**Formulary Amendment Form: Section 100 (S100) Medicine Addition**

# A. Introduction

Use this form to apply for:

* **Addition of a new drug, which is approved for reimbursement under Section 100, to the Formulary.**

For approval to use this drug on an individual patient basis for non-S100 indications, use the [IPU application form](https://www.nswtag.org.au/evaluating-new-drugs/)

For amendments to existing Formulary drugs, use the relevant customised [Formulary form](https://www.nswtag.org.au/evaluating-new-drugs/)

For all other Formulary requests, use the [Formulary Submission form](https://www.nswtag.org.au/evaluating-new-drugs/)

Complete Sections B-H.

# B. Product Profile

|  |  |
| --- | --- |
| **Active Ingredient Name(s)** |  |
| **Trade / Brand Name** |  |
| **Formulation(s) – provide full details** |  |
| **Manufacturer/Supplier** |  |
| **Pharmacological class and action (summary)** |  |

# C. Indication(s) for use

(This drug will only be considered for approval on the formulary for the indications listed for reimbursement under Section 100. For approval for non-S100 indications, please complete a full Formulary submission)

**List the S100 indications (or attach a copy of the relevant section of the PBS Schedule).**

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|  |

# D. Financial Implications

1. **List any cost implications for the hospital e.g. likelihood of having to provide inpatient supply, additional monitoring requirements.**

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1. **Will this drug replace any existing Formulary drug? Please supply details**.

|  |
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|  |

1. **How many patients per year do you estimate will be treated with this drug in this hospital/district?**

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|  |

# E. Safety Implications

1. **List any safety implications, e.g. drug interactions, poor packaging**

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| --- |
|  |

1. **Does a guideline/protocol need to be developed to assist prescribing and/or administration?**

Yes, please provide details below  No

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|  |

1. **Is training for prescribers or nurses needed to ensure safe and/or effective use of this medicine?**

Yes, please provide details below  No

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# F. Conflicts of Interest

Financial or other interests resulting from contact with pharmaceutical companies, which may have a bearing on this submission:

Gifts

Travel expenses

Samples

Industry paid food/refreshments

Honoraria

Research support

Nil conflict of interest

Other support (describe below)

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| --- |
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# G. Approval process

**The following must be completed prior to submitting application to the DTC**

**Details of Applicant making the request**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Applicant |  | | |
| Position / Appointment |  | | |
| Signature |  | Date |  |
| E-mail address for  correspondence |  | | |
| Phone number |  | | |

**Endorsed by**

(Must be completed by Head of Unit/Manager of Department)

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Unit Head/  Manager of Department |  | | |
| Position / Appointment |  | | |
| Signature |  | Date |  |

# H. Submission

Forward completed form to the Pharmacy department with supporting data and relevant protocol/guideline (if applicable).

For questions or discussions regarding this application, the Pharmacy Department may be contacted via:

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* + *Forward completed form to the Pharmacy Department*

**For Drug and Therapeutics Committee Use Only**

# Outcome of application process:

|  |  |
| --- | --- |
| **Process** | **Date / Details / Notes** |
| Application received  *(Date received by DTC secretary)* |  |
| Application considered  *(DTC meeting date)* |  |
| Outcome: | Approved  Rejected  Deferred |
| Conditions of approval  *(Specify restrictions)* |  |
| Approval review date *(If applicable)* |  |
| Applicant advised of outcome *(Date)* |  |

# Approved by:

|  |  |
| --- | --- |
| Signed on behalf of  Drug and Therapeutics Committee |  |
| Name |  |
| Date |  |