# Authorised Prescriber Scheme Submission 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!) |  |
| 3 TGA SAS B Approval Letters |  |
| Evidence of Professional Education in medicinal cannabis |  |
| +Patient Informed Consent Form |  |
| \*Evidence of other HREC AP approval |  |
| ^Proof of Payment |  |

\*if applicable

+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 HREC AUTHORISED PRESCRIBER SCHEME**

**MEDICINAL CANNABIS SCHEDULES 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. Provide details.*Please also append a minimum of three* ***TGA SAS B approval letters****.**Please also 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? 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 – see notes on Submission Checklist above).* |  |

# Section 2: Schedule-based approvals requested

Approval is being sought for the following scheduled medicinal cannabis products.

*INSTRUCTIONS:*

*Mark ‘X’ in the left-hand column for each row you wish to include.*

*Please do not modify pre-filled text; other product types can be added at the bottom of the table.*

*Note that the NIIM HREC grants ethical approval of APS applications with the condition that prescribed medicinal cannabis does not exceed 30mg THC daily.* *In such case as you believe a higher dose is clinically justified, you are welcome to obtain authorisation from the TGA and your state authority. Please inform the NIIM HREC of such action in your six-monthly reports.*

|  |  |  |  |
| --- | --- | --- | --- |
| **X** | **Products** | **Dosage form** | **Route of administration** |
|  | **Schedule 4 medicinal cannabis products** | **Oral liquids****Oils****Extracts****Tinctures** | **Oral and/or sublingual** |
|  | **Schedule 4 medicinal cannabis products** | **Wafers****Lozenges** | **Oral and/or sublingual** |
|  | **Schedule 4 medicinal cannabis products** | **Capsules****Tablets** | **Oral** |
|  | **Schedule 4 medicinal cannabis products** | **Edibles****Gummies****Chewables** | **Oral** |
|  | **Schedule 4 medicinal cannabis products** | **Sprays** | **Sublingual and/or buccal** |
|  | **Schedule 4 medicinal cannabis products** | **Vaporisation products****Dried flowers****Dried herbs****Crystals****Oils****Liquids****Resins****Metred dose inhalers** | **Vaporisation and/or inhalation** |
|  | **Schedule 4 medicinal cannabis products** | **Lotions****Salves****Balms****Sprays****Oils****Creams** | **External and/or internal** |
|  | **Schedule 4 medicinal cannabis products** | **Pessaries****Suppositories** | **Internal** |
|  | **Schedule 4 medicinal cannabis products** | **Transdermal patches** | **External** |
|  | **Schedule 8 medicinal cannabis products** | **Oral liquids****Oils****Extracts****Tinctures** | **Oral and/or sublingual** |
|  | **Schedule 8 medicinal cannabis products** | **Wafers****Lozenges** | **Oral and/or sublingual** |
|  | **Schedule 8 medicinal cannabis products** | **Capsules****Tablets** | **Oral** |
|  | **Schedule 8 medicinal cannabis products** | **Edibles****Gummies****Chewables** | **Oral** |
|  | **Schedule 8 medicinal cannabis products** | **Sprays** | **Sublingual and/or buccal** |
|  | **Schedule 8 medicinal cannabis products** | **Vaporisation products****Dried flowers****Dried herbs****Crystals****Oils****Liquids****Resins****Metred dose inhalers** | **Vaporisation and/or inhalation** |
|  | **Schedule 8 medicinal cannabis products** | **Lotions****Salves****Balms****Sprays****Oils****Creams** | **External and/or internal** |
|  | **Schedule 8 medicinal cannabis products** | **Pessaries****Suppositories** | **Internal** |
|  | **Schedule 8 medicinal cannabis products** | **Transdermal patches** | **External** |
|  | **OTHER (Specify)** |  |  |
|  |  |  |  |

Section 3: Indications List

*INSTRUCTIONS: Mark ‘X’ in the left-hand column for each indication you wish to include.*

*This Section should list ALL the indications to feature in the final approval letter.*

*Other indications may be added; these must be accompanied by medical justification in Section 4.*

|  |  |
| --- | --- |
| **X** | **INDICATIONS** |
|  | Alzheimer's Disease |
|  | Anorexia |
|  | Anxiety |
|  | Attention Deficit Disorder with Hyperactivity (ADHD) |
|  | Autism Spectrum Disorder (ASD) |
|  | Cachexia |
|  | Cancer symptom management |
|  | Cancer-related pain |
|  | Chemotherapy-Induced Nausea and Vomiting (CINV) |
|  | Chronic non-cancer pain |
|  | Crohn's Disease |
|  | Dementia |
|  | Depression |
|  | Endometriosis |
|  | Epilepsy |
|  | Inflammatory Bowel Disease (IBD) |
|  | Insomnia |
|  | Irritable Bowel Syndrome (IBS) |
|  | Mood Disorder |
|  | Multiple Sclerosis |
|  | Neuropathic Pain |
|  | Osteoarthritis |
|  | Palliative Care |
|  | Parkinson's Disease |
|  | Post-Traumatic Stress Disorder (PTSD) |
|  | Seizure Management |
|  | Sleep Disorder |
|  | Spasticity |
|  | Spasticity-associated Pain |
|  | Other: (specify)  | *(Go to Section 4)* |

# Section 4: Additional indications

*INSTRUCTIONS: This Section should only be used if the applicant wishes to add indications not previously evaluated by the NIIM HREC. It should include ALL ‘Other’ indications as listed in Section 3.* *Duplicate this form table for each indication if listing more than one ‘Other’ indication.*

|  |  |
| --- | --- |
| 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 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 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? |  |

# 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:

1. *[OPTIONAL]* [ ] I consent to the NIIM HREC sharing my contact details with NIIM and to being contacted by NIIM to discuss opportunities in Integrative Medicine.

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