



Regional Drug Formulary Management Procedure

1. Guiding Principles

This procedure outlines the processes that are to be utilised to maintain the WA Country Health Service - South West (WACHS-SW) Regional Drug Formulary.

The WACHS-SW Regional Drug Formulary is, as of the October 2017, a combination of the WA Statewide Medicines Formulary (SMF) and other approved medicine supply arrangements determined by the WACHS-SW Drugs and Therapeutics Committee (DTC) as listed in this procedure.

The SMF was implemented in Western Australia, with an initial soft launch, in July 2017. The SMF acts as the single list of approved medicines for all WA public hospitals, evaluated, implemented and managed in a statewide approach.

The scope of the SMF includes:

- pharmaceutical agents registered by the Therapeutics Goods Administration (TGA) for use in Australia
- medicines not listed by the TGA but used in an accepted 'off-label' manner including Special Access Scheme (SAS) medicines
- complementary and alternative medicines.

Items that come under the governance of the WACHS-SW DTC include:

- review and decision of any investigational medicinal products for use in a clinical trial
- review and decision of medicines supplied for use in a Medicines Access Program (MAP)
- access to medications listed on the SMF in relation to local service provision
- decision on local stock holdings in conjunction with the Chief Pharmacist
- review and decision on Individual Patient Approvals for outpatients for all medications
- review and decision on Individual Patient Approvals for inpatients for initiation of medications not listed on the SMF
- application of additional restriction, beyond any SMF restriction, if required in response to local circumstances.

Whilst a medication may be listed on the SMF it may not be stocked locally and therefore not be immediately available within a WACHS-SW site.

The details for the SMF are readily available to all clinicians via the electronic platform – [Formulary One](#). This can be accessed via the internet and via personal smart devices using individual access codes.

The handling, prescribing and administration of medications are governed by the [WA Medicines and Poisons Act 2014 and Regulations](#), [WA health system policies](#), [WACHS and WACHS - South West policies, procedures and guidelines](#).

2. Procedure

Request for addition of new medications to the SMF, or changes to existing listings, are to be made directly to the WA Drug Evaluation Panel (WADEP) using the [SMF Submission Form \(Appendix C\)](#) or the [SMF Minor Change Form \(Appendix D\)](#).

Inpatients taking medications not listed on the SMF

This may occur when the patient may have started treatment:

- before the implementation of the SMF
- before a medication is removed from the SMF
- in primary care or outside of WA.

For these patients treatment review is to occur with consideration given, as clinically appropriate, to switching to the preferred or first-line alternative listed on the SMF. Where the patient is stable and there is no clinical reason for change, treatment may be continued. This is to be clearly indication in the patient's clinical record.

The correct process to follow to apply to the WACHS-SW DTC for the review of an Individual Patient Approval (IPA) for a particular medication is the completion of an [Individual Patient Approval Form \(Appendix A\)](#).

Where an IPA is approved for supply of medications to outpatients, a patient co-payment fee will be incurred by the patient for each dispensing.

In exceptional circumstances, where patient safety may be compromised due to the requirement to pay this fee, the clinician can complete a [Request for Exemption from Payment Form \(Appendix B\)](#) to apply for this fee to be waived. This is in addition to the IPA form for approval for access to supply.

3. Definitions

Restricted medicine	Medications which must be used according to the restriction stated (e.g. population, speciality, treatment length, treatment site). Restrictions can be applied to a medication as part of the SMF listing or by the WACHS-SW DTC.
Council of Australian Therapeutics Advisory Group (CATAG)	Collaboration of representatives from all States and Territories that provide advice on medication use.
Contracted credentialed VMP	Visiting Medical Practitioner who holds a current contract and has been appropriately credentialed.
Individual Patient Approval	The application form that is required to be submitted to the DTC to request approval for Pharmacy to supply medication (non-formulary/ non-approved indication/ outpatient supply) to an individual patient. Where ten (10) IPA applications have been received statewide for a particular medication and indication, and application for listing on the SMF will be required.

