may be accepted as iterative submissions are:
        - An email with variable subject lines or footers
        - A website that will have mobile, desktop, and tablet versions of the layout
        - App store descriptions for different stores

c. For other series submissions, please note the following:
- please designate one file as the parent file, for which the others can be child files.
- the parent file will be charged a full fee, and the child files associated with this (i.e. at least 60% pickup from the parent file) will be charged a series fee.
- your request for series and the associated files should be clearly outlined in your cover letter.
- if upon closer review, the copy in the child file is not 60% identical to the parent file, your fee may be reassessed.

d. Any submission that does not meet all criteria listed in 'a', 'b' or 'c' above are separate submissions that will be assigned a full base fee. These include, but are not limited to:
    - APS which could be used as standalone pieces (e.g. posters, dose cards, product booklets stored in a binder, box, USB stick, or laptop) or contain distinguishingly different units (e.g. booklet containing discrete sections each for a different product)
    - APS which can have varying lengths/topics depending on need (see FAQ at bottom of this section)
    - tool with segments targeted to different populations (e.g. counseling flip chart containing patient-targeted copy on the front of each card and HCP-targeted copy on the back of each card)

3.3. Existing file incurring new file/fee

A new file/fee will continue to be assigned in the following circumstances:

- significant PM update during an ongoing review
- significant unsolicited changes during an ongoing review
- file has been open for 1 year
- 6 months has elapsed since the last client response (in an ongoing file)
- outdated library (modular submission)

Chapter 4: Post-approval

4.1. Approval period extension requests

Extension Letter requests should be submitted as a PDF and are required in writing to review@paab.ca and must include:

- the PAAB eFile # of the file requiring an extension
- the reason for the extension request
- the date of the most current TMA
- confirmation that there have not been any advertising complaints on the product since the most recent approval of the APS
- confirmation that the approved claims are still reflective of the current marketplace

If any of the above elements have not been provided in the Extension Request Form (see sample below), PAAB will reject the Extension Request. The form can be accessed from the Resources tab on the PAAB website. If all of the above requirements have been met, the PAAB

will extend the current acceptance period by a maximum of 2 months. A revised PAAB acceptance letter, reflecting the new expiry date, will be forwarded to the client and the original eFile will be updated with a copy of the written Extension Request. If any of the above requirements have not been met, the PAAB will investigate to determine if they affect the 2-month extension request and forward a reply accordingly.

Please Note: Renewal of previously PAAB-accepted APS should be submitted 6 weeks prior to the expiry of the acceptance period. **Requests for extension of expiry date should not be requested in lieu of timely renewal submissions.** If the file was forward-dated at initial acceptance, 2-month extension is not an option.

Extension Request Form

- complete PAAB acceptance ID #
- reason for the extension request
- date of the most current TMA
- confirmation that there have not been any advertising complaints on the product since the most recent approval of the APS.
- confirmation that the approved claims are still reflective of the current marketplace.

4.2. FYIs

FYIs are informative emails sent to review@paab.ca to make the PAAB aware of post-approval changes to an approved APS for the following reasons only:

- corporate logo, trademark changes
- version code changes
- French language grammar correction which does not alter the claim
- directly proportional resize of APS that results in no layout/flow/content/functionality changes

The client is responsible for ensuring that the TMA has not changed since initial approval of the piece. If your FYI falls into one of the four categories listed above, email review@paab.ca to include the reason for sending the FYI and attach final layouts which highlight the changes. Please include the previously approved eFile # and your telephone contact information. Your email will be processed and filed as an FYI and the email and final layouts will be uploaded to the originally approved eFile. You will be telephoned to advise that the FYI has been filed.

Please Note: Written confirmations in letter form or by email are not provided. The original PAAB acceptance letter will cover the FYI changes for the originally approved acceptance timeframe.

Please Note: All other post approval changes to previously approved APS, e.g. any copy or layout changes (including revisions that would be considered a minor update), flow changes, visual changes, and functionality changes are subject to further review and should be submitted in the form of new eFiles. Please also refer to *Section 4.3*.

Provincial governments have asked PAAB to ensure that APS containing formulary claims:

- clearly convey that restrictions exist within the claim (when applicable), and present the details relating to coverage when a coverage code is included in the advertisement
- do not imply contextual relationships between formulary status and other issues (e.g. an endorsement, a status, level of efficacy/safety…etc.)

All post approval changes involving addition of formulary statements (or modification of existing formulary statements) must therefore be submitted as new files complete with formulary references (see below).

4.3. All other post-approval changes

Post-approval changes are defined as any copy, layout, or flow change that occurs after an APS has received final PAAB approval and acceptance. This does not include FYI's (see FYI section). Post-approval changes must be reviewed for approval and a new eFile submission should be submitted.

Note the following:

- the new eFile should be completed per the Submission guidelines and include the previously approved eFile number
- updated copy and layout with highlighted changes should be submitted for review
- the most current TMA and Compliance Approval Letter should be uploaded along with any new references used to support the updated APS. All references must be cross-referenced with the updated copydeck as per this document

Chapter 5: Pre-NOC Advertising Submissions

The PAAB mandate is to review advertising and promotional systems (APS) for approved pharmaceutical products. However, PAAB recognizes the importance of product launch

timelines. This chapter clarifies procedures for advertising review before Notice of Compliance (NOC) has been granted.

When the PM is at Final Draft stage as confirmed by a letter from the manufacturer's regulatory department, the PAAB will accommodate up to two pre-NOC submissions at the discretion of the PAAB Commissioner with respect to workload at the time of submission. These submissions will not be subject to the standard turnaround time. As with all submissions for review, these APS require approval by the advertiser's medical/regulatory staff prior to PAAB review. While waiting for the final approval of the PM, the company should apply PAAB revision requests to all the items that form the launch campaign.

The eFile system will indicate a 15-business day turnaround to first response as an internal guideline. If NOC is received prior to completion of the first review and there are no further changes to the PM and no changes to copy/layout /references, the initial 15-day timeline is maintained. If changes to the PM occur upon the receipt of NOC, the submission is returned to be updated and upon resubmission to PAAB, the Full Review timeline of 10 days is initiated. All modified documents should be annotated to direct the reviewer's eyes to the changes.

When the pharmaceutical company receives its NOC, the final revised core APS should be submitted along with the NOC and PM. At this time, other launch APS may be submitted for PAAB review.

Advertisers should be aware that under PAAB's mandate, we can only provide acceptances for advertising for use post-NOC. PAAB does not issue acceptances for any branded promotional activities assessed pre-NOC.

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 meeting would be appropriate.

