Policy Directive

Approval Process for Medicines and Their Use

Summary This Policy Directive outlines governance structures and standard procedures for medicines use and approval within NSW public hospitals and health services.

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Audience Pharmacy Departments and COVID-19 Vaccination Clinic Staff with Local Health Districts;All Clinical and Allied Health Staff;Public Health Unit and Pharmacy Departments Staff within Local Health Districts

Secretary, NSW Health

NSW Health

POLICY DIRECTIVE

Approval Process for Medicines and Their Use

POLICY STATEMENT

NSW Health is committed to establishing a standard process for the approval of medicines for use within NSW public hospitals and health services in accordance with the NSW Medicines Formulary, or for approval of medicines for individual patient use.

SUMMARY OF POLICY REQUIREMENTS

All NSW public hospitals and health services are to have the following processes in place.

Submissions for addition, amendment, or removal of a medicine on the NSW Medicines Formulary. All medicines under consideration for addition, or for variation to an existing listing, need to undergo a thorough evaluation process. The NSW Medicine Formulary Committee's approval is required for all formulary listings of medicines that are for initiation within NSW public health facilities, including any prescribing restrictions associated with it.

Approval of specific medicines for Individual Patient Use (IPU) when a therapeutic need exists for a medicine or an indication which is not listed on the NSW Medicines Formulary. The Drug and Therapeutics Committee is responsible for management of Individual Patient Use and needs to have a standard process to guide their decision-making when evaluating a medicine for Individual Patient Use.

Prescribers considering use of a specific medicine for an off-label indication, or use of an unregistered medicine, need to follow a systematic evaluation process to assist with the assessment of whether such use is clinically justified.

REVISION HISTORY

Version	Approved By	Amendment Notes
PD2022_056 December-2022	Deputy Secretary, People, Culture and Governance	This policy is revised to reflect the changes to the process for the approval of medicines and their use in NSW public hospitals and health services that will take place with the implementation of the NSW Medicines Formulary.
PD2016_033 July-2016	Deputy Secretary, Governance, Workforce and Corporate	This policy updates and replaces PD2008_037. This policy has been revised to better reflect the purpose of the policy.
PD2008_037 July-2008	Director General	Medicine- Evaluation of Medicines for Use in Public Hospitals.

NSW GOVERNMENT

NSW Health

Approval Process for Medicines and Their Use

CONTENTS

1. BACKGROUND

This Policy Directive describes governance structures and standard procedures for approval of medicines for use within NSW public hospitals and health services. It includes procedures to support adoption and compliance with the Statewide NSW Medicines Formulary.

The NSW Medicines Formulary aims to reduce unnecessary clinical variation, increase equity of access to medicines, and improve both patient safety and quality use of medicines.

1.1. About this document

This Policy applies to all clinical staff working within NSW public hospitals and health services, involved in the prescribing, dispensing and administering of medicines, as well as those involved in the approval process for medicines.

All NSW public hospitals and health services are to have the process in place for:

- Medicines listed on the NSW Medicines Formulary
- Medicines that are registered or listed on the Australian Register of Therapeutic Goods that have not yet been added to the NSW Medicines Formulary
- Use of registered or listed medicines in a manner that is not included in the approved product information for that medicine
- Use of medicines that are not registered or listed on the Australian Register of Therapeutic Goods.

The process set out in this Policy, does **not** apply to:

- Medicines supplied through Medicines Access Programs (refer to the Council of Therapeutic Advisory Groups (CATAG) document on *Managing Medicines Access Programs: Guiding Principles for the governance of Medicines Access Programs in Australian hospitals*)
- The approval of medicine use for research refer to NSW Health Guideline Human *Research Ethics Committees: Standard Operating Procedures for NSW Health Public Health Organisations* (GL2013_099).

All public hospitals and health services in NSW are to adopt and comply with the NSW Medicines Formulary.

Drug and Therapeutics Committees (DTC) are to support local adoption of the NSW Medicines Formulary and provide oversight of the use of all medicines in local facilities.

Prescribers working within public hospitals and health services can only initiate medicines that are listed on the NSW Medicines Formulary or in accordance with this Policy.

