

DRUG TYPE OR USE	PURPOSE	PBAC OUTCOME
Reimbursement of biosimilar medicines	<p>The Minister (delegate) requested that the Pharmaceutical Benefits Advisory Committee (PBAC) provide advice on the following matter(s) under section 101(3) of <i>the National Health Act, 1953</i> (the Act):</p> <p>Reimbursement of biosimilar medicines on the Pharmaceutical Benefits Scheme (PBS).</p>	<p>The PBAC advised that biosimilar products would be “a” flagged, and therefore suitable for substitution at the pharmacy level, where the data are supportive of this conclusion. The PBAC considered that this would be the Committee’s default position.</p> <p>The PBAC advised that the following would be relevant considerations in establishing that a biosimilar product could be “a” flagged with the originator product:</p> <ul style="list-style-type: none"> • Absence of data to suggest significant differences in clinical effectiveness or safety compared with the originator product; • Absence of identified populations where the risks of using the biosimilar product are disproportionately high; • Availability of data to support switching between the originator product and the biosimilar product; • Availability of data for treatment-naïve patients initiating on the biosimilar product; • Whether the Therapeutic Goods Administration has deemed a product to be biosimilar with the originator product. <p>The PBAC considered that where a biosimilar product could not be “a” flagged at the time of PBS listing, data should be collected to support “a” flagging at a later point.</p>