

> CALL FLOW vs REVIEW FLOW

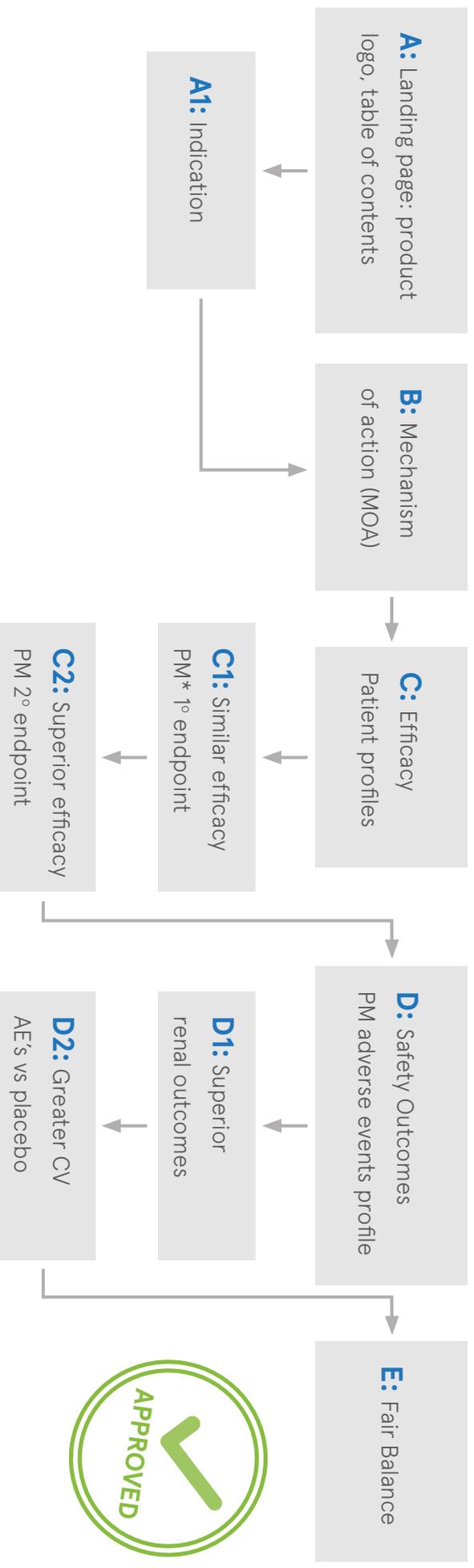
Does your eDetail need to be split into multiple APS submissions?

PAAB review is **highly contextual** and approval of content is often contingent on the **inclusion** (and relative location) of **other content** within the piece. Unless otherwise specified, reviews are performed under the **assumption of a linear flow**. When this is not the case, a **separate review** should be performed with all **predefined call iterations** in order to ensure that the revised flows are acceptable. Our position has been and remains that alternate fixed or pre-programmed paths or call flows are subject to review as a separate file.

Let's look at a couple examples of why this is required:

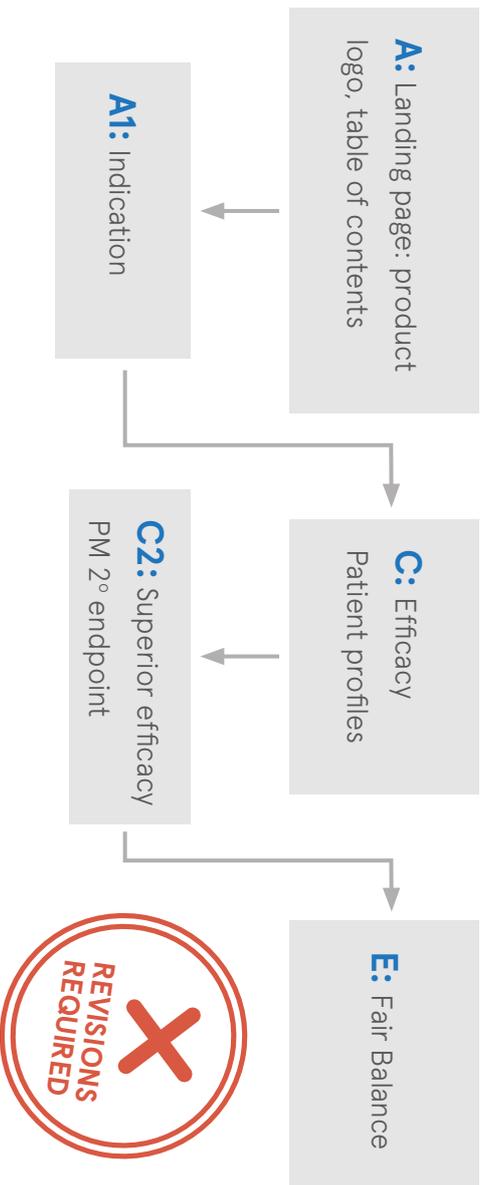
EXAMPLE A:

Submission reviewed under the assumption that this will be a linear piece detailed from start to finish.