1.2. Key definitions

Conditional Use	Refers to off-label use of medicines where [1]: • The quality of evidence is low to moderate; however, there is reasonable justification for use in certain types of patients • A Drug and Therapeutics Committee (DTC)-approved protocol, NSW Health Policy or Statewide/national Clinical Guideline guides the therapy • Evidence development is required with systematic reporting of effectiveness and safety outcomes to the Drug and Therapeutics Committee and relevant clinicians • There is regular review of continued therapy for an individual and group of patients. Approval applies to a specific group of patients.
Drug and Therapeutics Committee (DTC)	The Committee with delegated responsibility for the governance and quality of the medication management system and for ensuring the appropriate, safe, effective, and cost-effective use of medicines in the health facility, Local Health District or Speciality Health Network under their jurisdiction [2]. For further information on the role and operation of Drug and Therapeutics Committees, refer to the: • NSW Health Policy Directive *Medication Handling* (PD2022_032) • Council of Australian Therapeutic Advisory Groups' (CATAG) *Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals*. Some health facilities may have an equivalent committee (such as a Quality Use of Medicines Committee) that governs such quality use of medicine functions. For this Policy, equivalent committees are considered to have the same roles and responsibilities as Drug and Therapeutics Committees, and the same governance and quality responsibilities apply.

Exceptional Use	Refers to off-label use of medicines where [1]: • There is low or very low-quality evidence • The potential benefits may be greater than the potential harms for the specific individual circumstances that meet pre-specified criteria (such as a serious or rare condition and/or no other effective or safe alternative therapy). Approval is patient specific.
Health Service	Any hospital, clinic, institution, health service, or health support service controlled by a Local Health District, Statutory Health Corporation or Affiliated Health Organisation, as specified in *Health Services Act 1997* (NSW).
Hospital	A hospital designated as such by a Local Health District, a Statutory Health Corporation or an Affiliated Health Organisation, as specified in *Health Services Act 1997* (NSW).
Individual Patient Use (IPU)	A request to or approval by the Drug and Therapeutics Committee for the use of a medicine by a patient, where the requested medicine or indication is not available on the NSW Medicines Formulary.
Medicine	Used singularly throughout this Policy to describe a drug, medicine, pharmaceutical preparation (including an extemporaneously compounded preparation), therapeutic substance, complementary and alternative medicine, vaccine, diagnostic agent for patient administration, medicated dressing, device containing a medicine, and a fluid for intravenous use. Includes Scheduled medication and unscheduled medication.
Medicines Use Evaluation	A cyclical process involving a structured review of medicines use within and across healthcare organisations. The review determines whether medicines use is appropriate according to pre-determined standards, thereby targeting areas for interventions [3]. This process was previously referred to as Drug Use Evaluation (DUE).
NSW Medicines Formulary	A state-wide, continually updated list of medicines and other therapeutic agents that have been approved for use within NSW public hospitals and health services. It includes the generic medicine name, strength, indication(s) where appropriate, dosage form(s), and any prescribing restrictions, if applicable.

NSW Medicines Formulary Committee	The peak NSW governance committee for medicines and therapeutic agents approved for use within NSW public hospitals and health services. The committee oversees the maintenance of the NSW Medicines Formulary.
Off-label medicine use	Use of a medicine for a therapeutic purpose other than that specified in the Therapeutic Goods Administration (TGA)-approved Product Information. This may include when the medicine is prescribed or administered: • For another indication • At a different dose or frequency of administration • Via an alternate route of administration • For a patient of an age or gender outside the registered use [1].
Routine Use	Refers to medicines routinely used off-label where [1] high quality evidence supports such use, for example, once daily dosing of intravenous gentamicin. There is a favourable benefit/harm ratio for the intended off-label use.
Special Access Scheme	Arrangements which provide for the import and/or supply of a non-TGA approved therapeutic good for individual patient use [4].
Unregistered medicine	An unregistered medicine is a medicine or dosage form that is not currently approved for use in Australia and hence is not in the Australian Register of Therapeutic Goods [5].

1.3. Legal and legislative framework

The *Poisons and Therapeutic Goods Act 1966* (NSW) and *Poisons and the Therapeutic Goods Regulation 2008* (NSW) regulate the procurement, storage, labelling, prescribing, supplying, administering and recording of both scheduled and unscheduled medicines at health facilities, and by health practitioners and pharmaceutical wholesalers. This is the legislation that authorised prescribers, pharmacists and nursing staff are to adhere to when prescribing, dispensing, and administering medicines.