Chapter 6: Call Requests

For more information on eFiles Ticketing and Tagging please see Guidance on the eFiles Platform Ticketing and Tagging Functionality.

6.1. Opinion call request

If needed, the PAAB will provide one post-review call for clarification of the opinion provided. Generally, 5-10 minutes should be all that is needed. Please submit a ticket and provide the e-File #, a detailed reason for the call, your contact information, and the best time of day to reach you.

6.2. Ongoing Review call request

If you wish to speak to the Reviewer of record regarding a specific point on an eFile, please submit your request through the ticket system which can be accessed through your eFiles account.

Within your ticket, please specify all points to be clarified, your contact information, and the best time of day to return your call.

Please Note: Reviewers will not perform reviews over the phone

6.3. Consultation Meeting Request

If you wish to arrange a consultation meeting to discuss advertising concepts, distinguishing advertising vs. information, or pre-launch materials/information, please submit your request to review@paab.ca. Within your message, please specify the detailed description of the purpose for the request, the names of the attendees for the meeting along with suggested dates and times that your group is available.

6.4. Escalation Call Request

Escalation requests will be accepted only after having discussed a written review comment with the PAAB Reviewer, responding in writing and receiving a subsequent PAAB letter about the same issue for which an impasse has been reached. If you wish to escalate an issue regarding an eFile, please submit a ticket with a detailed reason for the request, the eFile # and points to be discussed, and the requestor's contact information. The administrator will forward the request to the Reviewer of Record and the Senior Reviewer of Preclearance will return the call. Please note that the manufacturer must participate in the escalation call.

6.5. General Questions

A general question is any question which seeks clarification of a PAAB or related Health Canada document, policy, or procedure.

For example:

- clarification of PAAB code
- whether a hypothetical advertising piece requires PAAB review
- clarification regarding types of APS and how they can be used
- administrative inquiries
- eFile system inquiries

An individual's first step should be to search and review the PAAB Forum to see if their question or one similar in nature, has been previously asked and answered. In the absence of an appropriate response or clarification through the additional resources provided, we encourage all members to ask the general question on the forum in relation to the relevant documents. PAAB aims to respond to all Forum questions within 24 hours.

If the individual does not wish to ask on the forum, a general question ticket can be opened. Once submitted through the eFiles system, the administrator will assign the ticket to a reviewer for response by end of the next business day.

Please note: Questions regarding specific APS pieces, claims, concepts, or visuals should be submitted for written opinion or a consult meeting.

Appendix A – Terms and Definitions

APS (Advertising/Promotion System): For purposes of the PAAB Code, an APS is defined as any paid message communicated by Canadian media, with the intent to influence the choice, opinion, or behavior of those addressed by commercial messages. This definition applies even if the information:

a. has been published independently of the manufacturer e.g. clinical reprints, meeting reports;
b. is from an independent authoritative source;
c. is unchanged and complete;
d. is claimed to be educational material. Distribution of any unsolicited material about a pharmaceutical product is deemed to be advertising if the information or its distribution serves to promote the sale of that product, either directly or indirectly

Iterative Submission: An iterative submission is a type of submission in which multiple versions (or iterations) of an APS can be submitted under the same eFile number. Iterative submissions can also be considered for projects that contain the same content but with different layouts configured for different platforms (e.g. PC, tablet, smartphone), or app store descriptions for different stores.

Minor update: A minor update is considered an existing presentation in the APS that 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.
- removal of the copy "new" from pieces when the product reaches one year post initial marketing

Module Library: The module library is the first document that should be created when you are considering submitting modular APS. It is a library of claim presentations or content blocks that

are reviewed independently from each other to ensure that their content is accurate and not misleading. The library then acts as a reference from which future modular APS can be built by selecting and sequencing a subset of the modules that have been pre-assessed in the library.

Modular APS: A modular APS is a submission based entirely on a subset of modules, in sequence, from the pre-assessed module library. Because the content for each module has already been reviewed, the context of this review is focused on ensuring the flow and context adheres to the standards of the code.

NOC: Notice of Compliance

Other series: A type of series submission in which there is a parent file, which is reviewed as a full submission, and subsequent submissions (series submissions) that are at least 60% pickup of identical copy from the parent file. These are not submitted within the same eFile (like an iterative submission) as there is more new content, but a series fee is applied. These files should all be submitted in the same day.

Parent file:

- In the context of an iterative submission, the parent document is the version of the APS that should be considered the main file (e.g. the desktop layout might be considered the parent, and the mobile and tablet layouts are the iterations). The other iterations will differ slightly from the parent. Note that this does not apply where the iterations are submitted within the same copydeck (e.g. subject lines). In that context, please appropriately label and note the iterations within the copydeck.
- Modular APS are all considered child files while the modular library is considered a parent file.
- In the context of an other series submission, the parent file is the first submission in the series, on which all the other series (or child) submissions are based. All child submissions must be ≥60% duplicate copy from the parent in order to be considered for a series fee.

The parent file is always assigned a full base fee while the corresponding child files are assigned a series fee.

PM: Product Monograph

Renewal submission: A submission that is 100% pickup from the previously approved version. If there are any updates to the piece, please do not submit your file as a renewal as a different fee structure will apply.

The following exceptions, if revised, can still be considered a renewal:

- Version code changes
- Trademark changes and corporate logo changes

- French language grammar correction which does not alter the claim
- Directly proportional resize of APS that results in NO layout/flow/content/functionality changes

TMA: Terms of Market Authorization. Is the information in the Product Monograph, labeling and product license and the document that assigns a Drug Identification Number (DIN), Natural Health Product number (NPN) or homeopathic product number (DIN-HM), including related product labeling material and prescribing information, authorized by Health Canada.

Appendix B – Minimum Copydeck Format Requirements

As the fee structure relies more heavily on copydeck length, we have provided some guidance on minimum format requirements to ensure that fee calculations are fair amongst submitters.

When creating your copydeck, please adhere to the minimum requirements below:

- 11-point font size minimum
- no condensed fonts
- minimum 1.5 spacing
- standard margins (not including annotations for the purposes of the submission requirements) and page sizes; acceptable example (11 pt Arial, 1.5 line spacing, 1 inch margins)

[HEADLINE]
New indication for Biologik: Adults with moderate to severe ulcerative colitis [PM p.2A]

[COPY]
We are pleased to inform you that Biologik is now indicated for the treatment of adult patients with moderate to severe ulcerative colitis. [PM p.2A]

Biologik is also indicated in adults with Crohn's disease [PM p.2A]

[CALLOUT]
Visit https://farmasil.ca/Biologikpm for more information [link to PM]

[FAIR BALANCE]
Biologik is indicated for the treatment of adult patients with moderate to severe Crohn's disease [PM p.2A]

Consult the Product Monograph at https://farmasil.ca/Biologikpm for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling 1-234-567-8999.