EXAMPLE B:

Efficacy call flow programmed but not disclosed for review by PAAB.



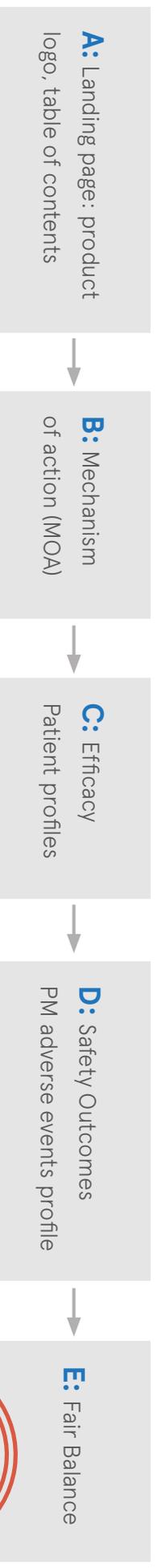
What's the problem?

A **shortened efficacy call** was programmed to focus on the positive secondary endpoint. By omitting the primary endpoint, the secondary endpoint is no longer presented in the **context** of the primary endpoint. **This presents an incomplete picture.**

This flow would contravene the PAAB code, despite the fact that all of the content has been previously reviewed. **The efficacy call flow should be submitted for review.**

EXAMPLE C:

Short call – Intended to touch the key concepts quickly.

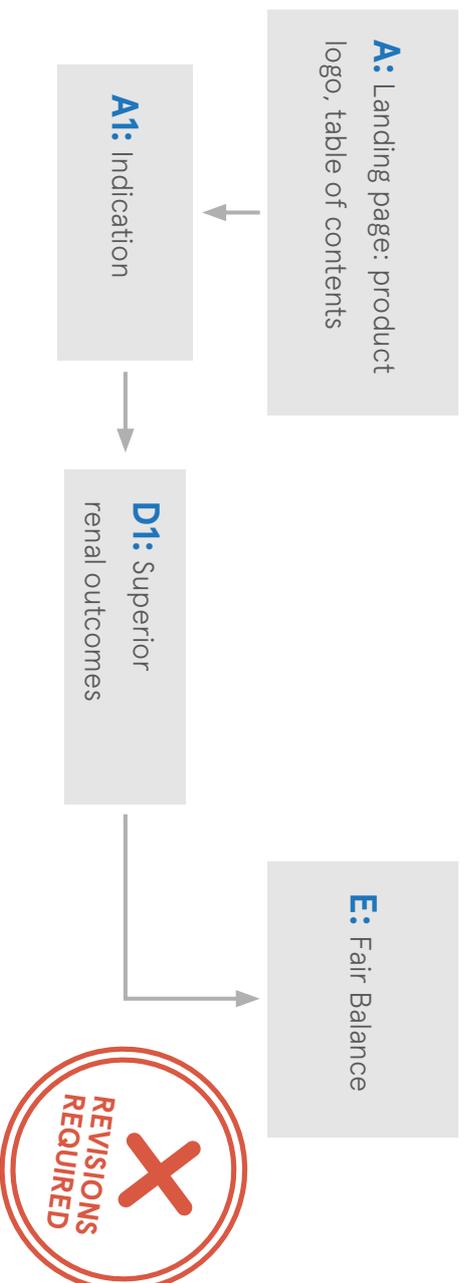


What's the problem?

While the intention was to create a condensed version of the presentation, by **skipping all the secondary pages**, the indication copy has been skipped over and thus **does not satisfy PAAB code section 2.10.1**. The short call should be submitted as a **second flow** at which point the indication copy would be asked to be included and thus meeting requirements of the code.

EXAMPLE D:

Renal safety call flow for use with nephrologists.



What's the problem?

The intention of this flow was to be **specific to the specialty** of the physician. However, by leaving out the complete safety profile and only focusing on the safety outcome which demonstrated **superiority**, this piece becomes **selective and unbalanced**. (s.2.4, 5.12) The renal safety flow should be submitted for review as a **separate piece**.

IN SUMMARY...

When alternate flows or call pathways are pre-determined or programmed, each pre-set should be reviewed by PAAB to ensure that each presentation meets all the requirements for advertising standards.