CATAG
Council of Australian Therapeutic Advisory Groups

Achieving Effective Medicines Governance

GUIDING PRINCIPLES FOR THE ROLES AND RESPONSIBILITIES OF MEDICINES AND THERAPEUTICS COMMITTEES IN AUSTRALIAN HOSPITALS

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EXECUTIVE SUMMARY

Medicines and Therapeutics Committees (MTCs) are interdisciplinary committees with a commitment to medicines governance within their hospital, organisation, local area health service or state/territory. MTCs support judicious, safe, effective and cost-effective medicines use within health service organisations,[1, 2] and play a key role in implementing the **National Medicines Policy**. These committees are also vital in supporting health service organisations to meet the **National Safety and Quality Health Service Standards**.[2, 3]

The Council of Australian Therapeutic Advisory Groups (CATAG) originally produced this guidance document in 2013, updating it in 2025 to build on this earlier work. These updated Guiding Principles address the importance of clearly defining the scope and functions of MTCs and providing advice for the structure, processes, communications and resourcing required for successful medicines governance in 2025 and beyond.

While the naming of MTCs has changed over time (see **Background**), these committees have been a core component of medicines governance in Australia for more than four decades.3 Despite this long history, the potential scope of MTC roles and responsibilities continues to shift with the emergence of new health technologies, changing patient care settings, and innovative treatment modalities. This guidance document has therefore been updated to support MTCs to continue to fulfil their important medicines governance role within a constantly evolving healthcare environment.

To achieve effective medicines governance, it is important that MTCs are recognised within the governance structure of their health service organisation as a key organisational committee, and that they are resourced appropriately to fulfil their important role. These actions will enable proactive medicines governance, while also allowing capacity for the MTC to react to changes in the healthcare landscape as they develop.

These Guiding Principles should be considered in conjunction with other resources for MTCs (or equivalent committees) and decision-making tools such as the following CATAG documents:

- **Rethinking medicines decision-making in Australian Hospitals**
  Guiding Principles to support the quality use of off-label medicines.
- **Managing Medicines Access Programs**
  Guiding Principles for the governance of Medicines Access Programs (MAP).
- **Biologics and biosimilars best practice**
  Guiding Principles that provide a national approach to the governance of biologics and their biosimilars.
- **Navigating high-cost medicines**
  Guiding Principles to support MTCs assess and make good decisions about the quality use of high-cost medicines.
- **Managing medication samples**
  Guiding Principles on using medication samples in Australian public hospitals.
- **Getting it Right for Medicines Stewardship** Guiding Principles for Medicines Stewardship Programs.
- **Position statement for the use of complementary and alternative medicines**.

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OVERVIEW

PURPOSE

These Guiding Principles outline a framework for each Medicines and Therapeutics Committee (MTC) to achieve effective medicines governance within their organisation. The guiding principles provide advice for the roles, responsibilities, operation and evaluation of the MTCs that provide medicines governance for Australian hospitals. These nationally endorsed guiding principles promote inter-jurisdictional consistency in the approach to medicines governance and support the aims of the **National Medicines Policy**.

Implementation of these guiding principles will assist health service organisations in meeting their medicines governance requirements as outlined in the National Safety and Quality Health Service (NSQHS) Standards.[1] For MTCs with a remit that includes areas outside of acute care, adoption of these guiding principles may also assist with accreditation against other standards such as the National Safety and Quality Primary and Community Healthcare Standards.[4]

BACKGROUND

The NSQHS Standards require health service organisations to have governance arrangements in place to support the safe and quality use of medicines (QUM), including an expectation for health service organisations to have a governance group with responsibility for medicines (such as an MTC or equivalent), with formal reporting lines to the organisation's clinical governance committee or management.[1] For more than four decades, MTCs have performed this role in Australian hospitals and have been important contributors to QUM and promotion of best practice.[3]

MTCs play a major role in delivering the aims of the National Medicines Policy through supporting:

- → equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines and medicines-related services
- → safe, optimal and judicious use of medicines with a focus on informed choice and well-coordinated person-centred care
- → a positive and sustainable medicines related policy environment.[2]

An MTC may also be known by other titles including:

- → Medicines Advisory Committee
- → Pharmacy and Therapeutics Committee
- → Drug and Therapeutics Committee
- → Medicines Management Committee
- → Medication Safety Committee
- → Quality Use of Medicines Committee.

In some organisations the MTC may coexist with other committees known by these names, as part of an overarching medicines governance structure.

VISION

An MTC is an interdisciplinary committee, dedicated to the overall governance of medicines, supporting the judicious, appropriate, safe, effective and cost-effective use of medicines within their health service organisation.

GUIDING PRINCIPLES FOR THE ROLES AND RESPONSIBILITIES OF MEDICINES AND THERAPEUTICS COMMITTEES IN AUSTRALIAN HOSPITALS

SCOPE

These guiding principles apply to MTCs that provide medicines governance for Australian public and/or private hospitals. The committee's scope may be hospital, district, network, region, or state/territory wide. These guiding principles are applicable to all organisations and individuals involved in delivering robust governance of medicines use in health service organisations including:

- → MTC chairs and members (including consumer representatives)
- → those responsible for corporate and clinical governance of a health service organisation or network
- → health service executive and MTC executive sponsors
- → those leading NSQHS Standards implementation
- → local, area and state/territory quality and safety committees
- → clinicians involved in medication management.

These guiding principles support the establishment of new MTCs and provide a framework against which an established MTC may review their practice. The guiding principles are intentionally broad in nature to encompass the diverse practices of MTCs with different medicines governance responsibilities.

These guiding principles are strongly recommended for all MTCs, however not all principles will apply equally to every committee. The degree to which an individual MTC follows each guiding principle will depend on the scope of the MTC and the size of the organisation that it services. Whether the MTC is new or well established may also impact how individual guiding principles are implemented. For example, a newly established MTC may need to prioritise a selection of these guiding principles while establishing their functions and processes.

For the purpose of this document, it is assumed that an organisation's MTC has primary responsibility for all aspects of medicines governance. However, the Council of Australian Therapeutic Advisory Groups (CATAG) acknowledges that, in many cases, some functions will be delegated to other medicines governance committees within the organisation, region, network or state/territory. In organisations where this is the case, these guiding principles may need to be considered within the context of all relevant committees' work, to determine whether the organisation meets these guiding principles across the work and scope of all its relevant committees.

GUIDING PRINCIPLES

PURPOSE, FUNCTION AND STRUCTURE

Guiding principle 1
MTCs provide governance and oversight of medicines-related systems within a hospital, local health district/network or state/territory.

Guiding principle 2
The MTC's place within the organisation's governance structure is clear and supports the scope and functions of the committee.

Guiding principle 3
MTCs consider the local governance environment when defining their scope and functions.

Guiding principle 4
MTCs have clear terms of reference that articulate their role, processes and position within the organisation's clinical and corporate governance structure.

Guiding principle 5
MTCs are interdisciplinary, including members with a range of expertise and skills to reflect the functions of the MTC.

PROCESSES

Guiding principle 6
MTCs define and implement standardised procedures and criteria for decision-making.

Guiding principle 7
MTCs implement transparent and ethically robust processes.

Guiding principle 8
MTCs are both proactive in medicines governance and responsive to issues arising.

Guiding principle 9
MTCs undertake risk assessments within the health service organisation with respect to medicines use and recommend strategies to mitigate identified risks.

Guiding principle 10
MTCs identify quality improvement initiatives and assign priority, responsibility and time frames for completion of these.

Guiding principle 11
MTCs use monitoring systems to evaluate their effectiveness.

DOCUMENTATION AND COMMUNICATION

Guiding principle 12
MTCs employ timely and accurate documentation and communication strategies.

Guiding principle 13
MTCs engage with internal and external stakeholders to strengthen medicines governance and promote quality use of medicines.

RESOURCING

Guiding principle 14
MTCs are supported and adequately resourced to undertake their functions and responsibilities by the hospital, local health district/network or state/territory that they service.

GUIDING PRINCIPLES

PURPOSE, FUNCTIONS, AND STRUCTURE

This section will help MTCs to define their **Purpose**, outline their **Functions**, and align their **Structure** with their medicines governance responsibilities.

GUIDING PRINCIPLE 1

MTCs provide governance and oversight of medicines-related systems within a hospital, local health district/network or state/territory.

All health service organisations should have access to the advice and services of an MTC, whether the MTC is at a hospital, health district/network or state/territory level. To support the governance role of the MTC, each health service organisation should have clear and documented responsibilities for the implementation of MTC decisions and advice, including any obligations of health service staff to comply with MTC direction.

To provide effective oversight and governance, MTCs require visibility of all medicine-related systems within the health service. In addition to the processes of medication management (prescribing, dispensing, administration etc),[5] MTCs also require visibility of areas such as:

- staff expertise, credentialling and scope of practice
- content and staff completion rates of medicines-related training
- policy documents that include any medicines
- medication safety incident/adverse event reporting
- medicines shortages and recall management
- pharmaceutical procurement and medicines supply.

As the committee with primary responsibility for medicines governance, the MTC requires visibility of all changes within the organisation that relate to medicines. While a project or matter may fall outside of the defined scope of the MTC, where the matter involves medicines, it is critical that the MTC has early involvement in the planning stage so that risks can be identified, and advice provided before irreversible decisions are actioned. This may include such diverse areas as waste management, electronic clinical systems, or construction projects affecting medicines storage areas.

GUIDING PRINCIPLE 2

The MTC's place within the organisation's governance structure is clear and supports the scope and functions of the committee.

The MTC's position should be articulated in the organisation's governance structure, with reporting lines that include executive-level committees or staff, or the organisation's clinical governance lead. These reporting structures should be clearly articulated in the MTC's terms of reference (see **Guiding principle 4**).

Ideally MTC reporting lines will enable:

- accountability to the organisation's executive and/or board of management
- regular interaction between the MTC and both the organisation's executive/board of management and the finance/budget committees
- provision of expert advice regarding medication management for higher-level committees and/or the organisation's executive/board of management
- escalation pathways for unresolved risks, appeals (if necessary), or out-of-scope decisions
- multi-directional communication with organisational executive members or committees, peer committees and subcommittees
- assignment of responsibility for implementing MTC recommendations through appropriate management structures
- delegation of responsibilities to, and reporting from, any MTC subcommittees.

A collaborative approach with the health service executive is necessary to ensure the MTC's delegated authority, resourcing and capabilities align with its expected functions. Failure to ensure this alignment may lead to unmanaged risks regarding medication management within the health service.

GUIDING PRINCIPLE 3

MTCs consider the local governance environment when defining their scope and functions.

Health service organisations have an obligation to provide appropriate governance of all aspects of medication management. MTCs have a key role in providing this governance, however an MTC's scope may include only certain aspects of medication management within their organisation. Each MTC, therefore, needs to define (and communicate to health service staff) its scope of responsibility regarding medicines governance. This should include factors such as:

- geographical or organisational limits regarding which hospitals and/or services are within the MTC's governance
- therapies governed by the MTC and those outside its scope (see Appendix 2 for examples)
- financial limits (both upper and lower) for decisions made by the MTC in accordance with any financial authority delegated by the organisation
- any authority to delegate work to health service staff, e.g. the implementation of policies/procedures, audit/monitoring of medicines-related systems.

With their scope of work defined, MTCs should work collaboratively with the executive and/or board of management so that:

- Medicines governance areas that are outside of the scope of the MTC are appropriately governed by other committees (see **Sections 4 and 5** in **Appendix 2**).
- The MTC has appropriate delegated authority, capacity, expertise and resourcing to provide timely and effective governance for the aspects of medication management that are within its designated scope.
- The MTC prioritises activities according to local need, the identified level of risk and the strategic priorities of the organisation.
- Where the scope of the MTC is expanded, this is done in conjunction with increased resourcing to allow appropriate management of new responsibilities, while continuing to manage the committee's existing governance responsibilities.

↳ ASSOCIATED COMMITTEES

To fulfil its functions, an MTC may be a stand-alone committee, may have multiple subcommittees, or be part of a wider medicines governance structure for the organisation. Where more than one committee is responsible for medicines governance, the scope of each committee should be clearly defined within the terms of reference documents, including role delineation and relationships to other medicines governance committees where relevant.

Where multiple committees are contributing to medicines governance for the organisation, the MTC requires clear communication lines with these other committees. This is especially relevant where the other committees are not MTC subcommittees. Cross-representation of one or more MTC members on the other committee(s), minute sharing, or other communication pathways should be considered to facilitate this communication. This may also be relevant for:

- committees that manage products used with medicines (e.g. clinical equipment, electronic medication management software, new health technologies, blood products)
- clinical trials and human research ethics committees
- medication safety or adverse drug reaction committees
- NSQHS accreditation standards committees and policy review committees
- stewardship committees (e.g. antimicrobials, analgesics).

GUIDING PRINCIPLE 4

MTCs have clear terms of reference that articulate their role, processes and position within the organisation's clinical and corporate governance structure.

Documented terms of reference (TOR) are essential for outlining the committee's role and functions. The TOR should articulate the authority delegated to the committee by the organisation, the MTC's mission or purpose, and its place within the organisation's clinical and corporate governance structure. The TOR should outline the committee's responsibilities, scope and membership (including member responsibilities) and document committee processes such as how meetings are run and how communication is managed. Detailed advice regarding content is provided in **Appendix 2** to guide MTCs in creating or reviewing their own TOR.

