

Top tips on the submission process:



Stay on the PAAB submission process path to avoid delays and resubmissions.

Key tips to staying on the path:

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 labelled.

When uploading references to Efiles, please name the file with the reference number and the title of the paper. (e.g. Ref 1 - Efficacy and safety of Product X)

Help us to help you efficiently...

See the images on **pages 17 – 24** of the **Submission Guidance** for optimal formatting.

Become familiar with key documents to guide you:

- ▶ [Submissions Guidance document](#)
- ▶ [PAAB code](#)
- ▶ [Efiles Client Training Video](#)

Many other Advisories and Guidance documents can be found on [PAAB.ca](#) and the Homepage of our [Efiles Electronic Submission System](#).

If the APS contains claims or presentations similar to what has been previously approved, please identify the relevant PAAB file numbers.

This should appear in close proximity and should be in a different colour from the advertising copy and referencing copy.

Help us to help you efficiently...

See the images on **pages 17 – 24** of the **Submission Guidance** for optimal formatting.

When submitting digital advertising such as websites, apps or e-detail aids, ensure that a copy of the information architecture is included.

View e-Detail Aid Submission example at the bottom of this page.

The Electronic Efiles system has many enhancements such as:

- ▶ A privatized company library stored on the Efiles system for easy access of files that are used repeatedly
- ▶ More information available regarding your submitted files, in the form of a dashboard
- ▶ A simplified and more flexible submission process with multiple ways to upload your documents (e.g. drag and drop, browse and attach from your library).
- ▶ We suggest that you simplify file names to 30 characters or less and avoid using special characters such as apostrophes

New Submissions should indicate the language in which the advertising piece will be produced, not just the language of the APS being submitted at the time. This will ensure that both languages can be reviewed to approval in the same efile.

Anytime a product's terms of market authorization is updated and approved by Health Canada, an annotated version of the new monograph must be included in the submission.

The annotated version should highlight all changes from the prior approved version of the product monograph.

If the changes are internal and deemed Level III or IV changes, a letter from the Manufacturer confirming the nature of the changes and confirming that they are indeed internal is required (please include this within your initial submission).

The previously approved file number is required for renewals.

A copy of the annotated version of the product monograph and the Health Canada approval letter should be included as required.

Previously approved references do not need to be uploaded when there is absolutely no change in content, layout, flow, visuals or functionality from the prior piece.

e-Detail Aid Submission Best Practices

As electronic APSs have become more and more common, we have seen a wide range in how these are submitted.

In order to facilitate the review of electronic APSs, we are providing a guide comprised of best practices for clear and complete submissions. Adoption of these best practices may lead to speedier reviews and fewer resubmissions.

The initial submission for an electronic APS should include:

- An **information architecture** (IA) showing how the APS is organised and linkages between sections
- A **copydeck** and **user flow**
- A **layout** (if a layout cannot be provided in an initial submission, include a detailed **wireframe** for the different pages in the APS)

We have put together an example of information architecture for an iPad detail aid...

[Click here to view the best practice example](#)



Our November workshop will discuss e-detail aids and submission best practice, alongside other topics such as fair balance, digital and evidence. To see every session, along with the full speaker line up [download the brochure here](#)