Authorised Prescriber Application

[insert date]

AHCL Human Research Ethics Committee

c/- AHCL Research Office

Sydney Adventist Hospital

185 Fox Valley Road

WAHROONGA NSW 2076

Dear AHCL HREC,

**Project Title:** Authorised Prescriber – [insert name of the therapeutic good]

In accordance with the TGA guidelines for the approval of Authorised Prescribers, I provide the following information in regard to my application:

1. **Medical practitioner details**
2. Your name:

Please respond:

1. Contact details:

Please respond:

1. Details of qualifications, specialty, training and experience   
   *[Guidance: In addition to an explanation below please attach a signed and dated CV to the application]*
   * 1. generally, applications from medical practitioners with non-practising, limited, student, provisional registration (requiring supervised practice), or conditions placed on their registration will not be considered for the Authorised Prescriber scheme:

Please respond:

1. have the training and expertise appropriate for the condition being treated and/or the proposed use of the product:   
   *[Guidance: please provide details in 50-150 words of your relevant training and professional expertise]*

Please respond:

1. a description of how they propose to use the goods:  
   *[Guidance: In addition to an explanation below, please attach product information leaflet/manuals on the therapeutic good and how it is used]*

Please respond:

1. details of the site(s) at which the goods will be used:

Please respond:

1. the qualifications and experience necessary to appropriately manage the medical condition and use the product:

Please respond:

1. access to the facilities needed to appropriately administer and monitor treatment.

Please respond:

1. Is the therapeutic good indicated for highly specialised medical conditions?

Please respond:

1. Does the therapeutic good have significant safety risks?

Please respond:

1. Does the therapeutic good require specialised monitoring?

Please respond:

1. Does the therapeutic good require specialised administration or handling?

Please respond:

1. **Unapproved therapeutic good description and evidence**

*[Guidance: please complete the applicable option below and delete the others]*

[OPTION 1]

Details for ‘unapproved’ **medicines**

1. Trade name:

Please respond:

1. Active ingredient:

Please respond:

1. Strength/concentration:

Please respond:

1. Dosage form:

Please respond:

1. Sponsor:

Please respond:

1. Whether the good is approved for the indication by an overseas regulatory body:

Please respond:

[OPTION 2]

For ‘unapproved’ **biologicals**

1. Name of biological:

Please respond:

1. Sponsor:

Please respond:

1. Whether the good is approved for the indication by an overseas regulatory body:

Please respond:]

[OPTION 3]

For ‘unapproved’ **devices**

1. name of the medical device:

Please respond:

1. Sponsor:

Please respond:

1. Whether the good is approved for this indication by an overseas regulatory body:

Please respond:

**Details of the use and monitoring of the therapeutic good:**

* 1. the dosage range (where applicable):

Please respond:

* 1. the route of administration or type of sample for IVDs:

Please respond:

* 1. the duration of treatment:

Please respond:

* 1. how the medical practitioner will determine if the use is effective:

Please respond:

* 1. how the medical practitioner will determine whether an adverse event has occurred:

Please respond:

* 1. what monitoring is required, how it will be done, and the interval and duration of monitoring:

Please respond:

**Details of the efficacy and safety of the therapeutic good:**

1. the ‘unapproved’ good’s efficacy and expected benefits:

Please respond:

1. any known/expected adverse effects, risks and safety issues:

Please respond:

1. related toxicology:

Please respond:

**Details of the sources of evidence of the therapeutic good:**

*GUIDANCE PLEASE DELETE ONCE REVIEWED:*

##### *Global regulatory status*

*The global regulatory status of the ‘unapproved’ good may affect the level of evidence required in the application.*

*This table describes differences in global regulatory status and the effect that status may have on the level of evidence required. This information is provided as a guide only.*

TABLE: Effect of global regulatory status

| **Regulatory status** | **Possible effect on the level of extra evidence required to be submitted to a HREC or specialist college** |
| --- | --- |
| *Goods which are not approved in Australia, but are approved for the indication and the conditions of use in countries with a regulatory standard comparable to Australia* | *Decreased* |
| *Goods previously approved by the TGA which have been withdrawn for non-safety reasons* | *Decreased* |
| *Goods which are not approved in Australia, but are approved in countries with regulatory standards that are not comparable to Australia* | *Increased* |
| *Goods that have not been approved anywhere for the indication and are still undergoing clinical trials* | *Increased* |
| *Goods previously approved by the TGA which have been withdrawn for safety reasons* | *Increased* |
| *Goods that have not been granted registration in Australian for safety reasons* | *Increased* |

|  |  |
| --- | --- |
| Information | When an HREC or specialist college assesses your application, they should consider the following factors to determine what level of evidence is required:   * whether other treatments registered on the ARTG are available and suitable for the intended class of patients * the seriousness of the medical condition * the global regulatory status of the therapeutic good * the relevant experience and qualifications of the applicant   You may wish to contact the HREC or specialist college before you submit your application to ensure you submit the necessary evidence. |

[Please delete above guidance once a-e below have been completed]

1. product information documents (of equivalent) (if the good is approved by an overseas regulator):

Please respond:

1. randomised controlled trials:

Please respond:

1. non-randomised controlled trials:

Please respond:

1. individual case studies:

Please respond:

1. consensus opinion of specialist colleges and societies:

Please respond:

1. **Clinical justification for the use of the goods**

**Details of the clinical justification of the therapeutic good:**

1. indication for which the good will be used:

Please respond:

1. seriousness of the condition:

Please respond:

1. expected benefits of the proposed treatment versus its potential risks:

Please respond:

**Details of the therapeutic good in circumstances where there are approved treatments for the same indication, specifically:**

* 1. have they been attempted or used?

Please respond:

* 1. will they be attempted prior to supplying the ‘unapproved’ good?

Please respond:

* 1. why are they inappropriate?

Please respond:

* 1. why is the proposed ‘unapproved’ good a more appropriate option than any approved available alternative?

Please respond:

**Details of how the risk associated with the use of an ‘unapproved’ good will be managed:**

1. the monitoring that will be undertaken:

Please respond:

1. the process of investigating and reporting adverse events:

Please respond:

*[GUIDANCE, please delete once reviewed: Please note the following are* ***not*** *acceptable justifications for the use of an ‘unapproved’ good:*

* *that the ‘unapproved’ good is less expensive than any suitable approved treatment*
* *personal preference for an ‘unapproved’ good]*

**Please complete and attach the *Authorised Prescriber Consent Form*:**

<https://www.sah.org.au/authorised-prescriber/>

I confirm that the following details have been included in the consent form:

* that the TGA has not evaluated the “unapproved” good’s safety, quality and efficacy.
* of the possible benefits and risks of its use
* of the possibility that there may be unknown side effects.
* of any alternative approved goods.

Please also see attached a letter signed by 3 of my colleagues within the same specialty at AHCL supporting my Authorised Prescriber application.

Yours sincerely,

*[Signature Block]*