

Medicine - Evaluation of Medicines for Use in Public Hospitals

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Summary Policy for a standard process for the evaluation of medicines and uses of medicines for listing on hospital formularies (or for individual patient use) in public hospitals, and for communicating the outcomes of those evaluations to other hospitals across the State.

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, Public Health System Support Division, Government Medical Officers, NSW Ambulance Service, Public Hospitals

Audience Administration, Drug & Therapeutics Committees, Human Research Ethics Committees, clinical staff

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This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

ROLE OF THE DRUG AND THERAPEUTICS COMMITTEE IN THE EVALUATION AND APPROVAL OF MEDICINES FOR USE IN PUBLIC HOSPITALS

Executive Summary

This Policy Directive establishes a standard process that is to be followed in all NSW public hospitals for the evaluation of medicines and uses of medicines for listing on hospital formularies, or for individual patient use, and for the communication of the outcomes of those evaluations to other hospitals across the state.

Each Area Health Service must develop and implement policy and procedures based on the standard process outlined in this Policy Directive.

Role of the Drug and Therapeutics Committee

It is a requirement that all public hospitals in NSW have a formally constituted, multidisciplinary, peer review committee, or have access to an Area committee, which is the responsible body for considering all aspects of medicine use in the hospital (refer to NSW Health Policy Directive PD2007_077, *Medication Handling in NSW Public Hospitals*).

One of the key responsibilities of the hospital or Area Drug and Therapeutics Committee is the evaluation and approval of medicines for use in the hospital.

This policy describes the evaluation process to be followed for:

- **Medicines that are registered or listed** on the Australian Register of Therapeutic Goods that have not yet been added to the formulary. Included are those medicines made available for use in hospitals under early access or product familiarisation programs (that is, subsidised access to registered medicines for public hospital patients prior to Pharmaceutical Benefits Scheme listing or other funding arrangements).
- **Use of registered or listed medicines** in a manner that is not included in, or is disclaimed in, the approved product information for that medicine (commonly termed '**off-label use**' or 'unapproved use'). This can include variation from approved dosage levels, patient age, indication or route of administration.
- **Medicines that are not registered or listed** on the Australian Register of Therapeutic Goods (commonly termed '**unregistered**' or 'unlicensed' medicines), such as those made available under the Commonwealth Special Access Scheme or Personal Importation Scheme. Dosage forms of medicines that are not registered or listed on the Australian Register of Therapeutic Goods should also be considered as unregistered medicines for the purpose of this policy.

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This policy does not apply to the evaluation of the use of medicines for research purposes, which must be referred to the relevant Human Research Ethics Committee (HREC). (Refer NSW Health Policy Directive PD2007_072, *Research – Model for Single Ethical and Scientific Review of Multi-Centre Research.*)

Policy

A. Evaluation process

Processes must be in place to ensure that all medicines and uses of medicines are evaluated by the Drug and Therapeutics Committee before they are considered for addition to the formulary.

All medicines that are under consideration by the Committee for addition to the hospital formulary must undergo an evaluation process that:

1. Critically evaluates the best available patient-based research evidence regarding both efficacy and safety. The level of evidence required concerning efficacy will depend on the particular medicine and the circumstances in which it is proposed to be used. Sufficient evidence will be required regarding the safety spectrum of the medicine to establish an acceptable benefit: risk ratio for the given clinical circumstances.
2. Evaluates the costs and potential benefits of a new medicine in comparison with existing therapies, including non-pharmacological therapies, where appropriate.
3. Ensures that, in the case of 'off-label' use of medicines and use of 'unregistered' medicines, the Committee considers, in the first instance, the use of an alternative registered product in accordance with its approval by the Therapeutic Goods Administration. In general, 'off-label' use or use of 'unregistered' medicines should only be considered when the approved use of a registered medicine does not address the clinical needs of the patient(s).
4. Ensures that, where required, appropriate policies and protocols for use of the medicine are developed and implemented, in order to standardise and guide appropriate and safe use.
5. Ensures that there is appropriate education for all relevant staff before the medicine is commenced in use. This may include accreditation or credentialing when necessary for particular medicines

Clinicians considering use of a particular medicine in an 'off-label' manner should follow a systematic process to assist their assessment of whether such use is justified and whether they should proceed with an application to the Committee (Refer **Appendix A**).

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Drug and Therapeutics Committees should ensure that policies and protocols for 'off-label' use of medicines and use of 'unregistered medicines' are developed and include provision for:

- Circumstances requiring informed consent
- Information for patients on the medicine
- Monitoring and reporting of outcomes to treatment, including adverse events
- Ongoing supply of medicines following discharge from hospital.

In circumstances where use of a particular medicine is considered by the attending clinician to be required urgently to prevent or minimise harm to a patient, Drug and Therapeutics Committees must ensure that there is a process in place to facilitate rapid assessment by a Committee delegate, and suitable supply arrangements, where approval is given. The circumstances and details of such approvals should be clearly documented and reported to the Committee.