2. APPROVAL PROCESS

All public hospitals and health services are to adopt and comply with the NSW Medicines Formulary. Medicines and their use for initiation within NSW public hospitals and health services are to be approved by the NSW Medicines Formulary Committee (see Section 2.1.1).

If a prescriber intends to initiate a medicine that is not listed on the NSW Medicines Formulary, an approval from the local Drug and Therapeutics Committee for Individual Patient Use is required prior to prescribing (see Section 2.1.2). Initiation of medicines that are out of scope of the NSW Medicines Formulary is to follow local Drug and Therapeutics Committee procedures.

If a prescriber intends to prescribe a medicine for continuation (i.e., the medicine was initiated prior to hospital admission), that is not listed on the NSW Medicines Formulary, an Individual Patient Use approval is not required. Medicines in this category may be kept in the hospital for inpatient use. The exception to this is; where the local Drug and Therapeutics Committee has specified particular products need an Individual Patient Use approval (e.g., unregistered Schedule 8 medicine).

Refer to NSW Health Policy Directive *Medication Handling* (PD2022_032) for direction on the use of patient's own medicines while an inpatient.

It is the responsibility of the Drug and Therapeutics Committee to decide which NSW Medicines Formulary medicines are to be routinely stocked in hospital, considering patient case mix, local services, and demographics. It is expected that a medicine not routinely stocked but listed on the NSW Medicines Formulary would be obtained in a timely manner, if required for initiation where no suitable alternative is available.

The Drug and Therapeutics Committee is to have a system in place for the management of non-formulary medicines regarding how they are approved, supplied during admission and on discharge, and any monitoring or reporting of outcomes requirements associated with their use.

For further information on the NSW Medicines Formulary Committee and its secretariat, please refer to the Clinical Excellence Commission (CEC) document *NSW Medicines Formulary Committee Business Processes*.

2.1. Submission processes

2.1.1. Addition, amendment or removal of a medicine

The NSW Medicine Formulary Committee's approval is required for any formulary listing of a medicine for initiation within NSW public health facilities, including any prescribing restrictions associated with it.

The approval process is outlined in Appendix 2.

All medicines under consideration by the committee for addition to the NSW Medicines Formulary, or for variation to an existing listing, need to undergo a thorough evaluation process.

The evaluation process will include some or all of the following steps (as applicable to the particular application):

- Critical evaluation of evidence supporting the inclusion in the NSW Medicines Formulary. The level of evidence required concerning effectiveness will depend on the specific medicine and the circumstances in which it is proposed to be used. Sufficient evidence regarding the safety profile of the medicine will be required to establish an acceptable risk/benefit ratio for the given clinical circumstances.

- Clear description of the objectives of formulary addition or amendment of listed indication(s) regarding the delivery of patient care, including the expected outcome(s) that the medicine will have on the medical condition being treated and the impact of this change.
- Assessment of the medicine costs (including costs associated with the use of the medicine such as the need for extra resources and associated diagnostic tests), including direct and indirect costs associated with the potential harms and benefits of the new medicine. This is in comparison with existing therapies, including non-pharmacological therapies where appropriate (known as **pharmacoeconomic analysis**).
- Assessment of ongoing cost to patient or health service for continuation of medicine outside of inpatient admission.
- Assessment of the requirement for a specific medicine protocol/guideline to standardise and guide judicious, appropriate, effective, safe and cost-effective medicine use.
- Assessment of the requirement for any specific training, qualifications, skills or competencies to prescribe, dispense or administer the medicine.
- Assessment of the equity and ease of access to the medicine, including ongoing supply after discharge from hospital.
- Assessment of medication safety impact i.e., potential risk for medication error.

The clinician(s) requesting the addition to, amendment of, or removal of a medicine from the NSW Medicines Formulary will need to complete and submit electronically the NSW Medicines Formulary Submission form to their local Drug and Therapeutics Committee (DTC) for endorsement, using the agreed mechanism determined by the NSW Medicines Formulary Committee secretariat.

The Drug and Therapeutics Committee are to have a standard process to guide decision making when endorsing a medicine for submission to the NSW Medicines Formulary.

