



Statewide Medicines Formulary Policy

1. Purpose

The purpose of the Statewide Medicines Formulary Policy is to specify the clinical governance, safety and quality requirements in relation to the initiation of prescribed medicines to ensure effective, equitable and consistent clinical care is provided across the WA health system.

The WA Statewide Medicines Formulary (SMF) is a single list of approved medicines which can be initiated by prescribers across the WA health system, along with any restrictions and guidance that may be in place for the prescribing of that medicine. The aim of the SMF is to promote and facilitate the delivery of optimal patient outcomes in Western Australia in an equitable manner. The SMF has been evaluated, implemented and managed in a systemwide approach with expert review by the WA Medicines Evaluation Panel (WAMEP). WAMEP is a multidisciplinary body that governs SMF decisions. WAMEP membership includes (but is not limited to), senior medical practitioners, senior nurses, senior pharmacists, Department of Health and consumer representatives.

The SMF is underpinned by the [Australian National Medicines Policy](#) which aims to improve positive health outcomes focusing on patients' access to, and wise use of, medicines. A central objective of the *Australian National Medicines Policy* is the quality use of medicines which encompasses:

- selecting management options wisely
- choosing suitable medicines if a medicine is considered necessary
- using medicines safely and effectively.

Legislation pertinent to this policy includes:

- [Medicines and Poisons Act 2014](#).

This policy should be read in conjunction with:

- [MP 0084/18 Credentialing and Defining the Scope of Clinical Practice Policy](#)
- [MP 0139/20 Medicines Handling Policy](#).

This policy is a mandatory requirement for Health Service Providers under the *Clinical Governance, Safety and Quality Policy Framework* pursuant to section 26(2)(c)(d) of the *Health Services Act 2016*.

2. Applicability

This policy is applicable to all Health Service Providers that prescribe medicines to the public, including outpatient services. It applies to all prescribers to support safe, cost-effective, equitable and evidence-based prescribing and medicine management governance.

The requirements contained within this policy are applicable to the services purchased from contracted health entities where it is explicitly stated in the contract between the contracted health entity and the State of Western Australia or Health Service Provider. The State of Western Australia or Health Service Provider contract manager is responsible for ensuring that any obligation to comply with this policy by the contracted health entity is accurately reflected in the relevant contract and managed accordingly.

3. Policy Requirements

3.1. Prescribing medicines on the SMF

Prescribers must ensure that medicines initiated for their patients comply with the prescribing restrictions and requirements stated by the SMF. The SMF is accessible on Formulary One, an electronic platform, which is available via the internet <https://formulary.health.wa.gov.au/> and the WA Health intranet <https://formulary.hdwa.health.wa.gov.au>.

The prescribing of all medicines listed on the SMF must also comply with local policies and procedures and the prescriber's defined scope of clinical practice.

3.2. Prescribing medicines that are not on the SMF, or outside the SMF specified criteria

Health Service Providers must ensure all hospitals or regions have an established Drug and Therapeutics Committee (DTC)/Medicines and Therapeutics Committee (MTC), or an equivalent authority responsible for local medicines governance.

To initiate a medicine or indication that is not listed on the SMF, or outside the SMF specified criteria, prescribers must apply to the relevant DTC/MTC or equivalent authority for an Individual Patient Approval (IPA) in accordance with local policies and/or procedures.

Where a medicine or indication has been evaluated by WAMEP and has been rejected for listing on the SMF, it will be listed as 'not approved by WAMEP' on the formulary. WAMEP may reject the listing with the following IPA clauses:

- DTCs/MTCs or the equivalent authority may only approve IPAs for this medicine or indication where an exceptional need has been justified and all other options are exhausted, or
- The medicine or indication cannot be initiated via an IPA.

Health Service Providers are required to report on IPAs (including details of the medicine, dose, frequency, duration, indication and decision of approval or rejection and outcome data) for medicines or indications not listed on the SMF, or outside the SMF specified criteria. This is to be reported through a WA Health approved electronic IPA system (such as the Western Australian Individual Patient Approval System [WAIPAS]).

3.3. Governance of medication management

All Health Service Providers must establish local procedures for medication management governance within their sites (and associated outpatient services) that is aligned to this policy. Local procedures must address the management and assessment of IPAs by the DTC/MTC or an equivalent authority via a WA Health approved electronic IPA system.

3.4. Additions and amendments to the SMF

Submissions for additions or amendments to the SMF must be submitted to WAMEP by using the SMF submission forms available on the [Formulary One](#) homepage.

Prescribers (within their scope of clinical practice) and members of a DTC/MTC or equivalent authority may make the following submissions for additions or amendments to the SMF:

A. Full submission:

A medicine and/or indication that is:

- Not currently listed on the SMF, and
- Not currently listed on the Pharmaceutical Benefits Scheme (non-PBS).

B. Pharmaceutical Benefits Scheme (PBS) submission:

- PBS listed medicine to be added to the SMF.
- New PBS indication for an existing medicine listed on the SMF.

C. Minor change submission: Change to the wording of an indication, restriction or formulation of an existing medicine listed on the SMF that does not have any significant clinical efficacy, safety, cost, or other concerns.

Authorisation by the relevant specialty Head of Department (HoD) is required for submissions. Where applicants are HoDs, authorisation by a higher level authority (i.e. Medical Services Director) is required.

4. Compliance Monitoring

The Medicines and Technology Unit, on behalf of the System Manager will monitor compliance with this policy by using dispensing and supply information (recorded in iPharmacy, procurement data and other relevant clinical and dispensing databases) and de-identified IPA data reported through WA Health approved electronic IPA recording systems such as WAIPAS.

