# Authorised Prescriber Scheme Application (General)

# Checklist

To assist with our processing of your application:

1. Please submit distinct documents as separate files, rather than merged into one file.
2. Please name each file clearly, including the applicant’s name.

|  |  |
| --- | --- |
| Application Form |  |
| (Form completed, signed, and dated!) |  |
| Evidence of Professional Education |  |
| Patient Informed Consent Form |  |
| \*Evidence of other HREC AP approval |  |
| Invoicing Party Contact Details to be provided:  Contact Name - Company or Individual Name:  Primary Person:  Email:  Address:  ABN:  Please wait for an invoice to be raised. An invoice will be raised after the application has been received. The invoice must be paid prior to the approval letter being issued. |  |

\*if applicable

**ABOUT THE AUTHORISED PRESCRIBER SCHEME**

According to the TGA, the ‘Authorised Prescriber Scheme allows authorised **medical practitioners** to supply [therapeutic goods](https://www.tga.gov.au/node/287205) (such as medicines, medical devices or biologicals) that are not included in the [Australian Register of Therapeutic Goods (ARTG)](https://www.tga.gov.au/node/287250) to a class of patients with a particular medical condition’.

The Standard Authorised Prescriber (AP) pathway entails a 2-step application process for products that are not included in subregulation 12B(1B) and 12B(1C) of the Therapeutic Goods Regulations 1990. Step 1 is approval from a human research ethics committee (HREC) or endorsement by specialist college. This must be obtained before applying to the TGA. Step 2 is approval from the TGA (<https://www.tga.gov.au/resources/resource/forms/authorised-prescribers>).

**NIIM HREC AUTHORISED PRESCRIBER SCHEME**

**APPLICATION FORM (General)[[1]](#footnote-1)**

# Section 1: The Prescriber

|  |  |
| --- | --- |
| Name |  |
| Qualifications including specialty |  |
| AHPRA No. |  |
| RACGP No. or other Professional Association membership No. (specify) |  |
| Address |  |
| Phone number |  |
| Email |  |
| Third-party contact  *If the applicant is being supported by a third party, to be copied in on correspondence, please include contact information here.* |  |
| Site(s) at which the unapproved good will be prescribed (list all addresses) |  |
| Qualifications, expertise and experience required to manage the medical condition(s) for which the good will be used. Provide details.  *Please attach supporting evidence including certificates from one or more* ***Professional Education*** *courses/activities related to the unapproved good(s)/device(s).* |  |
| How will risks associated with the use of the unapproved good (medicine or biological product) by managed? Provide details. This should address:   1. Process of obtaining informed consent from patients 2. Monitoring and reporting that will be undertaken (include details of interval and duration of monitoring) 3. Process of investigating and reporting adverse events   *Please also append* ***Informed Consent Form*** *(which will be signed by patients).* |  |

# Section 2: The unapproved good(s) and indication(s) summary table

Please insert the unapproved good product trade name(s) and the indication(s) for which you are applying. Add more rows and columns or duplicate this table as required.

MEDICINES

|  |  |  |
| --- | --- | --- |
| Indications: | Product Name (1) | Product Name (2) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

BIOLOGICALS

|  |  |  |
| --- | --- | --- |
| Indications: | Product Name (1) | Product Name (2) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Section 3: The unapproved good(s)

|  |  |  |
| --- | --- | --- |
| Product Trade Name | Product Name (1) | Product Name (2) |
| Product Company: |  |  |
| Sponsor: |  |  |
| Active ingredient(s) and concentrations: |  |  |
| Dosage form: |  |  |
| Dosage: |  |  |
| Dosage range  Initial dose  Max dose |  |  |
| Expected duration of treatment: |  |  |
| Whether the good is approved for the indication in another jurisdiction |  |  |
| Possible adverse effects and how they will be handled. |  |  |

# Section 4: The indication(s)

|  |  |
| --- | --- |
| Indication |  |
| Seriousness of the medical condition(s) for which the good (medicine or biological product) will be used |  |
| Class of patient to receive treatment |  |
| **Clinical justification for using the unapproved good** (medicine or biological product)**.** This should address expected benefits of the proposed medicine versus its potential risks, including evidence of:   1. the unapproved good’s suitability for the intended indication 2. the unapproved good’s efficacy and expected benefits 3. any unknown or expected adverse effects, risks and safety issues 4. related toxicology |  |
| **Where there may be approved treatments available** |  |
| Is there an approved good (medicine or biological product for the same indication as what you are applying to use the unapproved good for? |  |
| Have you already or will you attempt to use the approved good (medicine or biological product) prior to supplying the unapproved good? |  |
| Why is the approved good (medicine or biological product) inappropriate or unsuitable for use?  Why is the proposed unapproved good a more appropriate option than an approved available alternative? |  |

# Section 5: Disclosures

1. I certify that I

have not  have (tick one)

applied for Authorised Prescriber approval of another Australian HREC *(not NIIM)* within the last 12 months.

***Evidence:*** *Please append a copy of the* ***letter from the other HREC*** *and/or TGA*

Where an applicant has been refused approval for Authorised Prescriber by an Australian HREC or the TGA within the last 12 months, please detail why approval was denied.

|  |
| --- |
|  |

1. I undertake to remain up to date in relation to knowledge about potential future approved goods that may be entered on the ARTG that could be used instead of the unapproved good, and
   1. where a suitable alternative good becomes available on the ARTG, I will stop using the unapproved good, or
   2. where there is a good reason to continue using the unapproved good, I will reapply for approval, submitting a clinical justification to the HREC on why I want to use the unapproved good instead of the now-approved good.

Yes  No

1. I undertake to provide the HREC with six-monthly reports as required by the TGA.

Yes  No

1. I agree to abide by any conditions set by the HREC and/or TGA in relation to approval to use the unapproved good.

Yes  No

1. I certify that the information I have provided in this application is true and accurate.

Yes  No

1. I certify that I

do not have a commercial interest in any of the products which I may prescribe.

do have a commercial interest in one or more of the products which I may prescribe.

Details of my commercial interests and their management are as follows:

|  |  |
| --- | --- |
| **Full Name** |  |
| **Signature** |  |
| **Date** |  |

1. This form is to be used to apply to become an authorised prescriber for all unapproved goods except medicinal cannabis or medical devices. [↑](#footnote-ref-1)