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| 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 |

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| **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 | |

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| **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** | |