

# Achieving effective medicines governance

Guiding Principles for the roles and  
responsibilities of Drug and Therapeutics  
Committees in Australian public hospitals

**November 2013**

## Council of Australian Therapeutic Advisory Groups

### C/- NSW Therapeutic Advisory Group

**Postal Address:**

PO Box 766  
Darlinghurst  
NSW 2010

**Office Location:**

26 Leichhardt St,  
Darlinghurst  
NSW 2010

**Phone:** (02) 8382 2852**Fax:** (02) 8382 3529**Email:** [catag@stvincents.com.au](mailto:catag@stvincents.com.au)**Web:** [www.catag.org.au](http://www.catag.org.au)

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Council of Australian Therapeutic Advisory Groups. Achieving effective medicines governance.

Guiding principles for the roles and responsibilities of Drug and Therapeutics

Committees in Australian public hospitals.

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**CATAG**  
Council of Australian Therapeutic Advisory Groups

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# Executive Summary

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A Drug and Therapeutics Committee (DTC) (or equivalent) is a multidisciplinary committee with a commitment to the overall governance of the medicines management system in their health service organisation to ensure the judicious, appropriate, safe, effective and cost-effective use of medicines.<sup>1</sup>

Optimising the function, structure, operation and processes of DTCs using these Guiding Principles will facilitate sound, consistent and standardised decision-making and oversight of medicines within Australian public hospitals and promote safe and quality use of medicines leading to better patient outcomes.

The purpose of the Council of Australian Therapeutic Advisory Groups Guiding Principles for DTCs (Guiding Principles) is to provide guidance on the role, operation and evaluation of DTCs within Australian public hospitals to achieve effective medicines management governance. The Guiding Principles address the importance of clearly defining the scope and functions of a DTC and provide recommendations for structure, operations and processes, communications and resources for an effective DTC. DTCs should have a proactive rather than a reactive role within their health service organisation.

DTCs have been in existence in Australia for many years and play an important role in implementing the *National Medicines Policy*.<sup>2</sup> DTC roles and responsibilities have changed over time, reflecting the constantly evolving healthcare environment and guidance is needed to ensure that DTCs continue to play a vital role. It is recommended that DTCs evaluate how they are currently functioning using the Checklist in Appendix 6 and identify and prioritise areas for improvement.

The Guiding Principles will also assist DTCs to meet the *National Safety and Quality Health Service Standards*.<sup>3</sup>

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The Guiding Principles for the roles and responsibilities of DTCs are:

## SCOPE AND FUNCTIONS

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1. DTCs should have oversight of the medicines management system within a hospital, local health district/network or state/territory.
2. DTCs should have clear terms of reference that articulate its position within a hospital, local health district/network or state/territory clinical and corporate governance structure.
3. DTCs should consider the local environment when defining their functions.

## STRUCTURE

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4. DTCs should have formalised reporting structures to the organisation's executive or clinical governance lead.
5. Membership of the DTC should be multidisciplinary, with a range of expertise and skills to reflect the functions of the DTC.
6. DTCs may establish subcommittees to manage specific tasks.

## OPERATION AND PROCESSES

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7. Standardised procedures for decision-making regarding formulary management need to be defined and applied.
8. Standardised procedures for decision-making regarding individual patient requests need to be defined and applied.
9. Standardised processes and documentation should be implemented by the DTC.
10. DTCs should be both proactive and responsive to issues arising and develop an annual work plan.
11. DTCs should undertake risk assessments within the health service organisation with respect to medicines use and recommend strategies to mitigate that risk.
12. DTCs should identify and prioritise a systems improvement plan and assign responsibilities and timeframes for completion.
13. DTCs should have monitoring systems in place to evaluate their effectiveness.

## COMMUNICATION

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14. DTCs should develop a communication strategy that ensures timely, effective and appropriate information for the intended audience.
15. DTCs should promote the safe and quality use of medicines throughout the medicines management pathway by engaging with internal and external stakeholders.

## RESOURCES

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16. DTCs should be adequately resourced by the hospital, local health district/network or state/territory that they service to undertake their functions and responsibilities.

# Overview

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## Purpose

The purpose of these Guiding Principles is to provide guidance on the role, operation and evaluation of Drug and Therapeutics Committees (DTCs) or equivalent associated with public hospitals. This will provide a framework for DTCs to achieve effective medicines management governance within their organisation and promote national consistency. These Guiding Principles will assist DTCs to meet the *National Safety and Quality Health Service Standards*, particularly Standard 4: Medication Safety and also relevant aspects of Standard 1: Governance for Safety and Quality in Health Service Organisations and Standard 3: Preventing and Controlling Healthcare Associated Infections.<sup>3</sup>

## Background and rationale

DTCs have been in existence in Australia for many years and play a major role in delivering the *National Medicines Policy*.<sup>2</sup> A DTC may also be known as a Medicines Advisory Committee, Pharmacy and Therapeutics Committee, Drug Committee, Drug and Therapeutics Advisory Committee or Quality Use of Medicines Committee. A review of the literature indicates that DTCs in Australian public hospitals have diverse roles, responsibilities and structure.<sup>4,5</sup> The literature also suggests there has been a shift in the main responsibilities of a DTC from the approval of medicines that includes policy, rational use and cost containment<sup>6</sup> towards ensuring patient safety and promoting evidence-based medicine, with formulary management to a lesser extent.<sup>5</sup> An online survey of Australian DTC Chairs and members was conducted by the Council of Australian Therapeutic Advisory Groups (CATAG) during April to May 2013.<sup>7</sup> It highlighted a wide variation in the functions, structure and operation of DTCs in Australian public hospitals and informed the framing of these Guiding Principles by identifying current practices and stakeholder needs.

The *National Safety and Quality Health Service Standards* Standard 1: Governance for Safety and Quality in Health Service Organisation and Standard 4: Medication Safety require that health service organisations have governance arrangements in place to support the safety and quality of medicines.<sup>3</sup> The *Safety and Quality Improvement Guide* Standard 4: Medication Safety suggests the governance framework for medication safety include a governance group/committee that is responsible for the medication management system and outlines the composition, roles, responsibilities and functions of this committee.<sup>1</sup>

The Australian health system is constantly evolving at national and state and territory levels. For example, the introduction of Medicare Locals, Local Health Networks and Lead Clinician Groups and centralisation and de-centralisation of services by state and territory governments. The dynamic nature and frequent restructuring of the Australian health system, necessitates that the structures, roles and responsibilities of DTCs are reviewed periodically.

## Vision

A DTC is a multidisciplinary committee that is committed to the overall governance of the medicines management system to ensure the judicious, appropriate, safe, effective and cost-effective use of medicines in their health service organisation.<sup>1</sup>

## Scope

These Guiding Principles apply to DTCs in public hospitals, whether they are local, district/network, regional or state/territory committees. They are equally relevant to private hospitals and other health service organisations with a medicines use committee or equivalent, although these organisations have not been specifically consulted.

This resource is applicable to all organisations and individuals involved in delivering robust governance of medicines use in health services. These include:

- DTC chairs and members
- Local Health Network (also known as Local Health Districts, Health Service Networks, Local Hospital and Health Networks) leads for corporate and clinical governance
- *National Safety and Quality Health Service Standards*<sup>3</sup> implementation leads
- local, area and state/territory quality and safety committees
- health professionals who are involved in the medicines management pathway
- consumer and community representatives.

These Guiding Principles address the importance of clearly defining the scope and functions of a DTC and provide recommendations for the structure, operations and processes, communications and resources for an effective DTC. They provide a framework against which the DTC may review their established practice.

# GUIDING PRINCIPLES

# Guiding Principles | SCOPE AND FUNCTIONS

This section will help DTCs identify the SCOPE of their activities, outline their potential FUNCTIONS and ensure the overarching functions of medicines management are being undertaken

## GUIDING PRINCIPLE 1

**DTCs should have oversight of the medicines management system within a hospital, local health district/network or state/territory.**

DTCs are able to provide a strategic lead for a health service organisation across all steps of the medicines management pathway.<sup>8,9</sup> DTCs can assist in delivering consistent decisions and messages across the local health environment, whether it is at a hospital, health district/network or state/territory level. All health service organisations should have access to the advice and services of a DTC, whether the DTC is specific to that health service organisation, a local health network or state/territory.