The MTC's TOR should be available to staff who may submit items to the MTC for consideration and/or be impacted by MTC decisions. The TOR should include details about how the committee's performance will be monitored and where performance measures will be reported to (see also **Guiding principle 11**). The TOR should be reviewed regularly (ideally annually, but at least once every two years), with the timeframe, process and approval pathway for these reviews documented in the TOR.

GUIDING PRINCIPLE 5

MTCs are interdisciplinary, including members with a range of expertise and skills to reflect the functions of the MTC.

The work of the MTC is interdisciplinary, with members of diverse specialist skill sets collaborating to provide the best possible outcomes. MTC membership should reflect the committee's scope, function and accountability within the organisation, taking into consideration the local patient case mix and the range of services provided by the health service organisation. MTC membership categories that may be applicable are outlined in **Appendix 2**.

MTC membership has core representation from medical, nursing and pharmacy and should also include an executive (representing the hospital administration and/or finance) or a clinical governance delegate.[6] The majority of members should be experienced clinicians who can consider the broader healthcare environment in the MTC's decision-making. The MTC may also include junior clinical staff to provide insight into issues at an operational level. All clinician members, regardless of experience level, are expected to promote the MTC mission among their peers.

Each MTC is led by a nominated chair with appropriate expertise and a professional interest in medicines governance. The chair needs to be supported by the organisation to have adequate time to devote to the position, and be supported with dedicated secretarial support, adequate to allow optimal and efficient functioning of the committee.

Consumer representatives or patient advocates should be included in the membership of the MTC and associated subcommittees to include the person-centred perspective in all the committee's decisions. This aligns with the expectations of the NSQHS Standards for health service organisations to partner with consumers in their care.[1] Even when consumer representatives are included in the membership, MTCs should consider other ways that the consumer voice can be incorporated into decision-making. Use of various engagement methods (such as consumer surveys, focus groups and consultation hubs) can provide a more diverse consumer perspective and can support MTC consumer representatives in advocating for the wider healthcare consumer group.

For some meetings, it may be appropriate to invite additional specialists or experts to assist in deliberations. It is recommended that MTCs identify and establish connections with specialists or experts through their health service, district/state/national healthcare systems and/or the MTC network (e.g. through CATAG). These specialists may be invited to attend specific meetings or provide out-of-session advice as required (see also **Guiding principle 13**).

↳ MEMBER SKILLS AND INDUCTION

All MTC members should be equipped with the necessary knowledge and skills to facilitate the effective function of the MTC and achievement of its purpose. Clinician members of the MTC should have a robust understanding of evidence-based medicine, critical appraisal skills, pharmacoeconomics, and the ability to understand and balance financial and clinical pressures. Specific clinical, therapeutics, QUM and evidence evaluation expertise will also be routinely required. MTC-specific training for members will be required in most cases.

All new members of the MTC should be provided with an induction that includes education on:

- → committee processes and function
- → the processes and principles involved in MTC decision-making (e.g. evidence, safety, quality, cost-effectiveness, equity, affordability)
- → a copy of the TOR
- → member responsibilities and expectations
- → conflict of interest declaration and management (see also **Guiding principle 7** and **Conflicts of Interest**).

To make decisions that support culturally safe care, the MTC needs to understand the cultural mix of the community that the health service supports. MTC members need to acknowledge personal and system biases, including racism, sexism, assumptions, stereotypes and prejudices, and take steps to minimise the impact of these on their decision-making. Where cultural safety training is not already incorporated into organisation-wide mandatory training for all MTC members, this should be provided.

It is critical that all members receive adequate onboarding to allow effective participation in the MTC. As a group populated predominantly by health professionals, MTCs need to be especially conscious of the training and induction needs of consumer representative members. These needs will be different to those of clinician members, and additional resources may be required to appropriately support consumer representative members (see **Consumer representative training**).

↳ ONGOING TRAINING

MTCs should assess the need for ongoing member education and training. The organisation, in partnership with the MTC, should provide support to meet ongoing training needs. This includes addressing any specific training needs for consumer representatives/ patient advocates. Education and training areas to consider for MTC members include topics such as:

- → clinical governance
- → conduct of meetings
- → operation of the Australian medicines governance and health finance systems including the National Medicines Policy and National Health Reform Agreements
- → medication safety
- → QUM principles such as evidence-based medicine
- → accreditation processes
- → pharmacoeconomics
- → critical evaluation and review of literature
- → cultural competence
- → quality improvement methodology.

See **MTC resources** for examples of training packages.

↳ CONSUMER REPRESENTATIVE TRAINING

Consumer engagement can help improve the delivery of health services, the experience for individuals, and health outcomes.[7, 8] At all levels (front-line care provision to a policy/system level), partnering with consumers is a critical element of delivering person-centred care. Not only does this bring benefits for individuals, it improves workforce satisfaction and can lower the overall cost of care.[7]

To engage meaningfully with MTC discussions, consumer representatives will need training in areas such as MTC processes and QUM principles. In most instances their training needs will be different to clinician members. MTCs need to be adequately resourced to facilitate consumer-focused training for their consumer representatives. **MTC member training examples** in the resources section include some consumer-specific training examples.

Adequate clinician resourcing will also be required to provide support to consumer representatives, to allow them to participate fully in MTC discussions. This might, for example, include pre-meeting briefings for background on new concepts. Clinicians supporting consumer representatives will need to engage with the consumer members to clearly understand and support the training and information needs of the individual. These clinician members may require training on consumer engagement to perform this role effectively.

GUIDING PRINCIPLES

PROCESSES

This section provides broad direction on MTC **Processes** for decision-making and effective medicines governance.

GUIDING PRINCIPLE 6

MTCs define and implement standardised procedures and criteria for decision-making.

Standardised procedures for decision-making should be defined and implemented consistently across MTC decisions to facilitate fair process. Any deviation from the standard decision-making process needs to be clearly documented with reasoning (e.g. in meeting minutes) and communicated to the applicant when appropriate.

Principles, criteria or frameworks for decision-making should be made available to all health service staff within the organisation who may submit items for consideration by the MTC, or who may be required to implement MTC decisions. How applications are assessed, how policies/protocols are reviewed and endorsed etc should be clearly defined. If thresholds for approval have been set by the MTC (e.g. minimum evidence requirements for different application types, cost-effectiveness thresholds, required templates and consultation pathways for policy documents) then these should also be shared with health service staff.

For appropriate decision-making, MTCs require accurate and complete information relating to the decision being made. MTCs need to clearly articulate to health service staff the information and/or applications that are to be submitted to the MTC. This includes any endorsements required prior to submission (e.g. budgetary endorsement by a staff member with the relevant financial delegation, review of protocol documents by specific clinical roles). This information and associated endorsements should be captured in standardised forms wherever possible (see **MTC resources** for examples of application forms).

Health service staff members who may submit items to the MTC should be made aware of deadlines for document submission for MTC consideration, the format and method for submitting these documents, and which role is responsible for making each type of submission. Staff members should also be informed of the timeframe for making decisions of various types. This time should be as short as reasonably practical to allow efficient assessment of submissions and timely decision-making, without compromising the quality of the MTC's assessment and evaluation process.

MTCs should have a formal pathway to request reassessment of unsuccessful requests and/or a formal appeal process for MTC decisions (unless the MTC is advisory only).

↳ MEDICINES ACCESS DECISIONS

Where MTCs provide governance for medicines access, all applications (both formulary and individual patient usage [IPU] / individual patient approval [IPA] decisions) should be evaluated against defined criteria, with decisions made according to the best available evidence.

Considerations for IPU/IPA and formulary medicines access may include:

- the clinical effectiveness of the medicine for the specific indication and population, based on published evidence
- the safety of the medicine, including any additional risks associated with the overall treatment plan, e.g. from additional medicines needed to manage treatment side effects
- purchasing for safety with respect to aspects such as packaging and labelling
- patient safety risks such as the potential for medication errors (e.g. with an unfamiliar product)
- the place in therapy of the medicine, alternate treatment options, and the relative cost-effectiveness of each (including ancillary costs such as monitoring)
- affordability of the decision for the organisation, including any anticipated changes such as the end of an access program, or a pending Pharmaceutical Benefits Advisory Committee (PBAC) review (budget approval may also be required)
- continuity of care considerations including:
  - expected reliability of supply (e.g. Australian registered product versus imported Special Access Scheme supply)
  - ongoing medicines access (e.g. access to the medicine after discharge, including consideration of affordability)
  - ongoing access to administration services or other necessary supports for medicine use.
- impacts in the wider context (e.g. staff training requirements, work health and safety risks, antimicrobial resistance concerns, equity, medico-legal risks)
- the need to monitor for efficacy, safety and adverse events
- environmental sustainability of the medicine across its lifespan including production, transport and disposal
- whether there are any additional consent requirements (e.g. for Special Access Scheme medicines or off-label use)
- additional requirements for high-cost medicine applications (refer to the: **Navigating high-cost medicines: Guiding Principles for the governance of high cost medicines in Australian hospitals**)
- additional requirements for considering off-label indications (refer to the: **Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines**)
- requirements for considering treatments available through a compassionate supply agreement or Medicines Access Program (refer to: **Managing Medicines Access Programs: Guiding principles for the governance of Medicines Access Programs in Australian hospitals**).

At the time of approval, the MTC should specify any conditions, monitoring, or outcome evaluation required, and a time period for review of the medicines access approval. When the approval is contingent on achieving specific outcomes, this should be clearly defined by the MTC and outlined in the approval notification to the applicant. This should also include, where relevant, the course of action to be taken if those outcomes are not achieved.

For efficiency, MTCs should look to incorporate information already collated by other reliable sources to aid in the review of medicines access requests. This may include health technology assessments published by groups such as PBAC or the UK's National Institute for Health and Care Excellence (NICE), noting that local context and currently available pricing will need to be applied to these assessments.

Where available, the MTC should consider decisions made by their statewide/organisation-wide formulary committee. These decisions should be adhered to unless there are compelling local or individual circumstances, or important new information has become available since the state/organisation-wide decision was made. If this occurs, MTCs should communicate this information with the state/organisation-wide formulary committee so it can be considered in a future review of the medicine at a state/organisation-wide level.

CATAG recommends that a method for sharing assessments and outcome data nationwide be established (see **Guiding principle 13** for further information).

↳ FORMULARY DECISIONS

The purpose of maintaining a formulary is to support the judicious, safe, clinically appropriate and cost-effective use of medicines across a defined indication or patient group.[9] Formulary decisions need to consider the factors outlined above for all **medicines access decisions**, and may also need to consider the appropriateness of prescription/initiation by non-medical prescribers (e.g. nurse practitioners, podiatric surgeons).

Standardised processes for ongoing formulary management are required for:

- → reviewing requests for the addition of new medicines to the formulary, including who performs the review
- → reviewing formulary-listed medicines for deletion, or modification of the indications/restrictions
- → monitoring medicines usage following additions to formulary such as audits, outcome evaluation, and monitoring adverse events or medication safety incidents
- → communicating formulary changes to all relevant clinicians and other stakeholders.

Even when an MTC does not have formulary management responsibilities, most will still have a role in this governance through actions such as:

- → sharing IPU/IPA outcome data with the committee responsible for formulary management
- → facilitating formulary applications from within their organisation
- → promoting compliance with formulary restrictions among local clinicians.

Examples of formulary application documents and resources to assist in evaluating applications are found in the **MTC resources** section.

↳ INDIVIDUAL PATIENT USE APPLICATIONS

Application for individual patient use of a medicine is required when a therapeutic need exists for a medicine/indication that is not available on the formulary. These applications or medicines may be known as Individual Patient Use (IPU) or Individual Patient Approval (IPA). **Examples of IPU/IPA application forms** can be found in the resources section.

Like formulary decisions, IPU/IPA decisions need to address the same considerations outlined above for all **medicines access decisions**. IPU/IPA decisions, however, may allow for the extenuating circumstances of the individual to be considered. MTCs require a standardised approach to the IPU/IPA decision-making process, including when, how and what types of extenuating circumstances are included in the MTC decision-making process. These decisions can be complex, and MTCs may benefit from the use of a decision-making support tool which incorporates individual circumstances, approval thresholds and other considerations for consistent decision-making. MTCs also need to consider whether a patient's preference is considered in IPU/IPA decisions, and if so, when and how this is incorporated into the decision-making process.

MTCs should have a clear process to determine when an IPU/IPA-requested treatment should be evaluated for addition to the formulary. When the MTC has received multiple IPU/IPA requests for the same indication and there is robust evidence to support the treatment, the medicine and indication should be referred for formulary review. Likewise, if there have been repeated IPU/IPA requests for a treatment that lacks evidence to support its use, targeted efforts may be required to support evidence-based practice and QUM in the relevant area.

MTCs should have a documented process for the assessment of urgent IPU/IPA applications between meetings, including delegated authority to make urgent decisions (e.g. out of hours) and minimum information requirements for urgent applications. All approvals granted for IPU/IPA between MTC meetings should be reported to, and reviewed by, the MTC (preferably at the next meeting) to provide opportunity for discussion, and appropriate documentation in the MTC's records of the application and decision. A process to prevent urgent decisions from setting an inappropriate precedent should also be considered.

