NSW Medicines Formulary Committee

Terms of Reference

October 2022

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

Table of Contents

Vision

To ensure optimum clinical governance and value in medicines use, and to improve patient outcomes across NSW Health through clinical consistency and equity of access to medicines.

Purpose

The NSW Medicines Formulary Committee (the Committee) is the peak governance committee for medicines and therapeutic agents. The Committee will oversee the establishment and maintenance of the NSW Medicines Formulary, to ensure appropriate, safe and cost-effective use of medicines within NSW Public Health Organisations and NSW Ambulance.

The definition of the NSW Medicines Formulary is *Medicines and other therapeutic agents*[1] *approved for use in NSW public hospitals and health services that includes (where appropriate) the approved indications, dose formulations and any prescribing restrictions.*' This state-wide approach supports quality use of medicines by ensuring safe, equitable and reliable access to necessary medications in NSW.

Authority

The Committee is accountable to the Secretary, NSW Health through the Executive Sponsor (the Sponsor) being the relevant Deputy Secretary at the Ministry of Health.
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 NSW Medicines Formulary 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:

- Implement systematic, fair and transparent processes for adding, amending, removing and reviewing all medicines included in the NSW Medicines Formulary.
- Evaluate medicines for formulary inclusion in a considered and consistent approach, underpinned by evidence-based best practice and cost-effectiveness, and as outlined in the Policy Directive 2016_033 *Approval Process of Medicines for Use in NSW Public Hospitals* (or the approved equivalent).
- 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.

[1] The terms 'medicines', 'medications' and 'therapeutic agents' include a drug, medicine, pharmaceutical preparation (including an extemporaneously compounded preparation), therapeutic substance, complementary and alternative medicine, vaccine, diagnostic agent for patient administration, medicated dressing, device containing a medicine and a fluid for intravenous use. Includes Scheduled medication and unscheduled medication.

- Ensure effective and timely decision-making and communication of all formulary matters to existing Local Health District (LHD)/Speciality Health Network (SHN) Drug and Therapeutics Committees and other relevant medicines-related governance committees as required through the LHD Chief Executives.
- Consult with and take advice from the NSW High-Cost Medicines Subcommittee regarding formulary submissions for high-cost medicines, or those that may pose significant financial risk to any facility within the LHDs/SHNs.
- 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 a formulary evaluation is required.
- Advise the formulary secretariat regarding the need for medicines use evaluations (MUEs) to inform the review of formulary medicines, where required.

Decision making principles

Formulary decision making should:

- follow a systematic, evidence-based evaluation process incorporating quality use of medicines (QUM) principles
- be made in a timely manner without compromising the quality of information and evaluation required
- have clearly defined and communicated processes for appeals and reconsideration of applications.

And consider the complexity of:

- the medicine, e.g., evidence of efficacy and safety, indications, TGA registration, dose, administration
- the health system, e.g., diversity of health services, clinical expertise available, inpatient/outpatient settings
- funding, e.g., PBS, hospital, Medicines Access Programs (MAPS), compassionate supply, self-funding
- equity, e.g., impact of this formulary decision on equity of access.

Medicines approvals should include:

- the active ingredient, strength(s), dosage form(s), indication(s) and any restrictions (e.g., by prescriber, by indication or duration of therapy) for medical and non-medical prescribers
- recommendations for specific monitoring, e.g., audits, MUEs, adverse events or medication incidents
- recommendation for accompanying protocol/guidelines (or changes to existing state-wide Policy Directives)

Evaluation of medicines should be guided by the agreed principles and a defined decision algorithm (See Appendix 2).

Ongoing formulary management should include a systematic review process for medicines placed on formulary. The review of medicines on formulary should include (but not limited to); medicine utilisation trends, evidence of inappropriate use or emergence of safety implications, new evidence, or changes in indication for use, emergence of newer agents that supersede current listings, or evidence for disinvestment.

Membership

The NSW Medicines Formulary Committee will be multi-disciplinary and comprise representation from clinicians, clinical governance, senior executives, and relevant state-wide advisory groups. The Committee will liaise with other NSW Health committees, state-wide clinical networks and other expert groups to seek advice, or to make recommendations on the use of medicines and the development of clinical guidelines.

Committee members must be NSW Health employees (with the exception of the health economist and consumer member positions). Membership eligibility is determined by the Chair, in consultation with the secretariat, and is based on individual expertise and commitment.

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 include medical practitioners and other health professionals with expertise in—and a commitment to safe, cost-effective and quality use of medicines.

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 provide an opportunity for the committee to gain additional skills, knowledge and insight from incoming members. Each year, approximately one-third of the membership will complete a term.

Members will be selected based on their individual expertise, role, or organisational affiliation. In addition, as required, experts will be invited to attend meetings to advise on areas where the Committee does not have sufficient expertise. Core representation will include:

- Clinical pharmacologists
- Senior medical specialists:
  - Infectious diseases
  - Paediatrics
  - Cardiology
  - Endocrinology
  - Oncology/Haematology
  - Geriatrics
  - Psychiatry/Mental Health
  - Nephrology
  - Respiratory
  - Anaesthetics/Perioperative Medicine
  - Neurology
  - Critical Care (e.g. ED, ICU)
- Pharmacy (clinical and managerial)
- Chief Pharmacist of NSW or a delegate
- Director, Systems Improvement, Clinical Excellence Commission

- 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
- Health economist (as required)
- GP VMO
- Consumer Representative x 2 (as required)

Consumer Representation

The Committee will engage and seek feedback from Consumer representatives to ensure diverse voices and perspectives are included in problem solving and decision making.
Consumer input may range from one off consultations to ongoing collaboration through Committee membership.