[REFERENCES]
Biologik Product Monograph. Farmasil, January 1, 2021.

Unacceptable Example #1 – (9 pt condensed font, single line spacing)

[HEADLINE]
New indication for Biologik: Adults with moderate to severe ulcerative colitis [PM p.2A]

[COPY]
We are pleased to inform you that Biologik is now indicated for the treatment of adult patients with moderate to severe ulcerative colitis. [PM p.2A]

Biologik is also indicated in adults with Crohn's disease [PM p.2A]

[CALLOUT]
Visit https://farmasil.ca/Biologikpm for more information [link to PM]

[FAIR BALANCE]
Biologik is indicated for the treatment of adult patients with moderate to severe Crohn's disease [PM p.2A]

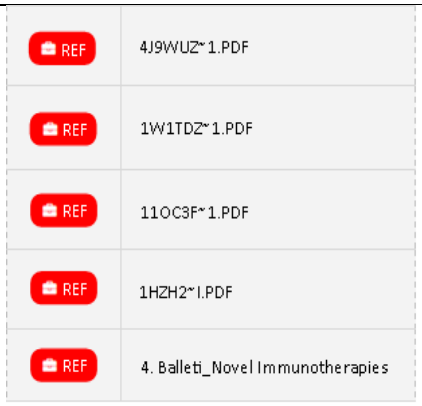
Consult the Product Monograph at https://farmasil.ca/Biologikpm for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling 1-234-567-8999.

[REFERENCES]
Biologik Product Monograph. Farmasil, January 1, 2021.

Unacceptable Example #2 – (narrow margins, spacing between copy removed)

[HEADLINE]
New indication for Biologik: Adults with moderate to severe ulcerative colitis [PM p.2A]
[COPY]
We are pleased to inform you that Biologik is now indicated for the treatment of adult patients with moderate to severe ulcerative colitis. [PM p.2A]
Biologik is also indicated in adults with Crohn's disease [PM p.2A]
[CALLOUT]
Visit https://farmasil.ca/Biologikpm for more information [link to PM]
[FAIR BALANCE]
Biologik is indicated for the treatment of adult patients with moderate to severe Crohn's disease [PM p.2A]
Consult the Product Monograph at https://farmasil.ca/Biologikpm for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling 1-234-567-8999.
[REFERENCES]
Biologik Product Monograph. Farmasil, January 1, 2021

Appendix C – Referencing examples

Example of APS Citation	Example Reference List
What you may expect from CAR T-cell therapies **Follow-up requirements and travel restrictions after CAR T-cell infusion** [Ref. Beaupierre Learning 2018_7B, 10A; Ref. Calmeti 2017_6A: Ref. Yogi-Bheara_11D; Ref. Johanssen 2020_8A; Ref. Smite 2019_5C]	

Acceptable Referencing? **No.**

Rationale: There is no way to corroborate the APS citation within the references. There are 2 main issues here:

1) The entire section should not be referenced in the subhead/headline only. References should accompany the specific claim.
2) The citation in the APS must align with the citation in the reference list. The reviewer would need to open every file within the reference list to find the associated source, for every paper.

Example of APS Citation	Example Reference List
SUBHEAD: Distribution of change from baseline to week 52 in ALS Functional Rating Scale-Revised scores[1,2] 1i.[PM/13/Fig 1] 3a. [Cameron/p44/Fig 2.7.4] Administer each 50 milligram dose as 2 consecutive 25 milligram intravenous infusion bags over a total of 60 minutes (infusion rate ~1 milli gram per minute)[1] 1j. [PM/p5] GRAPHIC COPY: [calendar icon] First cycle 1k. [PM/p4] 12 consecutive days on 12 consecutive days off [calendar icon] Subsequent cycles 1k. [PM/p4] 8 out of 12 days on 12 days of	
Acceptable Referencing? **Yes.** Rationale: This is a good example of referencing for the following reasons: 1. Reference citations are a different colour from the copy 2. Each claim is annotated and cross-referenced clearly 3. Annotations match reference labels in the reference list	

Example of APS Citation	Example Reference List
[CALLOUT] **Enroll Your Eligible Patients for the Pharmasill Injection Services Program Today!** (previously approved in efile 234567)	N/A
Acceptable Referencing? **Yes.** Rationale: This is a good example of how to cite a previously accepted claim that does not have an associated reference. It is in a different colour from the claim and clearly identifies the efile that the claim is picked up from.	

Appendix D – Modular submission example

Please note that the following copydeck example line spacing has been condensed for the purpose of this document. Please refer to Appendix B for formatting guidelines.

Bluzject (bluexetine hydrochloride) Modular library submission – Major depressive disorder indication

Table of Contents

Clinical content

Indication

Section code	
IND.MDD	Bluzject (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD). [PM 4A]

Fair balance

Section code	
FB.L	Consult the product monograph at www.bluzjectPM.ca for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.
FB.M	Consult the product monograph at www.bluzjectPM.ca for important information about: • Contraindications in patients with concurrent use of monoamine oxidase inhibitors [PM 4D] • The most serious warning and precaution regarding potential association with behavioural and emotional changes including self-harm and suicidal ideation. [PM 9A] • Other relevant warnings and precautions of discontinuation symptoms [PM 9B], QT prolongation [PM 10A], abnormal bleeding [PM 10B], bone fracture risk [PM 10C], serotonin toxicity / neuroleptic malignant syndrome [PM 11A], angle closure glaucoma [PM 11B], activation of mania / hypomania [PM 11C], insomnia [PM 11D], and sexual dysfunction [PM 12A]. • Conditions of clinical use, adverse reactions, drug interactions, and dosing instructions. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.
FB.H	**Clinical use:** Bluzject has not been systematically evaluated beyond 24 weeks in controlled clinical trials. The prescriber who elects to use Bluzject for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. [PM 4B] Geriatrics (>65 years of age): Caution should be exercised in treating geriatric patients. The lowest effective dose of 125mg injected intramuscularly every 42 days should always be used as the starting dose in elderly patients. [PM 4C] **Contraindication:** • In patients with concurrent use of monoamine oxidase inhibitors [PM 4D] **Most Serious Warnings and Precautions:** **Behavioural and emotional changes including self-harm and suicidal ideation:** There are clinical trial and post-marketing reports with SSRIs and other newer anti-

depressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia/psychomotor restlessness, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment. Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes. [PM 9A]

