## *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 Unpublished studies may be considered (reason for non-publication should be provided). For unpublished studies, sufficient detail must be provided to allow independent assessment of results.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