AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

D22-15202

ACSQHC Response to TGA Consultation: Priority Review pathway for biologicals: feasibility, potential eligibility criteria and determination process

Question 1: **Do you support introduction of a priority pathway for biologicals?**
Yes, supported.
Question 2: **Is there any expected impact if the proposed Priority Review pathway was to be implemented?**
The Priority Review pathway for biologicals is expected to benefit consumers needing emergency lifesaving treatment. The rate of review of applications for other medicines and biologicals could potentially be slowed and this would need to be mitigated. There is a risk the additional financial burden to cover cost of the priority pathway will deter applications and availability.
Question 3: **Do you agree that the 4 proposed criteria for Priority Review of biologicals address the objectives of an expedited pathway?**
Yes
Question 4: **Do you believe any eligibility criteria should be added, amended, or removed from the proposed Priority Review pathway?**
Criterion 1 – Consideration should be given to describe the biologic under priority review using ‘the trade name, active ingredient and type of cell or tissue’, rather than the active ingredient name alone, as outlined in other TGA publications. Criterion 3 – Consideration should be given to provide a strategy to determine how many and what treatments have been trialled. Criterion 4 - Provide a clear, quantitative guide to the terms ‘substantial’ evidence and ‘therapeutic advantage’. This will support sponsors in their decision to submit a priority application and avoid subjectivity.
Question 5: **Do you agree that the proposed determination process and timing of the steps is appropriate?**
Yes

Question 6: **Do you agree that there should be a six-month limit on the duration for the determination for Priority Review of biologicals?**
Yes. This aligns with other TGA schedules for prescription medicines and medical devices
Question 7: **Do you agree that we should publish the outcomes of approved applications for Priority Review determination of biologicals?**
Yes. It is important to be transparent. This supports confidence in the regulatory process and provides information on which to base future applications.
Question 8: **Do you agree that Decision Summaries and/or Australian Public Assessment Reports (AusPARs) should be published for applications approved through the Priority Review pathway?**
Yes. Publication of the decision-making process will provide meaningful insight for its continued evaluation and support.
Question 9: **Does the proposed application fee for a Priority Review determination and the expectation that a higher evaluation fee for an application through the Priority Review pathway seem reasonable?**
Provided the additional financial burden to cover cost of the priority pathway does not deter applications and availability
Question 10: **Do you anticipate utilising the Priority Review process for your products in the future?**
NA
Question 11: **Please tell us any other suggestions or comments that you believe will improve the proposed Priority Review pathway for biologicals.**
Please provide definitions to key terms in the document or reference a glossary to these terms