Other Relevant Warnings and Precautions:

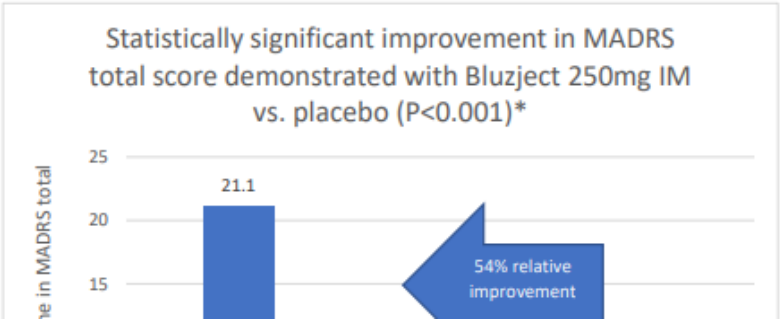
- discontinuation symptoms [PM 9B]
- QT prolongation [PM 10A]
- abnormal bleeding [PM 10B]
- bone fracture risk [PM 10C]
- serotonin toxicity / neuroleptic malignant syndrome [PM 11A]
- angle closure glaucoma [PM 11B]
- activation of mania / hypomania [PM 11C]
- insomnia [PM 11D]
- sexual dysfunction [PM 12A].

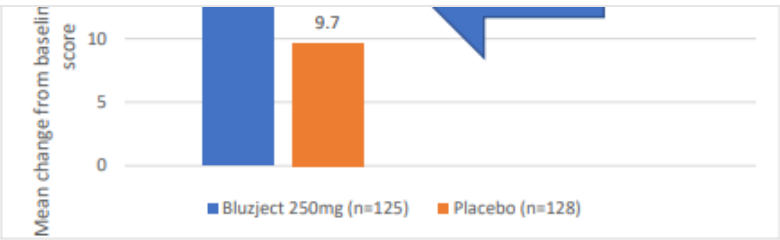
For more information:
Consult the product monograph at www.bluzjectPM.ca for important information relating to adverse reactions, interactions, and dosing which have not been discussed in this piece. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.

Efficacy

Section code	
EFF.1.1 *Review note: Visual efficacy presentation*	Headline: Demonstrated efficacy Subhead: Powerful symptom improvement shown in treatment of MDD Graph title: Statistically significant improvement in MADRS total score demonstrated with Bluzject 250mg IM vs. placebo at week 24 (P<0.001)* [PM 31D] Graph copy:

X-axis label	Bluzject 250mg (n=125) Placebo (n=128) [PM 30A]
Y-axis label	Mean change from baseline in MADRS total score
Mean change from baseline	Bluzject: 21.1 Placebo: 9.7 [PM 31C]



	 Graph disclaimer: Baseline MADRS score in both treatment arms: 28.3 [PM 30A] Callout: 54% relative improvement (Calculation for review: (0.211-0.097)/0.211= 54.03%) Qualifiers: IM: intramuscular, MADRS: Montgomery-Asberg Depression Rating Scale * Randomized, placebo-controlled, multicentre 24-week study of Bluzject 250mg injected intramuscularly vs saline injected intramuscularly every 42 days in adults aged 18 years and older. The primary endpoint was change in MADRS score from baseline. Key secondary endpoints included change in Sheehan Disability Scale and patient reported quality of life as measured by Quality of Life, Enjoyment and Satisfaction Questionnaire – short form. [PM 30A]
EFF.1.2 *Review note: When included, section will always follow EFF.1.1*	Subhead: Improvement of overall function shown in treatment of MDD Callout: Demonstrated improvement in function with Bluzject 250mg IM vs placebo as measured by mean change in total SDS score (absolute change -10.8 vs -7.8, p=0.01); secondary endpoint [PM 32A] Subhead: Improvement of quality of life as measured by patient self-report shown in treatment of MDD Callout: Demonstrated improvement in quality of life with Bluzject 250mg IM vs placebo as measured by mean change in Quality of Life, Enjoyment and Satisfaction Questionnaire- Short form (absolute change 20.8 vs 16.0, p=0.03); secondary endpoint [PM 32C]
EFF.1.3	Headline: Demonstrated efficacy Subhead: Powerful symptom improvement shown in treatment of MDD* Copy: Statistically significant greater improvement in depressive symptoms, as measured by MADRS total score, demonstrated with Bluzject 250mg IM (n=125) vs. placebo at week 24 (n=128) (Mean change from baseline Bluzject: 21.1 vs placebo: 9.7; Baseline MADRS score in both treatment arms: 28.3; P<0.001)* [PM 31D] Qualifiers: IM: intramuscular, MADRS: Montgomery-Asberg Depression Rating Scale * Randomized, placebo-controlled, multicentre 24-week study of Bluzject 250mg injected intramuscularly vs saline injected intramuscularly every 42 days in adults aged 18 years and older. The primary endpoint was change in MADRS score from baseline. Key secondary endpoints included change in Sheehan Disability Scale and patient reported quality of life as measured by Quality of Life, Enjoyment and Satisfaction Questionnaire – short form. [PM 30A]

Clinical call to action

Section code	
CCTA.1	Think Bluzject for your patients with MDD.

Non-clinical call to action

Section code	
NCCTA.1	Consider Bluzject.

Dosing

Section code	
DOS.1 *Review note: Separate and distinct from other content*	Corner nabisco: The first and only SSRI indicated in major depressive disorder injected intramuscularly every 6 weeks†. [DOF 1A] Qualifiers: †Comparative clinical significance is unknown. SSRI: Selective serotonin reuptake inhibitor
DOS.2	Headline: Recommended dosing¶ Copy: The starting and recommended dose for adults less than 65 years of age is 250 mg IM every 6 weeks. Although limited efficacy data is available, some patients not responding to 250 mg may benefit from a higher dose of 375 mg every 6 weeks. The maximum dose should not exceed 375mg every 6 weeks. It is recommended that responding patients be continued with the lowest dose needed and reassessed periodically to determine the need for continued treatment. [PM 6A] A dose reduction to 125mg IM every 6 weeks may be considered for patients who do not tolerate higher doses. [PM 6B] The starting and recommended dose for adults 65 years of age or older is 125mg IM every 6 weeks. Caution is advised when treating elderly patients. [PM 7A] Qualifiers: ¶Refer to the Product Monograph for complete dosing information. IM: Intramuscular

