

PURPOSE

To outline best practice in the use of unapproved medicines and use of medicines for unapproved indications for prescribers, pharmacists and administrators of medicines to meet the requirements of sections 25 and 29 of the Medicines Act 1981. This also meets the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Right) Regulations 1996.

STANDARD

Where possible, approved medicines will be used to treat patients in Bay of Plenty District Health Board (BOPDHB) inpatient and outpatient settings.

It is recognised that the use of an unapproved medicine / unapproved indication is sometimes necessary to provide optimum treatment for a patient and would in many circumstances fulfil the patient's right to treatment of an appropriate ethical and professional standard. (Right 4 of The Code of Health and Disability Services Consumer's Right).

Use of an unapproved medicine or use of medicine for an unapproved indication will be accepted provided that best practice, outlined in this protocol has been followed.

Section 29 (S29) of the Act permits the sale or supply to medical practitioners of medicines that have not been approved. As per S29 Act for the supplier to supply the medication the name of the patient and medical practitioner prescribing the medicine and date must be recorded see Medsafe NZ and contact Pharmacy for further details.

A medical practitioner prescribing an unapproved medicine or a medicine for an unapproved indication is professionally accountable for this judgement and may be called upon to justify their actions.

Adverse drug / medicine reactions and medicine incidents must be reported in the same manner as for approved medicines.

The practice of off label prescribing is common, with rates up to 40% in adults and up to 90% in paediatric patients. Off-label prescribing is not illegal and may be clinically appropriate (Refer to [Appendix 1](#)).

There are, however, a number of clinical, safety and ethical issues to be considered when prescribing off-label and this protocol outlines BOPDHB's requirements to ensure ongoing patient safety.

STANDARDS TO BE MET

- 1. Risk assessment of unapproved medicines or unapproved indication / dose / route of administration for medicines.** Decision Making Process ([Green - Low](#) / [Green – Pharmacy Compounded Medicines](#), [Amber - Medium](#), [Red – High category risk categories](#)) as follows and refer to [Appendix 2 Flow Chart](#)

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GREEN Category (Low Risk) – GENERAL USE e.g. [palliative care](#)

This category applies to medicines:

1. Which are approved for use in New Zealand BUT are prescribed for an unapproved indication / dose / route where professional consensus supports their use.
2. Obtained from other jurisdictions, specifically Australia, UK, EU or USA which are approved for the indication, dose and route of administration within that jurisdiction and have been endorsed by the Combined Medicines Review Committee.

Medicines in the Green Category do not require patients' written consent.

Please note the usual standards of care still apply **under Right 6 of the Code of Health and Disability Services Consumers' Rights: The right to be fully informed.**

Medicines in categories 1) or 2) are approved for use by the Combined Medicines Review Committee.

These medications, if used on a regular basis, require a Medication Clinical Practice Manual protocol developed and approved subject to controlled document standards.

GREEN Category – PHARMACY COMPOUNDED Medicines

This category applies to medicines:

1. Obtained from a third party compounder within New Zealand.
2. Compounded by Pharmacy.

Note: A Pharmacist has professional and ethical obligations to fulfil when supplying compounded medicines. Should a Pharmacist be unable to comply with these professional and ethical obligations with regard to a compounded medicine, for example through the absence of stability data for the compounded product, the medicine will be treated as per the categories below.

AMBER Category (Medium Risk) – Registered Medical Practitioner Use Only

This category applies to those medicines which are not approved for use in New Zealand, however professional consensus supports the use of the medicine for the indication / dose / route proposed. Examples include – high doses of antipsychotics for the treatment of refractory psychosis and sodium thiosulphate for calciphylaxis.

Consent to use the medicine must be obtained from each patient and documented in the patient's health record by the medical practitioner.

These medications should have a Medication Clinical Practice Manual protocol developed and approved subject to controlled document standards e.g. nifedipine for hypertensive crisis in pregnancy

RED Category (High Risk) - Medical Practitioner Use Only

This category applies to medicines:

1. Not in the Green or Amber categories.
2. To any New Zealand approved or unapproved medicines where the proposed indication for use is not supported by professional consensus.

The medical practitioner, in conjunction with a supporting Pharmacist, must request to use such a medicine by application to the Combined Medicines Review Committee using Form FM.M18.1 Medicine - Unapproved Medicine Request.

Written patient consent using Form FM.M18.2 Medicine – Patient Consent for Use of Non-Registered (Off-Label) Medicine Use is required in these circumstances in accordance with the Code of Health and Disability Services Consumers’ Rights, Code 7 – The right to give informed consent as in these cases it is likely that:

- There is minimal evidence to support the use of the medicine or the medicine for the indication.
 - The evidence of the efficacy or safety of the medicine used in this manner is equivocal
- OR
- The use is part of a clinical trial (investigational use of the medicine). Refer to policy 2.1.7 Research

Note: Obtaining written consent does not mean that the requirements of the Code have been complied with. Obtaining informed consent is a process which involves effective communication, frank information disclosure and freely given consent. It also involves careful investigation of the clinical condition of the patient and maintaining a current knowledge of treatment options.

These medications will have a Medication Clinical Practice Manual protocol developed and approved subject to controlled document standards.

REFERENCES

- Medicines Act 1981
- Code of Health and Disability Services Consumers’ Right Regulations 1996
- [Medsafe – NZ Compliance , Use of Unapproved Medicines and Unapproved Use of Medicines](#)
- Southern District Health Board – Unapproved Medicines Protocol
- [Palliative Care Formulary. Palliative Drugs.com](#)

ASSOCIATED DOCUMENTS

- Bay of Plenty District Health Board policy 7.1.1 Medications, IV Fluids and Medication Standing Orders
- Bay of Plenty District Health Board policy 1.1.1 Informed Consent
- Bay of Plenty District Health Board policy 6.1.5 Alerts
- Bay of Plenty District Health Board policy 6.1.5 protocol 0 Alerts – Standards
- Bay of Plenty District Health Board policy 6.1.5 protocol 1 Alerts – Medical – Allergic Responses, Adverse Reactions and High Risk Issues
- Bay of Plenty District Health Board Form FM.M18.1 Medicine - Unapproved Medicine Request

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- Bay of Plenty District Health Board Form FM.M18.2 Medicine - Patient Consent for Use of Non-Registered (Off-Label) Medicine Use

Appendix 1: Off-label Use of a Medicine Examples

Reason Use is Off-label	Explanation	Examples
No registered product available	Product not registered / approved for use by the NZ regulatory authority (Medsafe)	Tacrolimus – ointment not registered for use in New Zealand but used for ophthalmology conditions Esmolol – used commonly in anaesthesia
Dose	Medicines may be given at doses that are not included in the approved datasheet	Salbutamol - registered dose is 'up to 200 micrograms 4 times per day (max recommended daily dose = 8 inhalations)' Gentamicin - registered dose frequency in adults with normal renal function is '6 – 8 hourly'. Olanzapine 40mg - used in the acute setting
Age	Medicines may be used for patients outside of the approved age range in the datasheet	Tramadol - for use in children under 12 years of age Topical xylometazolone - for use in children.
Indication	Medicines may be used for indications that are not included in the approved datasheet	Metformin - for use in assisting with treatment of polycystic ovary syndrome Amitriptyline - for use in treating nerve pain
Route	Medicines may be prescribed and given via a route that is not included in the approved datasheet	Midazolam - for subcutaneous administration

Adapted from the New South Wales Therapeutic Advisory Group, 2003

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Appendix 2: Decision Making Process Flowchart