Rural Representation

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

Chair

The Chair will be appointed by the Ministry of Health Deputy Secretary. 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

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 participation 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 NSW Medicines Formulary Committee will be provided by the Clinical Excellence Commission (CEC).

Responsibilities

The secretariat will be responsible for:

- Providing administrative support to the formulary committee, including meeting co-ordination, minute taking and distribution of relevant papers.
- Receiving and reviewing all formulary submission applications 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 scan (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 medicines usage 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 Listed Approved Medicines (FLAMe).
- Liaising closely with the Strategic Procurement Services and the state-wide clinical procurement committee.
- Liaising with eHealth Clinical Application Support where required.
- Co-ordinating the formulary review process.
- 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 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 under the PD2015_045 and the NSW Health Code of Conduct.

Managing and Recording Conflict of Interest

1. '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.
2. Conflict of interest will be recorded and reported to the Secretariat.
3. 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.
4. 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.
5. 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.

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 decision for out-of-session consultation and timeframe for feedback will be made at the discretion of the Chair and will be determined on a case-by-case basis with consideration towards the nature and urgency of advice required.

Additionally, decisions can be made out-of-session by the committee. These decisions must be put forward in writing (email is sufficient) by the Chair or Deputy Chair, with members providing written approval of the position put forward.

Escalation

If a consensus or decision regarding a formulary medicine cannot be reached, the decision will be escalated to the Ministry of Health Deputy Secretary or 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 will be approved by the Chair.

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 and its 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

Formulary governance structure is in Appendix 1.

The Committee will provide reports on its activities as required to:

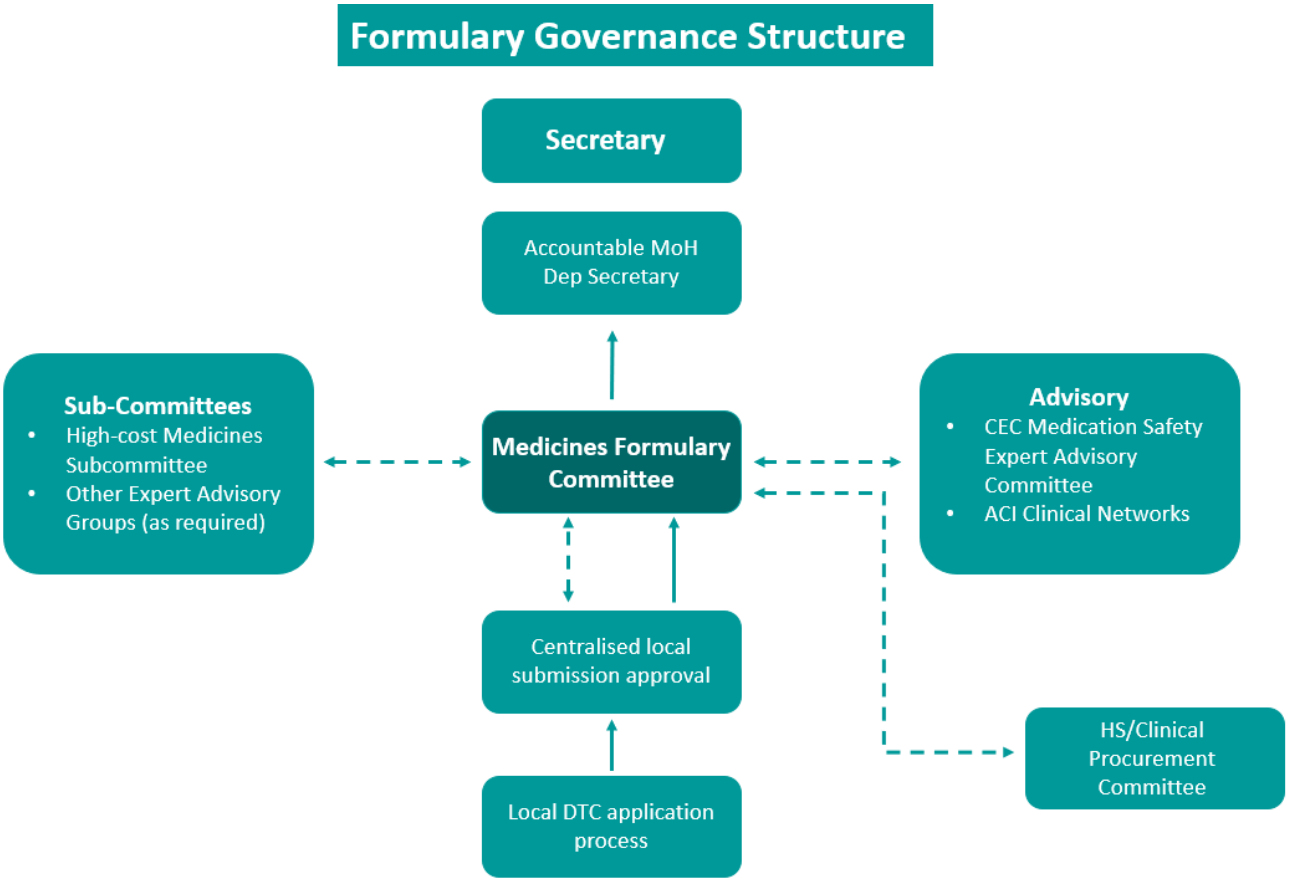
- Accountable Deputy Secretary

Committee Evaluation

The NSW Medicines Formulary 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 meeting attendance will be reported annually. It is expected that members attend 75% of meetings each year. The evaluation will be provided to the Deputy Secretary or nominated delegate via the Chair.

Appendices

Appendix 1. Governance



Appendix 2. NMFC- Formulary submission decision algorithm