Non-clinical content

Mechanism of Action

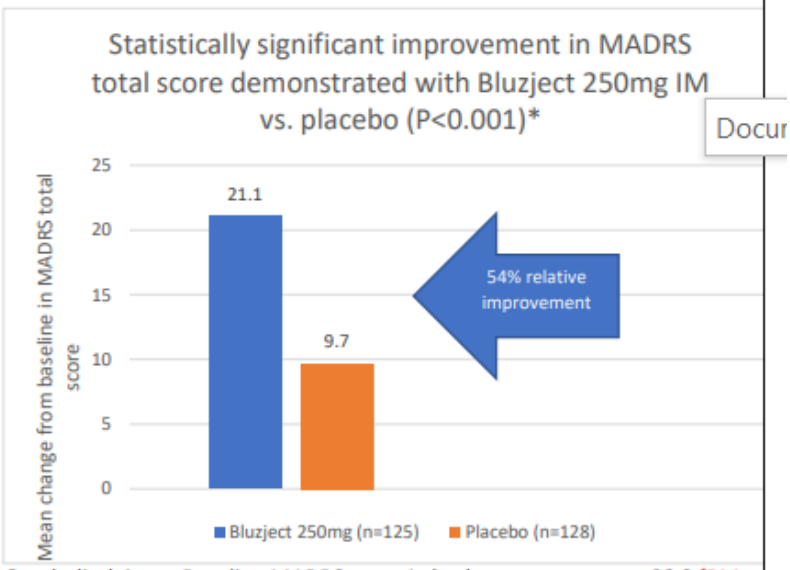
Section code	
MOA.1	Headline: Mechanism of action of Bluzject* The mechanism of antidepressant effect of bluexetine is thought to be through enhanced serotonin activity through neuromodulation in the CNS. Bluextine binds with low affinity to GABA, norepinephrine and dopamine receptors. The role and contribution of these targets to the overall effect of bluexetine is not fully understood. Copy: *Clinical significance is unknown

Resources

Section code	
RES.1	Visit BluzjectHCP.ca to learn more! [eFile XXXXX0]
RES.2	Download the following resources to share with your patients prescribed Bluzject. • Getting started patient brochure [eFile XXXXX1] • Dosing calendar [eFile XXXXX2] • Payment assistance card [eFile XXXXX3]
RES.3	Click here for more information on the efficacy and safety profile of Bluzject [Downloads PDF eFile XXXXX4]

Bluzject Modular APS submission 1 – Long efficacy email

<table>
<tr><td></td><td>Modular library section code</td><td>Content</td></tr>
<tr><td>Email envelope</td><td>N/A</td><td>Subject line: Interested in the efficacy data for Bluzject?
Preview Text: Click here to learn more</td></tr>
<tr><td>Greeting-variable element</td><td>N/A</td><td><table><tr><td>Option 1</td><td>Dear Dr.</td><td>[HCP name]</td></tr><tr><td>Option 2</td><td>Dear</td><td>[HCP name]</td></tr><tr><td>Option 3</td><td>Hello</td><td>[HCP name]</td></tr></table></td></tr>
<tr><td>Transactional element – open text greeting</td><td>N/A</td><td>[Open text field]
Review note: Open text fields will be used solely for personalized greetings and will not include other messages, even if they echo messages reviewed and accepted elsewhere in the current or previous APS. We confirm that representatives will be adequately trained on proper use of open text fields and there is an audit-type mechanism in place to monitor and ensure compliance with this directive.</td></tr>
<tr><td></td><td>IND.MDD</td><td>Bluzject (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD). [PM 4A]</td></tr>
<tr><td></td><td>EFF.1.1</td><td>Headline: Demonstrated efficacy
Subhead: Powerful symptom improvement shown in treatment of MDD
Graph title: Statistically significant improvement in MADRS total score demonstrated with Bluzject 250mg IM vs. placebo at week 24 (P<0.001)* [PM 31D]
Graph copy:<table><tr><td>X-axis label</td><td>Bluzject 250mg (n=125)
Placebo (n=128) [PM 30A]</td></tr><tr><td>Y-axis label</td><td>Mean change from baseline in MADRS total score</td></tr><tr><td>Mean change from baseline</td><td>Bluzject: 21.1
Placebo: 9.7 [PM 31C]</td></tr></table></td></tr>
</table>

		 Graph disclaimer: Baseline MADRS score in both treatment arms: 28.3 [PM 30A] Callout: 54% relative improvement (Calculation for review: (0.211-0.097)/0.211= 54.03%) Qualifiers IM: intramuscular, MADRS: Montgomery-Asberg Depression Rating Scale * Randomized, placebo-controlled, multicentre 24-week study of Bluzject 250mg injected intramuscularly vs saline injected intramuscularly every 42 days in adults aged 18 years and older. The primary endpoint was change in MADRS score from baseline. Key secondary endpoints included change in Sheehan Disability Scale and patient reported quality of life as measured by Quality of Life, Enjoyment and Satisfaction Questionnaire – short form. [PM 30A]
	EFF.1.2	Subhead: Improvement of overall function shown in treatment of MDD Callout: Demonstrated improvement in function with Bluzject 250mg IM vs placebo as measured by mean change in total SDS score (absolute change -10.8 vs -7.8, p=0.01); secondary endpoint [PM 32A] Subhead: Improvement of quality of life as measured by patient self-report shown in treatment of MDD Callout: Demonstrated improvement in quality of life with Bluzject 250mg IM vs placebo as measured by mean change in Quality of Life, Enjoyment and Satisfaction Questionnaire- Short form (absolute change 20.8 vs 16.0, p=0.03); secondary endpoint [PM 32C]
	CCTA.1	Think Bluzject for your patients with MDD.
	FB.H	**Clinical use:** Bluzject has not been systematically evaluated beyond 24 weeks in controlled clinical trials. The prescriber who elects to use Bluzject for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. [PM 4B] Geriatrics (>65 years of age): Caution should be exercised in treating

		geriatric patients. The lowest effective dose of 125mg injected intramuscularly every 42 days should always be used as the starting dose in elderly patients. [PM 4C] **Contraindication:** • In patients with concurrent use of monoamine oxidase inhibitors [PM 4D] **Most Serious Warnings and Precautions:** **Behavioural and emotional changes including self-harm and suicidal ideation:** There are clinical trial and post-marketing reports with SSRIs and other newer anti-depressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia/psychomotor restlessness, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment. Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes. [PM 9A] **Other Relevant Warnings and Precautions:** • discontinuation symptoms [PM 9B] • QT prolongation [PM 10A] • abnormal bleeding [PM 10B] • bone fracture risk [PM 10C] • serotonin toxicity / neuroleptic malignant syndrome [PM 11A] • angle closure glaucoma [PM 11B] • activation of mania / hypomania [PM 11C] • insomnia [PM 11D] • sexual dysfunction [PM 12A]. **For more information:** Consult the product monograph at www.bluzjectPM.ca for important information relating to adverse reactions, interactions, and dosing which have not been discussed in this piece. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.
	RES.1	Visit BluzjectHCP.ca to learn more! [eFile XXXXX0]
Transaction al element – open text closing	N/A	[Open text field] *Review note: Open text fields will be used solely for personalized greetings and will not include other messages, even if they echo messages reviewed and accepted elsewhere in the current or previous APS. We confirm that representatives will be adequately trained on proper use of open text fields and there is an audit-type mechanism in place to monitor and ensure compliance with this directive.*