MTCs need to keep a complete and easily searchable record of IPU/IPA decisions. This will assist in efficient and consistent decision-making and allow monitoring and appropriate referral for formulary review if there is regular usage. Electronic solutions that support MTCs with processing and documenting IPUs/IPAs are available, including use of a health service's existing IT systems/software, generic database software, or software developed specifically for IPU/IPA management. Use of such systems is recommended for efficiency of data recall and reporting, supporting consistency in decision-making.

↳ POLICY/PROTOCOL REVIEW AND ENDORSEMENT

Where MTCs are responsible for the approval or endorsement of medicine related policy, protocol and/or guidelines, standardised committee processes are required. Unless clear guidance is already provided at an organisation level, MTCs need to define, and communicate with relevant health service staff:

- → the scope of policy/protocol documents that can/will be considered by the MTC
- → the format/template that is to be used for each document type
- → document consultation that must occur prior to submission to the MTC for approval/ endorsement and how that consultation is to be documented/communicated to the MTC
- → any document endorsements required prior to submission (e.g. sign-off by specific senior clinical staff)
- → how the MTC will review submitted documents and what criteria must be met for MTC approval/ endorsement of the document
- → how decisions will be communicated to applicants, especially where a document is not approved/not endorsed, or where changes are required to the document prior to approval/endorsement.

↳ ENVIRONMENTAL SUSTAINABILITY

Concerns about the environmental impact of health care, climate change and the consequences of environmental changes for health worldwide, are impacting health policy decision-making.10 There are ongoing efforts to curtail the routine use of clinical procedures and technologies that emit disproportionate amounts of greenhouse gases, when equally effective or superior clinical alternatives are available. As part of this, MTCs need to consider the environmental sustainability of their decisions. This will be especially relevant when considering medicines access applications, but also applies to other areas that may fall within the MTC's scope, such as pharmaceutical waste management policy, or medicines procurement/contracting.

While resourcing is unlikely to be adequate to allow for the proactive environmental review of whole formularies, MTCs should be aware of publications within this space and respond accordingly. For example, in 2025, CATAG published a position statement on the formulary listing of desflurane, a volatile hydrofluorocarbon anaesthetic agent with a significantly greater effect as a greenhouse gas than clinically equivalent alternatives.11 This position statement encourages MTCs to exclude desflurane from hospital formularies, with a managed plan for removal or exceptional circumstances use when necessary.[11]

GUIDING PRINCIPLE 7

MTCs implement transparent and ethically robust processes.

MTCs provide advice (and in some cases directive decisions) that can have significant impacts within a health service organisation, including financial and patient-care impacts. Decision-making must therefore be standardised, transparent and ethically robust.

For consistent, ethically defensible decision-making, MTCs should:

- Facilitate access to medicines where appropriate, according to due process.
- Manage conflicts of interest to avoid any influence on decision-making.
- Promote equity of access (as distinct from equal access) by considering valid claims for special or differential treatment based on: social or economic vulnerability; barriers to accessing care; or for those at particular risk of poor health outcomes.
- Consciously consider long-term budget and resource sustainability to allow consistent decision-making for subsequent applications.
- Consider opportunity cost, and the appropriateness of allocating resources to medicine use as opposed to other areas of healthcare delivery.

Confidentiality and other MTC member expectations need to be clearly articulated and well understood by members. If not already clearly defined in the TOR, a separate Code of Conduct may be considered for this and other relevant areas such as conflicts of interest, expected standards of meeting behaviour, and member contributions to the work of the committee.

↳ CONFLICTS OF INTEREST

MTCs should have clear processes for declaring, documenting and managing conflicts of interest, including documentation of the processes and/or the member role(s) responsible for this. MTCs need to consider any conflict of interest that may materially impact, or may be perceived to impact, a member's decision-making, as well as any interaction of the MTC or its members with the pharmaceutical industry. Where an MTC considers applications for decision-making, conflicts of interest for applicants will also need to be considered and managed.

A conflict of interest can arise wherever there are conflicting motives between a professional obligation and either a personal interest or competing professional obligation. This includes both financial and non-financial conflicts. They may be actual, potential or perceived conflicts. Examples may include:

- gifts, benefits or payments received from a pharmaceutical company, including hospitality, education or paid work providing medical education to peers
- a financial interest (e.g. holding shares) in a pharmaceutical company
- deeply held values that relate to medical care, be these based in religion or not
- a close personal relationship with a person who will be impacted by the MTC's decision (e.g. a spouse who may benefit from a formulary decision)
- a professional relationship with the applicant where there is a power imbalance that may impact the MTC member's ability to be impartial.

MTCs require both a routine declaration process (e.g. annual conflict of interest declaration) and an avenue for new conflicts to be declared and managed as they arise (e.g. in relation to a specific agenda item).

The confidentiality of applicants' and members' declared conflicts need to be carefully considered. Declared conflicts of interest may include potentially sensitive information. MTCs will therefore require pathways to appropriately manage declared conflicts while maintaining the individual's right to privacy.

Unless an applicable organisation-wide document covers applicants and all members of the MTC, the MTC will require its own published policy position on interaction with the pharmaceutical industry. This makes clear to members, and the wider health service organisation, what is considered unacceptable regarding interactions between MTC members/applicants and the pharmaceutical industry.

↳ CONFIDENTIALITY

Clear guidance is required for committee members regarding confidentiality in any circumstances where the need for confidentiality is either not clearly defined in organisation-wide policy for MTC-specific circumstances, or where MTC confidentiality exceeds the organisation-wide requirements. This guidance may include aspects such as:

- → maintaining patient anonymity in committee discussions of applications relating to individuals
- → protection of commercial-in-confidence information
- → disclosure of committee decisions only through committee-managed channels
- → confidentiality of declared conflicts of interest, both submitted privately to the chair and disclosed openly within the meeting.

GUIDING PRINCIPLE 8

MTCs are both proactive in medicines governance and responsive to issues arising.

MTCs proactively set and manage the agenda for medicines governance within their health service organisation. MTCs should also be agile, responding to new issues within the medicines governance sphere as they arise. New issues may emerge from: newly marketed therapies; a newly identified safety risk; medicines shortages or recalls; or other dynamic changes in the medicines environment of the health service organisation.

To assist with proactive medicines governance, MTCs should undertake horizon scanning (locally, nationally and internationally) to anticipate issues that will impact the health service organisation. The ability of an MTC to do this successfully will be heavily dependent on available resourcing. For efficiency, MTCs should look to connect with horizon scanning that is occurring at a state/territory or national level whenever possible.

For all issues identified, proactively and reactively, MTCs need to have a documented forward work plan, for both ongoing horizon scanning and managing identified issues. A formal annual work plan allows an MTC to effectively plan activities for the year, defining the purpose and expected outcomes of each included activity, and tracking progress towards completion. In resource-constrained environments, documentation may take the form of a well-managed actions list that is regularly reviewed and updated. Importantly, any proactive plan must allow scope for the MTC to be responsive to issues that were unforeseen at the time that the plan was documented.

Through these processes, MTCs should anticipate demand, changes in 'usual' clinical practice, and the changes required to fund and deliver medicine-related services. These forecasts can assist MTC decision-making and assist with internal budget planning and negotiation.

↳ HORIZON SCANNING

MTCs can be proactive in their approach to medicines governance through actions such as:

- → reviewing newly marketed medicines
- → reviewing new medicine products in contracting and procurement processes
- → monitoring non-formulary medicines use, such as medicines approved for individuals, including measures of efficacy and safety/toxicity
- → planning and driving QUM and medication safety initiatives or strategies (e.g. in response to audit results)
- → monitoring current literature for publication of new or updated best practice guidelines that are practice changing
- → identifying the need for policy/processes in relation to specific medication management issues
- → identifying and overseeing conduct of quality improvement programs, e.g. medicine use evaluations, auditing and reporting
- → implementing new medicines-related systems (e.g. electronic prescribing, new infusion equipment)
- → monitoring high-cost medicines use
- → monitoring medication safety incident trends
- → assessing risk of new products to be procured in response to medicines shortages, to identify and mitigate any medication safety risks
- → liaising with those monitoring medicines shortages to make pre-emptive formulary changes, where necessary, to facilitate the use of therapeutic alternatives in response to medicines shortages
- → investigating and identifying actions required to address gaps in practice
- → evaluating the outcomes of implemented initiatives such as auditing non-medical prescribing
- → monitoring outputs from stewardship programs (e.g. antimicrobials, analgesics) for quality improvement opportunities
- → reviewing policy documents at defined time points, but also proactively monitoring for changes in practice, published evidence or national guidelines that may necessitate early policy review.

↳ DATA-DRIVEN DECISION-MAKING

For enhanced use of available data, MTCs may consider promoting (within their organisation) investment in unified/integrated data sources for medicine use (including medicine costs), including the adoption of artificial intelligence (AI) when data security and ethical use of the technology can be assured. Access to clean, integrated data and powerful data manipulation tools will aid the MTC in making data-driven decisions. Automation of manual data-manipulation tasks will enhance the capacity of MTCs to undertake Medicines Use Evaluation (MUE) projects and other quality assurance and quality improvement initiatives. In the long term, judicious use of AI by MTCs is likely to support evidence-based decision-making and accelerate medicines evaluation processes.

GUIDING PRINCIPLE 9

MTCs undertake risk assessments within the health service organisation with respect to medicines use and recommend strategies to mitigate identified risks.

Within their defined scope, MTCs perform risk assessments and recommend strategies for implementation into the medication management system to prevent errors or unintended outcomes. To allow MTCs to be proactive and systematic in their approach to these risk assessments, appropriate resourcing is critical (see also **Guiding principle 14**).

Depending on the scope of the MTC, risk assessments may cover areas such as:

- medication safety
- service delivery capacity relating to medicines such as dispensing and assisted administration capacity
- work health and safety hazards relating to medicine handling
- health service budget risks relating to medicine use
- medico-legal and reputational risk associated with MTC decisions
- environmental risks posed by medicine production, transport, use and disposal.

Using the collective expertise of the committee, the MTC is well placed to recommend mitigation strategies to address identified risks, as well as indicators that the organisation should monitor to assess whether the mitigation strategies have been effective. These indicators may be customised for an individual situation or may be a broader selection of key indicators for routine monitoring, such as those in formal tools (see below).

RISK ASSESSMENT TOOLS

To undertake risk assessments, MTCs may use formal risk assessment tools.

- A medication safety checklist tool, or self-assessment.
- Clinical care standard indicators and other indicators from the Australian Institute of Health and Welfare's METEOR (**Metadata Online Registry**).[12]
- **Failure Modes And Effects Analysis**.[13]
- Risk matrices to assist in prioritising management strategies for the most significant and most likely risks. Several examples can be found online including examples from Australian health departments.[14]
- Medication safety and documentation audits such as the **user applied labelling standard audit**[15] or the **National Standard Medication Chart (NSMC) audit**.[16]
- QUM assessments such as the **National Quality Use of Medicines Indicators for Australian Hospitals**.[17]

Regular assessment of the performance of the medication management system and activities that increase the safety, quality and effectiveness of medicines use will assist health service organisations to meet the expectations of the NSQHS Standards, including those relating to medication safety and clinical governance.[1, 3] See also the Advanced Pharmacy Australia **Medication Safety Standards**[18] for further information.

GUIDING PRINCIPLE 10

MTCs identify quality improvement initiatives and assign priorities, responsibilities and timeframes for their completion.

Within its organisation, the MTC is responsible for promoting QUM and aligning medicines use with best practice guidelines and standards. Through the routine work of the MTC, the committee is well-positioned to identify quality improvement opportunities relating to medicines. MTCs may also be the reporting point within the organisation for medicines-related quality improvement activities that are initiated outside of the MTC.

Quality improvement activities identified by the MTC should be assigned priority based on risk and available capacity to complete the necessary work. This process should include a cycle of audit/evaluation, intervention and re-audit or ongoing monitoring. This can be done using Plan-Do-Study-Act medicines use evaluation,[19] or other quality improvement processes. See **MTC resources** for examples of tools to assist with quality improvement activities.

MTCs should have a reliable method for recording quality improvement activities initiated by the MTC (and outside the MTC where this is applicable) such as a quality improvement register. This record should facilitate progress tracking of the quality improvement activities by the MTC, and allow the MTC to track when progress updates, completion reports or follow-up actions from each activity are due.

GUIDING PRINCIPLE 11

MTCs use monitoring systems to evaluate their effectiveness.

MTCs should develop agreed measures for monitoring the committee's effectiveness in terms of efficiency and meeting the needs of the health service organisation that it serves. MTCs should record clean, accurate data regarding MTC activity, to allow for efficiency and automation in this performance monitoring.

The MTC's TOR should outline how effectiveness measures are decided and how the MTC evaluates its practice against those measures. This should include the frequency of evaluation and where the results are reported to. At a minimum, MTC evaluation should be reported to the roles and committees that the MTC has accountability to within the organisation's clinical and corporate governance structure.

These guiding principles and the MTC Checklist in **Appendix 1** provide a framework against which MTCs can review aspects such as their membership, function and procedures. Other measures or additional indicators may also be appropriate for some MTCs and examples are given in the **MTC resources** section.

An annual report or work/action plan can be used to monitor the volume and breadth of MTC work, with completed items reflective of committee performance. MTC evaluation against a work plan or annual report can also aid in assessing the adequacy of resourcing, the appropriateness of the membership mix, and identify opportunities for improvement to committee processes. Assessment of MTC member education and training requirements can also be considered through this process.

