

Fact Sheet: Comparator Selection



The HTA Review acknowledges comparator selection impacts patient access to new medicines and recommends clarification in the PBAC Guidelines to provide flexibility to the PBAC to select an appropriate comparator.

Appropriate comparator selection is a long-standing issue. Despite Clause 6.6 of the Medicines Australia's Strategic Agreement with the Commonwealth, which states that the PBAC can determine whether a particular therapy is an alternative therapy regardless of whether it is the lowest cost comparator, the Department continues to interpret Sections 101(3A) and 101(3B) of the National Health Act to mean that the comparator to novel therapies must be the lowest-cost alternative therapy, regardless of its place in clinical practice.

Recommendation 40 of the Review proposes an update to the PBAC Guidelines to state the comparator need not be the lowest-cost alternative provided that, for some people, the lowest-cost alternative is inferior in efficacy or safety to the novel health technology; or that, for compelling clinical reasons, the lowest-cost alternative is no longer accepted in practice as clinically relevant.

The Review proposes updates to the Guidelines to include guidance on the types of evidence that sponsors should provide to support the exclusion of specific therapies as comparators. Any updates to the Guidelines will be made in consultation with stakeholders, including industry.

It remains industry's position that any changes to the PBAC Guidelines must be underpinned by changes to the National Health Act if they are to effect meaningful change in comparator selection. A new clause must be added to the Act to clarify that, when considering the comparator, the PBAC must consider the therapy or therapies most likely to be replaced in clinical practice, consistent with the current Guidelines.

Medicines Australia will continue to advocate for this legislative change.

Key takeaways

- Inappropriate comparator selection impacts the patient choice and access to some medicines
- Medicines Australia will continue to advocate for legislative change to underpin any changes to the PBAC Guidelines relating to comparator selection.