It is recognised that depending on local governance arrangements, the process of endorsement may vary in each Local Health District/Specialty Health Network. Therefore, there is a need for a defined local process for clinicians to follow when submitting a formulary application.

The final application to the NSW Medicines Formulary Committee is to be submitted by the Executive Sponsor or delegated officer of the Drug and Therapeutics Committee from the Local Health District/Specialty Health Network.

Submissions can only be made by clinicians within NSW Health. Submissions by pharmaceutical representatives or manufacturers will not be accepted.

2.1.2. Individual Patient Use approval

Approval of specific medicines for Individual Patient Use is required when a therapeutic need exists for a medicine or an indication which is not listed on the NSW Medicines Formulary [6].

The Drug and Therapeutics Committee is responsible for management of Individual Patient Use and needs to have a standard process to guide their decision-making when evaluating a medicine for Individual Patient Use.

The clinician(s) requesting a medicine for Individual Patient Use will need to complete the relevant Individual Patient Use application form for the Drug and Therapeutics Committee.

Depending on the medicine and its use, the Drug and Therapeutics Committee may require a written clinical protocol to accompany the application that includes indication(s) and circumstances of use, expected outcomes, safe prescribing and administration details, contraindications, precautions and interactions with other therapy, common and serious adverse effects.

There are additional considerations for Individual Patient Use applications for off-label or unregistered medicines (see Section 2.5).

Multiple Individual Patient Use requests for the same medicine/indication

The Drug and Therapeutics Committees are to have a system to monitor Individual Patient Use applications and approvals. High use of a specific Individual Patient Use medicine for a specific indication may prompt an evaluation for formulary submission to the NSW Medicines Formulary Committee.

In these cases, the NSW Medicines Formulary secretariat will consult with the relevant Drug and Therapeutics Committee(s) on whether a formulary submission is required. The secretariat may also facilitate a formulary submission in consultation with a Local Health District/Specialty Health Network or multiple Local Health Districts/Specialty Health Networks.

2.2. Management of applications

All applications submitted to the NSW Medicines Formulary Committee, and the outcome of these applications, are to be recorded by the NSW Medicines Formulary secretariat. The application of a medicine to be added to the NSW Medicines Formulary is to include the active ingredient(s), strength(s), dosage form(s), proposed indication(s) (where appropriate) and any restriction(s), for example, by prescriber, indication or duration of therapy.

Once a submission is received, the NSW Medicines Formulary secretariat will liaise with the applicant regarding timeline for review at an NSW Medicines Formulary Committee meeting.

All applications for Individual Patient Use (IPU) managed locally, including urgent out of session applications and the outcome of these applications, are to be logged by the Drug and Therapeutics Committee (DTC) using the agreed mechanism determined by the NSW Medicines Formulary Committee secretariat.

Members of the NSW Medicines Formulary Committee, local Drug and Therapeutics Committee s and others who may be involved in the approval of applications are to disclose any perceived or actual conflicts of interest, as per the NSW Health Policy Directive *Conflicts of Interest and Gifts and Benefits* (PD2015_045).

There must be full disclosure of any significant relationship (financial or otherwise) between the clinician who requests NSW Medicines Formulary addition or approval of individual patient or patient group use, and the supplier of the product or other significant party.

Notification of application outcomes

Regarding applications for formulary submission or amendment, Drug and Therapeutics Committees and any other endorser of the application will be informed of the outcome of the application. A decision log, kept by the NSW Medicines Formulary secretariat, will document all NSW Medicines Formulary Committee decisions and changes, including those that are not approved. The decision log will be made available by the NSW Medicines Formulary secretariat.

The clinician who submitted the application (for formulary submission or amendment) is to be informed of the outcome of their application, together with details of approved use, including indication(s) for use, any prescribing restrictions, and any monitoring and reporting requirements.

Processes are to be in place for communication of relevant decisions to all relevant clinicians and medication related governance committees (see Section 2.4).

Appeals Process for NSW Medicines Formulary Decisions

Appeals against decisions made by the NSW Medicines Formulary Committee may be made on the grounds of:

- Decisions based on inaccurate or incomplete information.
- Procedural fairness, i.e., the published submission process has not been followed.
- Decisions which are expected to have high-cost, high-impact, require large practice change or pose significant risk to any Local Health District, Specialty Health Network or facility.

For information on how to lodge an appeal, please refer to the CEC document *NSW Medicines Formulary Committee Business Processes*.