DOCUMENTATION AND COMMUNICATION

This section outlines key issues for consideration for MTC-related **Documentation**, as well as **Communication** strategies and engagement with stakeholders.

GUIDING PRINCIPLE 12

MTCs employ timely and accurate documentation and communication strategies.

MTCs need robust processes in place to clearly and accurately document committee discussions, decisions (including rationale), and the information used in decision-making. This applies to both MTC meetings and any deliberations, decisions or other activity occurring between meetings. The MTC's documentation processes should be adequately robust to allow for timely, complete and accurate recall of information relating to past MTC decisions (including aspects such as rationale and the evidence considered).

Unless there is an appropriate organisation-wide policy regarding document management and archiving, it is recommended that there is an MTC-specific process for managing meeting agenda papers, minutes, correspondence and other MTC documentation. When possible, a standardised template for these documents should be employed.

MTCs should have a framework for timely and effective communication with various stakeholder groups, including dissemination of its decisions and communication about any issues relating to medication management within their organisation. When relevant, reasoning for MTC decisions should be included in this communication.

Where the MTC is not communicating directly with health service staff, it is recommended that the responsibility for disseminating all MTC communications is clearly articulated in policy and supported by the organisation.

↳ MTC COMMUNICATION FRAMEWORKS

The MTC's communication framework will ideally be a written framework, agreed by the MTC. It should include details of the communication method, frequency, format and recipients for various communication types.[20] For example, the MTC should have a designated place for publicising formulary amendments that includes the active ingredient name, strength (when applicable), dosage form, indication, rationale for the change, and any restrictions (e.g. prescriber type, duration of therapy). The formulary list should be available to the relevant health service staff and updated in a timely manner following MTC decision-making.

Communication of decisions relating to individual patient requests should also be included in the MTC's communication framework. This should include details for how decisions are communicated to patients, which will be especially relevant when an application is not approved. Communication of an MTC decision to a patient should be undertaken by an appropriate person in the patient's treating team (preferably a senior clinician), who can competently explain the complexities of the information to the patient (or support the applicant to do this), in terms that the patient or carer can understand. CATAG has produced a suite of **resources to support consumers** in understanding medicines governance-related issues and these may assist in communication regarding MTC decisions and processes.

Where relevant, responsibility for inclusion of individual patient application outcomes into the persons medical history should also be outlined in the MTC's communication framework, for both approved and rejected applications.

GUIDING PRINCIPLE 13

MTCs engage with internal and external stakeholders to strengthen medicines governance and promote quality use of medicines.

Networking with internal and external stakeholders supports quality decision-making, enabling both advocacy and a wider view of issues relating to medication management, medication safety or QUM policy decision-making. MTCs should consider a multi-layered approach when communicating and networking with stakeholders, identifying relevant local, state and national stakeholders.

MTCs need to establish and maintain communication pathways with identified stakeholders to support the two-way movement of information as needed. The way MTCs engage will vary according to the local environment and the types of stakeholders identified.

Internal stakeholders will include the professional leads for each of the disciplines involved in medication management. At a minimum this will involve senior doctors, the director of pharmacy (or equivalent), and local nursing directors. MTCs will also need to engage with other committees within the health service that hold responsibilities relating to medicines and related areas such as patient safety and product evaluation (see **Associated Committees** for more information and further examples).

MTCs around the country often undertake similar reviews, evaluating the same medicines or QUM policy issues. For efficiency, and to avoid duplication of effort, communication with equivalent committees across the country is encouraged. Pooling outcome data may also provide feedback on the effectiveness and safety of specific medicines. These objectives can be facilitated through regular communication from hospital, local area health service or regional MTCs with their state/territory bodies (Therapeutic Advisory Group, statewide MTC or closest equivalent), with these statewide groups maintaining links with interstate counterparts. CATAG may further assist at a national level to facilitate inter-state communication.

↳ EXTERNAL STAKEHOLDER ENGAGEMENT

While MTC work is likely to relate heavily to internal stakeholders, there is much to be gained from also engaging with external stakeholders. Establishing links between the MTC and local healthcare networks (e.g. primary health networks) may assist in optimising QUM across the care continuum and facilitate two-way communication with external local healthcare providers and other stakeholders. This will assist MTCs when considering issues such as ongoing access to medicines at transitions of care and access to relevant prescribers outside the health service organisation. Similarly, establishing links between the MTC and other local health service organisations (e.g. residential care facilities, other hospitals), may assist in improving continuity of care on transition to and from an acute care environment.

Relevant national stakeholders may include organisations that work within the context of the National Medicines Policy such as the Therapeutic Goods Administration (TGA) and the Australian Commission on Safety and Quality in Health Care.

State/territory stakeholders may include statewide formulary committees, statewide patient safety services or a statewide medication safety collaborative.

Engagement with state or national expert clinical groups (e.g. lead clinician groups, statewide clinical networks) may also be useful, to enable access to the appropriate expertise when evaluating medicines for specific populations, such as paediatrics or oncology.

GUIDING PRINCIPLES

RESOURCING

This section considers the **Resourcing** requirements for an MTC to function effectively.

GUIDING PRINCIPLE 14

MTCs are supported and adequately resourced, by the hospital, local health district/network or state/territory that they service, to undertake their functions and responsibilities.

It is essential that health service organisations appropriately fund and support MTCs to enable them to effectively fulfil their functions and responsibilities. While broad MTC membership may be garnered from existing health service staff, dedicated resourcing to support the functioning of the MTC is essential. MTC resourcing may include:

- Allocated time for the MTC chair to attend meetings, review meeting papers and supporting documents, and attend to out-of-session issues.
- Protected time for committee members to attend meetings and review meeting papers/ supporting documents.
- Dedicated administrative/secretarial support to action MTC correspondence, communication and documentation (including agenda and minutes), and provide logistical support for meeting coordination.
- Dedicated staff with in-depth understanding of medicines issues (e.g. senior pharmacists) to compile discussion papers, review submissions, liaise with applicants and stakeholders, provide clinical input for review of agenda and minutes, follow-up action points from meetings, and manage reports within the hospital(s) or local health network. For some MTCs, this role may also support MTC member education, as well as the communication and review of MTC decisions.
- Personnel to undertake quality improvement projects and to support the MTC to undertake its functions and activities, including those identified and prioritised within the documented work/action plan, e.g. a clinical project officer, QUM or MUE pharmacist, or medication safety clinical nurse consultant.
- Financial resourcing for consumer representation.
- Financial resourcing for MTC member onboarding and ongoing training.
- Additional resources to support subcommittees to undertake activities within their remit.

All clinicians involved in medication management are responsible for implementing MTC decisions and supporting MTC activities within the health service organisation. Where quality improvement initiatives or other projects are undertaken, the work groups responsible for this work also need to be adequately resourced to undertake the required tasks.

Under-resourcing of the MTC compromises the committee's ability to be proactive in their medicines governance including proactive assessment of risks. This increases the likelihood of risks being unidentified (and therefore unmanaged) prior to an adverse or undesirable outcome occurring. This is relevant not only to patient safety, but also to system-level risks, including the medicines budget and health service accreditation.

↳ MTC STAFFING REQUIREMENTS

The nature and volume of dedicated MTC staffing resource required will depend on the roles and responsibilities of the MTC, its governance scope and the size of the organisation that it services. To provide guidance on the required fulltime equivalent (FTE) staffing for successful MTC operation, a random sample of Australian MTCs was surveyed in 2025 to determine the staffing resource used, and whether this was considered adequate in each case. Based on these results, most MTCs are expected to require between 1.2 and 3.0 FTE of dedicated staff time. The split across administrative support, chair, and specialist input (e.g. senior pharmacists, project nurses) will depend on the responsibilities across staff, and the nature of the work undertaken by the MTC.

As a guide, requirements are likely to include:

- → administrative support of 0.2-1.0 FTE
- → the chair 0.1-0.5 FTE
- → specialist pharmacist/Clinical Nurse Consultant support for MTC responsibilities 0.8-2.5 FTE.

MTCs with a wide scope of medicines governance responsibilities may require resourcing above this recommended 1.2 to 3.0 FTE. For any MTC, where additional governance responsibilities are added to the work of the committee, appropriate additional resourcing should be provided by the organisation.

FOR THE FUTURE

Stakeholder consultation identified additional MTC needs that should be considered in planning follow-on work from the update of these guiding principles. Outlined below are three high-priority areas identified by multiple stakeholders.

DECISION FRAMEWORK SUPPORT

Decision frameworks and/or other decision support tools can promote consistency in MTC decision-making. While some individual MTCs have decision frameworks, they do not appear to be widely used and there is no national-level guidance on what these frameworks should include, nor how they should be used. At a minimum, guidance for MTCs to develop their own decision frameworks should be provided.

Ideally, a nationally agreed decision framework for medicines access decisions should be developed. A nationally agreed decision framework would support cross-jurisdictional consistency in decision-making processes, promoting equity across populations and enhancing the ability of jurisdictions to share medicines access assessments. When medicines access decisions are made using a nationally agreed approach that has been validated for consistency in output, decision-making can be reliably applied to different local settings, minimising duplication of effort and further enhancing equity of access to medicines.

INTERACTION WITH THE PHARMACEUTICAL INDUSTRY

These guiding principles have provided examples of conflicts of interest that may arise from interactions between the pharmaceutical industry and MTC members or applicants. However, interactions between the pharmaceutical industry and MTCs can be far more nuanced and complex than what is able to be addressed in this document.

Pharmaceutical companies often hold unpublished data on file regarding efficacy, safety, technical specifications and health economics analyses that can be invaluable in assessing a medicines access request. While this can be highly beneficial for an MTC, pharmaceutical companies have a commercial interest in wider use of their medicines, and interactions may therefore present actual, potential or perceived conflicts of interest. MTCs require guidance and resources to optimise this relationship, allowing for a productive two-way dialogue while maintaining objectivity in decision-making.

TRAINING RESOURCES

In compiling lists of relevant training resources for MTC members, the scarcity of resources was apparent. MTCs have common training needs for committee members on general principles such as critical appraisal of evidence for medicines access decisions, managing conflicts of interest, and understanding funding mechanisms in the Australian healthcare environment. Additionally, MTCs often require education material on specific medicines governance issues for both health service staff and consumers. Centralised production of generic training resources for use by MTCs will assist in the delivery of high-quality education, again promoting cross-jurisdictional consistency in approach and reducing duplication of effort.

MTC RESOURCES

Within this section are collated lists of resources that may assist MTCs with various aspects of their work. Each MTC will need to evaluate the suggested resources for their suitability in the MTC's local context. Some of the included resources are from international sources, therefore the applicability to the Australian context will need to be assessed in each instance. The suitability of resources will depend on the type of information being accessed, and the way in which that information will be used by the MTC. While care has been taken to list information sources from reputable organisations, CATAG cannot guarantee the accuracy of information presented on these externally managed, public websites.

CATAG has endeavoured to provide a variety of resources under each section, however this is not an exhaustive list and MTCs should consider other available resources to support their practice. Other quality resources are available, including some that require a paid subscription for access.

MTC MEMBER TRAINING EXAMPLES

- Australian Commission on Safety and Quality in Health Care (ACSQHC) **Medication Safety Course** - This course explores the causes of medication errors and how to prevent them.
- ACSQHC **Quality use of medicines (QUM) for health professional students** – This guide discusses the principles of QUM and the roles different health professionals play in promoting QUM.
- **Deadly pharmacists: foundation training for pharmacists working within Aboriginal Community-Controlled Health Services** – Cultural competency training. Hosted by the Pharmaceutical Society of Australia (PSA) but available at no cost (participants need to register details with PSA to enrol).
- Charles Sturt University **What is Evidence-Based Practice?** – A brief overview of evidence-based practice with links to additional resources.
- World Health Organization **Training package for cost analyses and economic evaluation** – This training package covers the key components of economic evaluation and cost analyses relevant to health policy development.
- NICE (UK) **Developing and updating local formularies** – This resource is written in the context of the National Health Service in England however the principles are also applicable to Australia.
- The National Collaborating Centre for Healthy Public Policy (Canada) An **Introduction to Public Health Ethics** – This course discusses values and principles, frameworks and case studies that are relevant to public health practice.
- Swanson, JA, Schmitz D, Chung KC. **How to practice evidence-based medicine**." Plas Reconstr Surg 2010; 1): 286–94.

CONSUMER-FOCUSED TRAINING

- ACSQHC **Partnering with Consumers: A guide for consumers** – This resource outlines how consumer representatives can engage with health services at all levels to promote person-centred care. It also assists health services to determine whether they are engaging with consumers appropriately.
- Consumers Health Forum of Australia (CHF) **Resources** – Includes webinars, tools, free online courses and other resources for health consumer representatives.
- CHF **Introduction to being a consumer representative** – a 15-minute overview on how consumers contribute to the health system.
- CHF **The Australian Health System: an overview for young people** – a 1.5-hour webinar applicable to consumer representatives of any age, outlining the Australian healthcare system and its funding.
- CHF YouTube Channel **Consumers Health Forum of Australia - YouTube** – Includes videos such as **Youth Health Forum Webinar: Australian Health Policy** which gives the basics of the Australian healthcare landscape.