### Example:

It may be impractical for a small organisation to have its own DTC. In such cases, it may be represented at and function under the governance of a DTC from a larger facility, health district/network or a state/territory. When this is the case, the larger health service organisation's DTC should provide guidance to the smaller organisation to ensure standardisation or consistency with decision-making and policy or guideline advice across the network.

It is the responsibility of the smaller hospital to have a mechanism in place to implement the decisions, policy or guideline. It may also be appropriate for the functions of the DTC and the implementation of relevant policies and guidelines to be undertaken as part of a Clinical Governance or Quality Committee, provided there is appropriate representation and expertise on that committee.

## GUIDING PRINCIPLE 2

**DTCs should have clear terms of reference that articulate its position within a hospital, local health district/network or state/territory clinical and corporate governance structure.**

Health service organisations need to be aware of where and how the DTC fits into their governance structures. Ideally, the governance structure would allow for interaction between the organisation's board of management, executive and finance/budget committees (see Guiding Principle [GP] 4) and the DTC or any of its subcommittees (see GP 6).

The terms of reference (TOR) for a DTC should include:

- a mission statement
- objectives and strategic priorities
- scope and what is outside the scope

- reporting structure/organisational chart or governance structure within the health service organisation (see GP 4)
- Delegated authority to make decisions (e.g. financial or policy) vs advisory role
- outline of the function (see GP 3)
- relationship with other organisational committees
- membership and length of appointment (or appointment review process)
- appointment process (including length of term) for DTC Chair and DTC Secretary
- attendance expectation of committee members and use of alternates or delegates
- statement addressing conflicts of interest (see GP 5)
- information pertaining to frequency of meeting
- quorum requirements
- establishment and governance of subcommittees (see GP 6)
- process for approval and endorsement of TOR
- review timeframe for TOR (see GP 13).

DTC meetings should be held regularly. The meeting frequency should be defined within the TOR, and meeting times established in advance to ensure adequate opportunity for attendance of committee members, preparation of applications and reading of papers. Clear agendas should be set that include proactive and responsive items.<sup>10</sup> In addition, a clear understanding is required of the reporting structure, how recommendations are dealt with or supported and how identified risks are managed.

The TOR should also articulate how the DTC liaises and collaborates with other organisational committees or functions, such as clinical and human research ethics, new interventional procedures, health technology assessments, antimicrobial stewardship and infection prevention and control. This could be addressed via committee membership or through consultation.

### GUIDING PRINCIPLE 3

**DTCs should consider the local environment when defining their functions.**

DTCs have a key role in the management of medicines in the health service organisation and need to assist the executive and board of management by ensuring that the overarching functions (listed below) are being undertaken within the organisation, whether by the DTC or another committee. Authority for defining functions and assigning responsibility will vary depending on the local framework and need to be clearly defined.

The overarching functions of DTCs are to:

- incorporate quality use of medicines (QUM) principles into all decisions, policies, initiatives involving a medicine
- ensure patient and medication safety is incorporated into all medicines management decisions including monitoring the safety and quality of medicines use in the health service organisation<sup>11</sup>
- advise on local implementation of national, state/territory, district, regional or facility health policies and legislation relating to medicines.<sup>11</sup>

The functions outlined below demonstrate some of the responsibilities of DTCs. It is essential to prioritise the DTCs' activities according to the local environment and level of risk.

DTC functions are to:

- evaluate and approve specific medicines for prescribers' use within the organisation (formulary management)<sup>11-13</sup>

- review and approve policies and procedures relating to medicines management<sup>1,12,13</sup>
- develop and recommend approaches to implement new or revised policies, procedures and guidelines
- develop and promote ongoing quality improvement strategies including interventions to optimise QUM<sup>1,12,13</sup>
- implement processes to ensure adverse drug reactions and medication incidents (including close calls/good catches/near misses which are predictive) are monitored and investigated as part of a proactive approach for the overall monitoring of medicines use<sup>1,12,13</sup>
- undertake risk assessments within the health service organisation with respect to medicines use and apply strategies to mitigate that risk (see GP 11).

When defining the scope of functions, the DTC should define its remit with regards to medicines, devices and blood products.

DTCs should advise on decisions regarding the application and ongoing performance for devices, equipment and technology used in medicines management, e.g. intravenous infusion lines, specialty medication charts, automated dispensing cabinets, dose administration aids, electronic medication management systems and intravenous infusion safety software. At a minimum, one member of the DTC should also be a member of the hospital/health service's new technologies or clinical equipment advisory committees (or similar) and be able to report to the DTC on relevant matters.<sup>1</sup>

DTCs should also be aware of any clinical trials involving medicines occurring in the health service organisation. DTCs need to have a role assessing risks of clinical trials to the organisation other than the ethical considerations.

This section outlines the key issues to consider for reviewing the structure of the DTC including formalised reporting STRUCTURES, MEMBERSHIP and SUBCOMMITTEES

## GUIDING PRINCIPLE 4

**DTCs should have formalised reporting structures to the organisation's executive or clinical governance lead.**

DTCs should have formalised structures that are articulated in the organisational chart or the organisation's governance framework. An organisational chart should be included in the terms of reference to highlight direct reporting lines from the DTC to clinical governance and/or senior executive committees.

DTCs are able to advise and assist, as well as be accountable to, the organisation's executive and board of management. The DTC's position within the organisational structure should enable the assignment of responsibility for seeing the DTC's recommendations to fruition through the appropriate management structures. If a DTC is purely advisory, clear mechanisms must be established to allow advice from the committee to be enacted by hospital management.

DTCs must have their delegated authority regarding accountability and affordability clearly articulated, if this falls within its scope and function. A clear link to an accountable person as delegate of the executive should be defined, e.g. Director of Medical Services, Medical Superintendent, Director of Clinical Governance, Health Network Committee Chair or DTC Chair.

## GUIDING PRINCIPLE 5

**Membership of the DTC should be multi-disciplinary, with a range of expertise and skills to reflect the functions of the DTC.**

DTC membership should reflect the function of the DTC and its accountability within the organisation. The DTC should be a multidisciplinary committee with a core representation from medical, nursing and pharmacy and have an executive (representing the hospital administration and/or finance) or clinical governance delegate at a minimum.<sup>12</sup> It is important that the consumer perspective is considered in the deliberations of the DTC. The *National Safety and Quality Health Service Standards* Standard 2: Partnering with Consumers requires organisations to engage with consumers and carers.<sup>3</sup> This can be achieved by having a consumer representative or advocate on the DTC and associated subcommittees. This will also address several action items relating to the *National Safety and Quality Health Service Standards* Standard 2 (standard items: 2.1.1, 2.2.2, 2.4, 2.8.1, 2.8.2 and 2.9).<sup>3</sup> See *Safety and Quality Improvement Guide* Standard 2: Partnering with Consumers for further information.<sup>14</sup>

DTC members should have the appropriate skill mix and expertise to facilitate competent review and evaluation of all the steps in the medicines management pathway relevant to particular issues. Core membership should include clinicians with expertise in therapeutics and evidence-based medicine, critical appraisal skills and the ability to understand and balance financial and clinical pressures. For some meetings it may be appropriate to invite specialists/experts relevant to the topic under consideration to assist in this process.

The majority of members should be experienced clinicians and/or health professionals that are able to consider the broad healthcare environment and promote the DTC mission among their peers. The DTC may also include junior staff who experience issues at an operational level and may be able to provide new perspectives, insights and ideas to the DTC and champion the DTC mission among their peers. DTC membership should include representation that reflects the specialities and patient population of the organisation.

### Example:

DTC decisions about medicines use in specific populations, such as paediatrics, or those likely to be applied to such populations, should involve health professionals with clinical, therapeutics, QUM and evidence evaluation expertise relevant to that population.