Urgent applications

In circumstances of medicines shortages, recalls, public health responses, or unexpected discontinuation of medicines, the NSW Medicines Formulary Committee will have a process in place to facilitate rapid approval of an alternative medicine. The circumstances and details of such approvals is to be clearly documented and reported for review at the next NSW Medicines Formulary Committee meeting.

If use of a specific medicine is required urgently to prevent or minimise harm to a patient, there is to be a procedure in place that facilitates rapid assessment of the Individual Patient Use (IPU) application by a Drug and Therapeutics Committee. The circumstances and details of such approvals is to be clearly documented and reported for review at the next Drug and Therapeutics Committee meeting.

2.3. Review of NSW Medicines Formulary

The NSW Medicines Formulary Committee will have a formulary review process in place to ensure that the addition, amendment, removal and review of all medicines occur in a systematic, fair and transparent manner.

Ongoing management will include a regular review process for medicines placed on formulary. The review of medicines on the formulary will include (but not be limited to); medicine utilisation trends over time, new evidence for or changes in indications for use, evidence of inappropriate use or safety implications, and changes to Pharmaceutical Benefit Scheme (PBS) listings.

Medicines can be considered for deletion from the formulary when evidence or information emerges which identifies the medicine is no longer efficacious, is unsafe, or inferior to alternatives, or is to be discontinued in the Australian market.

Monitoring and reporting

Processes are to be in place for monitoring and reporting outcomes of medicines use to inform systems improvements, such as Medicines Use Evaluation or other clinical quality audit processes. This includes, where applicable, outcome data for Individual Patient Use (IPU) approvals, in particular where ongoing use is anticipated.

Medication incident reporting and adverse drug reaction reporting

Besides the usual reporting using the facility's incident management system and the Therapeutic Goods Administration's Adverse Event Management System, incidents associated with the use of medicines, including suspected adverse drug reactions, are to be reported to the Drug and Therapeutics Committee (DTC) for review, evaluation and action.

The evaluation is to include the review of any associated clinical protocol for use of the medicine. If deemed appropriate by the Drug and Therapeutics Committee, incidents are to be escalated to the NSW Medicines Formulary Committee or the Medication Safety Expert Advisory Committee via the secretariat (CEC-MedicineFormulary@health.nsw.gov.au, CEC-MedicationSafety@health.nsw.gov.au).

2.4. Communication of decisions

2.4.1. NSW Medicines Formulary Committee

The secretariat of the NSW Medicines Formulary Committee will facilitate communication of NSW Medicines Formulary Committee decisions to the Drug and Therapeutics Committees of NSW hospitals, Local Health Districts and Specialty Health Networks, District Director of Pharmacy and/or Director of Pharmacy.

2.4.2. Individual Patient Use

To facilitate communication of Drug and Therapeutics Committee (DTC) decisions to the Drug and Therapeutics Committee s of other NSW hospitals, Local Health Districts and Specialty Health Networks, the NSW Medicines Formulary secretariat maintains a register of Drug and Therapeutics Committee Individual Patient Use (IPU) decisions and patient outcome data for NSW public hospitals. The register will be accessible to authorised personnel, including Drug and Therapeutics Committee members.

All hospitals are to inform the secretariat of all Individual Patient Use decisions using the agreed mechanism determined by the NSW Medicines Formulary Committee secretariat.

2.5. Use of off-label or unregistered medicines

Off-label indications and unregistered medicines may be listed on the NSW Medicines Formulary for initiation and would, therefore, not require an Individual Patient Use submission.

Prescribers considering use of a specific medicine (whether listed on NSW Medicines Formulary or not) for an off-label indication, or use of an unregistered medicine, need to follow a systematic evaluation process (see Appendix 1) to assist with the assessment of whether such use is clinically justified.

See CATAG document, Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines, for further information on categories and conditions including for Research or Investigational Use.