FORMULARY – EXAMPLE APPLICATION FORMS AND SUPPORTING DOCUMENTS

- NSW Therapeutic Advisory Group (TAG) **Various formulary submission forms**.
- NSW Health Clinical Excellence Commission (CEC) **Formulary submission framework** – Outlines many points to consider when reviewing both formulary and IPU/IPA applications.
- Queensland **Formulary standard submission form**.
- Queensland **Guide for requesting changes to the List of Approved Medicines**.
- South Australia **Medicines Formulary Request Form** available **here**.
- **Western Australian Medicines Evaluation Panel** (WAMEP) Statewide Medicines Formulary:
  - **Full Submission Form**
  - **PBS Submission Form**
  - **Minor Submission Form**
- WAMEP Medical devices containing medicines – Request for WAMEP advice about the medicine component – **Application Form**.

INDIVIDUAL PATIENT USE OF MEDICINES – EXAMPLE APPLICATION FORMS AND SUPPORTING DOCUMENTS

- NSW TAG MTC **Individual patient use application form**.
- NSW Health CEC **Individual patient use application form**.
- Queensland Health **Management and governance of individual patient approvals**.
- SA Health information and forms for the **Individual patient use of high-cost medicines**.
- VicTAG **Individual patient use form**.
- See also the NSW Health CEC Formulary submission framework in the formulary section above, as this document outlines many points to consider when an MTC is reviewing any medicine access application.

QUALITY IMPROVEMENT ACTIVITIES – EXAMPLE TOOLS AND OTHER RESOURCES

- CATAG - Getting it Right for Medicines Stewardship – **CATAG Guiding Principles for Medicines Stewardship Programs**.
- **Medicines Advice Initiative Australia** (MAIA) – various toolkits for enhancing QUM in specific therapeutic areas.
- ACSQHC – **Australian hospital patient experience question set**.
- ACSQHC – **Patient-reported outcome measures**.
- ACSQHC – **Patient safety culture** survey and other resources.
- ACSQHC and NSW TAG – **National Indicators for Quality Use of Medicines (QUM) in Australian Hospitals** and other **supporting resources**.
- NSW TAG – **Polypharmacy QUM indicators and resources**.
- NSW TAG – **High risk medicines resources**.
- NSW Health CEC – High-risk medicines **implementation checklists** for individual medicine groups (e.g. anticoagulants).
- NSW Health CEC – **Quality improvement tools**.
- NSW Health CEC – **Quality improvement toolkits** to start and sustain quality improvement projects.

- → American Society of Health-System Pharmacists (USA) – **How to Design a Medication Use Evaluation**.
- → Agency for Healthcare Research & Quality (USA) – **Tools for monitoring and implementing quality improvement activities** in a healthcare environment.
- → Graudins LV, Fitzsimons K, Manias E, Mirkov S, Nguyen N-A, Munro C. **Medicines Use Evaluation Guideline**. J Pharm Pract Res 2020; 50: 166–79.

EXAMPLE TOOLS FOR MEASURING EFFECTIVENESS

- → ACSQHC – **National Standard Medication Chart (NSMC) audit system**.
- → ACSQHC – **National Safety and Quality Health Service Standards**.
- → The Medicines and Therapeutics Committee Checklist in **Appendix 1**.
- → Medicine Use Evaluation or other audit pre- and post-intervention for MTC-initiated quality improvement activities.
- → MTC developed key performance indicators (KPIs).
- → Medication safety checklists or self-assessments (various tools available, some with a fee).

INFORMATION SOURCES TO SUPPORT DECISIONS ABOUT APPROPRIATE USE OF MEDICINES

- → Primary sources of high-quality research published in peer-reviewed journals.
- → Secondary or summarised sources of high-quality research, including review of medicines by national regulatory bodies. Note that monitoring some of these resources can also be useful tools for horizon scanning:
  - Evidence summaries and reviews used for regulatory approval of medicines (typically in specific indications) in various countries.
    - **Australia**
      - ↳ **Australian Register of Therapeutic Goods** (ARTG)
      - ↳ **Pharmaceutical Benefits Advisory Committee (PBAC)** Public summary documents
    - **New Zealand**
    - **Europe**
      - ↳ **European Medicines Agency**
    - **United Kingdom (UK)** – NICE
    - **Scotland**
    - **Canada**
      - ↳ **Canada's Drug Agency**
    - **USA**
      - ↳ **Drugs@FDA** (Food and Drug Administration)
  - ACSQHC **On the Radar** – A once weekly summary of some of the recent publications in the areas of safety and quality in health care.
  - **NSW TAG Guidance and Reviews**.
  - NSW Health CEC Formulary guidance **documents** – See documents under 'Information for NSW Health Clinicians'.
  - **Cochrane database of systemic reviews** (UK) – Collated evidence for selected medicine/indication combinations as well as primary literature searching.
  - **Institute for Clinical and Economic Review** (USA) – An independent, non-profit research institute that conducts evidence-based reviews of healthcare interventions.
- → Evidence-based therapeutic guidelines and other medicines information examples:
  - **National Health and Medical Research Council** – See resources available in the 'About us' tab, but also health advice and general information under research policy.
  - Sub-specialty clinical practice guidelines, for example:
    - **National Comprehensive Cancer Network (NCCN) Guidelines**.
    - **eviQ** – Evidence-based information to support health professionals in the delivery of cancer treatments.
    - The **Tasmanian Palliative Care Formulary**.
- → Medicine information resources requiring a paid subscription are also available and should be used to support MTC decision-making where available.

- Information from the pharmaceutical industry may be considered. For example, safety information (including any unpublished data) and additional information a company may have on the use of a particular medicine. Consideration should be given to any conflicts of interest or study biases that may be present with information from, or funded by, pharmaceutical companies.
- CATAG – Rethinking medicines decision-making in Australian hospitals: **Guiding Principles for the quality use of off-label medicines** also includes a useful flow chart for decision-making.
- CATAG – Navigating high-cost medicines – **Guiding Principles for the governance of high-cost medicines in Australian hospitals** provides valuable advice for MTC decision-making processes.

HORIZON SCANNING RESOURCES

Monitoring the wider medicines supply, approval and funding environment through regular review of resources such as those listed below, can assist in pre-empting changes to usual practice. This may allow MTCs to be proactive in their QUM governance.

- The TGA's **Australian Register of Therapeutic Goods (ARTG) Search Visualisation Tool** can filter medicines (in the left-hand side menu) with an ARTG start date within a specified range. This displays new products listed in the defined time period. Alternatively, selected medicine information resources (requiring a subscription fee) such as eMIMS provide a monthly summary of this information.
- **PBAC meeting agendas** provide information about medicines being considered for PBS listing, or additional indications under consideration.
- **TGA medicines shortages and discontinuations** can be used to monitor expected supply disruptions for medicines which may require proactive management. Discontinuations are displayed according to the most recent update and can be monitored periodically. Active shortages (including newly listed discontinuations), can be downloaded in Excel spreadsheet format.
- **NSW Therapeutic Advisory Group – TAG Mail** lists recent publications and reports relevant to medicines governance from both Australian and International sources.
- **National Institute for Health and Care Research Innovation Observatory** (UK) is a health and care innovation scanning centre, providing data-driven insights to foster innovation in health care.
- Monitoring international safety alert bulletins or new safety warnings can help to identify medication safety risks before an event happens locally. Examples include Canada's **Institute for Safe Medication Practices (ISMP)** and the USA's **FDA alerts**.
- The secondary sources mentioned above to support decision-making are also potentially useful tools to monitor newly marketed medicines, especially new classes of medicines, biosimilar medicines, or new presentations (e.g. subcutaneous delivery devices).

GLOSSARY

Adverse event: An incident that results, or could have resulted, in harm to a consumer. A near miss is a type of adverse event.[21]

Agenda: A document outlining the items to be discussed during a formal meeting. Agendas are typically accompanied by discussion papers or other relevant documents.

Annual work plan: A detailed activity plan that sets out what will be accomplished during the coming year to achieve specific results. It usually contains the activities necessary to achieve anticipated outcomes, the timeframes, those responsible for the activities, and the steps that each activity entails. An annual work plan helps monitor how the desired goals are being accomplished.

Clinical governance: An integrated component of corporate governance of health service organisations. Everyone is accountable to healthcare consumers and the community for assuring the delivery of safe, effective and high-quality services. This includes everyone from frontline clinicians to managers and members of governing bodies, such as boards. Clinical governance systems provide confidence to the community and the healthcare organisation that systems are in place to deliver safe and high-quality health care.[22]

Clinician: A healthcare provider, trained as a health professional. Clinicians may provide care within a health service organisation as an employee, a contractor or a credentialed healthcare provider, or under other working arrangements. They include nurses, midwives, medical practitioners, allied health practitioners, technicians, scientists and other clinicians who provide health care, and students who provide health care under supervision.[1]

Commercial-in-confidence: Sensitive business information that is kept confidential e.g. contracted prices for medicines.

Conflict of interest: A conflict that arises when a person's private interests or other professional responsibilities are at odds with their professional obligations. Conflicts of interest may be actual, potential or perceived. They may relate to financial interests, personal relationships or other obligations of the individual. Typically, when a conflict of interest occurs, the individual (or someone close to them) stands to benefit personally from the individual acting or voting in a certain way, and this may therefore influence how the person behaves.

Consumer: A person who has used, or may potentially use, health services, or is a carer for a patient using health services.[21]

Cost-effectiveness: The degree to which something is effective, relative to its (typically financial) cost. This may be a comparative measure against other options, or a stand-alone assessment of whether an approach represents "good value".

Delegated authority: Formally transferred decision-making power or other authority from one person or group to another person or group.

Efficacy: In relation to medicines, this is how well the treatment works, typically measured in a controlled setting such as a clinical trial.

Equal access: Provides the same resources to all, regardless of need. Equal access will provide variability in outcome for individuals, depending on their baseline level of need (see also equity of access below).

Equity of access: Unequal allocation of resources based on need, to achieve the same outcome for all individuals. More resources are allocated to those with a greater baseline need, with the aim that all individuals can then achieve an acceptable outcome.

Evidence-based: A term used to describe a practice, medicine use or information that is backed by scientific evidence. Evidence-based medicine, which extends to the evidence-based use of medicines, is described as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individuals.

Formulary: A resource that includes, but is not limited to, a list of medicines and medicine-associated products or devices, with approved indications or patient groups for use. Formularies also typically include supporting resources such as medicine-use policies, important ancillary medicines information, and decision-support tools. Depending on the scope of the MTC that manages the formulary, the formulary may apply to an individual hospital, a hospital group, geographical region, or an entire state/territory. Ideally a formulary is a dynamic resource that is reviewed and updated regularly.

Governance structure: The system of roles, reporting lines, responsibilities and rules that guide decision-making and management within an organisation. The governance structure of an organisation may be illustrated using an organisational chart.

Health service organisation: An organisation responsible for the clinical governance, administration and financial management of a health service unit(s) providing health care.[21] A health service organisation may include one or many health service units, working across one or many physical locations (sites) within that organisation's governance.

Health service unit: A grouping of clinicians and others working in a systematic way to deliver health care. The unit can be in any location or setting, including clinics, outpatient facilities, hospitals, hospital pharmacies, practices and clinicians' rooms.[21]

Health technologies: Health technology is a broad term meaning something that is intended to do any of the following: prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; organise delivery of health care. Health technologies include tests, medical devices, medicines, vaccines, blood products, procedures, programs or systems involved in health care.

Horizon scanning: Systematic monitoring for early signals that indicate likely future changes, challenges or opportunities.

Individual patient use/approval/application (IPU/IPA): A request to the MTC (or approval by the MTC) for an individual patient to use a non-formulary medicine or to use a medicine outside of its existing formulary approval.

Interdisciplinary: Professionals from a range of disciplines with different but complementary skills, knowledge and experience working collaboratively

with a common purpose, to set goals, make decisions and create a unified understanding of a complex issue (see also **Multidisciplinary** below).

Local Health Network: Small groups of local hospitals or an individual hospital, linking services within a region, or through specialist networks across a state or territory. These were established under the National Health Reform in 2011.[23] Local Health Networks may also be known as Local Health Districts, Health Service Networks, and Local Hospital and Health Networks.[24]

Medication management: Practices used to manage the provision of medicines. Medication management has also been described as a cycle, pathway or system, which is complex and involves a number of different clinicians. The consumer is the central focus.

Medication management systems: The systems used to manage the provision of medicines to consumers that are specific to a healthcare setting. These systems include dispensing, prescribing, storing, administering, manufacturing, compounding and monitoring the effects of medicines, as well as the rules, guidelines, decision-making and support tools, policies and procedures in place to direct the use of medicines.[5]

Medicine: A chemical substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease, or otherwise improving the physical or mental welfare of people.[25] Prescription, non-prescription and complementary medicines, irrespective of their administration route, are included.[21] Depending on the context, medicines may also be referred to as medication or pharmaceuticals.

Medicines and Therapeutics Committee (MTC): The group assigned responsibility for governance of the medication management system, and for ensuring the safe and effective use of medicines in the health service organisation. MTCs may be responsible for medicines governance in a single hospital/facility, a local area health service, a healthcare network, or an entire state/territory. These committees may also be known by other names such as: Medicines Advisory Committee; Medication Management and Safety Committee; Drug and Therapeutics Advisory Committee, or Quality Use of Medicines Committee.

