# NSW Medicines Formulary Committee

# Formulary Submission Framework

Version 1.0

August 2022

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

# Overview

## Purpose

The purpose of this document is to provide a framework to assist the NSW Medicines Formulary Committee (NMFC) members with evaluating submissions for additions, amendments or deletions to the NSW Medicines Formulary.

This framework has been developed using other decision support tools, including Queensland Health Medicines Advisory Committee (QHMAC) 5 Pillars Decision Support Tool[1] and New Zealand's PHARMAC Factors for Consideration framework[2].

This framework is not a weighted scoring tool, it is intended to guide the committee's deliberations and ensure robust discussion and decision making occurs. The framework comprises questions structured under 5 key principles, not in any particular order.

Effectiveness
Safety
Cost Effectiveness (and financial impact)
Equity of Access
Implementation Implications

It's acknowledged that some principles may be more or less relevant depending on the type and nature of the decision and the population group affected.

This framework will be available to applicants to provide them with background and context involved in the approval process of medicines for listing on the NSW Medicines Formulary.

[1] State of Queensland (Queensland Health), March 2021; QHMAC 5 Pillars Decision Support Tool v1
[2] Pharmac, September 2020; Factors for Consideration, accessed 8 August 2022, https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/policies-manuals-and-processes/factors-for-consideration/

| Effectiveness: Quality of evidence; Efficacy versus effectiveness | Comments for Committee |
|---|---|
| 1. What is the level of the evidence supporting this request? | |

| 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 pseudo-randomised controlled trials (III-1), from well-designed comparative studies with concurrent controls: non-randomised, experimental trial, or cohort, case control or interrupted time series studies (III-2), or from a comparative study without concurrent controls (III-3) |
| Level IV | Case series with either post-test or pre-test/post-test outcomes |

*Table 1.0 NHMRC Evidence Hierarchy: designations of 'levels of evidence' according to type of research*[3]

2. Is there evidence that the medicine provides a positive clinical outcome for patients? Are the endpoints clinical ones or surrogates?
3. Does the evidence provide a clear therapeutic advantage over existing medicines on the NSW Medicines Formulary or non-therapeutic options?
4. Is there a published treatment algorithm available for the management of the intended indication/medical condition? If so, where does the medicine sit in the treatment algorithm? (i.e. first line, second line etc)
5. Are the clinical trial designs that generated the evidence applicable to NSW populations?
   (*Are the trials funded by pharmaceutical companies? Is there evidence of bias in study design?)*
6. Are there differences in the population studied in the evidence compared to the patient population that the applicant wishes to use the medication for?
7. Can the efficacy demonstrated in clinical trials be easily replicated in the proposed clinical setting?
8. What is the number needed to treat or to harm?

[3] National Health and Medical Research Council, December 2009; NHMRC levels of evidence and grades for recommendations for developers of guidelines

Comments from NSW Medicines Formulary Committee

| Safety | Comments for Committee |
|---|---|
| 1. What are the safety related endpoints (adverse events) reported in the evidence? Are these predictable and manageable?<br>2. How does the safety of this medicine compare with existing medicines listed on the NSW Medicines Formulary?<br>3. What risks could arise with prescribing or administering the medicine in NSW Health facilities?<br>*(Is there a potential for look-alike, sound-alike medication (name or packaging) errors with this medicine? Will restrictions be required on who can prescribe and administer the medicine? Will there be a need for development of a prescribing guideline? Is the medicine considered a High-Risk Medicine?)* | |

Comments from NSW Medicines Formulary Committee

| Cost effectiveness (and financial impact) | Comments for Committee |
|---|---|
| 1. How does the unit cost compare with existing medicines listed on the NSW Medicines Formulary? Can increased costs be justified by efficacy and safety gains?<br>2. What is the cost to prevent one event? Can these benefits be quantified? *(ie health related costs; reduced length of stay, avoided surgery, reduced risk of hospital readmission)*<br>3. What are the hidden, health related costs (direct, or downstream) to consider at the facility level or for the health system more broadly? (e.g. *Additional nursing staff time or specialist equipment required*)<br>4. How will patients access the medicine outside of hospital?<br>*(Will the medicine be required for inpatient use, outpatient or both? Is the medicine PBS listed/S100 for the requested indication)*<br>5. Is there evidence that indications for this medicine could be expanded over time? What is the likelihood of leakage of prescribing to off-label indications?<br>6. Are there any environmental costs that need to be considered? Are there more sustainable (lower carbon/waste) alternatives?<br>7. Is the Medicine a High-Cost Medicine (HCM)?<br>*(≥$10,000 per patient per treatment course or per year; or ≥$100,000 for an individual hospital per year)*<br>If considering a High-Cost Medicine for listing on formulary by NMFC, a referral to the NSW High-cost Medicines Subcommittee for review is required prior to final review and approval. | |
| Comments from NSW Medicines Formulary Committee | |

| Equity of access | Comments for Committee |
|---|---|
| 1. Have paediatric and aged-care patients and other high-risk patient groups been considered?<br>2. Are there any implications for rural and remote communities or Aboriginal peoples?<br>3. Will smaller hospitals/facilities be able to continue with clinical care when patients return from larger centres? *(drug cost burden/ lack of specialist availability)* | |
| Comments from NSW Medicines Formulary Committee | |

| Implementation implications | Comments for Committee |
|---|---|
| 1. Are there issues in prescribing or administering the medication at the local level? What risk mitigation strategies need to be considered? (*Restrictions to specialties/drug specific protocols*)<br>2. Will there be a need to educate prescribers, pharmacy, nursing staff and patients about the medication? How will this be achieved and what impact will this have on resources?<br>3. Are there extra monitoring requirements for this medication and what costs are involved?<br>4. Are there pharmacy implications to consider? (*Storage/imprest/cold chain*)<br>5. If approved, are there similar medicines that can be deleted or need their indications amended on the NSW Medicines Formulary? | |
| Comments from NSW Medicines Formulary Committee | |

| Final Assessment |
| --- |
| 1. Is further information or evidence required?<br>2. Is there evidence that initiation of this medicine will improve health outcomes through demonstrated: Effectiveness, Safety, Cost Effectiveness and Equity of Access?<br>3. Should the medicine be added to the NSW Medicines Formulary for the requested indication?<br>4. If not for listing, what are the main factors in this decision? (This will need to be communicated back to applicant)<br>5. If yes, what restrictions/ additional comments are required?<br>6. Are there implementation requirements that need to be actioned?<br>7. Is the medicine an HCM, to be forwarded for review by NSW High-cost Medicines Subcommittee?<br>8. What is the recommendation for review date on the Formulary? |
| Comments from NSW Medicines Formulary Committee |