# 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.

e.g. Smith, John\_Consent form

Smith, John\_APS Application form

|  |  |
| --- | --- |
| 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 |  |
| 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. The invoice must be paid prior to the approval letter being issued |  |

\*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)*

**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) (there must be at least one street address) |  |
| Class of Patient: Does the applicant intend to prescribe MC to under 18’s?*If the applicant has selected YES, please append a minimum of three* ***TGA SAS B approval letters*** *for paediatric patients (date of birth of the patient must be visible).*  Is the applicant a specialist?  If the applicant has selected NO, the TGA may decide not to grant approval. | Yes  No  Yes  No |
| Qualifications, expertise and experience required to manage the medical condition(s) for which the good will be used. **Provide specific details of your expertise and experience**.  *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).*  *\*Please note the HREC requires patients starting on THC to be monitored at least weekly for the first month.* |  |

# Section 2: Schedule-based approvals requested

Approval is being sought for the following scheduled medicinal cannabis products. **Please note** that the HREC is unable to process applications relating to specific medical devices, such as vaporising devices or vape batteries. This is beyond the scope of the NIIM HREC. Please contact the TGA directly for questions about medical devices and other technology.

*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 doctors will advise NIIM HREC in their NIIM APS Six-monthly report the number of patients prescribed:*

* *Over 40mg per day of THC for oral products*
* *Over 500mg\* per day of THC for inhalation products*

*(\*Note this relates to total gram THC/day - not total weight of a flower product)*

|  |  |  |  |
| --- | --- | --- | --- |
| **X** | **Products** | **TGA Dosage Form** (fromTGA Code Tables Dosage Forms, www.ebs.tga.gov.au**)** | **Route of administration** |
|  | **Schedule 4 medicinal cannabis products** | **Oral liquids**  **Oils**  **Extracts, Concentrated (includes Resins)**  **Tinctures**  **Wafers**  **Lozenges** | **Oral and/or sublingual** |
|  | **Schedule 4 medicinal cannabis products** | **Capsules**  **Tablets**  **Tablets, Chewable**  **Tablets, Effervescent**  **Pastilles (includes eg Gummies & Chewables)**  **Herb, Dried (includes Dried flowers)** | **Oral** |
|  | **Schedule 4 medicinal cannabis products** | **Sprays (oral, oro-mucosal)** | **Sublingual and/or buccal** |
|  | **Schedule 4 medicinal cannabis products** | **Inhalation (e.g. Vape Carts)**  **Herb, Dried (includes Dried flowers)**  **Granules (includes Crystals)**  **Oils**  **Liquids**  **Extracts, Concentrated, (includes Resins)**  **Inhalation**  **Inhalation, Pressurised** | **Vaporisation and/or inhalation** |
|  | **Schedule 4 medicinal cannabis products** | **Creams (includes Salves & Balms)**  **Lotions**  **Sprays**  **Oils** | **External** |
|  | **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, Concentrated (includes Resins)**  **Tinctures**  **Wafers**  **Lozenges** | **Oral and/or sublingual** |
|  | **Schedule 8 medicinal cannabis products** | **Capsules**  **Tablets**  **Tablets, Chewable**  **Tablets, Effervescent**  **Pastilles (includes eg Gummies & Chewables)**  **Herb, Dried (includes Dried flowers)** | **Oral** |
|  | **Schedule 8 medicinal cannabis products** | **Sprays(oral, oro-mucosal)** | **Sublingual and/or buccal** |
|  | **Schedule 8 medicinal cannabis products** | **Inhalation (e.g. Vape Carts)**  **Herb, Dried (includes Dried flowers)**  **Granules (includes Crystals)**  **Oils**  **Liquids**  **Extracts, Concentrated, (includes Resins)**  **Inhalation**  **Inhalation, Pressurised** | **Vaporisation and/or inhalation** |
|  | **Schedule 8 medicinal cannabis products** | **Creams (includes Salves & Balms)**  **Lotions**  **Sprays**  **Oils** | **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 | |
|  | Fibromyalgia and Arthropathic Pain | |
|  | 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 | |
|  | Wasting and Anorexia | |
|  | 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 certify that when prescribing medicinal cannabis for an individual patient, I will have a clinical rationale for doing so that includes consideration of whether there are approved treatments available for a particular indication and their suitability, and takes into consideration the expected benefits of the proposed medicine versus its potential risks, including evidence of: the unapproved good’s suitability for the intended indication, the unapproved good’s efficacy and expected benefits, any unknown or expected adverse effects, risks and safety issues and related toxicology.

Yes  No

1. I undertake to provide the HRECI 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** |  |