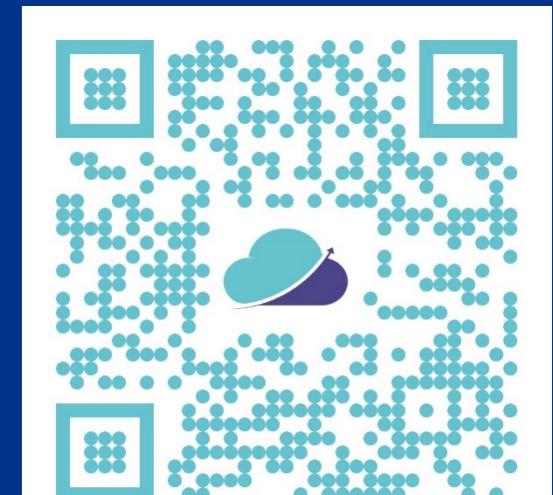


# Methodological Insights from Recent PBAC Recommendations to Support Biosimilar Reimbursement in Australia



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## INTRODUCTION

- Biosimilars present a critical strategy for improving patient access to advanced biological therapies and reducing pharmaceutical expenditure within publicly funded healthcare systems, thereby enhancing their sustainability and access<sup>1</sup>
- In Australia, reimbursement decisions are specifically informed by comprehensive evaluations conducted by the **Pharmaceutical Benefits Advisory Committee (PBAC)**, with their rationale transparently documented in **Public Summary Documents (PSDs)**<sup>2</sup>
- The objective of this study was to systematically synthesize the methodological insights derived from recent PBAC assessments of biosimilars, and to provide guidance for successful future biosimilar submissions within the Australian reimbursement landscape