Wider DTC membership should include:

- medical specialists
- clinical pharmacologist (where available)
- infectious diseases physician/clinical microbiologist (where available)
- other medical and surgical staff
- pharmacists, e.g. QUM/clinical pharmacist
- nurse representatives including clinicians and managers
- health professionals who are involved in the medicines management pathway
- clinical governance representative
- primary healthcare provider
- patient safety representative
- executive delegate (senior hospital administration and/or finance).

In addition, each DTC requires secretarial support to ensure optimal functioning.

The nominated Chair of the DTC must provide strong leadership.<sup>11</sup> The Chair requires the necessary expertise, interest and time to devote to the position.

Members are also required to have a strong commitment to the process, undertake work as necessary between meetings and play an active role in the DTC. This entails regular attendance at meetings. Members should demonstrate the mission of the DTC by ensuring that they act in accordance with the committee's policy and direction in everyday practice.

Any potential conflicts of interest should be declared, recorded and a report made available, if required.

New members of the DTC should have an orientation that includes the principles involved in DTC decision-making (evidence, safety, quality, cost-effectiveness and affordability), review of the terms of reference and an understanding of their role and responsibilities.

## TRAINING

DTC members should possess sufficient knowledge and skills to facilitate the effective function of the DTC and achievement of its purpose. DTCs should assess the members' need for training and provide support for such training, where possible. DTC members may require specific training to develop or maintain the required level of expertise in evidence evaluation and therapeutics/QUM to be able to effectively contribute to sound and consistent decision-making. Essential skills and knowledge may include an awareness of clinical governance; conduct of meetings; operation of the Australian medicines governance and financing system; medication safety and QUM principles; accreditation processes; pharmacoeconomics; and critical evaluation and review of literature and quality improvement methodology.

See Appendix 1 for examples of training packages.

## GUIDING PRINCIPLE 6

**DTCs may establish subcommittees to manage specific tasks.**

DTCs may appoint a subcommittee to manage specific projects or tasks, when appropriate. When establishing subcommittees, the governance and reporting arrangements need to be determined at the point of establishing the subcommittee and included in the DTC terms of reference.

Using a standard subcommittee terms of reference template may ensure that there is a consistent approach to the DTC subcommittee's governance and operation. These subcommittees should report directly to the DTC.

### Examples of subcommittees:

- medication safety
- antimicrobial stewardship
- drug use evaluation

It may be necessary to establish ad hoc working groups in relation to specific issues, as required.

This section will assist DTCs operation and processes in DECISION-MAKING, DOCUMENTATION and IMPLEMENTATION, RISK ASSESSMENT and QUALITY IMPROVEMENT and MONITORING of performance

## GUIDING PRINCIPLE 7

**Standardised procedures for decision-making regarding formulary management need to be defined and applied.**

The purpose of maintaining a formulary is to ensure the judicious, appropriate, safe, clinically appropriate and cost-effective use of medicines.<sup>13</sup>

Standard criteria for decision-making should be defined and implemented consistently across all formulary decisions. The decision-making framework should be available and accessible to applicants. All applications should be evaluated against the defined criteria and decisions need to be made according to the best-available evidence.

Standard criteria for decision-making may include:

- indication and patient population
- clinical effectiveness of the medicine
- evidence from the literature relating to the safety of the medicine, including the inherent risk associated with the use of the medicine, e.g. need for additional medicines to manage side effects
- place in therapy and alternate treatments
- patient safety
- any potential implications for the management of patients who receive the medicine
- cost effectiveness, including changes to cost of care, e.g. monitoring
- access considerations, e.g. equity of access
- financial implications for the organisation.

Decisions made by the DTC should take into consideration the benefits and harms of using the medicine for the specified patient population and take into account issues that may affect patient safety (e.g. potential for medication or administration errors) and the potential impact in the wider context (e.g. training requirements, antimicrobial resistance).

Where applicable, the DTC should take into account decisions made by a state-wide formulary committee unless there are compelling local circumstances or important new information has become available since the state-wide decision was made. DTCs should communicate these circumstances with the state-wide formulary committee.

DTCs should consider a risk management strategy, which include education programs that need to be implemented to address safety concerns and mitigate identified risk related to the medicine including those related to naming, labelling and packaging.

Approval of a medicine should include the active ingredient/generic name, strength(s), dosage form(s), indication(s) and any restrictions (e.g. by prescriber, by indication or duration of therapy) for medical and non-medical prescribers. Approval should also include monitoring usage of new additions to a formulary, such as audits, outcome evaluation, monitoring adverse events or medication incidents.

Decisions should be made in a defined time period without compromising the quality of information and evaluation required.

Standardised processes for ongoing formulary management are required for:

- defining mandatory information for applications for formulary addition
- reviewing requests for the addition of new medicines to the formulary, including who performs the review
- reviewing a high-cost medicine application
- reviewing a medicine for off-label use (Refer to the: *Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines.*)
- reviewing medicines for formulary deletion
- appealing unsuccessful applications.

Examples of formulary application documents and resources to assist in evaluating applications are found in Appendices 2 and 3, respectively.

## GUIDING PRINCIPLE 8

### Standardised procedures for decision-making regarding individual patient requests need to be defined and applied.

Approval for individual patient use of specific medicines is required when a therapeutic need (either a medicine or indication) exists for a medicine which would not otherwise be available on the formulary. These medicines may be known as Individual Patient Use (IPU) or Individual Patient Approval (IPA). These are often high-cost medicines where affordability issues may need to be taken into consideration. Often it is not possible to wait for the next DTC meeting and decisions need to be made in a defined time period without compromising the quality of information and evaluation required. A documented process should be in place for urgent IPU requests that includes who has the delegated authority to make the decision as well as minimum information requirements. A process to ensure that urgent decisions do not set precedents should be in place. All approvals granted for IPU between DTC meetings should be reported and reviewed at the next DTC meeting.

At the time of approval, any outcome evaluation, level of monitoring and review should be specified by the DTC. This will assist the DTC in decision-making for future IPU requests.

There should be a clear process to determine when a formal evaluation for formulary addition should be undertaken where multiple IPU requests for the same indication are received by the DTC.

DTCs should consider developing and keeping a database to track IPU approvals to allow monitoring and appropriate referral for formulary application, if there is regular usage.

Standardised transparent procedures within the organisation for IPU requests should include a process for application, evaluation, approval and appeals.

See Appendix 4 for examples of application forms for individual use of medicines.

## GUIDING PRINCIPLE 9

### Standardised processes and documentation should be implemented by the DTC.

DTCs should have standardised processes and documentation to assist in and provide transparency on its decision-making and communication pathways.

Clear agendas should be set prior to each meeting. These should be structured to include standing items and be able to address unexpected issues. Items for action and follow-up from previous meetings should be documented and reviewed at each meeting.

All decisions should be clearly documented and include the process and rationale for the decision and any action required.<sup>10</sup> Decisions should be transparent and documentation regarding the final decision, how the decision was reached, discussion of evidence, consultation, voting mechanisms and the rationale for all policy decisions should be evident. This would demonstrate that the procedures and criteria have been followed. Communication of these decisions is outlined in Guiding Principle 14.

DTCs should specify how and where the minutes are stored, requirements for length of time to archive minutes and processes for communication of decisions.

There should be a process to record any activities that may occur between meetings and for decision-making between meetings.

## GUIDING PRINCIPLE 10

**DTCs should be both proactive and responsive to issues arising and develop an annual work plan.**

DTCs should set and manage the agenda of medicines management within the health service organisation and develop an annual work plan. DTCs should undertake horizon scanning, nationally and internationally, when setting their annual work plan. This work plan should be proactive as well as be responsive to issues arising throughout the year that have not been included when the work plan was devised and agreed. The work plan should define the purpose and expected outcomes of the included initiatives.

### Examples of initiatives:

- proactively reviewing new medicine
- monitoring non-formulary medicines, such as those approved for individual patients
- planning and driving QUM and medication safety initiatives or strategies
- identifying the need for policy/processes in relation to specific medicines management issues
- identifying and overseeing conduct of quality improvement programs, e.g. drug use evaluations, audit and reporting, antimicrobial stewardship
- monitoring use of high-cost medicines
- monitoring incident trends relating to high-risk medicines
- investigating and identifying actions required to address gaps in practice and evaluate the outcomes of initiatives implemented.

