NSW Medicines Formulary Committee

Terms of Reference

April 2024

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

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Vision

To ensure optimum clinical governance that supports appropriate, safe, cost-effective, equitable and evidence-based medicine use across NSW.

Purpose

The NSW Medicines Formulary Committee (the Committee) is the peak governance committee for medicines and therapeutic agents initiated in inpatients within NSW public hospital and health services.

The Committee evaluates, approves and maintains the medicines included on the NSW Medicines Formulary (the Formulary).

Authority

The Committee is accountable to the Secretary, NSW Health through the Executive Sponsor (the Sponsor), being the Chief Executive, Clinical Excellence Commission.
The Sponsor empowers the Committee to:

- Operate without limitation of date.
- Deliberate on matters that affect NSW Health facilities and services.

The Committee will:

- Record recommendations made by majority in the meeting minutes.
- Note and record any urgent decisions that are managed as an out–of–session paper when authorised by the chair at the next Committee meeting.
- Refer any issues unable to be resolved by the Committee to the Sponsor (or nominated delegate) via the Chair.

Key responsibilities

The primary responsibilities of the NSW Medicines Formulary Committee are to:

- Ensure systematic, fair and transparent processes for adding, amending, removing and reviewing all medicines included in the NSW Medicines Formulary.
- Evaluate submissions for the addition or amendment of medicines on the Formulary in a considered and consistent approach, underpinned by evidence-based best practice and cost-effectiveness, and as outlined in the Policy Directive 2022_055 Approval Process for Medicines and Their Use.
- Ensure effective and timely decision-making and communication of all Formulary matters to Local Health District (LHD)/Speciality Health Network (SHN) Drug and Therapeutics Committees and other relevant medicines-related governance committees as required through the LHD/SHN Chief Executives.
- Consult with and take advice from the NSW High-Cost Medicines Subcommittee regarding submissions for high-cost medicines, or those that may pose significant financial risk to any facility within the LHDs/SHNs.
- Consult with expert advisory groups and committees, and other lead clinicians and experts where required.
- Recommend the development of state-wide clinical guidance, protocol or other educational resources to accompany Formulary medicines where required.

- Ensure all clinicians involved in the submission and assessment of applications for Formulary listings disclose any perceived or actual conflicts of interest. There must be full disclosure of any significant relationship (financial or otherwise) between the clinician and the supplier of the product or any other significant party.
- Review reports received of Individual Patient Use approvals and non-formulary medicine use within the LHDs/SHNs to determine if an evaluation is required.
- Recommend medicine use evaluations (MUEs) where required.

Decision making principles

The Committee's decision making principles and processes for Formulary submissions, restrictions, appeals, maintenance and scope are detailed here. The key considerations when evaluating medicines is outlined in the Formulary Submission Framework and decision algorithm (See Appendix 2).

Membership

The Committee membership will include multidisciplinary representatives across NSW health organisations. Members will have expertise in one or more areas of clinical specialty, pharmacy, clinical governance, executive leadership, medicines governance and/or safety.

Committee members must be NSW Health employees (except for the health economist).

Membership eligibility is determined by the Chair, in consultation with the Secretariat. Members are appointed by the Executive Sponsor (or nominated delegate) in consultation with the Chair. Confirmation of line manager/facility approval is required from the nominee prior to an offer of appointment.

Members will be selected based on their individual expertise, role, organisational affiliation and availability. All members will have expertise in, and a commitment to safe, cost-effective and quality use of medicines.

Core representation:

- Clinical pharmacologists
- Senior medical specialists, with expertise in one or more specialties
- Pharmacy (clinical and managerial)
- Chief Pharmacist of NSW (or delegate)
- Nursing (clinical and managerial)
- Director of Clinical Governance
- Director of Medical Services
- Chief Advisor and Program Lead, Medication Safety, Quality and Therapeutic Optimisation, Clinical Excellence Commission
- Director, Systems Improvement, Clinical Excellence Commission
- Health economist (as required)

Rural Representation

The core member positions will include individuals who work in rural or remote sites and can provide unique perspectives of rural settings in addition to their individual specialty expertise.