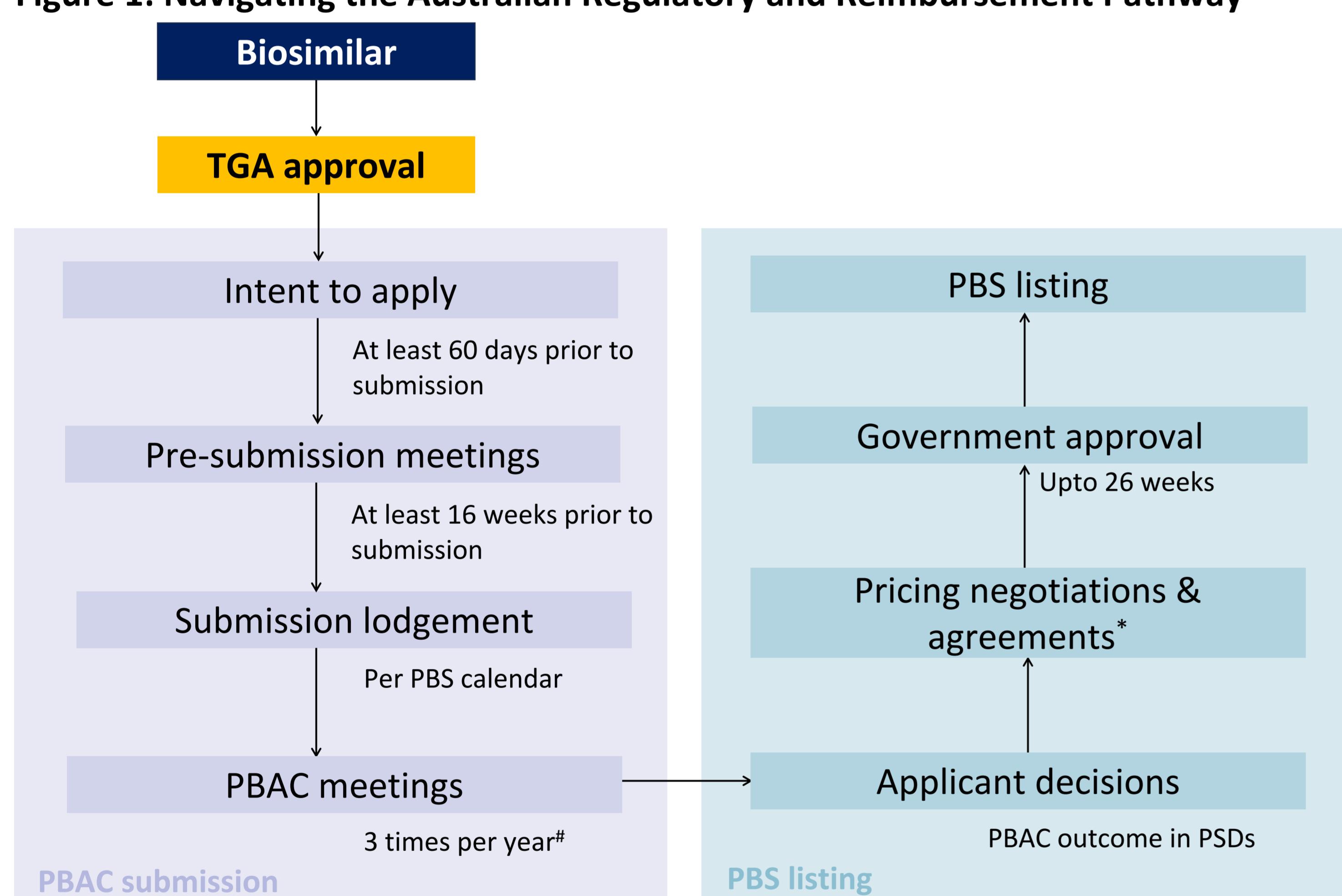
## METHODS

**Study Design:** Pharmaceutical Benefits Scheme (PBS) website was systematically searched for biosimilars recommended for PBS listing between March 2024 and March 2025. **Figure 1** presents the navigation pathway for reimbursement in Australia

**Data Extraction and Analysis:** PSDs for identified biosimilars were analysed. Information extracted included:

- Submission type and time to PBS listing
- Evidentiary requirements (clinical and pharmacokinetic comparability data)
- Economic justification (e.g., cost-minimization approach)
- Substitution status ('a' flagging, which means a pharmacist can dispense the biosimilar instead of reference biologic under certain conditions)<sup>3</sup>
- Policy-related recommendations promoting biosimilar uptake

**Figure 1: Navigating the Australian Regulatory and Reimbursement Pathway**



<sup>#</sup>March; July; November

\*Involves price offer, budget impact, potential deeds

Source: <https://www.pbs.gov.au/info/industry/useful-resources/pbs-calendar#PBACCycleTimeline>; accessed on 2025 July 04.

Abbreviations: PBAC: Pharmaceutical benefits advisory committee; PBS: Pharmaceutical benefit scheme; PSDs: Public summary documents; TGA: Therapeutic goods administration.

## RESULTS

PBAC recommended a total of nine biosimilars between March 2024 and March 2025: three for ustekinumab, two for adalimumab, and one each for denosumab, bevacizumab, natalizumab, and omalizumab (**Table 1**)

**Table 1: Biosimilar Timelines: TGA Approval to PBS Listing**

Biosimilar	Manufacturer	Active substance	TGA Approval	PBAC Meeting	PBS listing
Yuflyma	Celltrion	Adalimumab	Jun-23	Mar-24	Oct-24
Vegzelma	Celltrion	Bevacizumab	Sep-23	Mar-24	Oct-24
Wezlana	Amgen	Ustekinumab	Jan-24	Mar-24	Not listed
Hyrimoz	Sandoz	Adalimumab	May-24	Jul-24	Jan-25
Wyost	Sandoz	Denosumab	Aug-24	Nov-24	Aug-25
Steqeyma	Celltrion	Ustekinumab	Sep-24	Nov-24	Aug-25
Tyruko	Pfizer	Natalizumab	Sep-24	Mar-25	Not listed
Omlyclo	Celltrion	Omalizumab	Nov-24	Mar-25	Aug-25
Epyztek	Samsung bioepis	Ustekinumab	Oct-24	Mar-25	Not listed

Source: <https://www.pbs.gov.au/medicinestatus> accessed on 2025 October 24

Abbreviations: PBAC: Pharmaceutical benefits advisory committee; PBS: Pharmaceutical benefit scheme; TGA: Therapeutic goods administration.