DTCs should anticipate changes in the use of medicines and clinical practice, i.e. anticipate demand, changes in 'usual' clinical practice and the changes required to fund and deliver services to assist with internal budget planning and negotiation.

## GUIDING PRINCIPLE 11

**DTCs should undertake risk assessments within the health service organisation with respect to medicines use and recommend strategies to mitigate that risk.**

DTCs have traditionally addressed medication safety issues and should systematically address patient safety, identify opportunities for harm and recommend strategies for implementation into the system to prevent errors.<sup>1</sup> Regular assessment of the performance of the medication management system and activities that increase the safety, quality and effectiveness of medicines use will enable organisations to meet the *National Safety and Quality Health Service Standards* Standard 4: Medication Safety (particularly standard items 4.5.1 and 4.5.2).<sup>3</sup> Other *National Safety and Quality Health Service Standards* that may need to be addressed for risk assessment and mitigation include Standards 3, 5, 6 and 10.<sup>3</sup>

The use of high-risk medications or major system changes (e.g. new computer system, new administration equipment) offer opportunities to undertake proactive risk assessments.

Undertaking self-assessments, such as the Medication Safety Self Assessments<sup>15</sup> or utilising the Failure Mode Effects Analysis<sup>16</sup> can provide useful information for DTCs

and their subcommittees on the safety performance of the organisation's medicines management system and whether the intended strategy offers the best solution to an identified risk.

A risk matrix approach may be required to ensure that the most significant and likely risks are dealt with as a priority.

Medication risks, particularly those with high risk, must be identifiable, escalated and placed on the DTC and/or facility risk register. DTCs also have a role in informing budget requirements to enable (the enactment of) policies and activities to address identified risks.

DTCs should identify key performance indicators that the organisation should monitor in order to ensure that strategies or actions employed to address the risks are effective. These could include a selection of key indicators listed in the *Indicators for Quality Use of Medicines in Australian Hospitals*.<sup>17</sup> For example, where manual charting of medicines is in place, audit of the use of unsafe abbreviations can demonstrate compliance with safe prescribing practices. This addresses *National Safety and Quality Health Service Standards* Standard 4: Medication Safety (standard item 4.5.1).<sup>3</sup>

Refer to the Society of Hospital Pharmacists of Australia's *Standards of Practice for Medication Safety*<sup>18</sup> and the Australian Commission on Safety and Quality in Health Care's *Safety and Quality Improvement Guide* Standard 4: Medication Safety<sup>1</sup> for further information.

## GUIDING PRINCIPLE 12

**DTCs should identify and prioritise a systems improvement plan and assign responsibilities and timeframes for completion.**

DTCs are responsible for ensuring the QUM within its organisation. All therapeutic interventions require ongoing monitoring with regard to use, outcomes and adverse events. The type of outcome evaluation, level of monitoring and review processes will vary. Regular assessment of the performance of all phases of the medication management system and implementation of appropriate quality improvement activities will assist health service organisations meet the *National Safety and Quality Health Service Standards* Standard 4: Medication Safety.<sup>3</sup>

Requirements for ongoing monitoring and audit of decisions can be included as part of the approval process and should occur within a defined time period. This may involve monitoring of new medicines, reviewing the use of high-cost medicines or identifying when medication incidents or adverse events occur.

Quality improvement plans should be developed and implemented, where applicable. This process should include a cycle of audit, intervention followed by re-audit and ongoing monitoring. This can be done using Plan-Do-Study-Act<sup>19</sup>, drug use evaluation or other quality improvement processes. Other activities include regular assessment of the medication management system see *National Safety and Quality Health Service Standards* Standard 4: Medication Safety (standard items 4.2.1, 4.2.2, 4.5.1 and 4.5.2).<sup>3</sup>

Where there is the appropriate authority, DTCs should assign responsibility for the implementation of policies, procedures and monitoring of decisions and clearly communicate this to the department or personnel identified as having responsibility.

See Appendix 5 for examples of tools to assist with quality improvement activities.

## GUIDING PRINCIPLE 13

**DTCs should have monitoring systems in place to evaluate their effectiveness.**

These Guiding Principles provide an initial standard against which DTCs can review their membership, functionality, policies and procedures.

DTCs should review the terms of reference and membership regularly, e.g. every one to three years.

Review of the annual work plan can be used as a measure of how many decisions have been actioned or successfully implemented.

DTCs should use a meaningful tool to evaluate their current practice and progress. Appendix 6 provides a checklist to evaluate current performance. This checklist can be customised according to the role and responsibilities of the DTC.

See Appendix 7 for examples of other tools for measuring DTC effectiveness.

This section outlines key issues for consideration for COMMUNICATION STRATEGIES and ENGAGEMENT with stakeholders

## GUIDING PRINCIPLE 14

**DTCs should develop a communication strategy that ensures timely, effective and appropriate information for the intended audience.**

It is the responsibility of the DTC to ensure all relevant health professionals are informed of issues relating to medicines management and that its advice and decisions are implemented. DTCs are responsible for the process to ensure appropriate and relevant education is provided about all areas of medicines management, although it may not be the provider of such education.

DTCs should establish an overall framework for the timely and effective dissemination of its decisions (e.g. details of method, frequency, format and recipients of communication)<sup>10</sup> and implement an effective communication strategy.

### Examples of methods of communication:

- letters and feedback
- distribution of minutes to Safety and Quality or Clinical Governance Committee
- pharmacy or therapeutic drugs bulletin, fact sheets, high-risk medicine alerts
- intra-departmental meetings
- intranet or internet website
- alerts in electronic medicines management systems (e.g. dispensing, prescribing and administration software)
- consumer and patient brochures.

Decisions relating to individual patient requests, along with the rationale for these decisions, should be communicated in a timely manner. A process for how the information is communicated to the patient, especially when it is not approved, is required. This communication should be undertaken by an appropriate person (preferably a senior clinician), who can competently explain the complexities of the information in terms the patient or carer can understand.<sup>10</sup>