The Drug and Therapeutics Committees (DTC) are to have policies and protocols for off-label use of medicines and use of unregistered medicines. Policies and protocols need to address:

- Consent and documentation requirements as outlined in Table 1
- Patient's and/or carer's involvement in any decision-making regarding off-label medicine use
- The provision of medicine information and resources for the patient and/or their carer
- The provision of product information in English, when available, for clinicians involved in the administration of the off-label or unregistered medicine when the medicine is procured from overseas, for example, Special Access Scheme (SAS) products
- Labelling of medicines that are imported from overseas to ensure generic name, strength and route of administration are clearly identifiable and are printed in English
- Monitoring and reporting of outcomes from treatment, including adverse events
- Ongoing cost considerations to the patient and hospital, and continuity of the supply of medicines following discharge from hospital or transition of care
- Other requirements for use of the unregistered medicines, including prescriber and hospital reporting requirements
- Any requirement for specific training, qualifications, skills or competencies.

Off-label medicines

Guidance may be required to support decision making by health professionals, consumers and Drug and Therapeutics Committees in their evaluation, approval and use of off-label medicines.

Unregistered medicines

All medicines under consideration for use that are unregistered are to undergo an evaluation process that first considers the use of an alternative Therapeutic goods Administration (TGA)-registered product, if available. Unregistered medicine use will only be considered when the approved use of a registered medicine does not address the clinical need(s) of the patient(s).

Drug and Therapeutics Committee s are to have processes in place that evaluate and manage the risk that may be associated with the use of unregistered medicines, such as those obtained under Schedule 5A of the *Therapeutic Goods Regulation 1990* (Commonwealth), Section 19A of the *Therapeutic Goods Act 1989* (Commonwealth) and via the Special Access Scheme.

Conditional registration of a product may occur under Section 19A of the *Therapeutic Goods Act 1989* (Commonwealth), for example, during times of medicine shortage. If a product is replacing a medicine on the NSW Medicines Formulary, the replacement product will be assessed as outlined in the NSW Policy Directive *Coordination of responses to urgent system-level medicine or medical device issues* (PD2019_019) and referred to the NSW Medicines Formulary Committee for listing.

Table 1: Patient consent and other documentation requirements for off-label and unregistered medicines

Off-label medicine	
Routine use	• Follow usual processes for patient consent to therapy with provision of information and discussion. • This is to occur as part of routine clinical care and does not require additional measures.
Exceptional use	• Approval is patient specific. • Informed patient consent is to be obtained (refer to the NSW Health *Consent to Medical and Healthcare Treatment Manual* (Consent Manual) for further details). • Reasons for use are to be documented in the medical record. • The prescriber is to conduct a detailed discussion about uncertainty of benefits and harms with use of the medicine with the patient and/or carer.
Conditional use	• Informed patient consent is to be obtained (refer to the NSW Health *Consent to Medical and Healthcare Treatment Manual* (Consent Manual) for further details). • Reasons for use need to be documented in the medical record. • Approval of use is conditional on further monitoring and assessment of effectiveness and safety. • Detailed discussion about these aspects with the patient and/or carer and the benefit/ harms of alternatives and potentially sharing information with others is required.
Unregistered (unlicensed) medicine	
Informed patient consent is to be obtained (refer to the NSW Health *Consent to Medical and Healthcare Treatment Manual* (Consent Manual) for further details). Refer to the Therapeutic Goods Administration website (Information for Health practitioners) for specific requirements.	

3. REFERENCES

1. Council of Australian Therapeutic Advisory Groups. *Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines*, Darlinghurst, 2013.
2. Australian Commision on Safety and Quality in Healthcare, *Safety and quality improvement guide. Standard 4: Medication safety*, Sydney 2012.
3. Graudins LV, Fitzsimons K, Manias E, Mirkov S, Nguyen AN, Munro C, *Medicines Use Evaluation Guideline*, *Journal of Pharmacy Practice and Research*, vol.50, pp. 166–179, 2020.
4. Therapeutic Goods Administration. Special access scheme. Australian Government, Department of Health 2020 (accessed 6 October 2020).
5. Gazarian M, Kelly M, McPhee JR, Graudins LV, Ward RL, Campbell TJ. *Off-label use of medicines: consensus recommendations for evaluating appropriateness*. Medical Journal of Australia. 2006;185:544-8.
6. 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*, Darlinghurst, 2013.

