Formulary Submission Form

A. Introduction

Use this form to apply for:

- Approval for a new drug to be added to the formulary, or
- Approval for use of a drug under other circumstances (e.g. familiarisation program).

For approval for addition of a new formulation of an existing formulary product or approval for variation to an existing formulary listing (e.g. S100 addition) – use the relevant customised Formulary form

For approval to use this drug on an individual patient basis, use the IPU application form.

Completion of this form is intended as multidisciplinary, collaborative approach. Some submissions may not require all sections of the form to be completed. Please seek advice from a member of the Drug and Therapeutics Committee/hospital pharmacy department when completing your application, prior to submission to the Drug and Therapeutics Committee for consideration.

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

1. Is the drug approved by the Therapeutic Goods Administration (TGA) for marketing in Australia? ☐**YES /** ☐**NO**

2. What are the proposed indication(s) for use in the hospital?

a. Is this is a TGA approved indication? ☐**YES /** ☐**NO**

3. Is the drug already listed on the hospital formulary for other indications? ☐**YES /** ☐**NO**

b. If **YES**, list current formulary approval (including restrictions):

D. PBS Listing and Continuity of Supply

1. Has the drug been considered by the PBAC for the proposed indication for use? ☐**YES /** ☐**NO**
   a. If **YES**, are PBAC Public Summary Documents available? ☐**YES /** ☐**NO**

2. Is the proposed indication approved for subsidy under the PBS? ☐**YES /** ☐**NO**
   a. If **YES,** (tick one) ☐General Benefit **OR** ☐Authority **OR** ☐Streamline Authority **OR** ☐Section 100
   b. If **NO**, explain implications for continuity of supply. (Will the drug be supplied for inpatient use only, outpatient use or both? Will the hospital be required to provide ongoing therapy after discharge?)

E. Reasons for Request

(i) ☐ New addition to the formulary

(ii) ☐ Other (e.g. type of Medicines Access Program)

See section A on page 1 if your request type is not listed.

Explain your reasons for wanting to use this drug and state if the intended use of the drug is for **initiation** (new therapy commenced whilst in hospital) or **continuation** (to continue therapy initiated outside the hospital, prior to admission).

Provide the following details:

Treatment details: Recommended dosage, administration details, duration of treatment etc. List drugs recommended for co-administration or used in combination.	
Impact on electronic Medical records including eMeds Provide recommendations for order sentences, care sets	
Relevant comparator(s): Describe the therapy currently available for this indication, if any. If this drug is added to the formulary, which drug(s) should be deleted?	
Monitoring requirements: Describe the objective criteria that will be used to monitor effectiveness.	
Proposed place in therapy: Describe investigations necessary for patient selection and treatment. Which patient groups are most likely to benefit? Will this drug be used as first, second or third-line therapy? What prescribing restrictions should be in place (e.g. medical officers authorised to prescribe)?	

Attach details of proposed prescribing criteria, guidelines and/or protocols (see prescribing protocol template for guidance about the details required).
Other supporting documentation should also be attached (e.g. consensus guidelines, approval by overseas agencies, published data, clinical trial data, etc.)**.**

Grading for Level of Evidence*

Level I	Evidence obtained from systematic review of relevant randomised controlled trials
Level II	Evidence obtained from one or more well-designed, randomised controlled trials
Level III	Evidence obtained from pseudo-randomised controlled trials (III-1), from well-designed comparative studies with concurrent controls: non-randomised, experimental trial, or cohort, case control or interrupted time series studies (III-2), or from a comparative study without concurrent controls (III-3)
Level IV	Case series with either post-test or pre-test/post-test outcomes

* From NHMRC additional levels of evidence and grades for recommendations for developers of guidelines 2009: https://www.nhmrc.gov.au/sites/default/files/images/NHMRC%20Levels%20and%20Grades%20(2009).pdf

F. Comparative Safety and Efficacy*

- When submissions are for TGA-approved indications the Product Information documentation may provide some of the information below.
- For drugs that have been considered by the PBAC for the proposed indication: the Public Summary Documents should be provided *(when available).*
- Include names of comparators. If necessary, attach additional information as a separate document.