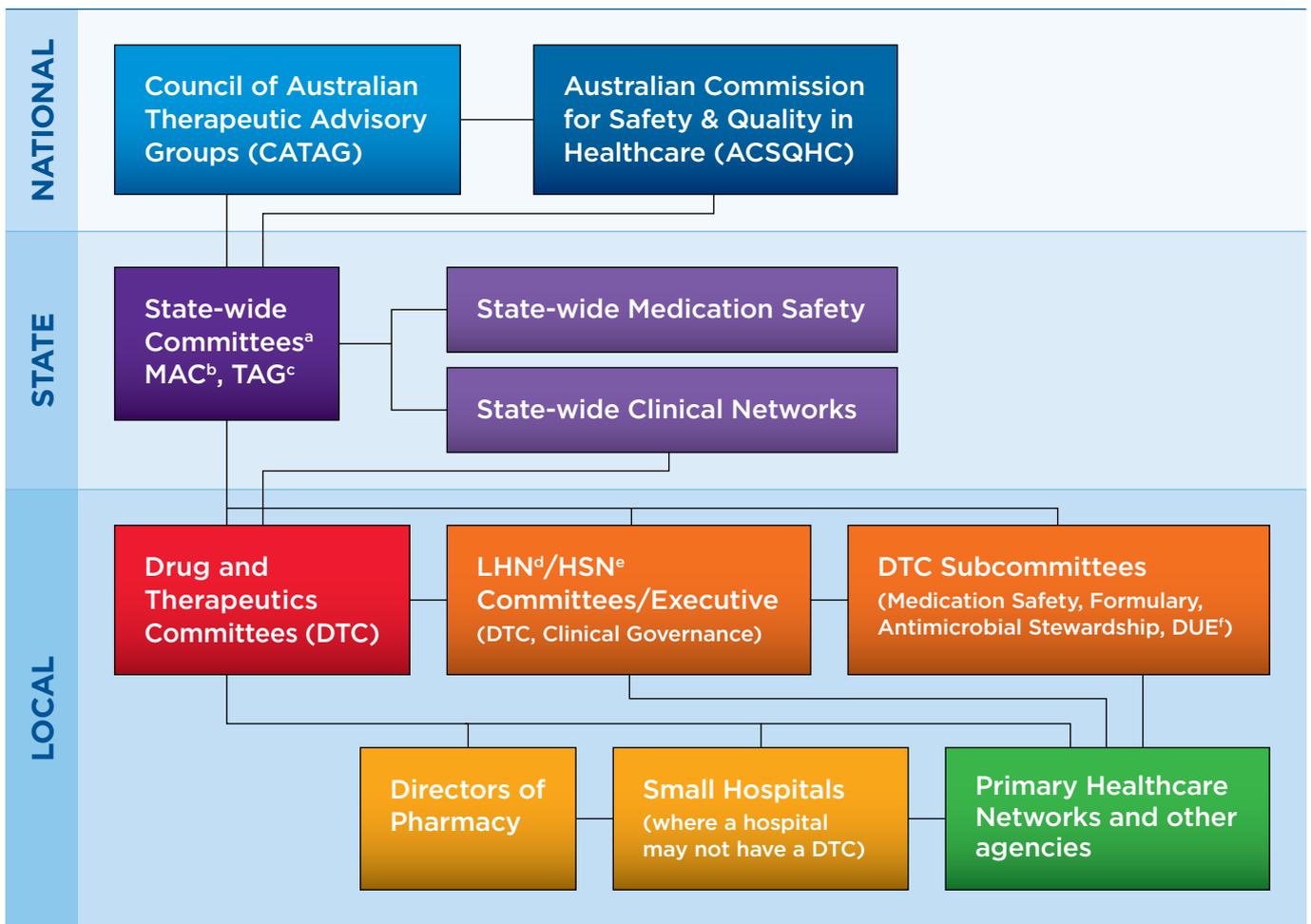
## GUIDING PRINCIPLE 15

**DTCs should promote the safe and quality use of medicines throughout the medication management pathway by engaging with internal and external stakeholders.**

Networking with internal and external stakeholders and partners is an important aspect of communication, enabling advocacy and involvement in the broader context of medicines management, medicine safety or QUM policy decision-making.

DTCs should consider using a multi-layered approach at local, state and national levels when communicating and networking with internal and external stakeholders as shown in Figure 1. The manner in which DTCs engage will vary, according to the local environment. However, suggested engagement includes formalised reporting and communications. DTCs may also communicate with organisations that work within the context of the *National Medicines Policy*,<sup>2</sup> such as the TGA and NPS MedicineWise.

**FIGURE 1:** Communication linkages between DTCs and other committees or organisations



- a Statewide Committees may include state-wide formulary, safety, clinical governance and regulatory committees
- b MAC – Medicines Advisory Committee
- c TAG – Therapeutic Advisory Group

- d LHN – Local Health Network
- e HSN – Health Service Network
- f DUE – Drug Use Evaluation

At the local level, a DTC will most often engage with the Pharmacy Department through the Director of Pharmacy (or their DTC delegate).

DTCs should also consider the potential impacts of their decisions in the wider community. This may influence matters such as the ongoing supply of medicines and prescribing practices outside the health service organisation. As continuity of care is an ongoing concern, establishing links between the DTC, Local Health Networks and primary healthcare networks (e.g. Medicare Locals), may assist in developing strategies to optimise communication and medicines supply across the continuum. Similarly, establishing links with Medicines Advisory Committees associated with aged care facilities may also assist in improving communication about medicines on transition to and from an acute care environment.

Links between DTCs within each state and nationally should be established. DTCs around the country are frequently undertaking similar reviews and evaluations of the same medicines. DTCs should communicate as appropriate with their state Therapeutic Advisory Group or closest equivalents to facilitate wider communication regarding medicines use or policy implementation. CATAG may further assist at a national level to facilitate inter-state communication.

Links to state or national expert clinical groups (e.g. Lead Clinician Groups, state-wide clinical networks) may be useful, to enable access to the appropriate expertise when evaluating medicines for specific populations, such as paediatrics, oncology.

This section considers the RESOURCE requirements for a DTC to function effectively

## GUIDING PRINCIPLE 16

**DTCs should be 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 DTCs to enable them to fulfil their roles and responsibilities as listed in Guiding Principle 3. This support depends on the defined scope and function of the DTC and the size of the health service organisation(s) it serves and may include:

- allocating time for the DTC Chair to attend meetings, review meeting papers and supporting documents and attend to out of session issues (suggest 0.1 – 0.2 FTE)
- ensuring committee members have adequate time to attend meetings, review meeting papers and supporting documents
- resourcing a person with understanding of medicines issues ( e.g. senior pharmacist) to compile papers for submissions, review submissions, liaise with applicants and stakeholders, assist with agenda and minutes, follow-up action points from meetings and manage reports within the hospital or hospitals or local health network. The required time to undertake these tasks will depend on the size and work load of the DTC and level of administrative support and input from the DTC Chair (suggest 0.4 – 1 FTE for a senior pharmacist)

- funding and adequate time for administrative support (0.2 – 0.5 FTE) to assist the DTC with correspondence, communication (agenda and minutes), room bookings and diaries, as agreed by management
- providing resources such as personnel to undertake quality improvement projects and to support the DTC to undertake its functions and activities, including those identified within the annual work plan. An example would be up to 1 FTE project (or QUM or DUE) pharmacist depending on the size of the health service organisation to support the communication, education, implementation and review of DTC decisions
- providing additional resources to support subcommittees undertake activities within their remit. If activities such as medication safety and antimicrobial stewardship are undertaken by the DTC, then the DTC will require additional resources to support alignment with the *National Safety and Quality Health Service Standards*.<sup>3</sup>

The examples of recommended FTEs are suggestions based on the experience of active DTC members at the time of writing and reflect the level of support for a DTC of a medium to large health service organisation.

In most institutions the responsibility for implementing DTC decisions and supporting DTC activities is delegated to the pharmacy department. Where there is no on-site pharmacy service the responsibility should be delegated to the appropriate person within the health service organisation's management team. The person responsible should be adequately resourced to undertake the tasks.

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# Appendices

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## APPENDIX 1: Examples of training packages

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- › NPS MedicineWise online Medication Safety Course <http://learn.nps.org.au/course/category.php?id=56>
- › NPS MedicineWise online Quality use of medicines - why what how and who? <http://learn.nps.org.au/course/category.php?id=42>
- › NSW TAG Issues in Medication Safety Resource List March 2010 <http://www.ciap.health.nsw.gov.au/nswtag/documents/publications/other-docs/safer-resource-list-mar-2010.pdf>
- › Australian Commission on Safety and Quality in Health Care National Patient Safety Education framework <http://www.safetyandquality.gov.au/publications/national-patient-safety-education-framework-2005/>
- › Victorian Quality Council Resources Archive contains resources on change management, clinical governance, clinical leadership, communication among health professionals and safety and quality among others. <http://www.health.vic.gov.au/qualitycouncil/index.htm>
- › Victorian Commission for Hospital Improvement <http://health.vic.gov.au/chi/index.htm>
- › National Prescribing Centre (UK) e-Learning packages are useful for those involved in local decision-making about the funding of medicines and treatments. [http://www.npc.nhs.uk/local\\_decision\\_making/elearn\\_management.php](http://www.npc.nhs.uk/local_decision_making/elearn_management.php)
- › The UK National Institute for Health and Care Excellence provides guidance on good practice recommendations for the systems and processes needed to ensure NHS organisations develop and update local formularies effectively and in accordance with statutory requirements. It supports the development of local formularies that reflect local needs, reduce variation in prescribing, and allow rapid uptake of innovative medicines and treatments. It is written in the context of the NHS in England. However, the principles are also applicable to Australia. <http://www.nice.org.uk/mpc/goodpracticeguidance/GPG1.jsp>
- › WHO Multi-professional Patient Safety Curriculum Guide <http://www.who.int/patientsafety/education/curriculum/tools-download/en/index.html>

## APPENDIX 2: Examples of formulary application documents

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- › NSW TAG DTC formulary submission template <http://www.ciap.health.nsw.gov.au/nswtag/pages/evaluating-new-drugs.html>
- › Queensland formulary submission forms <http://www.health.qld.gov.au/qhcss/mapsu/sdl.asp>
- › South Australia high costs medicine formulary information <http://www.sahealth.sa.gov.au/samep>
- › Western Australian Drug Evaluation Panel has information pertaining to formulary submissions <http://www.watag.org.au/wadep/submission.cfm>
- › Rethinking medicines decision-making in Australian hospitals: Guiding Principles for the quality use of off-label medicines (www.catag.org.au) also outlines a useful algorithm for decision-making.

