Formulary Amendment Form (For use with Existing Formulary-Approved Medicines Only)

A. Introduction

This form only applies to a medicine that is already approved for inpatient/day surgery use or has PBS approval for the new indication.

Application type*	Tick which is applicable, both may be applicable	Complete
Request a new formulation of an existing formulary medicine to be added to formulary	☐	Sections B, C, E, F, G, H
Request to modify/add indications and/or prescribers for an existing formulary listing (e.g. adding PBS indications and/or changing prescriber restrictions)	☐	Sections B, D, E, F, G, H

* If both application types, complete all Sections B-H.

For requests to add drugs approved for reimbursement under Section 100, use the relevant customised Formulary Form
For all other Formulary requests, use the Formulary Submission form
For approval to use this drug on an individual patient basis, use the IPU application form

B. Profile of Currently Approved Medicine

Active Ingredient Name(s)	
Trade/Brand Name	
Medicine Formulation(s) currently approved on formulary	
List current formulary approval (including restrictions)	
Is the medicine used for	☐ inpatients/day procedures only ☐ outpatients only* ☐ both inpatients and outpatients*

*If, for outpatient and not subsidised by PBS**,** use the Formulary Submission form

C. Request to add new formulation

What is the proposed new formulation?	
Trade/Brand name	
What is the recommended dose? Please indicate whether it is different to current formulation in use.	

1. What are the perceived advantages of the new formulation?

2. Is the proposed use for the new formulation (e.g. indications, prescribers) the same as the current approved formulation?

☐ YES ☐ NO If NO, also complete Section D.

3. Is it proposed the old formulation(s) be removed from formulary?

☐ YES ☐ NO

4. If the new formulation is added to formulary, will there need to be a change in local documents e.g. guidelines, protocols, standing orders?

☐ YES, please provide more details below ☐ NO ☐ NOT KNOWN

D. Request to modify indications and/or prescribers

1. What/who are the proposed new indication(s) and/or prescribers?

Proposed modification	Tick whichever is applicable (both may be applicable)	Detail proposed change
Change to indications	☐	Are the new indication(s) PBS-approved? ☐Y / ☐N Is the medicine for inpatient or day procedure use only? ☐Y / ☐N
Change to prescribers	☐	If applicable, do the proposed prescribers(s) meet PBS criteria? ☐Y / ☐N Should any existing prescriber group(s) be removed? ☐Y / ☐N

2. What are the perceived advantages to modifying indications and/or prescribers?

3. If the proposed change(s) are added to formulary, will there need to be a change in local documents e.g. guidelines, protocols, standing orders?

☐ YES, please provide more details below ☐ NO ☐ NOT KNOWN

E. Financial Implications

What are the comparative costs of proposed therapy changes versus current therapy)? (Current prices can be obtained from Pharmacy)

Therapy	Cost/patient/day (a)	Volume of use (patient numbers/ day) (b)	Duration (days) (c)	**Total cost [(a x b) x c]**
Proposed therapy				
Current therapy				
Other current therapy, if applicable				

List any other cost implications or advantages (including drugs which may be replaced; need for training; use of other devices).

F. Safety Implications

List any medication safety implications, including design of packaging that may occur with proposed formulary amendment

G. 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)

H. 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

Check List (New Formulation)

- ☐ Drug already on Formulary for indications requested
- ☐ No significant cost implications
- ☐ No significant safety implications
- ☐ Inpatient use only or ongoing supply available via PBS

Check List (New indications/prescribers)

- ☐ Drug already on Formulary
- ☐ New indications/prescribers approved for supply under PBS
- ☐ No significant cost implications
- ☐ No significant safety implications

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	