Conflicts of interest must be disclosed. There must be full disclosure of any significant relationship (financial or otherwise) between the clinician requesting approval and the supplier of the product or other significant party. Members of Drug and Therapeutics Committees and others who may be involved in assessment of applications must disclose any perceived or actual conflicts of interest. (Refer NSW Health Policy Directive PD2005_469, *Conflicts of Interest in the Public Health System*.)

Formulary application and evaluation process

1. Drug and Therapeutics Committees must use a **standard, step-by-step process** to guide their decision (a decision algorithm) when evaluating a medicine for formulary listing. It is strongly recommended that Committees use the decision algorithm developed by the NSW Therapeutic Advisory Group, which can be downloaded on <http://www.ciap.health.nsw.gov.au/nswtag/publications/otherdocs/DTC0506/Part60506.pdf>
2. In the case of evaluation of an application for use of a medicine in an individual patient, it is strongly recommended that Committees also use the IPU decision algorithm that is developed by NSW TAG for this purpose. The IPU decision algorithm can also be downloaded on <http://www.ciap.health.nsw.gov.au/nswtag/publications/otherdocs/DTC0506/Part60506.pdf>
3. An application form should accompany all applications to the Drug and Therapeutics Committee for formulary listing of medicines or medicine uses. It is strongly recommended that the formulary application form templates that are developed by NSW TAG are used for this purpose. These can be found on the NSW TAG website at:

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<http://www.ciap.health.nsw.gov.au/nswtag/>. The clinician(s) or unit(s) wishing to use the medicine should complete the application form. An application for 'off-label' use or use of an 'unregistered' medicine may need to be accompanied by written patient information and consent forms.

4. The clinician(s) or unit(s) wishing to use the medicine should prepare a written clinical protocol, where appropriate, that includes, as a minimum, such details as indications and circumstances of use, prescribing and administration details, contraindications, precautions and interactions with other therapy. It is strongly recommended that the protocol template developed by NSW TAG is used for this purpose. This can be found on the NSW TAG website at: <http://www.ciap.health.nsw.gov.au/nswtag/>.
5. All applications for Drug and Therapeutics Committee approval must be recorded by the Committee, including urgent out-of-session applications. The outcomes of all applications must be recorded.
6. Applicants must be informed of the outcome of their application together with details of approved indications, any prescribing restrictions and any monitoring and reporting requirements.
7. Drug and Therapeutics Committees should have a mechanism for review, should an applicant wish to seek a review of a decision by the Committee.
8. The Drug and Therapeutics Committee should consider the need for staff education, training and credentialing for newly approved medicines. Education should take into consideration the needs of all personnel who may be involved in the medicines management pathway including junior and senior medical staff, pharmacy staff, nursing staff, allied health staff and support staff involved in procurement and stock management. Specific patient education may also be required.
9. Processes must be in place for communicating Drug and Therapeutics Committee decisions to all relevant staff and to the NSW Therapeutic Advisory Group (Refer part B below).
10. Processes must be in place for monitoring and reporting outcomes of medicines use to inform system improvements. Drug Usage Evaluation or other clinical quality audit processes should be utilised.

In addition to the usual reporting mechanisms for medication incidents via the NSW Health Incident Information Management System (IIMS) and the Adverse Drug Reactions Advisory Committee (<http://www.tga.gov.au/adr/bluecard.pdf>), all incidents associated with the use of medicines, including suspected adverse drug reactions, must be reported to the Drug and Therapeutics Committee for review, evaluation and appropriate action. The evaluation should include review of any associated clinical protocol for use of the medicine.

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B. Communication of formulary decisions to other health services

In order to facilitate communication of Drug and Therapeutic Committee decisions to other NSW hospital/Area Health Service Drug and Therapeutic Committees, the Committee should inform the NSW Therapeutic Advisory Group of all formulary decisions, including details of approved indications and/or prescribing restrictions. Decisions to not approve formulary applications should also be notified. NSW TAG will maintain a register of formulary decisions for public hospitals in NSW that will be accessible to authorised personnel from Area Health Services. It is strongly recommended that Area Health Services make use of this resource.

Those Committees that do not currently have a routine reporting mechanism of their formulary decisions to the NSW Therapeutic Advisory Group should contact NSW TAG on ph: (02) 8382 2852 or email: nswtag@stvincents.com.au for information and advice on how to report.

Acknowledgements

This policy has been developed with the assistance of the NSW Therapeutic Advisory Group (NSW TAG), an independent, non-profit association, funded by NSW Health, which represents experts in medicines use in NSW hospitals. The Department of Health gratefully acknowledges the work of NSW TAG and, as previously indicated, strongly recommends that Area Health Services utilise the decision support tools and other resource materials for evaluating medicines that are available on the NSW TAG website at <http://www.ciap.health.nsw.gov.au/nswtag/>.