Bluzject Modular APS submission 2 – Short efficacy email

	Modular library section code	Content
Email envelope	N/A	Subject line: Efficacy data inside Preview Text: Click here to learn more about Bluzject
Greeting-variable element	N/A	Option 1 | Dear Dr. | [HCP name] Option 2 | Dear | [HCP name] Option 3 | Hello | [HCP name]
Transactional element – open text greeting	N/A	[Open text field] *Review note: Open text fields will be used solely for personalized greetings and will not include other messages, even if they echo messages reviewed and accepted elsewhere in the current or previous APS. We confirm that representatives will be adequately trained on proper use of open text fields and there is an audit-type mechanism in place to monitor and ensure compliance with this directive.*
	IND.MDD	Bluzject (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD). [PM 4A]
	EFF.1.3	Headline: Demonstrated efficacy Subhead: Powerful symptom improvement shown in treatment of MDD* Copy: Statistically significant greater improvement in depressive symptoms, as measured by MADRS total score, demonstrated with Bluzject 250mg IM (n=125) vs. placebo at week 24 (n=128) (Mean change from baseline Bluzject: 21.1 vs placebo: 9.7; Baseline MADRS score in both treatment arms: 28.3; P<0.001)* [PM 31D] Qualifiers IM: intramuscular, MADRS: Montgomery-Asberg Depression Rating Scale * Randomized, placebo-controlled, multicentre 24-week study of Bluzject 250mg injected intramuscularly vs saline injected intramuscularly every 42 days in adults aged 18 years and older. The primary endpoint was change in MADRS score from baseline. Key secondary endpoints included change in Sheehan Disability Scale and patient reported quality of life as measured by Quality of Life, Enjoyment and Satisfaction Questionnaire – short form. [PM 30A]
	CCTA.1	Think Bluzject for your patients with MDD.
	FB.H	**Clinical use:** Bluzject has not been systematically evaluated beyond 24 weeks in controlled clinical trials. The prescriber who elects to use Bluzject for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. [PM 4B] Geriatrics (>65 years of age): Caution should be exercised in treating geriatric patients. The lowest effective dose of 125mg injected intramuscularly every 42 days should always be used as the starting dose in elderly patients. [PM 4C] **Contraindication:**

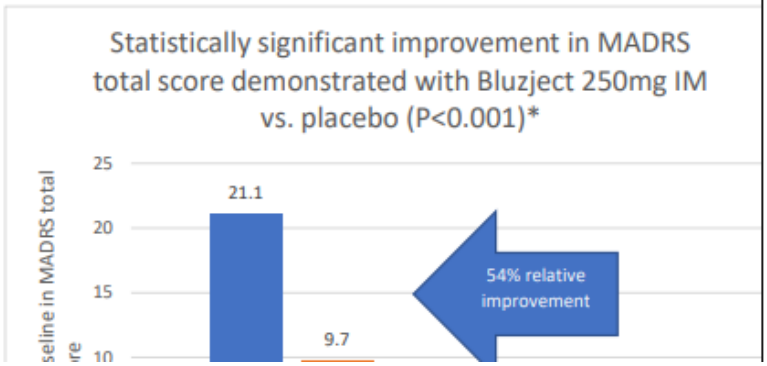
		• In patients with concurrent use of monoamine oxidase inhibitors [PM 4D] **Most Serious Warnings and Precautions:** **Behavioural and emotional changes including self-harm and suicidal ideation:** There are clinical trial and post-marketing reports with SSRIs and other newer anti-depressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia/psychomotor restlessness, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment. Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes. [PM 9A] **Other Relevant Warnings and Precautions:** • discontinuation symptoms [PM 9B] • QT prolongation [PM 10A] • abnormal bleeding [PM 10B] • bone fracture risk [PM 10C] • serotonin toxicity / neuroleptic malignant syndrome [PM 11A] • angle closure glaucoma [PM 11B] • activation of mania / hypomania [PM 11C] • insomnia [PM 11D] • sexual dysfunction [PM 12A]. **For more information:** Consult the product monograph at www.bluzjectPM.ca for important information relating to adverse reactions, interactions, and dosing which have not been discussed in this piece. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.
	RES.3	Click here for more information on the efficacy and safety profile of Bluzject [Downloads PDF eFile XXXXX4]
Transactional element –	N/A	[Open text field]
open text closing		*Review note: Open text fields will be used solely for personalized greetings and will not include other messages, even if they echo messages reviewed and accepted elsewhere in the current or previous APS. We confirm that representatives will be adequately trained on proper use of open text fields and there is an audit-type mechanism in place to monitor and ensure compliance with this directive.*

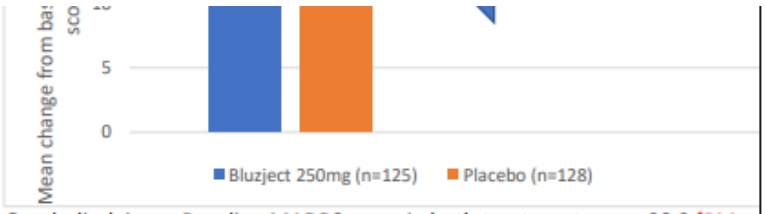
Bluzject Modular APS submission 3 – Dosing email