4. APPENDICES

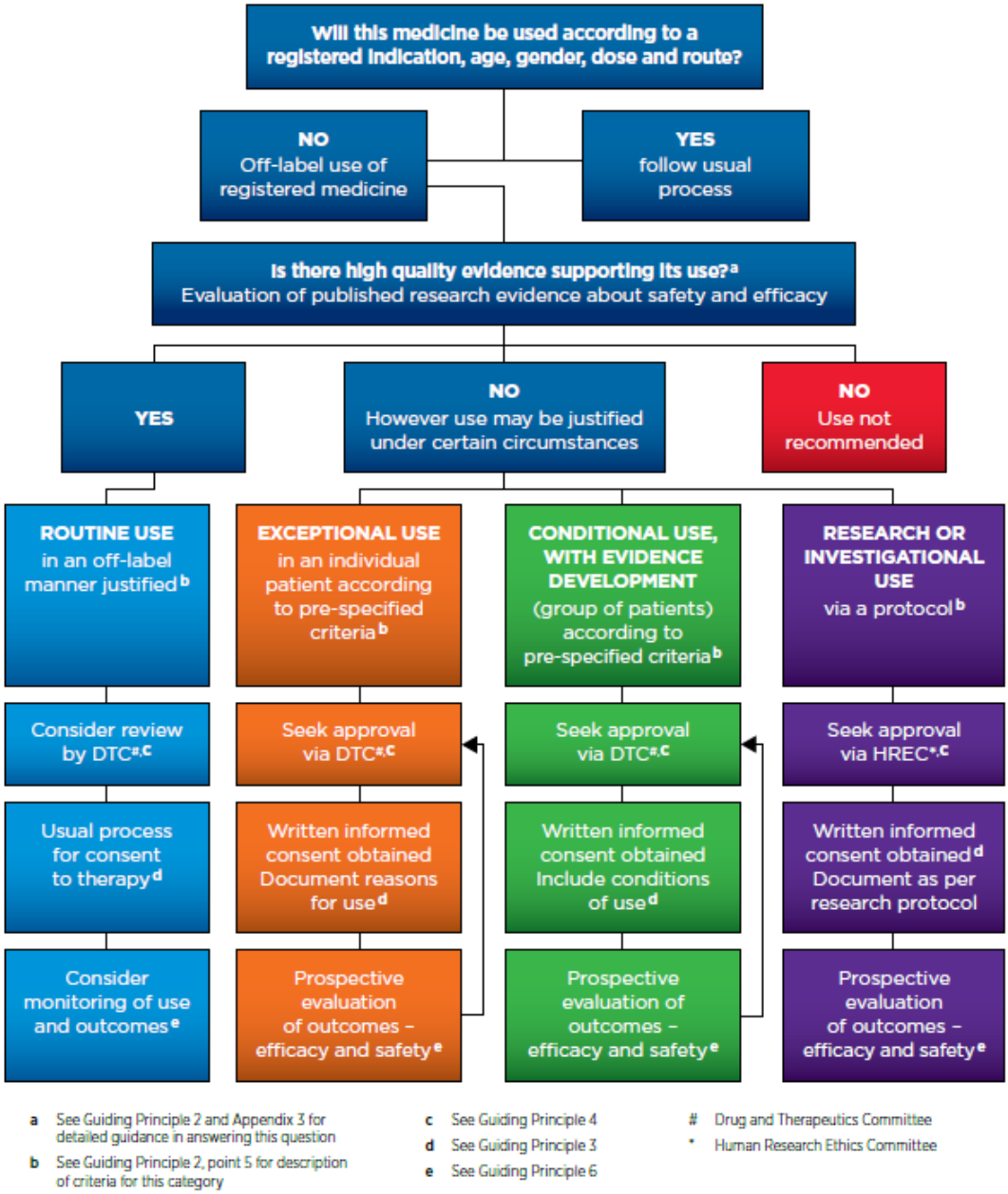
1. Assessing appropriateness of off-label medicine use
2. Submission processes for addition, amendment or removal of a medicine on the NSW Medicines Formulary

4.1. Assessing appropriateness of off-label medicine use

The figure below is adopted, with the permission of the Council of Australian Therapeutic Advisory Groups, Darlinghurst, from the document: *Rethinking medicines decision making in Australian Hospitals.Guiding principles for the quality use of off-label medicines*.

Figure 1 Assessing appropriateness of off-label medicine use and process for approval, consent and monitoring.

Note: This Policy does not cover the 'Research or Investigational Use' pathway



4.2. NSW Medicines Formulary submission processes