Supplementary information template

To be completed by Drug and Therapeutics Committee delegate in consultation with applicant

Evidence Supporting Application

Include all relevant randomised controlled trials and/or systematic reviews (meta-analyses).
(Copy following page if more space is required.)

Notes:

1. Copies of key papers should be included with the submission.
2. Unpublished studies may be considered (reason for non-publication should be provided). For unpublished studies, sufficient detail must be provided to allow independent assessment of results.
3. If no head-to-head studies are available for drug and comparator, other studies may be considered if they are likely to assist with decision-making, eg randomised, controlled studies with arms that include the various comparators.
4. Indicate if comparators, dosing regimens and duration of trial are relevant to local practice.
5. Indicate if study population(s) are relevant to local practice.
6. Indicate if benefits are likely to extend beyond the period of the trial.
7. If post-hoc sub-group analysis is included, highlight the limitations of the analysis so that risks associated with decision-making can be assessed.

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 well-designed, non-randomised controlled trials; or from well designed cohort, case control or interrupted time series studies
Level IV	Case series with either post-test or pre-test/post-test outcomes

* From NHMRC interim levels of evidence 2005: www.nhmrc.gov.au/publications/_files/levels_grades05.pdf

Reference number____ (Please copy and attach additional pages as required)

Title: _____

_____

_____

Author(s): _____

_____

_____

Journal: _____

_____

Date/Year: _____

Drug and Comparators(s): _____

_____

_____

Number of patients in each arm: _____

_____

_____

Dose regimens:_____

_____

Duration of trial: _____

Outcome measure(s): _____

_____

_____

_____

Study type:

Meta-analysis	Yes	No
Randomised Trial	Yes	No
Non-Randomised Trial	Yes	No
Case study with no controls	Yes	No

Efficacy:

Absolute Risk Reduction vs control	_____	
Statistically Significant ($p<0.05$)	Yes	No
95% Confidence Interval	_____	
Number Needed to Treat	_____	

Evidence of clinical improvement

_____% Active vs _____% Control

Safety:

Number Needed to Harm	_____

Evidence of safety improvement

_____% Active vs _____% Control

Evidence grading* I II III IV

* See Notes

Comments (please refer to notes)**:

** In particular, please comment on generalisability of trial data to specified hospital patient population