Medicine use evaluation (MUE): A systematic quality improvement activity with the purpose of improving patient care through improved quality and cost-effective use of medicines.[26] An MUE may be part of a larger ongoing MUE program or may be a stand-alone project. Medicine use is evaluated using pre-determined standards, and efforts are initiated to correct patterns of use that are not consistent with these standards.[26] MUE also includes a mechanism for measuring the effectiveness of these corrective actions.[26] Previously known as Drug Usage Evaluation or "DUE".

Minutes: The official written record of a meeting, including details such as the names of individuals present, the issues discussed, and decisions made.

Multidisciplinary: Professionals from a range of disciplines with different but complementary skills, knowledge and experience who are working independently on different aspects of a project or problem (see also **Interdisciplinary** above).

Organisational chart: A diagram that illustrates how an organisation is structured, including illustration of relationships between different organisational elements (roles, committees, boards), reporting lines etc.

Policy: In this document, "policy" is used to describe all organisational documents that outline principles, plans for action or processes, and includes policies and all related documents such as guidelines, protocols, procedures and position statements.

Quality improvement: The combined efforts of the workforce and others – including consumers and their families, researchers, planners and educators – to make changes that will lead to better health outcomes, better system performance (care) and better professional development.[27] Quality improvement activities may be undertaken in sequence, intermittently or continually.[1]

Quality use of medicines (QUM): The judicious, appropriate, safe and effective use of medicines.[28] This includes selecting treatment options wisely, choosing suitable medicines, and using medicines safely and effectively.[2]

Risk assessment: A systematic process of identification, evaluation and estimation of the potential risks that may be involved in a situation.

Risk management: The design and implementation of a program to identify and avoid or minimise risks to consumers, employees, volunteers, visitors and the organisation.[21]

Safety incident: An event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a consumer. An incident may also be a near miss.

Stewardship: With respect to medicines, stewardship is the coordinated strategies and interventions to optimise medicines use, usually within a specific therapeutic area.[29] Medicines stewardship programs can reduce variations in practice and improve health outcomes.[29]

Terms of reference (TOR): A document outlining the purpose, roles and structure of projects, working groups, reference groups and committees. These are guidelines for the way group members will work together.

Transitions of care: Situations when all or part of a consumer's care is transferred between healthcare locations, providers, or levels of care within the same location, as the consumer's conditions and care needs change.[21]

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APPENDIX

Appendix 1
Medicines and Therapeutics Committee Checklist

Appendix 2
Terms of Reference (TOR) Guidance

Appendix 3
How these Guiding Principles were developed

APPENDIX 1 - MEDICINES AND THERAPEUTICS COMMITTEE CHECKLIST

This checklist can be used to measure the performance of a Medicines and Therapeutic Committee (MTC) against the CATAG **Guiding Principles for the roles and responsibilities of Medicines and Therapeutics Committees in Australian hospitals**. The results of this checklist can be used to identify areas for improvement. Where resourcing allows, MTCs should consider using these results to develop an action plan for addressing identified development areas.

Date of Review: ___ / ___ / ___

Review undertaken by: _____

Presented to MTC on ___ / ___ / ___ (meeting date)

Purpose, Functions and Structure		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 1							
MTCs provide governance and oversight of medicines-related systems within a hospital, local health district/network or state/territory.	All facilities and services of the health service organisation can access the services of the MTC, or they have their own MTC equivalent.						
	The obligations of the health service organisation, health service units and individual staff regarding implementing MTC decisions or advice is clearly documented and endorsed by the organisation's executive.						
	The MTC has ready access to the information that it requires to fulfil its roles and responsibilities (see dot points in **Guiding principle 1** for examples).						
	The scope of the MTC's responsibilities is clearly defined (therapies included/ excluded, geographical or service limitations, financial limits).						
	The scope of the MTC's responsibilities is published in a format that is available to health service staff who may submit items to the MTC for consideration.						

Continued →

Purpose, Functions and Structure		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 2							
The MTC's place within the organisation's governance structure is clear and supports the scope and functions of the committee.	The MTC has reporting lines to, and regular interaction with, the executive/board of management/finance/clinical governance committees (as applicable to the scope and functions of the committee).						
	There are documented escalation pathways for unresolved risks, appeals of MTC decisions and referral of out-of-scope decisions.						
	There is a clearly defined relationship of the MTC to all subcommittees, working groups and any other groups with reporting responsibilities to/from the MTC. *A measure of whether this is clearly defined could be whether reporting and communication responsibilities are articulated in MTC and subcommittee documentation (e.g. in terms of reference documents for each group).*						
	The MTC and other committees/roles with medicines governance responsibilities appropriately use communication/ collaboration pathways to support the MTC's role and functions.						
	The MTC has appropriate delegated authority from the organisation for its required functions.						

Continued →

Purpose, Functions and Structure		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 3							
MTCs consider the local governance environment when defining their scope and functions.	The MTC has governance over all areas of medication management, or there is a clear delineation of responsibility between the MTC and other committees/roles so that all areas are appropriately governed. *See section* **4. Scope** *in* **Appendix 2** *- Terms of Reference Guidance for areas of medication management to consider*						
Guiding principle 4							
MTCs have clear terms of reference that articulate their role, processes and position within the organisation's clinical and corporate governance structure.	The MTC has agreed terms of reference (TOR) that have been reviewed within the specified review period.						
	The MTC's TOR have been endorsed by the health service organisation executive (or equivalent).						
	Considering the agenda items from the past year, the work undertaken by the MTC has been in line with its stated purpose. *If not, consider whether the purpose statement requires amendment, or whether the work of the committee requires re-focus.*						
	The MTC's position within the health service organisation's governance framework is documented in the TOR.						
	The MTC's authority and accountability for decision-making is defined in the TOR.						

Continued →

Purpose, Functions and Structure		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 4							
MTCs have clear terms of reference that articulate their role, processes and position within the organisation's clinical and corporate governance structure. *Consider also reviewing the MTC TOR against the recommendations in Appendix 2 – Terms of Reference Guidance.*	**The TOR include:**						
	reporting lines/communication obligations to and from the MTC.						
	a membership list.						
	details of appointment processes and length of appointment for members, the chair and the secretary (where applicable).						
	member expectations.						
	meeting frequency and structure, including quorum requirements.						
	decision-making processes including voting procedures (where relevant).						
	processes for urgent or out-of-session decisions (including how these are documented).						
	management of disputes/appeals.						
	subcommittees and their role, relative to the MTC, including scope to develop ad hoc working groups as needed to address specific issues.						
	the review period for the TOR and the process for their approval.						

Continued →

Purpose, Functions and Structure		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 5							
The MTC is interdisciplinary, including members with a range of expertise and skills to reflect the functions of the MTC.	The MTC membership is interdisciplinary including representatives across a range of disciplines (e.g. medical, nursing, pharmacy) and specialty areas.						
	The breadth of MTC member expertise reflects the issues discussed and decisions made by the MTC. *Consider reviewing past agendas against the membership list to determine whether the skills mix of members appropriately matches the types of applications/issues discussed.* *Consider also reviewing attendance records from the previous year to determine whether the appropriate skill mix has been available at most meetings.* *If out-of-session decisions are made by the MTC, consider reviewing member engagement with these deliberations to determine whether the appropriate skill mix has been accessed for these decisions.*						
	There is an appropriate mix of managerial and clinician members, including representation from health service organisation executive / clinical governance/budget and finance.						
	There is at least one consumer representative or patient advocate member for the MTC and its subcommittees.						
	The membership is representative of the size and scope of the organisation that the MTC services. *Consider the scope of services provided by the organisation and the populations serviced.*						

Continued →

Purpose, Functions and Structure		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 5							
The MTC is interdisciplinary, including members with a range of expertise and skills to reflect the functions of the MTC.	There is adequate access to ongoing training to support MTC members in their MTC-related work including appropriate training for the consumer representative(s).						
	There are adequate provisions (financial and time) for identifying and meeting the orientation, training and development needs of MTC members.						
	There is a process for accessing additional specialist skills from outside of the MTC membership when necessary for MTC decision-making/advice.						
	The chair is supported by the organisation to have adequate time to devote to the requirements of the position.						
	There is adequate dedicated secretarial support for the MTC.						
	There is an induction process for new MTC members that includes education on the processes and principles for MTC meetings and decision-making.						

Continued →

Processes		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 6							
MTCs define and implement standardised procedures and criteria for decision-making.	There are standardised templates/ application forms for matters to be referred to the MTC for decision/advice.						
	The MTC has clearly defined minimum information requirements for each category of decision-making (e.g. medicines access decisions, policy decisions).						
	There are agreed criteria to be considered in each category of decision-making. *For example: efficacy, safety, cost-effectiveness, equity.*						
	Minimum evidence requirements are defined for various settings. *For example: formulary, IPU/IPAs, rare diseases.*						
	Timeframes for each decision category are set and this information is made available to health service organisation staff.						
	MTCs assessing IPU/IPA applications have defined thresholds for referring a medicine for formulary consideration.						
	The MTC keeps a detailed and accurate record of committee decisions.						
	The MTC's decision record supports consistency in future decision-making by allowing efficient and accurate recall of past decisions.						
	The MTC decision-making processes are documented and (where appropriate) shared with health service organisation staff.						

Continued →

Processes		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 7							
MTCs implement transparent and ethically robust processes.	There is a clear process for proactive documentation of conflicts of interest (CoI) for all MTC members including proxies.						
	All current members have completed/updated a CoI declaration within the last 12 months.						
	There is a standing agenda item to call for any new CoI at the start of the meeting, or to raise an existing CoI that is relevant to an item on that agenda.						
	There is a documented process for managing declared CoI including the role responsible for this.						
	There is documented policy regarding interaction between MTC members and pharmaceutical industry representatives/ companies.						
	Confidentiality is maintained throughout MTC processes in line with MTC/ organisational requirements.						

Continued →

Processes		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 8							
MTCs are both proactive in medicines governance and responsive to issues arising.	The MTC regularly documents planned actions and follows up completion of these. *For example: an annual work plan, an actions arising list.*						
	The MTC undertakes routine horizon scanning (locally, nationally and internationally) to pre-empt and proactively manage new issues.						
Guiding principle 9							
MTCs undertake risk assessments within the health service organisation with respect to medicines use and recommend strategies to mitigate identified risks.	Within their defined scope, the MTC performs risk assessments and recommends strategies for implementation into the medication management system to prevent errors or unintended outcomes.						
	Where a risk cannot be managed or adequately mitigated by the MTC, it is escalated to an appropriate higher authority within the health service organisation.						
	The MTC identifies indicators that the organisation should monitor to assess whether strategies or actions employed to address risks have been effective.						
	The MTC reviews these measured indicators to assess effectiveness, and where necessary, takes corrective action to improve risk-mitigation strategies.						

Continued →

Processes		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 10							
MTCs identify quality improvement initiatives and assign priorities, responsibilities and timeframes for their completion.	The MTC identifies and implements (or refers for implementation) quality improvement (QI) initiatives to improve QUM within the organisation.						
	The MTC assigns responsibility for the QI initiative, including timeframes/priority for completion according to the level of risk posed by existing practice and the available capacity to complete the required work.						
	Implementation of any QI initiative is followed by re-audit, re-evaluation or ongoing monitoring to inform the need for further intervention.						
Guiding principle 11							
MTCs use monitoring systems to evaluate their effectiveness.	The MTC has a documented process for evaluating its effectiveness.						
	The MTC monitors its effectiveness regularly.						
	Outcomes of effectiveness evaluations are shared with the MTC's executive sponsor/ parent committee and the health service organisation's executive/board of management.						
	The MTC implements improvements to address any identified inadequacies.						

Continued →

Communication		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 12							
MTCs employ timely and accurate documentation and communication strategies.	The MTC has processes to clearly and accurately document committee discussions, decisions (including rationale), and the information used in decision-making. *Consider whether any out of session deliberations are also documented appropriately.*						
	There is a clear process for document management (either organisation-wide or MTC specific), for the storage, management and archiving of minutes, agenda papers, correspondence and other MTC documentation.						
	Where the MTC is not communicating directly with health service staff, responsibility for disseminating MTC communication is clearly articulated and supported by the organisation.						
	There is an agreed framework for MTC communication method, frequency, format and recipient for each communication/ decision category.						
	For decisions relating to individual patient requests, a process is documented for how the information is communicated to the patient.						

Continued →

Communication		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 13							
MTCs engage with internal and external stakeholders to strengthen medicines governance and promote quality use of medicines.	The MTC has identified relevant internal and external stakeholders for their business-as-usual practice and has established communication pathways with each.						
	The MTC has a reliable communication channel to relevant health service organisation staff members. *Depending on the remit of the MTC, this may be all staff, or only selected senior management.*						
	Continuity in medication management is considered in MTC decision-making, particularly for transitions between different care settings.						
	The MTC has links with other MTCs within Australia for support in decision-making, to promote consistency in approach.						
	The MTC has access to a network of clinical experts (or expert groups) in specialties relevant to their usual business to draw in expertise as needed.						

