# Authorised Prescriber Renewal and Amendment 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.

|  |  |
| --- | --- |
| Renewal and Amendment Form |  |
| Section 6 of 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 |  |
| \*`Product information for each new product applied for |  |
| \*Evidence of Other HREC AP approval |  |
| ^Proof of Payment |  |

\*if applicable

`or equivalent

+required for Renewal Applications

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

**NIIM AUTHORISED PRESCRIBER SCHEME**

**RENEWAL AND 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 |  |

# Section 2: Renewal and/or Amendment(s) requested

Approval is being sought for (tick all that apply):

[ ] Renewal of Authorised Prescriber Approval as per the unapproved good(s) and indication(s) in the original approval letter. (Complete this table and complete Sections 3 and 6.)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Unapproved Good 1 | Unapproved Good 2 | Etc. |
| Indication 1 |  |  |  |
| Indication 2 |  |  |  |
| Indication 3 |  |  |  |
| Etc. |  |  |  |

[ ] Amendment: addition of unapproved good(s) and/or indication(s) to current Authorised Prescriber Approval as per the summary table below. (Complete this table and complete Sections 4 and/or 5 as necessary, and Section 6.)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Unapproved Good 1 | Unapproved Good 2 | Etc. |
| Indication 1 |  |  |  |
| Indication 2 |  |  |  |
| Indication 3 |  |  |  |
| Etc. |  |  |  |

*Attachments required:*

* *Original* ***NIIM HREC Approval Letter***
* *All* ***NIIM HREC Amendment Letter(s)*** *(if applicable)*

# Section 3: Renewal

[ ]  Renewal is being sought for the unapproved goods and indications as per the previous NIIM HREC approval.

Have you undertaken any CPE specific to the unapproved goods since your previous approval?

[ ] Yes[ ] No

Have you submitted all six-monthly reports for the previous approval of these products?

[ ]  Yes [ ]  No

*Attachments required:*

* *Evidence of any* ***Continuing Professional Education***
* *Previously submitted* ***six-monthly reports***

# Section 4: Addition of unapproved product(s) to the current Authorised Prescriber Approval

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Product Trade Name |  |  |  |  |  |  |
| Product Company |  |  |  |  |  |  |
| Sponsor  |  |  |  |  |  |  |
| Active ingredient(s) and concentrations |  |  |  |  |  |  |
| Dosage form |  |  |  |  |  |  |
| Dosage |  |  |  |  |  |  |
| Dosage range Initial doseMax dose |  |  |  |  |  |  |
| Expected duration of treatment |  |  |  |  |  |  |
| Whether the good is approved for the indication in another jurisdiction |  |  |  |  |  |  |

*Attachment required:*

* ***Product Information*** *(or equivalent) for each product listed*

Note that **dosing guidelines** are available on the NIIM website.

# Section 5: Addition of indication(s) to the current Authorised Prescriber Approval

|  |  |
| --- | --- |
| 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 6: 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.

|  |
| --- |
|  |

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** |  |