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## Time to PBS listing analysis

While biosimilars often advance from Therapeutic goods administration (TGA) registration to PBAC recommendation within a year, a significant, often undetailed lag exists before PBS listing, creating a market access bottleneck. These delays can be due to commercial negotiations and administrative processes. Notably, only **six of nine recommended biosimilars achieved PBS listing** during the review period (**Table 1**)

## PBAC Evaluation: Distinct Approaches for Biologics & Biosimilars

**Table 2** highlights the key differences in PBAC submission requirements for biologics (reference products) versus biosimilars. It provides a contrast in terms of the clinical evidence required (de novo trials vs. comparability studies), economic evaluation approaches, and distinct financial implications, including the focus on net PBS savings and market-wide price reductions for biosimilars

**Table 2: PBAC Submission: Key Differences for Biologics & Biosimilars**

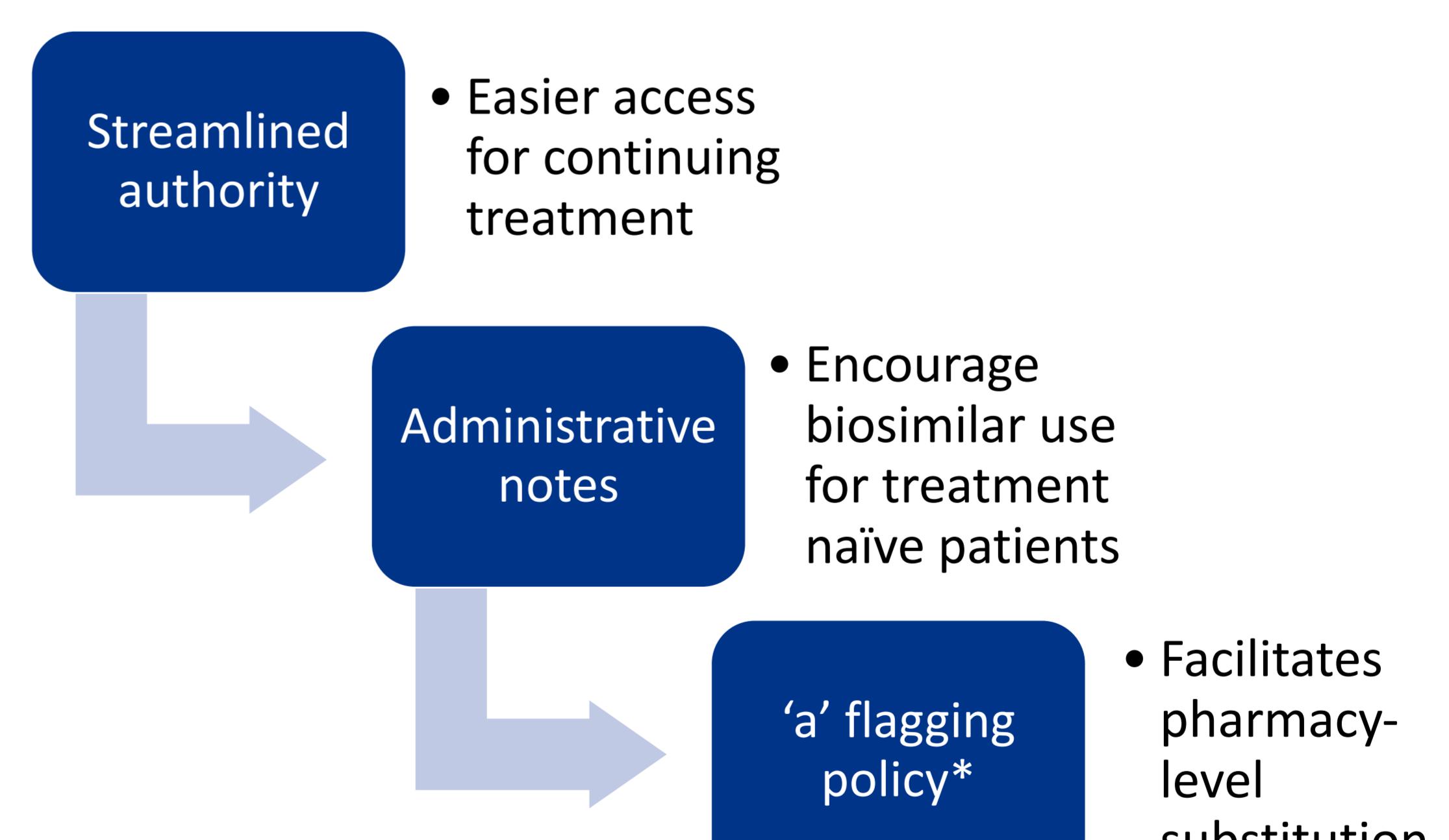
PBAC Section	Biologics (Reference Products)	Biosimilars	Key Differences in Approach
Clinical Information	<ul style="list-style-type: none"><li>Pivotal clinical trial reports (Phase I, II, III trial)</li><li>Non-clinical study reports</li><li>PK/PD Studies</li><li>RMP</li></ul>	<ul style="list-style-type: none"><li>Comparability Studies: Comprehensive analytical, non-clinical (if needed), and clinical data demonstrating <b>similarity to the reference biologic</b></li><li>Justification for extrapolation</li><li>Immunogenicity data and RMP</li></ul>	<b>Biologics:</b> Establishes efficacy and safety of a novel entity <b>Biosimilars:</b> Relies on a "totality of evidence" approach to demonstrate comparability
Economic Evaluation	CEA or CUA preferred in most cases.	CMA is sufficient in most cases.	<b>Biologics:</b> Focuses on demonstrating "value for money" <b>Biosimilars:</b> Focuses on demonstrating cost-savings
Utilisation and Financial Implications	<b>Financial Impact on PBS:</b> Detailed 6-year budget impact model, including drug costs, administration costs, and potential offsets.	<b>Financial Impact on PBS:</b> Detailed 6-year budget impact model, with strong emphasis on the cost savings generated by biosimilar uptake	<b>Biologics:</b> Focuses on the incremental cost to the PBS <b>Biosimilars:</b> Focuses on the net savings to the PBS
Proposed PBS Listing Details	<ul style="list-style-type: none"><li>Proposed PBS Restriction</li><li>EMP</li><li>Comparator(s): mostly reference product</li><li>RSAs</li></ul>	<ul style="list-style-type: none"><li>Proposed PBS Restriction</li><li>EMP</li><li>Comparator(s): mostly reference product</li><li>RSAs</li></ul>	<b>Biologics:</b> Negotiating price based on incremental clinical benefit and economic value. <b>Biosimilars:</b> Pricing aims for affordability, driven by the reference product's cost, often resulting in market-wide price reductions.

