SESLHD POLICY COVER SHEET

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KEY TERMS	off label, unlicensed, registered medicines
SUMMARY	This Policy Directive provides a Quality Use of Medicines (QUM) framework to assist clinicians and managers in systematically evaluating the appropriateness, safety and effectiveness of proposed "off-label" or "unlicensed" use of medicines administered in public health facilities. The policy is applicable to all public health facilities in South Eastern Sydney Local Health District.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

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Medicine: Off-label use of registered medicines and use of unlicensed medicines

SESLHDPD/182

1. POLICY STATEMENT

The *Council of Australian Therapeutic Advisory Groups (CATAG) Rethinking medicines decision-making in Australian Hospitals - Guiding Principles for the quality use of off-label medicines (2013)* is adopted as policy governing the use of "off-label" medicines in South Eastern Sydney Local Health District (SESLHD). These principles apply equally to "unlicensed" use of medicines with additional considerations such as evaluation of quality and stability, appropriateness of altered route of administration and potential legal issues required.

Figure 1 in *CATAG. Rethinking medicines decision-making in Australian Hospitals. Guiding principles for the quality use of off-label medicines* outlines the framework for assessing appropriateness, approval processes, consent and monitoring of off-label and unlicensed medicines under the seven Guiding Principles. Consult the original document for full details.

TGA approved medicines remain first line options for treatment whenever available, suitable or tolerated.

If there is no high quality evidence supporting use of a particular medicine, and it is not suitable for "exceptional" or "research" indications, use of the medicine is not recommended.

The prescribing of unregistered medicines in non-research settings is a related but separate issue to off-label use and is covered by Special Access Schemes (SAS). All facilities must utilise formal processes to evaluate requests for medicines use under SAS via SESLHDPD/183 Medicine: Drug Formulary Policy.

Consent must be obtained as outlined in the CATAG Guiding Principles and documented using SESIH Exceptional Use of Medicine Consent Form.

Any **adverse drug reactions or interactions** involving medicines used off-label should be reported to the Therapeutic Goods Administration (TGA) Australian Adverse Drug Reaction Reporting System (either directly at: https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase, or via MIMs at: https://www.mimsonline.com.au/Search/ADRSNotification.aspx

2. AIMS

To provide the appropriate governance framework to support the quality use of "off-label" or "unlicensed" use of medicines in SESLHD.

3. TARGET AUDIENCE

The policy is applicable to all public hospitals and public health facilities in SESLHD, and includes medicine use for inpatients, discharge, outpatients and at continuity of care points.

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4. RESPONSIBILITIES

SESLHD Quality Use of Medicines Committee will apply and oversee implementation of the CATAG Guiding Principles across SESLHD.

Facility Drug Committees and **Managers** will apply and oversee implementation of the CATAG Guiding Principles within their own facility.

Clinicians will apply the CATAG Guiding Principles in their practice related to off-label and unlicensed use of medicines.

5. DEFINITIONS

"**Off-label"** refers to the prescription and use of registered medicines in a way that is not included in the Australian Therapeutic Goods Administration (TGA) approved product information or is disclaimed in the approved information. Off-label use of registered medicines can include variation from prescribed dosage levels, age of recipient, indication or route of administration.

A "**registered medicine"** is one which has been evaluated and approved by the TGA and which has been entered into the Australian Register of Therapeutic Goods for the treatment of specified medical conditions. Once registered, a medicine is deemed 'labelled' for use as outlined in the approved Product Information.

Use of a medicine or a dosage form of a medicine which has not been evaluated or approved for use in Australia by the TGA is called **"unlicensed"** use. This includes TGA registered medicines whose formulation is modified (e.g. preparing a suspension by crushing tablets).

6. DOCUMENTATION

SESIH Consent for Exceptional Use of Medicines Form (Form SEI020.025) must be completed for all off-label and unlicensed use except that considered routine.
Formulary submission form (F021) – for use when requesting approval for medicine use in a group of patients.
Individual Patient Use (IPU) form (F020) – for use when requesting approval for medicine use in an individual patient.
Individual Patient Use (IPU) report form (F019) – to report outcome of IPU use.

7. REFERENCES

- Rethinking Medicines Decision Making: Guiding Principles for the quality use of off-label medicines. Council of Australian Therapeutic Advisory Groups (CATAG), 2013
- SESLHDPD/183 Medicine: Drug Formulary Policy

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8. REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
June 2012	1	Consent documentation added, updated and rebadged to LHD- Julie Thompson - SESLHD Drug and Quality Use of Medicines Committee April 2012
June 2012	1	Review and changes approved by Medical Executive Director
June 2015	2	Redraft reflecting updated CATAG guidance Julie Thompson of behalf of SESLHD Drug and Quality Use of Medicines Committee
July 2015	2	SESLHD Drug and Quality Use of Medicines Committee review and approval
July 2018	3	Reviewed by QUM Pharmacy Directors Sub- committee. Minor amendments and hyperlinks updated by SESLHD Quality Use of Medicines Lead Pharmacist.
August 2018	3	Endorsed by SESLHD Quality Use of Medicines Committee

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