

Hospital Pharmaceutical Assessment Template for Pharmaceutical Suppliers

The Hospital Pharmaceutical Assessment Process (HPAP) was developed as part of the Hospital Strategy. Pharmaceutical suppliers are asked to inform PHARMAC and hospitals of new hospital pharmaceuticals that are available. This assessment form is designed for suppliers to enable simple and consistent reporting of new hospital pharmaceuticals for consideration by PHARMAC for national assessment. Please note that this differs from the information that is required when submitting an application to PHARMAC for inclusion in Sections B to G of the Pharmaceutical Schedule.

As stated in the Hospital Strategy, national assessment by PHARMAC does not confer any obligation on DHBs to fund or not to fund new pharmaceuticals. Hospitals may commence funding of the new pharmaceuticals prior to any PHARMAC review and may continue to do so irrespective of any recommendation that PHARMAC may make following a review.

The HPAP is intended to promote the following benefits:

- facilitate the introduction of economic analysis into hospital pharmaceutical assessments;
- reduce duplication of work;
- promote dialogue between DHBs and PHARMAC on clinical and fiscal issues;
- facilitate review;
- improve the consistency and quality of assessments; and
- improve consistency of access to pharmaceuticals.

In order to achieve the aims of the process, supplier involvement is crucial in the following areas:

- Suppliers need to notify PHARMAC of new hospital pharmaceuticals available, or pharmaceuticals that are likely to be available within the next year.
- Suppliers can assist PHARMAC with assessments of their pharmaceuticals, and have an input into the process by completing this assessment template.
- When PHARMAC has completed the draft analysis it is sent to DHBs and the supplier of the pharmaceutical for comment. All comments are addressed or incorporated in the final version of the analysis. The final version of the analysis is then distributed to DHBs and placed on the Hospital Pharmaceutical Assessment Database (HPAD) website. Results of the analysis are also included in Part III of Section H of the Pharmaceutical Schedule.

Why complete this template?

Under Section 4.2.2 of the Hospital Strategy, pharmaceutical suppliers are asked to submit applications to PHARMAC for the listing of pharmaceuticals in Section H (note that this includes Part III of Section H). For further information, please refer to the final version of the National Hospital Strategy (<http://www.pharmac.govt.nz/pdf/nhps.pdf>).

Involvement in the HPAP has the following benefits:

- input into PHARMAC's assessment of pharmaceuticals;
- wide circulation of information regarding the cost-benefit of new pharmaceuticals;
- inclusion of hospital pharmaceuticals in Part III of Section H of the Pharmaceutical Schedule.

When should this template be completed?

PHARMAC is interested in assessing the following pharmaceuticals:

- those recently approved for use in New Zealand that are currently being considered for use within a hospital;
- high cost pharmaceuticals (i.e. pharmaceuticals that have a substantial impact on the budget) – this includes both registered and unregistered pharmaceuticals;

- pharmaceuticals that a number of DHBs are assessing;
- new indications for pharmaceuticals.

This assessment template should therefore be completed in the following situations:

- when making a submission to a DHB hospital for the addition of a new hospital pharmaceutical on the hospital formulary, or the addition of a new indication to an existing pharmaceutical;
- when a listing in Section B is not requested but the pharmaceuticals are used in the community as well as hospitals;
- when making a submission for PHARMAC consideration following notification that PHARMAC is assessing a pharmaceutical.

Each submission will be prioritised for national assessment according to the criteria of the HPAP (i.e. highest priority given to those pharmaceuticals that a number of DHBs are assessing and those associated with very high costs to DHBs). Individual suppliers will be kept informed of the progress of the assessment of their pharmaceutical.

As there could potentially be a number of new hospital pharmaceuticals, it is recommended that pharmaceutical suppliers prioritise what pharmaceutical assessments to send to PHARMAC, according to expected population numbers and cost. If unsure, please contact PHARMAC staff before beginning the assessment, so that we can discuss where the pharmaceutical would be placed on the priority list for assessment, whether PHARMAC would assess the pharmaceutical and, if so, the timeframe for the assessment.

When does this template not need to be completed?