Further Resources

Gazarian M, Kelly M, McPhee JR, Graudins LV, Ward RL, Campbell TJ. Off-label use of medicines: consensus recommendations for evaluating appropriateness. MJA 2006;185:544-548
http://www.mja.com.au/public/issues/185_10_201106/gaz10250_fm.html

NSW Health Information Bulletin 2004/15: *Off-label use of registered medicines and use of medicines under the personal importation scheme in NSW public hospitals.*
<http://www.health.nsw.gov.au/publichealth/pharmaceutical/resources.asp>

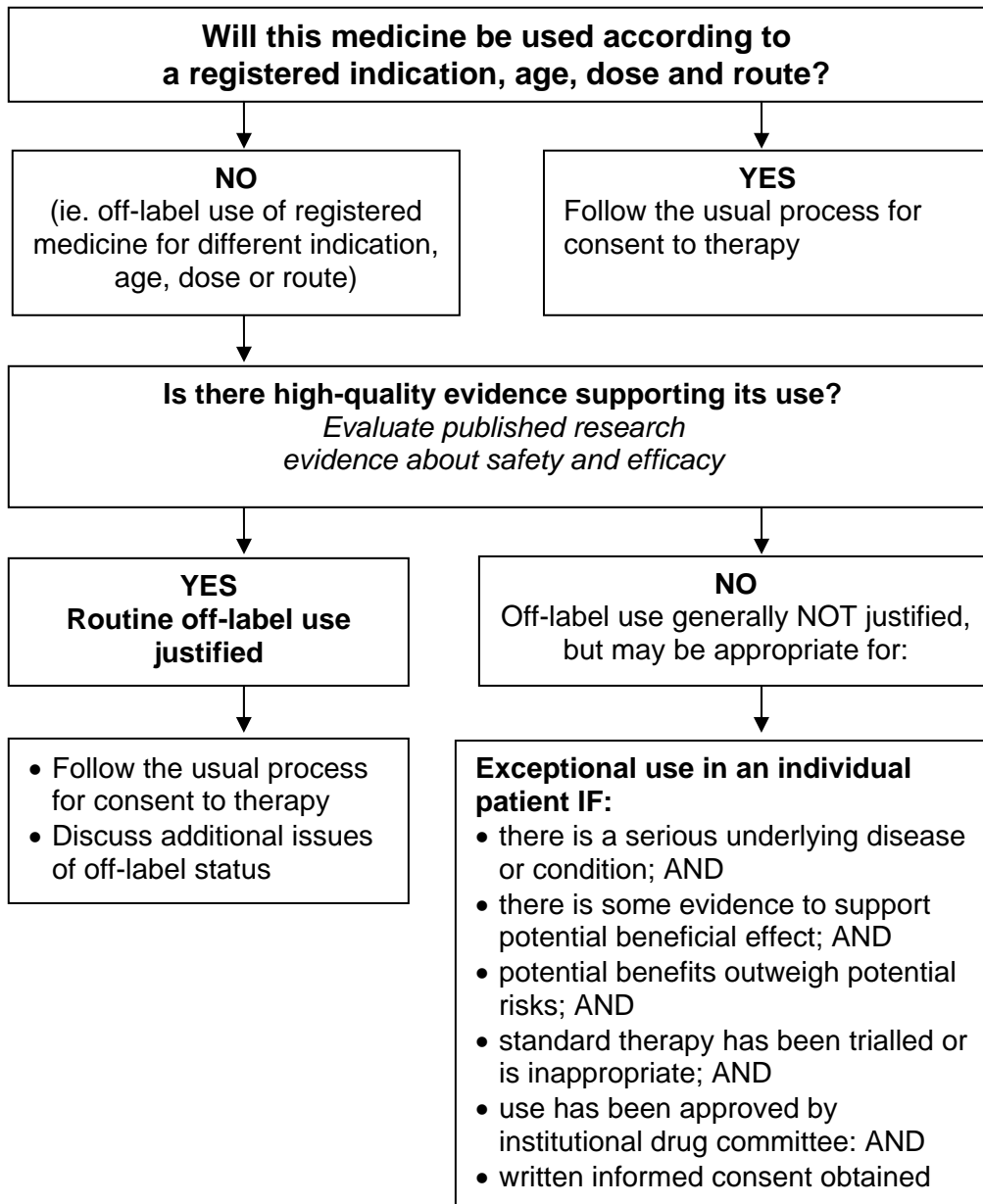
NSW Health Policy Directive PD2005_608, *Patient Safety and Clinical Quality Program.*
http://www.health.nsw.gov.au/policies/pd/2005/PD2005_608.html

Australian Pharmaceutical Advisory Council, July 2005, *Guiding principles to achieve continuity in medication management.* <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/nmp-guiding>

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Appendix A: Assessing appropriateness of off-label medicines use (other than clinical trials or other formal research)



Adapted from: Gazarian M, et al. Off-label use of medicines: consensus recommendations for evaluating appropriateness. *MJA* 2006;185:544-548. © Copyright 2006. The Medical Journal of Australia – reproduced with permission.

For detailed guidance refer to the complete article:

http://www.mja.com.au/public/issues/185_10_201106/gaz10250_fm.pdf.

For a detailed analysis of the legal and ethical dimensions associated with consent and administration of off-label medicines, see Appendix 4 of NSW Health Information Bulletin 2004/15: *Off-Label use of registered medicines and use of medicines under the personal importation scheme in NSW public hospitals*

<http://www.health.nsw.gov.au/archive/cib/information-bulletins/2004/index.html>