Pharmaceutical Company Acknowledgement Form

Medicines Access Programs - SA Health

|  |  |  |
| --- | --- | --- |
| Type of Program: Expanded access  Cost-share  Product familiarisation  Compassionate use | | |
| Program Name | | |
| Sponsor company: | | |
| Medicine generic name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Medicine brand name:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Indication for use of this medicine under this Medicines Access Program: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Is this medicine Therapeutic Goods Administration (TGA) approved? YES  NO  TGA listed indications (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Is this medicine listed on the PBS for this indication? Yes  No  If not PBS listed, PBS listing being sought for this medicine for this indication? Yes  No | | |
| Maximum number of patients (if applicable): | | |
| Any other relevant information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Is the program for an individual patient? Yes  No | | |
| I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name) representing \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (company) acknowledge that the Medicines Access Program above is offered to the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Local Health Network (LHN), hospital, or health service) under the following conditions:   1. The Medicines Access Program must be considered and approved by the LHN, hospital or health service Drug and Therapeutics Committee (DTC) (or equivalent committee) before commencement. 2. The medicines supplied through the Medicines Access Program medicine(s) must be stored, managed, and dispensed through the hospital pharmacy in accordance with procedures applicable to other medicines. 3. Inclusion criteria are for TGA approved indications and within the requested PBS indications being sought, where applicable; **OR** for an unregistered medicine or indication where supplied as part of an Access Program, as allowed via the TGA Special Access Scheme. 4. The medication will continue to be provided free of charge by our company to the hospital (or as agreed by LHN DTC [or equivalent committee]) for as long as the patient is judged to benefit clinically from the treatment and the medicine remains available in Australia. Supply will continue until the medicine is available to those patients through a formal funding mechanism, such as the PBS or the relevant formulary. 5. Acceptance of this Medicines Access Program does not commit SA Health to subsequently place the medicine on the formulary.   Other comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Company representative’s signature:    Print name:  Title:  Company:  Date: | | LHN DTC (or delegate) representative’s  Signature:  Print name:  Title:  DTC (or delegate):  Date: |