## APPENDIX 3: Information sources to support decisions about appropriate use of medicines

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[Adapted from CATAG Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines November 2013]

### 1. Decisions of competent regulatory bodies:

- Therapeutic Goods Administration (TGA) (<http://www.tga.gov.au/>)
- US Food and Drug Administration (FDA) (<http://www.fda.gov/>)
- European Medicines Agency – European public assessment reports ([http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/epar\\_search.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/epar_search.jsp))
- NZ Medsafe (<http://www.medsafe.govt.nz/>)

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2. Secondary or summarised sources of high quality research evidence:
    - Cochrane database of systematic reviews
    - UK National Institute for Health and Care Excellence (NICE) Evidence summaries: <http://www.nice.org.uk/mpc/evidencesummaries/unlicensedofflabelmedicines/home.jsp>
    - US Agency for Healthcare Research & Quality (AHRQ) <http://www.ahrq.gov>
    - Canadian Agency for Drugs and Technologies in Health (CADTH) <http://www.cadth.ca>
    - UpToDate (<http://www.uptodate.com/home/product>)
    - British National Formulary/ British National Formulary for Children (BNFC)
    - eviQ (<https://www.eviq.org.au/>) provides evidence-based information to support health professionals in the delivery of cancer treatments
    - Sub-specialty clinical practice guidelines, for example Palliative Care Guidelines
    - NSW TAG therapeutic review documents and position statements <http://www.ciap.health.nsw.gov.au/nswtag/reviews/lit-reviews.html>
    - NPS MedicineWise RADAR (<http://www.nps.org.au/publications/health-professional/nps-radar>)
  3. Evidence-based therapeutic guidelines and other medicines information sources:
    - National Health and Medical Research Council
    - Therapeutic Guidelines Ltd
    - Australian Medicines Handbook (AMH) / AMH Children's Dosing Companion
  4. Primary sources of high quality research evidence published in the peer-reviewed literature.
  5. 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.

**Note:** Secondary sources of summarised evidence, guidelines or other medicines information sources may have limitations. They are generally variable in quality and currency, or not available in a timely manner to provide useful guidance for newly marketed medicines, where many off-label uses are frequently initiated in hospitals. They may also not provide useful information on comparative effectiveness, safety or cost-effectiveness. Therefore, rigorous review of primary research evidence is often needed to enable well informed decisions.

## APPENDIX 4: Examples of application forms for individual patient use of medicines

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- › NSW TAG DTC formulary submission template has an example of an individual patient use application form. <http://www.ciap.health.nsw.gov.au/nswtag/pages/evaluating-new-drugs.html>
- › Queensland guidelines and forms for individual patient approvals are in Appendix 10 of the List of Approved Medicines <http://www.health.qld.gov.au/qhcss/mapsu/documents/lam/lam.pdf>
- › SA Health information and forms for the Individual patient use of high-cost medicines <http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/medicines+and+drugs/prescribing+medicines+regulations+and+requirements/high+cost+medicine+formulary/individual+patient+use+of+high+cost+medicines>

## APPENDIX 5: Examples of tools to assist with quality improvement activities

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- › Indicators for Quality Use of Medicines in Australian Hospitals: NSW TAG; 2007 <http://www.ciap.health.nsw.gov.au/nswtag/pages/indicators.html> (Note a new edition is due for release late 2013)
- › Medication Safety Self Assessment® for Australian Hospitals [http://mssa.cec.health.nsw.gov.au/MSSA\\_introduction.html](http://mssa.cec.health.nsw.gov.au/MSSA_introduction.html)
- › Medication Safety Self Assessment® for Antithrombotic Therapy in Australian Hospitals [http://mssa.cec.health.nsw.gov.au/at2/MSSAT\\_introduction.html](http://mssa.cec.health.nsw.gov.au/at2/MSSAT_introduction.html)
- › National Inpatient Medication Chart Audit System <http://117.53.164.80/AustralianCommission/>
- › NPS MedicineWise drug use evaluation for hospitals <http://www.nps.org.au/health-professionals/professional-development/due-programs/due-kit-for-hospitals>
  - Discharge management of acute coronary syndromes (DMACS) e-DUE toolkit
  - Acute postoperative pain (APOP) e-DUE toolkit.

# Appendices

## APPENDIX 6: Drug and Therapeutics Committees Checklist (version 1)

The purpose of these Guiding Principles for Drug and Therapeutics Committees (DTCs) is to provide guidance on the scope and function, form, operations and processes and communication of DTCs (or equivalent) associated with Australian public hospitals. This will provide DTCs support in achieving effective medicines management governance and promote national consistency.

The Guiding Principles (GPs) are a starting point against which the DTC may review their roles and responsibilities. The checklist is based on these principles and should be used to assess current DTC operations to identify the gaps in functions and/or areas for improvements.

Each section commences with the GPs that are relevant to the section, followed by a list of questions, which can be answered 'yes' or 'no'. If the answer is 'no', this is an area the DTC may wish to investigate further and endeavour to improve.

SCOPE AND FUNCTIONS		Yes	No	Comment
<b>GUIDING PRINCIPLE 1:</b>				
The medicines management system of each health service organisation should be under the governance of a DTC within a hospital, health district/network or state/territory.	Is the medicines management system of your health service organisation under the governance of a DTC?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>GUIDING PRINCIPLE 2:</b>				
DTCs should have clear terms of reference that articulate its position within a hospital, local health district/network or state/territory clinical and corporate governance structure. DTCs should consider the local environment when defining their functions.	Has the relevant Executive Group formally agreed the remit of the DTC? Is there clarity about the status of decisions made, i.e. is the DTC decision-making or advisory?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the DTC have clear terms of reference as defined in GP 2?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there a defined quorum? Is there a formalised process for decision-making, e.g. voting or consensus?	<input type="checkbox"/>	<input type="checkbox"/>	
	Do the DTC terms of reference include a statement dealing with conflicts of interest?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>GUIDING PRINCIPLE 3:</b>				
DTCs should consider the local environment when defining their functions.	Are the functions of the DTC defined according to the local environment?	<input type="checkbox"/>	<input type="checkbox"/>	

FORM		Yes	No	Comment
<b>GUIDING PRINCIPLE 4:</b>				
DTCs should have formalised reporting structures to the organisation's executive or clinical governance lead.	Does the DTC have a formalised structure that is articulated in the organisational chart or the organisation's governance framework?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are there direct links from the DTC to clinical governance and/or the executive?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is the authority and accountability for decision-making clearly defined and fully communicated to relevant stakeholders?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>GUIDING PRINCIPLE 5:</b>				
Membership of the DTC should be multidisciplinary, with a range of expertise and skills to reflect the functions of the DTC.	Is the membership of the DTC multidisciplinary? Does it include representatives across a range of disciplines, e.g. medical, nursing and pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the expertise of the membership reflect the decisions the DTC is being asked to make? Is there a suitable mix of clinical and managerial professionals?	<input type="checkbox"/>	<input type="checkbox"/>	
	Do members have the appropriate range of skills?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the DTC and/or its subcommittees have consumer representation?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there provision (financial and time) for identifying and meeting the training and development needs of DTC members?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there access to adequate ongoing training and resources to support the DTCs' work?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there a process for accessing additional specialist skills when making decisions and providing advice, when necessary?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>GUIDING PRINCIPLE 6:</b>				
DTCs may establish subcommittees to manage specific tasks.	Is there a mechanism to manage specific tasks and projects, as required? Have subcommittees been established to manage specific tasks?	<input type="checkbox"/>	<input type="checkbox"/>	