Other information that may be requested by the System Manager includes the meeting minutes of the DTC/MTC or equivalent authority upon ratification. The System Manager may also request a sample of prescriptions. The sample chosen may be random, based on a perceived risk or from information provided by Health Service Providers. The above information will be provided to the System Manager by the DTC/MTC Executive Officers, Chairs or Secretaries, or equivalent authority as per local governance, the Chief Pharmacist, data custodian or the appropriate tier of delegation for access to information.

The System Manager may also review Health Service Providers' local procedures for medication management governance within their sites to ensure that these are aligned to this policy.

The System Manager will request access to reports and data from Health Service Providers to ensure policy compliance and to determine the effectiveness of this policy and the SMF in the usage of medicines at the end of each financial year or on an as needed basis.

5. Related Documents

The following documents are mandatory pursuant to this policy:

- N/A

6. Supporting Information

The following information is not mandatory but informs and/or supports the implementation of this policy:

- [WA Statewide Medicines Formulary Guidelines](#)
- [Individual Patient Approval \(IPA\) Guideline for the WA Individual Patient Approval System \(WAIPAS\)](#)
- [Antimicrobial Stewardship Guidance Document](#)
- [Australian Government, Department of Health and Aged Care: National Medicines Policy](#)
- [Council of Australian Therapeutic Advisory Groups \(CATAG\): Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines](#)
- [CATAG: Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals](#)
- [CATAG: Guiding Principles for Medicines Stewardship Programs](#)
- Government of Western Australia, Department of Health: [Who can prescribe medicines in Western Australia?](#)

7. Definitions

The following definition(s) are relevant to this policy.

Term	Definition
Drug and Therapeutics Committee (DTC)/Medicines and Therapeutics Committee (MTC) or equivalent authority	A multidisciplinary committee with a commitment to the overall governance of the medicines management system in their health service organisation to ensure the judicious, appropriate, safe, effective and cost-effective use of medicines. DTCs/MTCs or an equivalent authority own the primary governance role in relation to the use of medicines at a local hospital or regional level.
Individual Patient Approval (IPA)	An IPA is a hospital-based, patient-specific approval by the DTC/MTC or equivalent authority for a prescriber to initiate a medicine or indication not listed on the SMF, or outside the SMF specified criteria. The request must include justified clinical need with evidence or expert advice supporting use, as well as the predicted cost of treatment. IPA processes are governed by the hospital or area DTCs/MTCs or equivalent authorities.
Prescribers	A health practitioner registered under the Health Practitioner Regulation National Law (WA) Act 2010 , for whom the Medicines and Poisons Regulations 2016 include prescribing as a professional authority.
Scope of clinical practice	The extent of an individual practitioner's approved clinical practice within a particular organisation based on an individual's credentials, competence, performance and professional suitability and the needs and capability of the organisation to support the practitioner's scope of clinical practice.

Statewide Medicines Formulary (SMF)	The SMF is a list of approved medicines which can be initiated across the WA health system. The formulary includes details on the prescribing restrictions and requirements where applicable, available formulations and strengths, safety alerts and other relevant information for the medicine.
Western Australian Individual Patient Approval System (WAIPAS)	The WA Individual Patient Approval System (WAIPAS) is the Department of Health approved platform for the electronic management of IPAs. The use of WAIPAS assists sites to meet the specific requirements contained within this policy and the IPA Guideline for WAIPAS, and positively contributes to the quality use of medicines by creating a statewide repository of IPA data to promote equity of access.
WA health system	The WA health system is comprised of: <ul style="list-style-type: none"> (i) the Department; (ii) Health Service Providers (North Metropolitan Health Service, South Metropolitan Health Service, Child and Adolescent Health Service, WA Country Health Service, East Metropolitan Health Service, PathWest Laboratory Medicine WA, Quadriplegic Centre and Health Support Services); and (iii) contracted health entities, to the extent they provide health services to the State.

8. Policy Contact

Enquiries relating to this policy may be directed to:

Title: Manager, Medicines and Technology Unit

Directorate: Patient Safety and Clinical Quality

Email: WAMEP@health.wa.gov.au

9. Document Control

Version	Published date	Review date	Amendment(s)
MP 0077/18	31 January 2018	January 2019	Original document
MP 0077/18 v.1.1	8 March 2019	December 2023	Minor amendment to supporting information link – WA Statewide Medicines Formulary Guidelines.
MP 0077/18 v.2.0	3 April 2024	April 2027	Policy review and amendments as listed below.
<ul style="list-style-type: none"> • Purpose section refined for clarity and improved readability. • Applicability section updated to include contracted health entities. • Clarified and updated policy requirements on governance arrangements for the Statewide Medicines Formulary. • Clarified compliance monitoring requirements from Department of Health and Health Service Providers. • WA Drug Evaluation Panel (WADEP) renamed to WA Medicines Evaluation Panel (WAMEP). • Updated supporting information: included link to the updated WA Statewide Medicines 			

Formulary Guidelines, Individual Patient Approval (IPA) Guideline for the WA Individual Patient Approval System (WAIPAS), updated Antimicrobial Stewardship Guidance Document and CATAG: Guiding Principles for Medicines Stewardship Programs.

- Definitions section: updated 'Drug and Therapeutics Committee (DTC)/Medicines and Therapeutics Committee (MTC) or equivalent authority' 'Individual Patient Approval' and 'Prescribers'. Included definitions for 'Western Australian Individual Patient Approval System (WAIPAS)', 'Statewide Medicines Formulary', 'Scope of clinical practice' and 'WA health system'. Deletion of Formulary definition.
- Policy contact updated.

Note: Mandatory policies that exceed the scheduled review date will continue to remain in effect.

10. Approval

Approval by	Dr David Russell-Weisz, Director General, Department of Health
Approval date	20 December 2017

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

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