Appointment

The maximum term of appointment of members is two years, with a maximum of three reappointments.

Appointment terms are generally staggered to ensure business continuity as well as providing an opportunity for the Committee to gain additional skills, knowledge and insights from incoming members.

Chair

The Chair will be appointed by the Sponsor (or nominated delegate). This will be a practising Clinical Pharmacologist, with experience in Drug and Therapeutics Committees.

The maximum term of appointment of the Chair is two years, after which the appointment will be reviewed for continuation. There is no limit to the number of times the Chair may be reappointed, as long as each appointment is no longer than two years in duration.

A deputy Chair will be appointed from the membership by the Chair in consultation with the Sponsor (or nominated delegate). The duration for term of appointment will follow the same process as for the Chair.

If the Chair is absent from a meeting or vacates the chair at a meeting, the deputy Chair or (in that member's absence) an experienced member, who has been nominated by the Chair, may assume control of the meeting on a temporary basis (however all decisions would need to be ratified by the Chair out of session).

Member responsibilities

Responsibilities of Committee members are to:

1. Declare all perceived or potential conflicts of interest.
2. Consult with colleagues and relevant staff within their organisation/networks to inform the advice given to the Committee.
3. To advocate for the role of the Committee to colleagues and relevant staff within their organisation/networks and on the compliance with the state-wide formulary and its processes.
4. Identify and take action on allocated actions/tasks within agreed timeframes. All documents circulated for comment will include a response deadline.

Other participants

Additional experts may be invited to attend meetings, as required, to advise on areas where the Committee does not have sufficient expertise.

Where agreed by the Chair, other persons may participate in committee proceedings/activities where relevant to an agenda item. However, such persons do not assume membership or participate in any decision–making processes of the Committee.

Sub-committees

The NSW Medicines Formulary Committee may create relevant sub-committees or other subordinate bodies (including time limited working groups) as deemed necessary to assist the committee in discharging its responsibilities. Existing subcommittees are:

- the High-Cost Medicines Subcommittee (HCMS).

Secretariat

Secretariat support for the Committee will be provided by the Clinical Excellence Commission (CEC).

Responsibilities

The Secretariat will be responsible for:

- providing administrative support to the Committee, including meeting co-ordination, minute taking and distribution of relevant papers
- receiving and reviewing all Formulary submissions and liaising with referring DTCs and applicants
- providing additional information to Committee members to support medicines evaluations and assist in decision-making, where required
- undertaking regular environment scans (PBS updates, medicines shortages, discontinuations, safety notices, eTG updates etc)
- receiving reports to be tabled, including IPU application outcomes, use of non-Formulary medicines and medicine use evaluations (MUEs)
- maintaining a log of all Formulary and Committee decisions
- communicating Committee decisions and providing regular formulary updates to the LHDs via the CEs (requesting distribution to DTCs)
- maintaining clinical content of the Formulary online platform
- liaising closely with HealthShare NSW and the Procurement Reform Steering Committee
- liaising with eHealth Clinical Application Support where required
- co-ordinating appeals process as required.

Meeting Procedures

Frequency and Duration

The Committee will meet once a month for a duration of two hours. Meetings will be held virtually unless otherwise advised by the Secretariat.

Quorum

At any meeting of the Committee, a quorum will be attained when half plus one of the currently filled committee positions are in attendance. A quorum is required to conduct the business of the meeting.

If a quorum is not met, the following will occur:

- continuation of the meeting will be confirmed at the Chair's discretion
- if the meeting proceeds, all recommendations will be preliminary
- any preliminary recommendations will then proceed to seek an out-of-session quorum consensus.

Confidentiality

Members of the Committee may from time to time be in receipt of information that is regarded as 'commercial in confidence', clinically confidential or have privacy implications. Committee members, secretariat and observers are required to sign a *Confidentiality Undertaking* and acknowledge their responsibility to maintain confidentiality of all information that is not in the public domain.