Restricted medicine	Medications which must be used according to the restriction stated (e.g. population, speciality, treatment length, treatment site). Restrictions can be applied to a medication as part of the SMF listing or by the WACHS-SW DTC.
Formulary	A list of approved medications which may be used in a hospital or Health Service; the list may also include the approved indications, dose formulations, treatment details and prescribing restrictions relevant to each medicine.
Pharmaceutical Benefit Scheme (PBS)	The schedule of medications which the Commonwealth Government subsidises the cost of for Australian citizens and citizens of countries with which Australia has a reciprocal health care agreement.
Preferred agent	The preferred agent(s) from a therapeutic class with more than one agent. If a different agent in the same group as a preferred agent is prescribed, the prescriber may be required to justify that choice.
Statewide Medicines Formulary (SMF)	The single list of approved medicines for all WA public hospitals, evaluated, implemented and managed in a statewide approach.
WACHS - South West Regional Drug Formulary	The list of medications that encompasses the SMF and other approved medicine supply arrangements determined by the WACHS-SW Drugs and Therapeutics Committee (DTC) as outlined in this procedure. Not all medications will be stocked by the Bunbury Hospital Pharmacy Department and therefore specific medicines may not be immediately available within a WACHS-SW site
WACHS - South West Drugs and Therapeutics Committee (DTC)	The Committee of appropriate delegates who are the primary governing group in relation to use of medicines within WACHS-SW.
Western Australian Therapeutics Advisory Committee (WATAG)	Collaboration of representatives from across the State that provide advice on medication use.
SMF Submission Form	The application form that is required to be completed and submitted to WADEP for review in order to request the addition of a medication, or amendment of a current listing to the SMF.
Western Australian Drug Evaluation Panel (WADEP)	The Panel who have the role of peak formulary review committee managing the SMF.

4. Roles and Responsibilities

All Medical

Medical staff are required to follow the formulary listings as defined by the SMF and WACHS-SW DTC and be actively involved in the process to promote medication safety, equity of access and the quality use of medications. Medical staff are required to follow the appropriate processes governing access to medicines and complete the correct applications depending on the nature of their request.

All Nursing

Nursing staff are required to have an understanding of the function and role of the DTC, as well as the concept of the WACHS - South West Regional Drug Formulary.

Pharmacy Staff

Pharmacy staff are required to have an understanding of the SMF and DTC application processes and be an advocate for the SMF and DTC principles.

All Staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

5. Compliance

Failure to comply with this policy document may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the [Employment Policy Framework](#) issued pursuant to section 26 of the [Health Services Act 2016](#) (HSA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies is mandatory.

6. Evaluation

Review of the WACHS - South West Regional Drug Formulary will occur via the Drugs and Therapeutics Committee. The Drugs and Therapeutics Committee will review their efficiency as per the endorsed Terms of Reference.

7. Standards

[National Safety and Quality Health Care Standards](#) – 1.7.1, 4.1.2

8. Legislation

[Medicines and Poisons Act \(2014\)](#) (WA)

[Medicines and Poisons Regulations \(2016\)](#) (WA)

9. References

DoH Statewide Medicines Formulary Policy

DoH WA Statewide Medicines Formulary Framework 2014

10. Policy Framework

[Clinical Governance, Safety and Quality](#)

11. Appendices

- Appendix A: [Individual Patient Approval Form](#)
- Appendix B: [Request for Exemption from Payment Form](#)
- Appendix C: [SMF Submission Form](#)
- Appendix D: [SMF Minor Change Form.](#)

**This document can be made available in alternative formats
on request for a person with a disability**

Contact:	Chief Pharmacist (N. Lillywhite)		
Directorate:	Medical Services	TRIM Record #	ED-CO-14-61740
Version:	2.00	Date Published:	4 January 2018

Copyright to this material is vested in the State of Western Australia unless otherwise indicated. Apart from any fair dealing for the purposes of private study, research, criticism or review, as permitted under the provisions of the *Copyright Act 1968*, no part may be reproduced or re-used for any purposes whatsoever without written permission of the State of Western Australia.