This assessment template does not need to be completed in the following situations:

- applications for listing in Section B of the Pharmaceutical Schedule (supplier submission template should be completed);
- applications for cancer drugs – the Cancer Treatment Subcommittee of PTAC (CaTSOP) needs to evaluate applications for cancer treatments, hence the applications should be completed using the supplier submission template;
- rare and unusual indications (less than 10 patients per year nationally).

A flowchart outlining when this template needs to be completed and its relationship to other PHARMAC processes is at the end of this document.

How do we get the pharmaceutical listed in Part II of Section H?

If desired, a proposal for a national contract involving listing of the pharmaceutical in Part II of Section H of the Pharmaceutical Schedule can be included with the submission. The proposal should include the following information as a separate document:

- chemical name,
- strengths,
- forms,
- brand name,
- pack size,
- packaging type,
- pharmacode,
- price, and
- an indication of potential national volumes used and savings achievable at the submitted price.

PHARMAC would assess this proposal and consult the Hospital Pharmaceuticals Advisory Committee (HPAC) on any potential value this proposal could provide DHB hospitals. If the assessment were favourable, PHARMAC would then contact the supplier with a standard terms hospital provisional agreement. PHARMAC would then consult on this provisional agreement and seek a decision from the PHARMAC Board or the Chief Executive under Delegated Authority to approve the agreement. Subject

to consultation and final PHARMAC Board approval, PHARMAC would list the pharmaceutical in Part II of Section H of the Pharmaceutical Schedule as soon as practicable.

Note however that PHARMAC would be unable to provide any market exclusivity provisions (such as Hospital Supply Status) for the pharmaceutical, as the proposal would have been received outside of the competitive process timetable.

Does any other information need to be provided?

A submission need not restrict itself to answering only those questions specified in this template. Pharmaceutical suppliers are welcome to provide any further information relating to the pharmaceutical assessed or comparator pharmaceutical. Even though pharmaceutical suppliers are not required to undertake a full cost-utility analysis, it may be useful to provide a perspective on the cost-benefit of the pharmaceutical.

If you have any questions, please contact Rachel Grocott, Senior Hospital Pharmaceutical Analyst, at PHARMAC (DDI: (04) 916 7535).

A. *Pharmaceutical Details*

1. Chemical Name: _____

2. Brand Name: _____

3. Strength(s): _____

4. Dosage form(s) (e.g. oral, intravenous, long-acting infusion etc.): _____

5. Pack size: _____

6. Registered Indications:

7. Contraindications:

8. Drug interactions:

7. Pharmacode (if available): _____

9. Price: \$ _____

2. Attach key publications that provide evidence of the safety, effectiveness and cost-effectiveness of the pharmaceutical, and any other evidence.

3. Please complete the following table on the key studies:

- *Please indicate p-values for all outcomes*
- *Please indicate if analysis is based on intention-to-treat population*
- *Please state if there is more there are more than three key studies.*

Study Authors and Year			
<i>Study design</i>			
<i>Sample size</i>			
<i>Intervention</i>			
<i>Comparator</i>			
<i>Eligibility criteria</i>			
<i>Study duration</i>			
<i>Primary outcome results</i>			
<i>Secondary outcome results</i>			
<i>Total rate of adverse events</i>			
<i>Rate of serious adverse events</i>			
<i>Total number of withdrawals</i>			
<i>Number of withdrawals due to adverse events</i>			

4. Based on the evidence, what are the benefits and risks of the pharmaceutical compared to existing treatment? Please complete the following tables:

Benefits of proposed pharmaceutical	Benefits of comparator
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.
6.	6.
7.	7.
8.	8.
9.	9.
10.	10.
11.	11.
12.	12.

Risks of proposed pharmaceutical	Risks of comparator
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.
6.	6.
7.	7.
8.	8.
9.	9.
10.	10.
11.	11.
12.	12.