Conflicts of interest

Committee members are required to complete a conflict-of-interest declaration form on an annual basis.

Committee members are required to declare any real, potential or perceived pecuniary or non-pecuniary conflicts of interests relating to an agenda item at the beginning of each meeting.

The Conflicts of Interest and Gifts and Benefits Policy Directive (PD2015_045) states a conflict of interest may occur where a staff member could be influenced or perceived to be influenced by a competing interest when carrying out their public duty. Competing interests may arise through personal or private interests, or through separate professional interests. If matters arise where there is an actual or perceived conflict of interest, they will be managed as per the policy directive and the NSW Health Code of Conduct.

Managing and Recording Conflict of Interest

Annual conflict of interest declaration forms will be recorded and reported to the Secretariat.

- Declaration of any actual, potential or perceived conflicts of interests will be discussed with the Chair to determine if any actions required.
- 'Declarations of interest' will be a standing item at the beginning of each Committee meeting to provide members the opportunity to declare any conflict of interest in relation to any item of agenda.
- Members cannot take part in any discussion of the Committee relating to the interest or issue and cannot vote on the matter. This would require the member to be absent from the meeting room when any discussion or vote is taking place and to not receive any relevant Committee papers. This is to be recorded in the Committee minutes.
- The meeting minutes are to reflect the nature of the conflict, whether it is a 'material' conflict, how the conflict is being managed in the public interest; and the times that a Committee member is absent from the meeting room due to the conflict.
- In an extreme case, this may require resignation by the member from the Committee.

Voting and decision making

During a meeting

All members/nominated approved proxies have one vote. Decisions will be passed by the majority of members/nominated approved proxies present. Where a quorum has not been reached, endorsement will occur through out-of-session vote, or at the next scheduled meeting.

The Chair may consider and propose an alternative recommendation to enable a clear majority vote from members where required.

Out-of-session Consultation and Decisions

Members may be requested to provide out-of-session review and endorsement of documents, and advice on specific matters. The need for out-of-session consultation and the timeframe for feedback will be made at the discretion of the Chair on a case-by-case basis, with consideration towards the nature and urgency of advice required. Requests for out-of-session review/endorsement will be put forward in writing (email is sufficient) by the Secretariat, on behalf of the Chair, with members providing written approval of the recommendation.

In circumstances that require urgent/rapid changes to Formulary listings (for example critical medicine shortages), the Chair, in consultation with the Sponsor (or nominated delegate), may approve out-of-session amendments to the Formulary. Out-of-session decisions made by the Chair will be included in the papers of the next Committee meeting for ratification.

Escalation

If a decision regarding a Formulary medicine cannot be reached, it will be escalated to the Sponsor (or nominated delegate).

Meeting papers

The agenda and meeting papers shall be distributed to members at least seven (7) days before the meeting date.

Apologies and Proxies

All members should advise the secretariat at least 5 days prior to the meeting if they will be an apology. If members nominate a proxy, that proxy must be equivalent in terms of expertise/credentials and be approved by the Chair prior to the meeting.

Due to the nature of the deliberations, proxies are generally discouraged. However, the use of a proxy may be necessary where a member expects a short-term absence from the Committee (e.g. annual leave). The proxy must complete the relevant conflict of interest declarations. A member who nominates a proxy is expected to brief the proxy about the Committee's roles and responsibilities. Proxies accepted by the Chair count towards the quorum for a meeting and are entitled to participate in Committee discussion and decision-making.

Reporting relationships

The Formulary governance structure is detailed in Appendix 1.

The Committee will report on its activities through the Sponsor, to the accountable Deputy Secretary and Secretary as required.

