

Information about Submissions to Drug & Therapeutics Committees

A Decision Tool

Information about the formulary submission template

This decision tool provides guidance for Drug and Therapeutics Committees (DTCs) undertaking review of applications and for clinicians submitting applications for hospital use of new drugs, new drug presentations, additional indications or new medicines access programs. It identifies the information that is required for DTC decision-making, and provides a decision algorithm for use of this information. It may be used by DTCs to guide the approval process for new formulary listings. It may also be used to guide the process for individual patient use (IPU) approvals.

This decision tool consists of a number of documents relating to:

Formulary submissions:

- Formulary submission template(s)/form(s)
- Prescribing protocol template
- Supplementary information form
- DTC decision algorithm
- Questions to ask when evaluating a new drug

IPU submissions:

- IPU submission template/form
- Supplementary information form
- IPU decision algorithm

All documents are available here: <https://www.nswtag.org.au/evaluating-new-drugs/>

How should the submission forms be used?

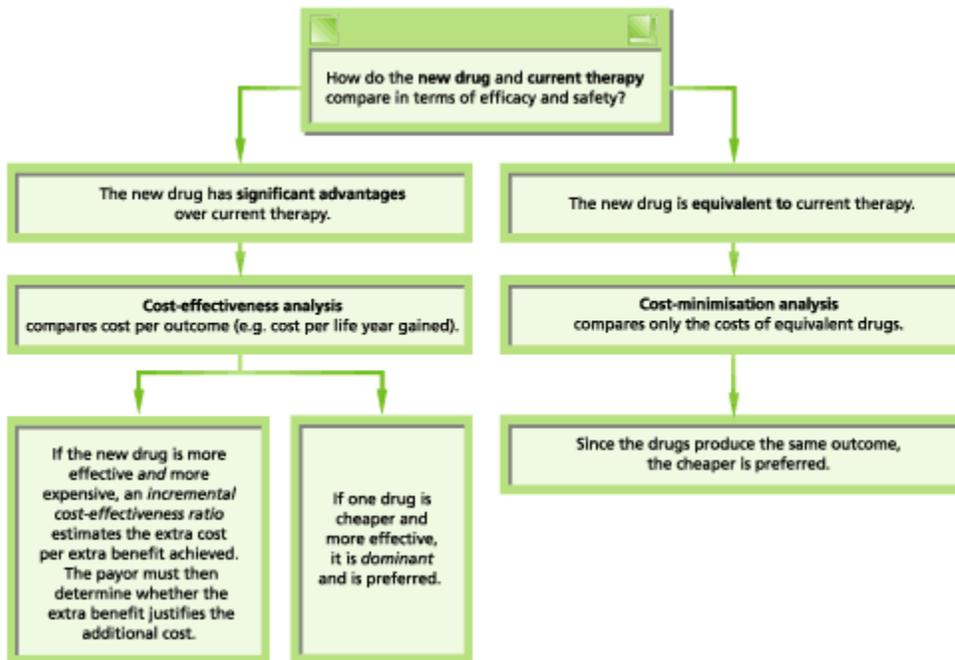
The relevant submission form (*Formulary submission form(s)* or *IPU submission form*) should be completed by the clinician requesting approval (the applicant). In most cases it will be appropriate for prescribing guidelines (*Prescribing protocol template*) to be proposed and included in the submission. A *Prescribing protocol template* is provided to assist this process. Once completed, the submission form (and prescribing protocol) should be forwarded to the relevant DTC personnel (the Secretary, the Chair or the Director of Pharmacy) who will coordinate preparation of supplementary information before referral to the DTC.

What happens to completed forms?

The completed submission will be considered by the DTC, together with information in the *Supplementary information form*. Supplementary information will usually be prepared by a delegate of the DTC in consultation with the applicant. All of this information is important for appropriate DTC decision making. **Missing information may delay the decision process.**

In considering a new formulary listing, the DTC will assess the new drug in comparison with current therapy using a structured approach that addresses specific [questions](#). The DTC will use a standard [decision algorithm](#) to guide its decision process. This decision algorithm is recommended for use in all NSW hospitals, to encourage consistency in approach and equity of access to pharmaceuticals for hospital patients in NSW. The DTC will consider not only clinical issues, but also economic issues (i.e. value for money). Economic analysis may be undertaken on either a cost-effectiveness or cost minimisation basis depending on the circumstances. The DTC is encouraged to consider economic analyses undertaken by the Pharmaceutical Benefits Advisory Committee when considering hospital formulary decisions.

The following schema, produced by NPS, gives an overview of the kinds of economic analyses that may be used. **Comparison of cost-effectiveness and cost-minimisation** *



* New (and old) ways of looking at new drugs. NPS Newsletter 31. December 2003. Permission to use obtained from NPS.

Advice about completing the submission form, as well as further information about DTC processes, may be obtained from the Director of Pharmacy in your hospital.

Acknowledgements:

This decision tool was produced by the NSW TAG High Cost Drugs Working Group*, in consultation with members of the NSW TAG network. The Working Group particularly acknowledges the contribution of Mr David Ingram and Ms Margaret Duguid from Royal North Shore Hospital in leading this process. The decision algorithm is based on a concept developed by South Australian Therapeutic Advisory Group.

NSW TAG is grateful to the following organisations who provided information about their assessment processes and generously shared the tools they have developed. Some of these tools have been adapted for use in this decision tool:

- Victorian Therapeutics Advisory Group**
- Hunter Drug Information Service**
- West Australian Therapeutics Advisory Group Drug Evaluation Panel**
- South Australian Therapeutic Advisory Group**

NSW Therapeutic Advisory Group (NSW TAG) is an independent, non-profit association which represents Drug and Therapeutics Committees in NSW hospitals. Our members are committed to promoting quality use of medicines in NSW hospitals and the wider community. For more information about NSW TAG see www.nswtag.org.au or look under Other Drug Information on the CIAP menu via your intranet site. NSW TAG is an initiative of clinical pharmacologists and pharmacists, funded by NSW Health.

*Members of the High Cost Drugs Working Group at the time of writing this document included: Ms Margaret Duguid (Chair) and Mr David Ingram (Royal North Shore Hospital), Prof Richard Day and Ms Terry Melocco (St Vincents Hospital), A/Prof Andrea Mant (South Eastern Sydney and Illawarra Area Health Service), Ms Elizabeth Perks, (Prince of Wales Group Hospitals), Ms Terry Maunsell (Royal Prince Alfred Hospital), Ms Gabrielle Couch (Greater Southern Area Health Service), Mr John Whiteford (Northern Rivers Area Health Service).