# Authorised Prescriber Schedule Transition Amendment 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.
	1. E.g. Smith, John\_consent form
	2. Smith, John\_APS application form

|  |  |
| --- | --- |
| Transition Amendment Form |  |
| (Form completed, signed, and dated!) |  |
| Original NIIM HREC AP Approval Letter |  |
| \*NIIM HREC AP Amendment Letter(s) |  |
| \*Evidence of Continuing Professional Education |  |
| +Copies of all six-monthly reports for current approval |  |
| \*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

+required if original approval was granted more than six months ago

**NIIM HREC AUTHORISED PRESCRIBER SCHEME**

**SCHEDULE TRANSITION AMENDMENT FORM**

# Section 1: The Prescriber

|  |  |
| --- | --- |
| Name |  |
| Qualifications including specialty  |  |
| AHPRA No. |  |
| RACGP No. or other Professional Association Membership No.  |  |
| 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 have been approved for prescribing |  |
| Class of Patient: Does the applicant intend to prescribe MC to under 18’s?If yes, has the applicant already provided three TGA SAS-B approval letters for paediatric patients*If the applicant has selected NO, Please append a minimum of three* ***TGA SAS B approval letters*** *for paediatric patients (date of birth of the patient must be visible).* | [ ]  Yes [ ]  No[ ]  Yes [ ]  No |

# 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 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** | **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 |
|  | 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: ‘Other’ 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:

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