Committee Evaluation

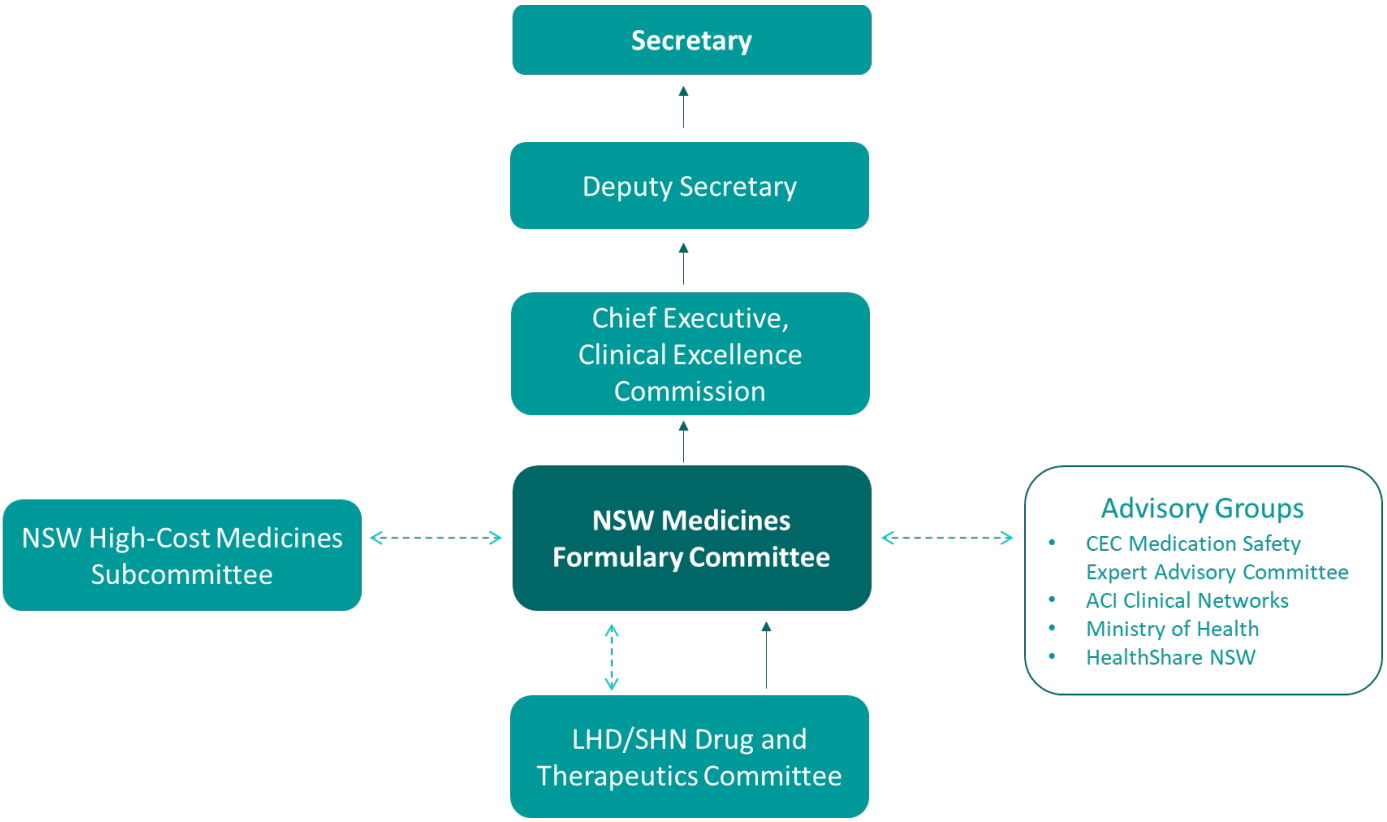
The Committee shall review its terms of reference, membership, and performance annually via a self-assessment process that may involve surveys and/or interviews with various stakeholders or parties involved with the Committee.

Member's meeting attendance will be reported annually. It is expected that members attend 75% of meetings each year. The evaluation will be provided to the Sponsor (or nominated delegate) via the Chair.

A discussion between the Chair and a member may be prompted where members attend less than 75% of meetings in a calendar year or have been absent for 3 or more meetings in a row without an apology.

Appendices

Appendix 1. Governance



Appendix 2. NMFC- Formulary submission decision algorithm