|  |
| --- |
| REQUEST FOR ENDORSEMENT OF INDIVIDUAL’S APPLICATION FOR TGA AUTHORISED PRESCRIBER OF UNAPPROVED DRUGS AND DEVICES*Complete the form below and submit to the CHQ HREC Office.* |
| **Section 1: Application & Applicant’s Details** |
| **1.1 Applicant’s name** | Click here to enter text |
| **1.2 Title** | Click here to enter text |
| **1.3 Position** | Click here to enter text |
| **1.4 Name of Department (within CHQ)** | Click here to enter text |
| **1.5 Telephone number** | Click here to enter text |
| **1.6 Email address** | Click here to enter text |
| **1.7 Name of product** | Click here to enter text |
| **1.8 Initial application or renewal** | Click here to enter text |
| **Section 2: Description of unapproved therapeutic good** |
| **2.1 Description***Provide a brief plain language statement describing the unapproved therapeutic good* *(if drug) dosage, route of administration, duration of treatment, active ingredient, trade name, supplier, manufacturer**(if device)manufacturer, supplier, mode of operation* | Click here to enter text |
| **2.2 Use of product elsewhere***Describe any known use of unapproved therapeutic good nationally or internationally* | Click here to enter text |
| **2.3 Approvals/registrations***List any current or pending international approvals/ registrations for the therapeutic good* | Click here to enter text |
| **2.4 Availability and cost***Provide, comments on availability**(if drug) Active ingredient, trade name, dose form, supplier* *Provide comments on costs including cost of existing treatment compared to cost for use of unapproved therapeutic* | Click here to enter text |
| **Section 3: Clinical need** |
| **3.1 Clinical condition***Specify the clinical indication/disease/condition that the unapproved therapeutic good will be used for including an outline of its seriousness* | Click here to enter text |

|  |  |
| --- | --- |
| **3.2 Current therapeutic approach** *What existing and approved therapeutic good(s) is/are used for the clinical condition?*  | Click here to enter text |
| **3.3 Comparison to current therapeutic approach***Describe how the proposed use of the therapeutic good differs from each of these:** *Significant clinical advantages over existing treatment- for example-*
* *No worse than existing treatment in terms of effectiveness/toxicity or*
* *Less effective than existing treatment, but less complication*
 | Click here to enter text |
| **3.3 Patient population***What are the subgroups of the patient population that will benefit from the use of this therapeutic good?* | Click here to enter text |
| **3.4 Number of patients to receive the therapeutic good***If this number is expected to increase over time, please specify the predicted number of patients per year for 5 years* | Click here to enter text |
| **Section 4: Evidence of safety, efficacy and clinical effectiveness** |
| **4.1 Safety evidence***Comment on safety evidence base*  | Click here to enter text |
| **4.2 Side effects***List nature and incidents of side effects, contraindications, cautions, warnings and adverse effects for the therapeutic good and the source of this information* | Click here to enter text |
| **4.3 Comparison to current therapeutic approach** *What are the main differences between the side effects, contra indications, cautions warnings and adverse effects between the unapproved therapeutic good and existing treatments and the source of this information* | Click here to enter text |
| **4.4 Efficacy and clinical effectiveness***Summarise the best available evidence, outlining key aspects, for clinical effectiveness of the therapeutic good for defines clinical problems including** *Supporting references*
* *Level and source of evidence*
 | Click here to enter text |

|  |
| --- |
| **Section 5: Clinical feasibility** |
| **5.1 Operator competency***Describe what, if any, credentialing and competency assurance is needed to ensure safe implantation of the unapproved therapeutic.* | Click here to enter text |
| **5.2 Team environment***Are all others involved (e.g. allied health/research assistants) familiar with the requirements of dealing with this unapproved therapeutic good?* | Click here to enter text |
| **5.3 Associated service utilisation***Specify all services, such as intensive care, operating theatre, imaging, pathology, outpatients and others that will be involved in the implementation of the unapproved therapeutic.**Are these available within existing capacity and, if not, why not?* | Click here to enter text |
| **5.4 Future service impacts***If additional services are required to implement the unapproved therapeutic good, specify what these are and how they will be sourced (including any maintenance/ service requirements).**Are there any emerging trends in the use of this therapeutic good that may have future substantive impacts on services? If so, specify and briefly describe.* | Click here to enter text |
| **5.5 Future Australian approval***What is the projected timeframe for this unapproved therapeutic good to receive approval from the TGA?* | Click here to enter text |
| **Section 6: Governance** |
| **6.1 Clinical governance***Describe the arrangements and processes for clinical governance and management of the therapeutic good, including arrangements for patient informed consent.*  | Click here to enter text |
| **6.2 Monitoring***Specify how the unapproved therapeutic good will be monitored once it is introduced into the clinical setting.* | Click here to enter text |
| **6.3 Evaluation***Specify an evaluation protocol, including performance indicators and defined time points, for the therapeutic good.* | Click here to enter text |
| **6.4 Reporting***Describe the reporting schedule for TGA and other relevant bodies.* | Click here to enter text |
| **Section 7: Signatures** |
| **Medical practitioner: I certify that the information contained in this application form is true. I certify that I have no real or perceived conflict of interests or relationships with supplier or manufacturers of this unapproved therapeutic good.**  |
| **Name:***Printed name in full.* | **Click here to enter text** |
| **Signature** | **X\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­Medical practitioner****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Date** |
| **Chair of the HREC: I certify that I have read this application, and endorse this application for the above medical practitioner to become an Authorised Prescriber.** |
| **Name:***Printed name in full.* | **Click here to enter text** |
| **Signature** | **X\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Chair of RCH HREC** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Date** |