Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Determination checklist: for sponsor seeking provisional determination

Please note: This checklist is intended to assist applicants to determine if they have provided all the necessary information to allow the TGA to make an informed decision on the determination application.

It is your responsibility to download, complete and attach the checklist as part of the supporting documentation provided for a determination application. See **TGA Business Services** for more information. <https://www.tga.gov.au/tga-business-services>.

1. **Is your intended application for only one medicine and one indication?**

   ☐ Yes ☐ No

   You should submit separate applications for each medicine and indication

2. **Is the proposed medicine a new prescription medicine or a prescription medicine that has the same chemical, biological or radiopharmaceutical active ingredient (or fixed combination of such ingredients) as an already registered prescription medicine with a new indication (new indications medicine)?** ☐ Yes ☐ No

   The provisional approval process is only applicable to new prescription medicines and new indications medicines

3. **Have you prepared a cover letter for your application?** ☐ Yes ☐ No

4. **Have you included a justification of the life threatening or seriously debilitating* nature of the condition?** ☐ Yes ☐ No

   *A prominent feature of the condition (i.e. affecting an important portion of the target population) is morbidity with a well-established, major impact on the functioning of the person based on objective and quantifiable medical or epidemiological information. Short lived and/or self-limiting morbidity is not considered seriously debilitating.

5. **Have you included a comparison against registered* therapeutic goods for the prevention, diagnosis or treatment of the proposed condition based on preliminary clinical data?**

   – Details of registered* therapeutic goods ☐ Yes ☐ No

– Declaration that there are no registered* therapeutic goods ☐ Yes ☐ No

– Justification of improved safety and/or efficacy ☐ Yes ☐ No

**Note: for the purposes of this comparison, registered therapeutic goods do not include therapeutic goods in the part of the Register for provisionally registered goods.*

6. **Have you included a justification that indicates the medicine will provide a major therapeutic advance based on preliminary clinical data?** ☐ Yes ☐ No

7. **Have you included sufficient evidence of a plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that provisional registration of the medicine would commence if the Secretary were to provisionally register the medicine?** ☐ Yes ☐ No

8. **Have you included a bibliography containing all published references referred to in your application?** ☐ Yes ☐ No