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OPERATION AND PROCESSES		Yes	No	Comment
<b>GUIDING PRINCIPLE 7:</b>				
Standardised procedures for decision-making regarding formulary management need to be defined and applied.	Have procedures for formulary management been agreed by the DTC and documented?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there a standard template/ application form for formulary submissions?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the DTC have clearly defined criteria to be considered in decision-making for formulary management regarding the use of a medicine, including risks and benefits, financial and ethical considerations?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are there procedures for reviewing formulary decisions based on subsequent evidence? For example, when treatment outcomes are poor or new clinical trial data are available.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>GUIDING PRINCIPLE 8:</b>				
Standardised procedures for decision-making regarding individual patient requests need to be defined and applied.	Have procedures for individual patient requests been agreed by the DTC and documented?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there a standard template/ application form for individual patient use requests?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the DTC have clearly defined criteria to be considered in decision-making for individual patient requests regarding the use of a medicine, including risks and benefits, financial and ethical considerations?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are there defined procedures in place to manage urgent individual patient requests and are these appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is the minimum documentation required for urgent requests defined?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there a defined process to appeal a decision?	<input type="checkbox"/>	<input type="checkbox"/>	

<b>OPERATION AND PROCESSES</b> <i>continued...</i>		<b>Yes</b>	<b>No</b>	<b>Comment</b>
<b>GUIDING PRINCIPLE 9:</b>				
Standardised processes and documentation should be implemented by the DTC.	Are there standard templates for agendas, minutes and executive decisions (with supporting notes)?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the DTC have transparent and accessible documentation which describes how decision-making procedures were applied, and the rationale for each decision which can be reviewed and/or audited?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are decisions minuted with clear rationale, decision points and action required?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the DTC have a policy which defines timely decision-making and communication of outcomes?	<input type="checkbox"/>	<input type="checkbox"/>	
	Where, due to unusual or unexpected circumstances, defined timeframes are unlikely to be achieved, is this explained to the relevant stakeholders and a realistic timeframe proposed?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there a set agenda prior to each meeting? Is there provision for proactive and responsive agenda items and a mechanism for stakeholders to submit items for consideration?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>GUIDING PRINCIPLE 10:</b>				
DTCs should be both proactive and responsive to issues arising and develop an annual work plan.	Does the DTC develop and follow an annual work plan informed by local issues and horizon scanning, nationally and internationally?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>GUIDING PRINCIPLE 11:</b>				
DTCs should undertake risk assessments within the health service organisation with respect to medicines use and apply strategies to mitigate that risk.	Does the DTC undertake risk assessments within the health service organisation with respect to medicines use? When risks are identified, are strategies identified and recommended to mitigate that risk?	<input type="checkbox"/>	<input type="checkbox"/>	

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<b>OPERATION AND PROCESSES</b> <i>continued...</i>		<b>Yes</b>	<b>No</b>	<b>Comment</b>
<b>GUIDING PRINCIPLE 12:</b>				
DTCs should identify and prioritise a systems improvement plan and assign responsibilities and timeframes for completion.	Is there a framework for the implementation and ongoing monitoring of decisions to ensure that criteria for decision-making are being consistently applied?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the DTC identify and implement quality improvement activities when needed, assigning responsibilities and timeframes for completion?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>GUIDING PRINCIPLE 13:</b>				
DTCs should have in place monitoring systems to evaluate their effectiveness.	Are the terms of reference and membership regularly reviewed to reflect organisational or functional changes?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the DTC use a meaningful tool to evaluate their current practice and progress? Is there an assurance process to monitor its effectiveness and to enable learning to be incorporated into future process improvements?	<input type="checkbox"/>	<input type="checkbox"/>	

COMMUNICATION		Yes	No	Comment
<b>GUIDING PRINCIPLE 14:</b>				
DTCs should develop a communication strategy that ensures timely, effective and appropriate information for the intended audience.	Is there a communication strategy for the timely and effective dissemination of decisions? For example, detailing method of communication, frequency, format and recipients.	<input type="checkbox"/>	<input type="checkbox"/>	
	Is responsibility assigned for communicating decisions?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there a communication process to ensure relevant information reaches the correct audience?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>GUIDING PRINCIPLE 15:</b>				
DTCs should promote the medicines management pathway by engaging with internal and external stakeholders.	Does the DTC engage with and involve relevant stakeholders, e.g. local health networks and primary healthcare networks?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is continuity of medication management taken into consideration when making decisions?	<input type="checkbox"/>	<input type="checkbox"/>	

RESOURCES		Yes	No	Comment
<b>GUIDING PRINCIPLE 16:</b>				
DTCs should be adequately resourced to undertake their functions and responsibilities.	Are resources available to support audit of the DTC's activities, in terms of internal functions and outcomes of decisions/recommendations?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the DTC have appropriate resources to support the secretariat functions, e.g. agenda setting, documentation, follow-up of actions and minute taking?	<input type="checkbox"/>	<input type="checkbox"/>	
	Do members have adequate time to spend on DTC activities, such as attend meetings, and review meeting papers and supporting documents?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is the DTC resourced to provide training where appropriate for its members?	<input type="checkbox"/>	<input type="checkbox"/>	

[Adapted with permission from: National Prescribing Centre. Supporting rational local decision-making about medicines (and treatments). A handbook of good practice guidance. Liverpool, UK: National Prescribing Centre; 2009.]

# Appendices

## APPENDIX 7: Examples of tools for measuring effectiveness

- › Indicators for Quality Use of Medicines in Australian Hospitals: NSW Therapeutic Advisory Group, 2007 <http://www.ciap.health.nsw.gov.au/nswtag/pages/indicators.html> (Note a new edition is due for release late 2013/early 2014)  
Specifically indicators:
  - 2.2 Percentage of prescriptions for restricted antibiotics that are concordant with Drug and Therapeutics Committee approved criteria
  - 6.4 Percentage of submissions for formulary listing of new chemical entities for which the Drug and Therapeutics Committee has access to adequate information for appropriate decision making.
- › Standard 4: Medication Safety. Safety and Quality Improvement Guide. Australian Commission on Safety and Quality in Health Care 2012.  
Specifically examples of outputs from Criterion: Governance and systems for medication safety items 4.1, 4.2, 4.4, 4.5.
  - Standard 4.1 Developing and implementing governance arrangements and organisational policies, procedures and/or protocols for medication safety, which are consistent with national and jurisdictional legislative requirements, policies and guidelines
  - Standard 4.2 Undertaking a regular, comprehensive assessment of medication use systems to identify risks to patient safety and implementing system changes to address the identified risks
  - Standard 4.4 Using a robust organisation-wide system of reporting, investigating and managing change to respond to medication incidents
  - Standard 4.5 Undertaking quality improvement activities to enhance the safety of medicines use
- › Indicators for Drug and Therapeutics Committees <http://www.ciap.health.nsw.gov.au/nswtag/documents/publications/indicators/archive-manual-jan-1997.pdf>

## APPENDIX 8: Therapeutic Advisory Groups or equivalent

- › NSW Therapeutic Advisory Group (NSW TAG) <http://www.ciap.health.nsw.gov.au/nswtag/>
- › Victorian Therapeutics Advisory Group (VicTAG) <http://www.victag.org.au/>
- › Queensland Health Medicines Advisory Committee (QHMAC) <http://www.health.qld.gov.au/qhcss/mapsu/default.asp>
- › South Australian Medicines Advisory Committee (SAMAC) <http://www.sahealth.sa.gov.au/SAMAC>
- › Western Australian Therapeutics Advisory Group (WATAG) <http://www.watag.org.au/home/>
- › Department of Health and Human Services Tasmania – Statewide Therapeutic Drug Committee (intranet)
- › Council of Australian Therapeutic Advisory Groups (CATAG) <http://www.catag.org.au>

## APPENDIX 9: Glossary

- › **Annual work plan:** A detailed activity plan that sets out what will be accomplished during the year in order to achieve specific results. It usually contains the activities necessary to achieve anticipated outcomes, the time frame involved, those responsible for the activities, and what each activity entails. An annual work plan helps monitor how the desired goals are being accomplished.
- › **Clinical governance:** A system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. This is achieved by creating an environment in which there is transparent responsibility and accountability for maintaining standards and by allowing excellence in clinical care to flourish.<sup>1</sup>
- › **Drug and Therapeutics Committee (DTC):** 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.<sup>2</sup> These may also be known as a Medicines Advisory Committee, Pharmacy and Therapeutics Committee, Drug Committee, Drug and Therapeutics Advisory Committee or Quality Use of Medicines Committee.