	Modular library section code	Content
Email envelope	N/A	Subject line: Learn how to dose Bluzject *Preview Text: none*
Greeting-variable	N/A	Option 1 | Dear Dr. | [HCP name] Option 2 | Dear | [HCP name]

element		Option 3 | Hello | [HCP name]
Transactional element – open text greeting	N/A	[Open text field] *Review note: Open text fields will be used solely for personalized greetings and will not include other messages, even if they echo messages reviewed and accepted elsewhere in the current or previous APS. We confirm that representatives will be adequately trained on proper use of open text fields and there is an audit-type mechanism in place to monitor and ensure compliance with this directive.*
	DOS.1	Corner nabisco: The first and only SSRI indicated in major depressive disorder injected intramuscularly every 6 weeks†. [DOF 1A] Qualifiers: †Comparative clinical significance is unknown. SSRI: Selective serotonin reuptake inhibitor
	IND.MDD	Bluzject (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD). [PM 4A]
	DOS.2	Headline: Recommended dosing¶ Copy: The starting and recommended dose for adults less than 65 years of age is 250 mg IM every 6 weeks. Although limited efficacy data is available, some patients not responding to 250 mg may benefit from a higher dose of 375 mg every 6 weeks. The maximum dose should not exceed 375mg every 6 weeks. It is recommended that responding patients be continued with the lowest dose needed and reassessed periodically to determine the need for continued treatment. [PM 6A]
		A dose reduction to 125mg IM every 6 weeks may be considered for patients who do not tolerate higher doses. [PM 6B] The starting and recommended dose for adults 65 years of age or older is 125mg IM every 6 weeks. Caution is advised when treating elderly patients. [PM 7A] Qualifiers: ¶Refer to the Product Monograph for complete dosing information. IM: Intramuscular
	RES.1	Visit BluzjectHCP.ca to learn more! [eFile XXXXX0]
	FB.L	Consult the product monograph at www.bluzjectPM.ca for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.
Transactional element – open text closing	N/A	[Open text field] *Review note: Open text fields will be used solely for personalized greetings and will not include other messages, even if they echo messages reviewed and accepted elsewhere in the current or previous APS. We confirm that representatives will be adequately trained on proper use of open text fields and there is an audit-type mechanism in place to monitor and ensure compliance with this directive.*

Bluzject Modular APS submission 4 – Comprehensive email

<table>
<tr><td></td><td>Modular library section code</td><td>Content</td></tr>
<tr><td>Email envelope</td><td>N/A</td><td>Subject line: Interested in Bluzject?
Preview Text: Open this email to learn more!</td></tr>
<tr><td>Greeting-variable element</td><td>N/A</td><td><table><tr><td>Option 1</td><td>Dear Dr.</td><td>[HCP name]</td></tr><tr><td>Option 2</td><td>Dear</td><td>[HCP name]</td></tr><tr><td>Option 3</td><td>Hello</td><td>[HCP name]</td></tr></table></td></tr>
<tr><td>Transactional element – open text greeting</td><td>N/A</td><td>[Open text field]
Review note: Open text fields will be used solely for personalized greetings and will not include other messages, even if they echo messages reviewed and accepted elsewhere in the current or previous APS. We confirm that representatives will be adequately trained on proper use of open text fields and there is an audit-type mechanism in place to monitor and ensure compliance with this directive.</td></tr>
<tr><td></td><td>IND.MDD</td><td>Bluzject (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD). [PM 4A]</td></tr>
<tr><td></td><td>NCCTA.1</td><td>Consider Bluzject.</td></tr>
<tr><td></td><td>EFF.1.1</td><td>Headline: Demonstrated efficacy
Subhead: Powerful symptom improvement shown in treatment of MDD
Graph title: Statistically significant improvement in MADRS total score demonstrated with Bluzject 250mg IM vs. placebo at week 24 (P<0.001)* [PM 31D]
Graph copy:<table><tr><td>X-axis label</td><td>Bluzject 250mg (n=125)
Placebo (n=128) [PM 30A]</td></tr><tr><td>Y-axis label</td><td>Mean change from baseline in MADRS total score</td></tr><tr><td>Mean change from baseline</td><td>Bluzject: 21.1
Placebo: 9.7 [PM 31C]</td></tr></table> 
</td></tr>
</table>

		 Graph disclaimer: Baseline MADRS score in both treatment arms: 28.3 [PM 30A] Callout: 54% relative improvement (Calculation for review: (0.211-0.097)/0.211= 54.03%) Qualifiers IM: intramuscular, MADRS: Montgomery-Asberg Depression Rating Scale * Randomized, placebo-controlled, multicentre 24-week study of Bluzject 250mg injected intramuscularly vs saline injected intramuscularly every 42 days in adults aged 18 years and older. The primary endpoint was change in MADRS score from baseline. Key secondary endpoints included change in Sheehan Disability Scale and patient reported quality of life as measured by Quality of Life, Enjoyment and Satisfaction Questionnaire – short form. [PM 30A]
	MOA.1	Headline: Mechanism of action of Bluzject* The mechanism of antidepressant effect of bluexetine is thought to be through enhanced serotonin activity through neuromodulation in the CNS. Bluextine binds with low affinity to GABA, norepinephrine and dopamine receptors. The role and contribution of these targets to the overall effect of bluexetine is not fully understood. Copy: *Clinical significance is unknown
	DOS.2	Headline: Recommended dosing¶ Copy: The starting and recommended dose for adults less than 65 years of age is 250 mg IM every 6 weeks. Although limited efficacy data is available, some patients not responding to 250 mg may benefit from a higher dose of 375 mg every 6 weeks. The maximum dose should not exceed 375mg every 6 weeks. It is recommended that responding patients be continued with the lowest dose needed and reassessed periodically to determine the need for continued treatment. [PM 6A] A dose reduction to 125mg IM every 6 weeks may be considered for patients who do not tolerate higher doses. [PM 6B] The starting and recommended dose for adults 65 years of age or older is 125mg IM every 6 weeks. Caution is advised when treating elderly patients. [PM 7A] Qualifiers: ¶ Refer to the Product Monograph for complete dosing information. IM: Intramuscular
	RES.2	Download the following resources to share with your patients prescribed Bluzject. • Getting started patient brochure [eFile XXXXX1] • Dosing calendar [eFile XXXXX2]

		• Payment assistance card [eFile XXXXX3]
	FB.H	**Clinical use:** Bluzject has not been systematically evaluated beyond 24 weeks in controlled clinical trials. The prescriber who elects to use Bluzject for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. [PM 4B] Geriatrics (>65 years of age): Caution should be exercised in treating geriatric patients. The lowest effective dose of 125mg injected intramuscularly every 42 days should always be used as the starting dose in elderly patients. [PM 4C] **Contraindication:** • In patients with concurrent use of monoamine oxidase inhibitors [PM 4D] **Most Serious Warnings and Precautions:** **Behavioural and emotional changes including self-harm and suicidal ideation:** There are clinical trial and post-marketing reports with SSRIs and other newer anti-depressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia/psychomotor restlessness, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment. Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes. [PM 9A] **Other Relevant Warnings and Precautions:** • discontinuation symptoms [PM 9B] • QT prolongation [PM 10A] • abnormal bleeding [PM 10B] • bone fracture risk [PM 10C] • serotonin toxicity / neuroleptic malignant syndrome [PM 11A] • angle closure glaucoma [PM 11B] • activation of mania / hypomania [PM 11C] • insomnia [PM 11D] • sexual dysfunction [PM 12A]. **For more information:** Consult the product monograph at www.bluzjectPM.ca for important information relating to adverse reactions, interactions, and dosing which have not been discussed in this piece. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.
	RES.1	Visit BluzjectHCP.ca to learn more! [eFile XXXXX0]
Transactional element – open text closing	N/A	[Open text field] *Review note: Open text fields will be used solely for personalized greetings and will not include other messages, even if they echo messages reviewed and accepted elsewhere in the current or previous APS. We confirm that representatives will be adequately trained on proper use of open text fields and there is an audit-type mechanism in place to monitor and ensure compliance with this directive.*

