



## Advisory: Increased specificity in series fee criteria

Closely related files submitted on the same day have historically been eligible for a series fee. This discounted price was intended to reflect an envisioned lower utilization of review resources for series submissions. Upon launch of the AROs, the approach for determining which submissions are eligible for the series fee will be more specific than it had historically been. The less ambiguous approach outlined herein is intended to optimize consistency in fee assignment, to promote sustainability by better aligning the review fee with review resource utilization, and to account for new types of submissions that will become eligible to series fees.

This document outlines which types of submissions will be eligible for series fee. While the approach outlined herein will be implemented concurrently with the ARO launch in July 2022, it will be applicable to all submissions (including those through the standard pathway). This is important as the timing of new submission types that are eligible for series fees (including minor updates, modular submissions, and iterative submissions) will be also coincide with the ARO launch even though they will apply equally to the standard pathway.

Section 1

Which APS will now be eligible for a series fee?

1.1

APS that are ≥60% duplicated from a simultaneously submitted parent file

1.2

APS that is a minor update to a previously approved file which is still within its approval period

1.3

APS comprised solely of content from a previously reviewed module library 1.4

Iterations of a concurrently submitted APS

Section 2

## What else is changing from a fee perspective?

Submissions that have "little new content" are those that have 2 or fewer pages of new content. While having ≤ 2 pages of new content does not in and of itself render an APS eligible for a series fee, it makes the APS eligible for an increase of one urgency level at no cost. Refer to the Fee Schedule for more details. While this will benefit short APSs, it would also benefit APSs of any length that have fewer than 2 cumulative pages of updates. This is discussed in greater detail in the **ARO Features Detailer** on the PAAB website.

Also refer to the **ARO Features Detailer** for an outline of how the cost-per-page of new content will be introduced.

The **fee calculator** on the PAAB website can also help you anticipate how any relevant combination of submission properties / attributes can impact the review cost.

<sup>&</sup>lt;sup>1</sup> Guidance on Submission Process and Format Requirements

<sup>&</sup>lt;sup>2</sup> Explainer videos