- › **Drug use evaluation (DUE):** An authorised, structured, ongoing system for improving the quality use of medicine within a health service organisation. Medicine use is evaluated using pre-determined standards, and efforts are initiated to correct patterns of use which are not consistent with these standards. It includes a mechanism for measuring the effectiveness of these corrective actions.<sup>3</sup>
- › **Formulary:** A continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medicines and medicine-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organisational guidelines.<sup>4</sup>
- › **Health professional:** Qualified individuals who provide healthcare.<sup>5</sup>
- › **Health service organisation:** A constituted health service that is responsible for the clinical governance, administration and financial management of a service unit(s) providing health care. A service unit involves a grouping of clinicians and others working in a systematic way to deliver health care to patients and can be in any location or setting, including hospital pharmacies, clinics, outpatient facilities, hospitals, practices and clinicians' rooms.<sup>1</sup>
- › **Individual patient use/approvals (IPU/IPA):** A request to or approval by the DTC for the use of a medicine by an individual patient outside the formulary regulations.
- › **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.<sup>6</sup> These may also be known as Local Health Districts, Health Service Networks, Local Hospital and Health Networks.
- › **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. Prescription, non-prescription and complementary medicines, irrespective of their administration route, are included.<sup>17</sup>
- › **Medication management pathway:** The cognitive and physical steps involved in the use of medicines, with a focus on the consumer.<sup>8</sup>
- › **Medicine management system:** The system used to manage the provision of medicines to patients that are specific to a healthcare setting. This system includes 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.<sup>1</sup>
- › **Multidisciplinary:** Professionals from a range of disciplines with different but complementary skills, knowledge and experience working collaboratively.
- › **Quality use of medicines (QUM):** The judicious, appropriate, safe and effective use of medicines.<sup>9</sup>
- › **Risk:** The chance of something happening that will have a negative impact. It is measured by consequences and likelihood.<sup>1</sup>
- › **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 patients, employees, volunteers, visitors and the institution.<sup>1</sup>
- › **Terms of reference:** These are used to describe the purpose, roles and structures of projects, working groups, reference groups and committees. These are guidelines for the way group members will work together.

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# Appendices

## APPENDIX 10: How these guiding principles were developed

These Guiding Principles were prepared by a Project Team, convened by CATAG, with funding support from NPS MedicineWise. The Project Team reviewed the published literature and synthesised concepts and themes from key work on the roles and responsibilities of Drug and Therapeutics Committees (DTCs).

The literature review informed a survey to investigate current practices of DTCs and a web-based survey was developed. This survey was distributed by state-based Therapeutic Advisory Group organisations or jurisdictional equivalent directly to the DTC Chairs in each state. Where applicable, a representative from the state-wide committees was surveyed. The DTC Chair or nominated delegate was asked to complete the survey. Survey respondents had the option of including their name and contact details if they were interested in elaborating on their answers. A qualitative interview was conducted with some respondents. Ethics approval for low and negligible risk research was obtained via The University of Sydney, Human Research Ethics Committee.

To review current composition of DTCs, terms of reference were sourced from a number of DTCs.

The survey was conducted during April and May 2013 and the results were analysed. A first draft of the Guiding

Principles was prepared by the Project Team for discussion by an Expert Advisory Group (EAG). The EAG was comprised of individuals with recognised expertise in a range of areas, such as therapeutics/quality use of medicines, evidence-based medicine and DTC Chairs.

A face-to-face meeting of the EAG was held on 31 May 2013, following which a second draft of the Guiding Principles was prepared by the Project Team and circulated to the EAG for further comment.

The Project Team reviewed all comments provided by the EAG and prepared a third draft for review by the CATAG. Consultation via the Therapeutic Advisory Groups/Medicines Advisory Committees occurred at a state level with key stakeholders.

External consultation with key national organisations occurred during August and September 2013. Comments were collated and reviewed by the Project Chair, Project officer and CATAG Coordinator and changes made to the document. This iteration was sent to the EAG for review by e-mail. Any disagreements were resolved by discussion among the Project Team and, if necessary, with individual members of the EAG. A final version was approved by the EAG and CATAG. The final document represents consultation with the groups detailed below.

## PROJECT TEAM

- › **Ms Lisa Pulver** – Project Officer, CATAG
- › **Mr Steve Morris** (*Co-Chair EAG*) – CATAG Chair
- › **Ms Jane Donnelly** – CATAG Coordinator
- › **Ms Gillian Sharratt** – Co-Executive Officer, NSW TAG
- › **Ms Ruth Hay** – Director, Medication Services Queensland, Health Services Support Agency, Department of Health, QLD
- › **Ms Stephanie Boydell** – Pharmacist Manager, QHMAC Secretariat, Health Services Support Agency, Department of Health, QLD
- › **Dr Joel Heeg** – Executive Officer, Department of Pharmacy, Sir Charles Gairdner Hospital, WA
- › **Ms Catherine Spiller** – Director, Medication Strategy and Reform, Department of Health and Human Services, TAS
- › **Ms Eliana Della Flora** – Senior Scientific Officer, South Australian Medicines Advisory Committee, Medicines and Technology Policy and Programs, SA Health, SA

## EXPERT ADVISORY GROUP

- › **Dr Jason Armstrong** – Emergency Physician, DTC Chair, Sir Charles Gairdner Hospital, WA
- › **Dr Sasha Bennett** – Co-Executive Officer, NSW TAG
- › **Mr Luke Christofis** – Emergency Nurse Practitioner, Emergency Department, Lyell McEwin Hospital, SA
- › **Ms Helen Dowling** – Chief Executive Officer, Society of Hospital Pharmacists of Australia, VIC
- › **Ms Margaret Duguid** – Pharmaceutical Advisor, Australian Commission on Safety and Quality in Health Care, NSW
- › **Professor Albert Frauman** – Clinical Pharmacology & Therapeutics Unit, Austin Health, VIC
- › **Dr Michael McGlynn** – Medical Executive Director, South Eastern Sydney Local Health District, NSW
- › **Dr Matthew Pincus** – Cardiologist, DTC Chair, The Prince Charles Hospital, QLD
- › **Emeritus Professor Lloyd Sansom** (*Co-Chair EAG*) – Division of Health Sciences, University of South Australia, SA

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## EXTERNAL CONSULTATION

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- › Australian Commission for Safety and Quality in Health Care
- › NPS MedicineWise
- › Society of Hospital Pharmacists of Australia
- › Australian Healthcare and Hospital Association
- › Royal Australasian College of Medical Administrators
- › Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
- › Australasian College of Health Service Management
- › Australian Medicare Local Alliance
- › Australian College of Nursing
- › Clinical Excellence Commission, NSW
- › Queensland Health Medicines Advisory Committee
- › Statewide Therapeutic Drug Committee, TAS
- › NSW Therapeutic Advisory Group
- › South Australian Medicines Advisory Committee
- › Victorian Therapeutics Advisory Group
- › Western Australian Therapeutics Advisory Group
- › Northern Territory Department of Health

### These guiding principles build on key concepts from the following previous work.

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- › Professor Jo-anne Brien, School of Pharmacy, University of Sydney, NSW
- › Ms Benafsha Khariwala, Medical Editor, VIC
- › Professor Andrew McLachlan, School of Pharmacy, University of Sydney and Concord Hospital, NSW

## DISCLOSURE

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