Continued →

Resources		Always/fully	Usually/ partially	Sometimes/ incomplete	Unmet	N/A	Comment/evidence
Guiding principle 14							
MTCs are supported and adequately resourced, by the hospital, local health district/network or state/ territory that they service, to undertake their functions and responsibilities.	The MTC chair has protected time to undertake the necessary elements of their role (meeting preparation, dispute resolution etc).						
	There is dedicated administrative support for the MTC, adequate to allow for all documentation etc to be appropriately processed within the meeting cycle period.						
	The MTC has adequate dedicated resourcing (e.g. specialist pharmacist) to undertake tasks such as compiling discussion papers, reviewing submissions, and providing clinical input for review of agenda and minutes.						
	The MTC has adequate dedicated resourcing (e.g. specialist pharmacist or Clinical Nurse Consultant) support to undertake quality improvement projects, including those in any documented workplan.						
	Members have adequate time to spend on MTC activities (meeting paper review, attending meetings, progressing actions out-of-session) without needing to use their personal time.						

APPENDIX 2 - TERMS OF REFERENCE (TOR) GUIDANCE

An MTC's Terms of Reference (TOR) define the committee's purpose, structure, scope and position within the organisation's clinical governance framework. It is an important document for both MTC members and the wider health service organisation, providing a framework for consistency in MTC practices. Sharing the TOR provides visibility to the wider health service of the MTC's functions, scope and delegated authority.

Below is a framework that can be used to guide the development of new TOR or review an existing MTC TOR document. Following this framework will support MTCs to create a TOR document specific to their role and function within their health service organisation. Each section below relates to the **Guiding Principles for the roles and responsibilities of Medicines and Therapeutics Committees in Australian hospitals**, which should be read in conjunction with this guidance. Individual guiding principles have been noted where there is a particularly strong link to a TOR element.

This guidance includes multiple examples of phrases that may be included in the TOR. These are for illustrative purposes only and are not necessarily considered to be a best practice goal for MTCs.

1. AUTHORITY

The authority statement describes, in broad terms, the committee's delegated authority within the health service organisation for decision-making (or advisory capacity only), including any financial delegations. It outlines assigned responsibilities and the group or role that the MTC reports to. To give context to this statement, it usually also provides a very brief overview of the MTC's function within the organisation.

DELEGATED AUTHORITY EXAMPLE

[The MTC] is responsible for medicines governance within *[the health service organisation]* and oversight of requirements under the NSQHS Standards that relate to medication safety. *[The MTC]* reports to the *[health service organisation's delegate/clinical governance group]*, acting as its delegated authority with respect to medicines access decisions, up to a budgetary ceiling of $*[financial threshold]* per decision.

ADVISORY EXAMPLE

[The MTC] provides expert advice to *[the health service organisation]* regarding medication management, under the authority and delegations of *[the health service organisation's delegate/clinical governance group]*, to who it reports, providing advice and recommendations. The role of the committee is advisory only.

2. MISSION/PURPOSE

An MTC's mission statement provides a concise statement of the committee's objectives within the health service organisation.

EXAMPLE

[The MTC] is responsible for promoting the appropriate, safe, efficient and cost-effective use of medicines within *[the health service organisation]*. *[The MTC]* is the key body responsible for monitoring *[the health service organisation's]* compliance with the NSQHS Standards that relate to medication safety.

EXAMPLE

[The MTC] is the strategic lead for medication management within *[the health service organisation]*, overseeing quality use of medicines and related quality improvement initiatives for the medication management system.

3. GOVERNANCE POSITION

The TOR give a clear outline of the MTC's position within the health service organisation's clinical governance structure, including its relationship and reporting lines with other committees/roles. An organisational chart or governance structure diagram may be the most efficient way to illustrate this information within the TOR.

See also **Guiding principle 2**.

THE REPORTING STRUCTURE OUTLINED IN THE TOR SHOULD ILLUSTRATE:

- → accountability lines to the health service organisation executive (directly or via other committees/roles)
- → reporting obligations to and from: other committees; the health service executive; any other relevant roles within the organisation
- → communication/delegation pathways for recommendations/ decisions to be actioned within the organisation
- → pathways for escalating identified risks that cannot be resolved by the MTC
- → referral pathways for appeals or out-of-scope decisions (e.g. above financial threshold)
- → how the MTC communicates/collaborates with other committees
- → subcommittees and working groups that report to the MTC (see also **Section 10**).

4. SCOPE

Outlining the MTC's scope defines the limits of the MTC's governance responsibilities. It is important to include what is both in and out of scope. Limits of scope to consider include:

- → any geographical or organisational limits regarding which hospitals and/or services are within the MTC's governance
- → therapies that are not included within the MTC's governance (see right for examples)
- → financial limits (both upper and lower limits) for decisions that can/will be made by the MTC in line with any financial authority delegated by the organisation
- → areas covered by other committees (e.g. statewide formulary committee).

See also **Guiding principle 3**.

WHEN DETERMINING THE MTC'S SCOPE FOR DECISION-MAKING, CONSIDER:

- → subgroups of medicines and related products such as: unscheduled medicines; intravenous (IV) fluids; and nutritional supplements including parenteral or enteral feeding
- → medical devices that contain a medicine (e.g. drug-eluting stents, bone cements containing antibiotics)
- → medical devices associated with medicines use (e.g. IV pumps and associated software, medicine administration lines/connectors/syringes)
- → medicine-like devices (e.g. surgical lubricants)
- → blood products and products derived from blood (e.g. IVIg – intravenous immunoglobulin)
- → cell-therapies (e.g. CAR-T therapy)
- → gene therapies
- → clinical trial medicines
- → medicines procurement and purchasing for safety
- → medication charts (including electronic charts)
- → electronic medication management systems and associated drug files.

5. RESPONSIBILITIES

Defining the MTC's responsibilities delineates the committee's tasks, elaborating on the purpose statement to detail the MTC's functions. This may include broad functions such as strategic leadership for medicines governance, or specific duties such as formulary management.

See also **Guiding principle 3**.

EXAMPLES

- → Formulary management and review of applications for formulary additions/changes
- → Review of applications for individual patient use of non-formulary medicines/indications
- → Approval of medicines-related policy and procedure documents
- → Advising on medicines-related legislation and standards
- → Monitoring medication safety incidents (and near misses) and other QUM indicators, identifying trends and implementing corrective actions or risk-mitigation strategies
- → Identifying education and training needs regarding medication management
- → Developing quality improvement strategies including interventions to optimise QUM across the organisation
- → Identifying best-practice models of care that promote individual and organisational accountability for achieving the best possible healthcare outcomes
- → Governance of digital systems for medication management, with a focus on safety, security and fit for purpose.

6. MEMBERSHIP

Below are factors to consider when selecting members for an MTC, or reviewing a membership list within existing TOR. Note that one individual member may fulfil more than one of the categories suggested below. For example, a haematologist with clinical ethics expertise, an MUE pharmacist with extensive telehealth experience or expertise. See also **Guiding principle 5**.

	Notes
MTC membership should be multidisciplinary, with core membership from medical, nursing and pharmacy. Consumer representation (or a patient advocate) is also strongly recommended.	**At a minimum the MTC should include representation from:** → medical specialists → pharmacy → nursing (including both senior frontline nurses and management staff) → healthcare consumers.
MTC membership should reflect its accountability within the organisation.	**Depending on the MTC's accountability and reporting lines within the organisation it may also be necessary to include representation from:** → hospital executive → finance → clinical governance → patient safety.

	Notes
The mix and breadth of membership should reflect the scope and functions of the MTC. The membership should be reflective of the scope and volume of services provided by the health service organisation that the MTC serves.	**It may be necessary to include specialist members such as:** → digital health technology experts → primary healthcare representative → pathology staff members → telehealth experts → ambulance → allied health professionals → other health professionals who are involved in the medication management pathway.
The sub-specialties of members should be reflective of the types of applications/ decisions that the MTC is required to make.	**EXAMPLES** → Infectious diseases physician or clinical microbiologist → Haematologist → Other medical/surgical staff from areas such as rheumatology, gastroenterology, critical care, oncology, ophthalmology, paediatrics, psychiatry → Clinical pharmacologist → QUM pharmacist → MUE pharmacist → Health economist → Clinical ethics consultant → Non-medical prescribers (e.g. nurse practitioner) → Junior medical staff representation
There are transparent membership appointment processes for both general members and specific roles within the MTC (e.g. chair, secretary).	The TOR outline the process for how members are nominated for MTC membership, any endorsement or approval process, the length of their appointment to the committee (if time limited), and the processes for any member who wishes to resign from the MTC. Likewise, there are separate processes outlined for how the chair and any other MTC member roles (e.g. deputy chairperson, secretary) are nominated, selected/approved, and their length of appointment to the specialist member role.
Any specific responsibilities for individual committee members are outlined in the TOR, including processes for managing these responsibilities in the absence of that member.	In addition to general member responsibilities, individual members may have additional responsibilities. For example, a pharmacy manager may be required to verify costing on applications, the chair will likely be responsible for chairing meetings and managing appeals. The responsibilities of each member (where they exceed the responsibilities of general members) should be outlined in the TOR. Documented processes for delegating these tasks to an alternative member are important to avoid delays/ inefficiencies due to the absence of an MTC member who holds additional responsibilities. **EXAMPLE** *In the absence of the chair, the deputy chair will assume all responsibilities of the chair, for the duration of the chair's absence.*

It is recommended that membership lists be written as position titles (e.g. Executive Director of Nursing – Hospitals West), rather than the names of the people employed in those positions. This allows for seamless transition of MTC membership as individual staff members move in and out of various roles within the organisation.

MTCs should consider the time requirements for different MTC roles. Members should be encouraged to seek endorsement from their managers before accepting an MTC role, checking that their manager supports the individual to be absent from their usual duties for enough time to actively participate in the MTC. Dedicated funding for selected roles (administrative support, senior pharmacists, chair, project officer) will generally be required to provide adequate working hours for MTC business to be completed.

7. MEMBER RESPONSIBILITIES

Examples of member responsibilities are outlined below. Consideration should be given to include these in the TOR, or in a separate code of conduct document. Where these aspects are appropriately addressed in organisation-wide policy (and where these policies are applicable to all MTC members), the TOR may only require brief mention of these responsibilities and/or reference to the relevant organisation-wide documents. See also **Guiding principle 7**.

PARTICIPATION IN THE MTC

Member contribution expectations should be clearly articulated in the TOR. This may also include statements regarding meeting etiquette.

EXAMPLE

Members need to have a strong commitment to the purpose of the committee, actively contributing to the work of *[the MTC]* both within and between meetings. Members should demonstrate the mission of *[the MTC]* by acting in accordance with the committee's policy and direction in everyday practice and promote this within their professional peer group. Attendance in person in the designated meeting room is preferred, however online participation is welcomed. All online participants are expected to have their cameras turned on for the duration of the meeting.

CONFLICTS OF INTEREST

The TOR should outline clear processes regarding the declaration, documentation and management of any actual, potential or perceived conflicts of interest. This includes both financial and non-financial interests. The TOR should also outline who is responsible for managing declared conflicts of interest.

EXAMPLE

Each member must complete an annual conflict of interest (CoI) declaration prior to 30 June each year. This is to be reviewed by the chair and held within MTC archives for a period of *[number]* years. It is the responsibility of the chair to discuss with the member any CoI which may have a material impact on MTC decision-making and document the agreed management strategy for each CoI on the CoI declaration.

On identification of a new CoI, each member must declare any previously undeclared conflict: to the chair prior to the next meeting; to the MTC at the start of the next meeting; or to the MTC as the conflict is identified by the member during the meeting. Details of any CoI declared in-session will be recorded both in the minutes and on the member's annual CoI declaration.

The chair must also complete an annual CoI declaration, with any identified CoI discussed with both the deputy chair and the *[executive representative]* as the executive sponsor of the MTC.

CONFIDENTIALITY

The TOR should provide clear instruction for MTC members for circumstances where confidentiality requirements are either not clearly defined in organisation-wide policy for the specific circumstances, or where MTC confidentiality exceeds these requirements (see **Confidentiality** in the Guiding Principles for examples).

EXAMPLE

All members must adhere to the **health service organisation confidentiality policy** and the **employee code of conduct** at all times. Additionally, the outcomes of MTC decisions must remain confidential until the applicant has been formally notified by the MTC in writing. Any applicant requesting details of an MTC decision prior to this formal communication is to be referred to the chair.

8. MEETINGS

The TOR should clearly outline the mechanics of how meetings will run, including how decisions will be made, documented and communicated. An agreed approach to this will provide consistency in MTC meeting conduct. This, in conjunction with member responsibilities above, will also allow potential members to understand what to expect from their commitment to the MTC. Aspects to consider under this section of the TOR are outlined below. See also **Guiding principle 6**.

