# Authorised Prescriber Scheme Submission Checklist

To assist with our processing of your application:

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

|  |  |
| --- | --- |
| Application Form |  |
| Section 5 of Application Form completed, signed, and dated |  |
| 3 TGA SAS B Approval Letters |  |
| Evidence of Professional Education in medicinal cannabis |  |
| +Patient Informed Consent Form |  |
| `Product information for each product applied for |  |
| \*Evidence of other HREC AP approval |  |
| ^Proof of Payment |  |

\*if applicable

`or equivalent

+template available on NIIM website *(you may use your own form, but it MUST state emphatically that driving under the influence of THC is ILLEGAL and there is NO medical defence at law)*

^see our current Fee Schedule, or email hrec@niim.com.au for assistance

**NIIM AUTHORISED PRESCRIBER SCHEME APPLICATION FORM**

# 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*Please append a minimum of three* ***TGA SAS B approval letters****.**Please attach supporting evidence including certificates from one or more* ***Professional Education*** *courses/activities related to Medicinal Cannabis.* |  |
| How will risks associated with the use of the unapproved good by managed? 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 append* ***Informed Consent Form*** *(which will be signed by patients – see notes on Submission Checklist above).* |  |

# 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.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Unapproved good 1 | Unapproved good 2 | Etc. |
| Indication 1 |  |  |  |
| Indication 2 |  |  |  |
| Etc. |  |  |  |

# Section 3: The unapproved good(s)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Product Trade Name |  |  |  |  |  |  |
| Product Company |  |  |  |  |  |  |
| Sponsor (company from whom you will obtain the unapproved good) |  |  |  |  |  |  |
| 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 |  |  |  |  |  |  |

Please append **product information** (or equivalent) for each product listed.
Note that **dosing guidelines** are available on the NIIM website.

# Section 4: The indication(s)

|  |  |
| --- | --- |
| Indication |  |
| Seriousness of the medical condition(s) for which the good will be used |  |
| Class of patient to receive treatment |  |
| **Clinical justification for using the unapproved good.** This should address expected benefits of the proposed medicine versus its potential risks, including evidence1 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 for the same indication as what you applying to use the unapproved good for? |  |
| Have you already or will you attempt to use the approved good prior to supplying the unapproved good? |  |
| Why is the approved good inappropriate or unsuitable for use?Why is the proposed unapproved good a more appropriate option than an approved available alternative? |  |

*Repeat this table for additional indications*

# 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 if applicable.*

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.

|  |
| --- |
|  |

b. 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 where a suitable alternative good becomes available on the ARTG, stop using the unapproved good. Where there is a good reason to continue using the unapproved good, I undertake to reapply for approval, submitting a clinical justification to the HREC on why you want to use the unapproved good instead of the now approved good.

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

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

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

f. I certify that I

[ ]  do not have a commercial interest in any of the products for which I am applying.

[ ]  do have a commercial interest in one or more of the products for which I am applying.

Details of my commercial interests are as follows:

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