Appendix E – Iterative submission examples

Acceptable examples for iterative submissions include:

- APS with variable subject lines or footers
- app store descriptions for different stores
- layouts for desktop, tablet and mobile

Below is an example of where the iterations are small elements of copy, such as different subject lines. This type of iterative content is best presented grouped in a table, with each iteration clearly identified.

[RTE: Disease state materials catalogue: Cardiovascular disease]

[EMAIL ENVELOPE – NOTE: includes iterative subject lines – All copy beyond these subject lines is identical for each version of the email]

Iteration 1	A cardiovascular disease resource for your patients
Iteration 2	Learn more about Stroke and MI with our helpful patient resources
Iteration 3	Drugex Pharmaceuticals is committed to supporting your CVD patients.

[EMAIL BODY]

At Drugex Pharmaceuticals, we're making it easier for you to receive your cardiovascular disease patient resources to help support your practice and provide education for your patients.

Please find attached a list of resources. To order, please complete the attached order form and return the form to me via email.

[LINK TO ORDER FORM AT: www.drugex.ca/resources/orderform] [PAAB efile 999999]

Best regards,

[REP NAME]

[REP EMAIL]

[REP PHONE]

[LEGAL]

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[LOGOS]

Drugex Pharmaceuticals

PAAB/IMC

For app store descriptions, please align the content in columns for each store, and rows for each app store element. Where sections differ, please indicate this with N/A.

Please see below for an example of an app store iterative submission.

App store element	GOOGLE APP STORE DESCRIPTION	APPLE APP STORE DESCRIPTION
[Icon]		
[App Name]	PAAB Support Program (PSP)	PAAB Support Program (PSP)
[Subtitle – appears in small text below app name – 30 characters long]	Brought to you by PAAB	Brought to you by PAAB
[App meta data - below]		
[Rating]	[X] ,insert rating number and stars	[X] ,insert rating number and stars
[Age]	17+ Years old	17+ Years old
[Category]	Medical	Medical
[Developer]	PAAB	PAAB
[Language]	EN/FR	EN/FR
[Size]	4 MB	4 MB
[What's new]	Version 1.0.0 <insert how long ago the app was updated (example x days/months)>	Version 1.0.0 <insert how long ago the app was updated (example x days/months)>
[Short Description – up to 80 characters]	N/A for Google	Monitor your submissions and find helpful resources in the PAAB Support Program App.
[Full Description – up to 4000 characters]	The PAAB support program is an application that allows you to track and monitor your APS submissions, access helpful resources.	The PAAB support program is an application that allows you to track and monitor your APS submissions, access helpful resources.
[Ratings and Reviews]	<insert ratings out of 5> <insert list of submitted reviews from user> **[NOTE: These reviews will be monitored for off label content and misinformation, and reported for AEs within 24 hours]**	<insert ratings out of 5> <insert list of submitted reviews from user> **[NOTE: These reviews will be monitored for off label content and misinformation, and reported for AEs within 24 hours]**

For submissions with different layouts, please clearly label each file, both within the document name and upon opening the layout so that it is clear to the reviewer which layout is being reviewed.

Document name examples:

- MOBILE Layout v1 – relevant agency-specific codes
- TABLET Layout v1 – relevant agency-specific codes
- DESKTOP Layout v1 – relevant agency-specific codes.

Appendix F – Percent Pickup highlighting example

See below for an example of how to highlight the previously accepted copy within an eFile for our admin team. Note the highlighted copy is the copy that has been previously accepted in another eFile.

Email Envelope

Subject Line: Product ABC is now covered on formulary in your province (with criteria)!

Preview Text: Click inside to learn more.

Email Body

Copy:

Dear Dr. [Name],

We are pleased to announce that Product ABC is now covered on formulary in your province (with criteria). Click here (link URL: https://www.formulary.health.gov.on.ca/formulary/)for full coverage information. (Ref 1A, page 45)

[insert visual]

previously approved in efile 234567

As a reminder, Product ABC has a flexible dosing schedule. Patients can take one 10 mg tablet once daily or one 20 mg tablet weekly. Product ABC is to be taken with a full cup of water on an empty stomach. Patients should use the lowest dose and shortest duration appropriate. (Ref 2A, page 8)

Please consult see the Product Monograph for full dosing and administration information.

Product ABC is indicated for the treatment of disease XYZ in adults. (Ref 2B, page 3)

Consult the Product Monograph at www.ProductABC.ca/PM for important information on contraindications, warnings, precautions, adverse reactions, and dosing. The Product Monograph is also available by calling us at 1-800-xxx-xxxx.

Sincerely,

[Rep Name]

Email: [Rep Email]

Appendix G – Other Series highlighting example

See below for an example of how to highlight the common copy between parent and child submissions to demonstrate ≥60% identical copy between the files for our admin team. Note the non-highlighted copy is the unique copy.

Email Envelope

Subject Line: Product DEF is now covered on formulary in Ontario (with criteria)!

Preview Text: Click inside to learn more.

Email Body

Copy:

Dear Dr. [Name],

Product DEF is now covered on the Ontario Drug Benefit (ODB) list in Ontario (with criteria)! Click here for full coverage information. (Ref 1A, page 12)

[creative]

The DEFG Patient Support Program is available for your DEF patients! We are committed to supporting your patients throughout their treatment journey. We offer:

- Welcome call upon program enrollment
- Reimbursement navigation
- Educational tools and resources
- And more!

Speak to a representative and enroll your patients today!

Product DEF is indicated for the treatment of disease LMN in adults. (Ref 2A, page 3)

Consult the Product Monograph at www.ProductDEF.ca/PM for important information on contraindications, warnings, precautions, adverse reactions, and dosing. The Product Monograph is also available by calling us at 1-800-xxx-xxxx.

Kind regards,

[Rep Name]

Email: [Rep Email]