		Example Statements
Meeting frequency/ schedule	MTC meetings should be held regularly, at an interval that allows for timely decision-making, while allowing appropriate time between meetings for administrative duties to be completed within available resourcing (e.g. minutes, correspondence, agenda preparation). Meeting date/time and associated agenda close dates should be shared with members and the wider health service staff well in advance of meetings (e.g. scheduled 6 to 12 months in advance). This will allow staff to schedule time for preparing and submitting applications, and maximise opportunity for members to attend meetings.	[The MTC] *will meet on the first Tuesday of every month, excluding January. Where this falls on a public holiday, the meeting will be held on the second Tuesday of the month. Meeting dates and agenda close dates for the following calendar year will be published on the* [MTC] *intranet page no later than 30 June of each year.*
Meeting records	The TOR should outline how committee deliberations are to be recorded, which role is responsible for the administrative tasks associated with this, and any clearances required before these records are considered finalised. Consideration should be given to records for in-meeting and out-of-session discussions/ decisions.	[MTC] *meetings will be recorded through Microsoft Teams for minute taking purposes only. Once minutes are ratified by the Committee, the recording will be deleted. The* [MTC administrative assistant] *will generate written meeting minutes from the recording, for clearance by the chair prior to tabling at the next MTC meeting. Meeting minutes are not considered final until ratified by a quorum of members at the following meeting. For out-of-session decisions…*
Meeting attendance	The TOR should state any member expectations regarding meeting attendance and the process for members unable to attend. This should also outline the process for nominating a delegate or proxy if this is allowed. The process for inviting specialist members for specific meetings should be outlined within the TOR. Likewise, if an observer role is permitted by the committee, this should be articulated in the TOR.	*Members are expected to attend all meetings. Any member unable to attend a meeting should send an apology to the chair via email (please include the* [administrative assistant role]*) as soon as possible. A proxy can be nominated to attend in the member's place and this should be outlined in the apology email. If approved by the chair, the* [administrative assistant role] *will forward a meeting invite, conflict of interest declaration and terms of reference to the proxy along with the meeting papers.*

		Example Statements
Agendas	The TOR should outline member responsibilities for contributing to the agenda, as well as the process for members (and non-members where applicable) to submit agenda items. This should also include any clearances required (e.g. from the chair). The TOR should nominate the role responsible for compiling and distributing the agenda prior to meetings, and timeframes for agenda dissemination. The TOR may also outline a structure for the agenda (especially if this is notably different to other committees within the health service organisation) and/or standing agenda items to be considered each meeting. Each agenda should allow for action items from the previous meeting to be followed up, and enable the committee to be responsive to new business at each meeting.	[Health service organisation] *staff and* [MTC] *members are to submit any meeting papers or issues for discussion to the chair via email no later than 10 days prior to the scheduled meeting. Members must include the* [administrative assistant role] *in this email.* *The agenda and associated papers will be compiled by the* [administrative assistant role] *for clearance by the chair no later than 8 days prior to the meeting. The agenda will be circulated to members no later than 6 days prior to the meeting.* *Each agenda will include an outstanding actions list and members are required to provide a verbal update within the meeting for each action that has been allocated to their work area.*
Quorum requirements	The required members needed for decision-making should be stated in the TOR. This will include quorum requirements for meetings, and may also include any authority for an individual or smaller group of members to make decisions out-of-session. Consideration should be given to stating not just a number or percentage of members required, but whether there needs to be minimum representation from any core groups to meet quorum requirements.	*Quorum requirements: at least 50% of members must be in attendance for the meeting to be quorate for decision-making. At a minimum, this group must include at least 3 doctors, 1 nurse and 1 pharmacist.*
Decision-making process	The process for how decisions are made should be articulated in the TOR. Decision-making, especially where individual patient factors are taken into consideration, can be highly nuanced and a separate decision-making framework/support document may therefore be required. Where there is MTC capacity for out-of-session decision-making, the TOR should articulate which application types can be considered out-of-session, and any ways in which the decision-making process differs for these out-of-session deliberations.	*Decisions will be made by consensus of the committee. Where consensus cannot be reached, a vote will be made. Members must consider the safety, efficacy, cost-effectiveness and equity of each decision in their decision-making.* *Urgent individual patient applications can be considered out-of-session by the MTC. This will be conducted via email discussion, with a decision communicated to the applicant within 4 business days.*
Voting processes	Where voting is necessary, the TOR should outline how the vote will be conducted (e.g. raising of hands) and the process for managing any situations where for and against votes are equal.	*Where a vote is required, members will be asked to vote by raising their hand. In the event of a tied vote, the chair will hold the deciding vote.*
Disputes/ appeals	Particularly for MTCs with decision-making authority, a process needs to be outlined in the TOR for managing disputes and appealing MTC decisions. This should outline who can request an appeal, and the process for reassessment or referral of the application to a higher authority. Depending on the appeal processes, the TOR may also need to include an escalation pathway for applicants if the decision remains unacceptable to them following the appeal process.	*The applicant, or the* [executive representative] *on behalf of a patient, can request a reassessment of any MTC decision. This request must be made in writing to the chair.* [The MTC] *must re-engage with the applicant to check that all relevant information has been considered by the committee. The application is to be reassessed at the next available* [MTC] *meeting. Any further appeal of a reassessed application is to be referred to* [higher level governance and/or finance committee] *for a final assessment.*

9. COMMUNICATION STRATEGY

To aid transparency, the TOR should outline the MTC's communication strategy including:

- how applicants and other health service staff can communicate with the MTC
- how to submit meeting papers or applications for discussion or decision, and
- how MTC decisions or advice are communicated to the applicant and (where applicable) the wider health service organisation.

The communication strategy may also include advice about where to find information about committee processes, how minutes and other documents are stored, and how to request access to MTC-related information that is not already routinely shared with health service staff.

See also **Guiding principle 12**.

EXAMPLE

All application forms are made available to *[health service]* staff on the *[MTC]* intranet page. Completed applications or policy documents for consideration by the committee should be forwarded to the *[administrative assistant role]* via email at least 7 business days prior to the scheduled meeting. *[MTC]* decision outcomes will be communicated to the applicant in writing within 10 business days of the meeting. This will be in the form of a decision letter from the chair.

Meeting minutes are tabled at the next available meeting for ratification. These are then stored in accordance with the *[organisation wide archive policy]*.

10. SUBCOMMITTEES/WORKING GROUPS

MTCs may need to establish subcommittees to manage specific aspects of medication management such as:

- medication safety
- formulary management
- policy review
- medicine usage evaluation
- electronic/digital medication management
- specific therapeutic areas such as venous thromboembolism prevention
- high-cost/high-complexity areas such as cancer medicines
- stewardship of specific areas such as antimicrobials or analgesics.

Similarly, for specific projects, the MTC may need to establish a time-limited working group.

The MTC TOR should provide scope for the MTC to establish subcommittees and working groups as required.

EXAMPLE

[The MTC] may establish permanent subcommittees and/or temporary working groups as required to meet the objectives of the MTC. Each subcommittee or working group must have their own terms of reference, endorsed by *[the MTC]* and the *[executive level committee]*.

The purpose, governance and reporting arrangements of any subcommittee or working group need to be determined at the point of establishment. The TOR for both the MTC and its subcommittee(s) should include detailed descriptions of how tasks are delegated to the subcommittee, reporting responsibilities to and from the MTC, and any delegated authority for decision-making. Any subcommittee/working group should report directly to the MTC. The subcommittee's role, relative to the MTC, must be clear.

EXAMPLE

[The subcommittee] is a subordinate committee to *[the MTC]* with a primary purpose of reviewing submitted policy documents and providing recommendation to *[the MTC]* for a final decision by *[the MTC]*. *[The subcommittee]* has the delegated authority to return any policy documents to the author with recommendations for changes prior to reconsideration by the *[subcommittee]*.

The author may appeal the recommendations to *[the subcommittee]* initially, with any unresolved appeals referred to *[the MTC]* for final decision. Reviewed policy documents for approval will be forwarded by *[the subcommittee]* with recommendations (in meeting paper format) to *[the MTC administrative support role]*. These policy documents will be tabled for final *[MTC]* decision at the next available meeting.

The subcommittee TOR could use a standard subcommittee TOR template from the health service organisation, or use a TOR format similar to that of the MTC. Mirroring the MTC's TOR can help to foster a consistent approach to governance and operation across the MTC and its subcommittees. A similar scaled version of the TOR may also be useful when establishing ad hoc working groups.

11. PERFORMANCE

See also **Guiding principle 11**.

The TOR should clearly state how the performance of the MTC will be measured, including metrics or key performance indicators (KPIs) where applicable. The frequency of this performance review is stated in the TOR as well as the role or governance group to whom performance measures will be reported.

EXAMPLE

[The MTC's] performance against objectives outlined in their annual work plan will be reviewed in February of each year and reported to the *[executive role title]* as executive sponsor of the committee.

EXAMPLE

Key performance indicators (KPIs) are outlined in the appendix to these terms of reference. Committee performance against these KPIs will be measured annually. This will be reported to the *[executive clinical governance committee]* and published on the *[MTC's]* intranet page.

EXAMPLES OF METRICS THAT COULD BE CONSIDERED FOR MTC PERFORMANCE MONITORING

- → Number of applications for formulary or individual patient use considered in the reporting period
  - Percentage of applications approved, not approved or deferred
  - Cumulative financial value of applications considered
- → Number of policy documents reviewed by the MTC
  - Percentage approved/endorsed at first review
  - Number of reported medication safety incidents where a lack of direction in policy documents was identified as a contributing factor
- → Number of quality improvement activities commenced during the reporting period
  - Number of quality improvement activities completed (including post-implementation audit)
  - Percentage of post-implementation audits that showed positive benefit
- → Number of interventions (e.g. system improvements, education) implemented in response to identified trends in medication safety incidents

If defining metrics or KPIs for performance monitoring, MTCs should determine the acceptable level of compliance. To choose appropriate metrics, the MTC needs to consider what a higher- or lower-than-expected result might indicate, and what actions the MTC could take in response to such results. For example, the number of reported medication safety incidents is not a good metric for measuring MTC performance, as an increased number of reports could be reflective of either a poor medication safety record or a good reporting culture among health service staff. The converse also applies. An increase in the number of IPA/IPU applications may indicate a need for formulary amendments, or alternative approval pathways for lower-cost/lower-risk treatments to manage MTC workload appropriately. This metric provides an outcome that is actionable by the MTC.

12. TOR APPROVAL AND REVIEW

Any TOR should have a documented process for approval and endorsement of the TOR, including a timeframe and process for review.

Example TOR may be available online. Examples available at the time of publishing include:

- → **South Australian Medicines Advisory Committee**
- → **NSW Medicines Formulary Committee**
- → **VicTAG Inc Quality Use of Medicines Committee**
- → **Western Australian Medicines Evaluation Panel**
- → **Western Australian Therapeutics Advisory Group**

EXAMPLE

These terms of reference (TOR) were approved by *[the MTC]* on *[DD Month YYYY]* following unanimous agreement by committee members present at the inaugural meeting. It was subsequently endorsed by the *[higher level governance committee or executive delegate]* on *[DD Month YYYY]*. These TOR and committee membership will be reviewed at least once every 2 years. Earlier review of the TOR can be requested by any two committee members, with the request made in writing to the chair. Review of the TOR is to occur in session, following circulation of proposed amendments to members at least 10 days prior. Any amendments to the TOR must be agreed by at least 80% of voting members.

APPENDIX 3 - HOW THESE GUIDING PRINCIPLES WERE DEVELOPED

These Guiding Principles provide an update to the 2013 CATAG document **Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals (Version 1).** This updated document reflects the evidence available in 2025 and has been contemporised according to current practice, with funding support from the Australian Commission on Safety and Quality in Health Care (ACSQHC).

Alongside review of the literature, qualitative interviews were conducted with representatives from Medicines and Therapeutics Committees (MTCs) across Australia. These qualitative interviews and submitted terms of reference informed the update of these Guiding Principles, defining current MTC practice and identifying stakeholder needs. Interview results aligned broadly with the results recorded from the 2013 CATAG online survey, with both indicating that MTCs have variation in their functions, structure and operation.

MTC functions have evolved since CATAG's survey in 2013, in part due to the emergence of state or territory formularies that evaluate the evidence for treatments and assess cost-effectiveness at a state or territory level. Over time the main responsibilities of MTCs have expanded from approval of medicines-related policy, rational medicines use and cost containment to encompass broader aspects of medicines governance such as:

- → patient safety, including monitoring and reporting on medication safety incidents and adverse event reports
- → promoting evidence-based use of medicines
- → implementing QUM quality improvement strategies
- → assessing and reducing the risk of medicines-related harm
- → guiding health services regarding the governance of new healthcare therapies and technologies
- → providing guidance documents to standardise practice
- → supporting health service organisations in meeting NSQHS Standards.

These findings highlighted the importance of MTCs clearly defining their scope and functions within their health service organisation while remaining agile in their approach to medicines governance, responding to locally identified need, changes in the healthcare environment, and continuous quality improvement through evaluation of MTC performance.

CATAG convened an Expert Advisory Group (EAG) to review the original guiding principles document and advise on changes to support MTC practice in 2025 and beyond. The EAG was comprised of individuals with recognised expertise in areas such as therapeutics/quality use of medicines, evidence-based medicine use, medicines governance and MTC operations. All comments provided by the EAG were discussed and considered for incorporation into these Guiding Principles. Input on the document was also sought from the ACSQHC.

The EAG met on two occasions via video conference, with emailed discussions and document review between meetings. The EAG provided endorsement of the final draft document on 29 May 2025.

External stakeholder consultation was undertaken in April 2025. CATAG member organisations and 48 external stakeholder organisations were invited to provide feedback on the drafted document. Responses were received from representatives of 21 organisations, including public and private hospitals, state and territory health departments, and national professional organisations.

These Guiding Principles were developed in consultation, with and endorsed by, representatives from the CATAG member organisations on 30 June 2025. See **catag.org.au/organisations/** for details and contacts.

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