Significant adverse effects	**New drug:**	**Current formulary alternative(s)^:**
Common: *(i.e. incidence of 1% or more)* **Infrequent:** *(i.e. incidence between 0.1% and 1%)* **Rare:** *(i.e. incidence less than 0.1%)*		

Main benefit in safety	**New drug:**	**Current formulary alternative(s)^:**
Incidence of main adverse event expressed as a percentage. *Specify (e.g. stroke, mortality, allergic reaction, etc.)*. Level of evidence (see page 7)	%	%

Main benefit in effectiveness*	**New drug:**	**Current formulary alternative(s)^:**
Incidence of main effectiveness outcome measure expressed as a percentage. *Specify outcome measure (e.g. cure rate, relapse rate) and whether measure represents a surrogate marker or an actual health outcome.* Level of evidence (see page 7)	%	%

Additional benefits*	
Specify (e.g. surgery or procedure averted, admission averted, reduced length of stay, etc.).	

* Reference the sources used for above data. Literature references should cite the primary clinical trial(s).
^ If there are no current formulary alternatives, please reference other appropriate comparators (e.g. head-to-head trials etc.).

G. Comparative costs of drug treatments:

Include names of comparators	**New**	**Current (1)**	**Current (2)**
a. Average dose per day			
b. Average duration of treatment in days			
c. Average number of dosage units per day			
d. Cost per dosage unit	$	$	$
e. Cost per standard course *(b x c x d)*	$	$	$
f. Additional costs per patient per course *(e.g. additional drugs, monitoring requirements, etc.)*	$	$	$
g. Total annual cost per patient *(e + f)*	$	$	$
h. Expected number of patients per year (*indicate the basis for this estimate)*			
i. Annual cost (g *x h)*	$	$	$
j. Difference (new cost – current cost)		$	$
k. Cost offsets if the new drug were introduced:			
l. Proposed source of funding:			

H. Issues regarding safe use:

Product packaging and labelling

E.g. Is product nomenclature likely to lead to confusion in selection? Is packaging clearly labelled? Is each dosing unit labelled in such a way to allow identification up to the point of administration? Does packaging facilitate clear and practical storage? Is appropriate Consumer Medicines Information available?

Administration

E.g. Are physical incompatibilities with the diluent or other medicines likely in the administration of the product? Are there potential adverse events associated with administration techniques? What are the nursing implications of product preparation and/or administration requirements?

Education

E.g. Will hospital staff require training regarding prescribing, handling, or administration? OHS issues?

I. Contributors to this submission

Name	Profession/Affiliation (e.g. Medical, Nursing, Drug Company/Industry, Pharmacy)

J. Conflicts of Interest of applicants

If the applicant has received funds, or may receive future benefit from companies or other institutions, there may be a real or perceived conflict of interest from your application.

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)

Please Note: This declaration of conflict of interest must be completed for all relevant applicants.

NB. Medicines Australia member company reports of payments to healthcare professionals and third party meeting sponsorships can be accessed at https://medicinesaustralia.com.au/code-of-conduct/transparency-reporting/payments-to-healthcare-professionals/member-company-reports/ and https://medicinesaustralia.com.au/code-of-conduct/transparency-reporting/new-third-party-meeting-sponsorships/ From 1 October 2016, Medicines Australia's Code of Conduct requires mandatory reporting of payments or educational support (e.g. airfares, accommodation or registration fees) to healthcare professionals. Companies will report the payments made during a six-month period, within 4 months of the end of each reporting period (i.e. by the end of August and end of February each year).

K. APPROVAL PROCESS

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

Details of Applicant:

Name of Applicant			
Position / Appointment			
Signature		Date	

Endorsed by:

Name of Manager of Department			
Signature		Date	

Executive sign-off (when relevant)

The Executive is aware of the financial implications of addition of this product and accepts these as reasonable:

Name of Executive			
Signature		Date	

L. Submission

Tick

☐ All sections of form completed (including endorsement)

☐ Supporting data attached (relevant clinical papers, consensus guidelines, etc.)

☐ Prescribing criteria / protocol / guideline attached (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

Comparative Approvals:

Has this drug been considered for formulary approval by other DTCs in NSW hospitals? ☐**YES** / ☐**NO**

If **YES**, list relevant DTCs and their decisions. (NB: Information available via NSW TAG website)

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	