Abbreviations: CEA, Cost-Effectiveness Analysis; CMA, Cost-Minimisation Analysis; CUA, Cost-Utility Analysis; EMP, Ex-Manufacturer Price; PBAC, Pharmaceutical Benefits Advisory Committee; PBS, Pharmaceutical Benefits Scheme; PK/PD, Pharmacokinetics/Pharmacodynamics; RMP, Risk Management Plan; RSAs, Risk Sharing Arrangements.

## PBAC's Proactive Biosimilar Uptake Strategy

The Australian government, through PBAC recommendations, actively promotes biosimilar adoption via uptake drivers like streamlined authority and administrative notes (**Figure 2**). This strategic intervention aims to shift prescribing patterns, leverage biosimilars for PBS sustainability, and generate cost savings for reinvestment in new treatments

**Figure 2: PBAC's Biosimilar Uptake Strategy**



\* 'a' flagging, means a pharmacist can dispense the biosimilar instead of reference biologic under certain conditions<sup>3</sup>

## CONCLUSIONS

- Australia's biosimilar pathway, from TGA approval to PBS listing, is evolving towards a more consistent and streamlined framework. While PBAC's review for biosimilars is efficient and largely defers to TGA biosimilarity assessments, post-PBAC negotiations and administrative processes can introduce listing delays
- However, the consistent application of cost-minimisation, coupled with active uptake drivers like streamlined authorities (a simplified approval process) and administrative notes, demonstrate a strong government commitment to leveraging biosimilars for substantial PBS savings and sustainability

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