D *Quality of Life and Other Outcomes*

1. What effect does the pharmaceutical have on patients' quality of life?

2. Utility values:

Patient group	Utility value	Source

3. Are there any other important outcomes that need to be considered?

Yes No

If so, please describe:

E. Costs - Pharmaceutical

- 1. Dose: _____
- 2. Daily cost per patient: _____
- 3. Cost/day of comparator treatment: _____

4. What side effects are associated with treatment? What pharmaceuticals/procedures are used to treat these side effects, and what is the estimated cost of the treatment for side effects? Please list in the following table:

Side-effects	Treatment for side-effects	Cost
<i>Intervention</i>		
1.		\$
2.		\$
3.		\$
4.		\$
5.		\$
6.		\$
7.		\$
8.		\$
<i>Comparator treatment(s)</i>		
1.		\$
2.		\$
3.		\$
4.		\$
5.		\$
6.		\$
7.		\$
8.		\$

5. Are there any additional pharmaceuticals that need to be co-administered with the treatment and/or after the treatment? What is the cost of these pharmaceuticals?

Co-administered pharmaceuticals	Cost	Pharmaceuticals administered after treatment	Cost
<i>Intervention</i>			
1.	\$	1.	\$
2.	\$	2.	\$
3.	\$	3.	\$
4.	\$	4.	\$
5.	\$	5.	\$
6.	\$	6.	\$
7.	\$	7.	\$
8.	\$	8.	\$
9.	\$	9.	\$
10.	\$	10.	\$
11.	\$	11.	\$
12.	\$	12.	\$
<i>Comparator treatment(s)</i>			
1.	\$	1.	\$
2.	\$	2.	\$
3.	\$	3.	\$
4.	\$	4.	\$
5.	\$	5.	\$
6.	\$	6.	\$
7.	\$	7.	\$
8.	\$	8.	\$
9.	\$	9.	\$
10.	\$	10.	\$
11.	\$	11.	\$
12.	\$	12.	\$

F. Costs – Hospital

- How long is the patient likely to remain in hospital compared to alternative treatment?

LOS - Intervention	LOS – Comparator(s)

- What DRG code(s) will these patients be coded to?

Code	Code Description
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	

- Is there likely to be any flow-on costs or benefits to the hospital from the utilisation of this medicine? E.g. improved patient management, reduced hospital stay, reduction in monitoring/lab tests, or reduced nursing time.

Flow-on costs to the hospital	Cost per patient
1.	\$
2.	\$
3.	\$
4.	\$
5.	\$
Flow-on benefits to the hospital	Saving per patient
1.	\$
2.	\$
3.	\$
4.	\$
5.	\$

G. Costs – Other

1. Are there likely to be any other flow-on costs or benefits from the utilisation of this medicine?

Other flow-on costs	Cost per patient
1.	\$
2.	\$
3.	\$
4.	\$
Other flow-on benefits to	Saving per patient
1.	\$
2.	\$
3.	\$
4.	\$

2. What other resources might these patients be anticipated to consume compared with the alternative treatment?

Other resource costs for intervention	Cost per patient
1.	\$
2.	\$
3.	\$
4.	\$
5.	\$
Other resource cost for comparator treatment	Cost per patient
1.	\$
2.	\$
3.	\$
4.	\$
5.	\$

Please complete the following cost summary table:

Cost item	Data source	Cost per patient	Number of Patients	Total Cost
<i>Cost of pharmaceutical</i>				
<i>Cost of significant side-effects</i>				
<i>Cost of hospital admissions</i>				
<i>Cost of other hospital resources</i>				
<i>Community costs</i>				
Total Cost of Proposed Treatment (a)				
<i>Cost of alternative pharmaceutical</i>				
<i>Cost of significant side-effects</i>				
<i>Cost of hospital admissions</i>				
<i>Cost of other hospital resources</i>				
<i>Community costs</i>				
Total Cost of Existing Treatment (b)				
NET COST (a-b)				

I. Cost-effectiveness

1. If an analysis has been completed in New Zealand, what is the cost per life year gained, or cost per quality-adjusted life year gained of the pharmaceutical compared with the current treatment? Please attach details of assumptions and results.

J. Implementation

1. Should prescribing be restricted to certain clinicians? If so, who?

2. Who would most benefit from this pharmaceutical (i.e. to whom should access be targeted)?

