1 Purpose
The purpose of the Statewide Medicines Formulary Policy (the Policy) is to specify the clinical governance, safety and quality requirements in relation to 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 may be initiated in public hospitals in Western Australia, along with any restrictions and guidance that may be in place on the prescribing of that medicine. The aim of the SMF is to assist 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 as stated in the SMF Guidelines, with expert review by the WA Drug Evaluation Panel (WADEP). WADEP is a multidisciplinary body that governs the formulary; membership includes Consultants, Senior Nurses, Senior Pharmacists, Department of Health representatives and one consumer representative.

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, this encompasses:

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

This Policy is a mandatory requirement under the Clinical Governance, Safety and Quality Policy Framework.

This Policy supersedes OP 1755/04 Rationalisation of Warfarin Brands and OD 0626/15 Antimicrobial Stewardship Policy.

2 Applicability
This Policy is applicable to all Health Service Providers that provide medicines to the public. It applies to all prescribers to guide appropriate and equitable access to medicines and medicine management governance.

3 Policy requirements

3.1 Prescribing medicines on the SMF
Prescribers working in Health Service Providers are required to prescribe medicines according to the restrictions and requirements stated by the SMF. The SMF is accessible on Formulary One, an electronic application, which is available via the internet https://formulary.health.wa.gov.au/ and the WA Health intranet https://formulary.hdwa.health.wa.gov.au.
3.2 Prescribing medicines that are not on the SMF
Health Service Providers must ensure all hospitals have an established Drugs and Therapeutics Committee (DTC) or an equivalent authority responsible for local medicines governance.

Prescribers wanting to initiate medicines not listed on the SMF will be required to apply, according to local policies and/or procedures, to the relevant DTC for an Individual Patient Approval (IPA).

Hospitals must keep a record of accepted and rejected IPAs and provide de-identified data on IPAs to WADEP. The provision of information to WADEP should be in accordance with the Health Services Act 2016 and the Information Management Policy Framework.

3.3 Governance of medication management
All Health Service Providers are required to establish local policies or procedures for medication management governance within their sites that is aligned to this Policy and includes the management and assessment of IPAs by the DTC.

3.4 Changes to the SMF
Request for changes or submissions for new additions to the SMF must be made to WADEP by using the SMF Submission Form for Full and PBS submissions or the Minor change form available from Formulary ONE.

Consultants may make the following submissions for additions or change to the SMF:

A. Full submission: Non PBS medicine to be added to the SMF or new non PBS indication for an existing medicine listed on the SMF.

B. Pharmaceutical Benefits Scheme (PBS) submission: PBS listed medicine to be added to the SMF or new PBS indication for an existing medicine listed on the SMF.

C. Minor change submission: change to the indication of an existing medicine listed on the SMF including change to a PBS listed medicine.

4 Compliance, monitoring and evaluation
Health Service Providers are required to monitor compliance with this Policy. The development of local policies and/or procedures will ensure the initiation of medicines for public patients complies with this Policy.

Compliance with this Policy will be monitored by the System Manager, using prescribing information recorded in iPharmacy and other relevant clinical and dispensing databases. The System Manager may also request reports on the compliance with this Policy from Health Service Providers to ensure policy compliance and to determine the effectiveness of this policy and the SMF in the usage of medicines.

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.
5 Related documents
The following documents are required to give affect to this Policy (i.e. the documents included are mandatory):
- N/A

6 Supporting information
The following documents inform this Policy (i.e. documents that are not mandatory to the implementation of this Policy but may support the implementation of the Policy):
- WA Statewide Medicines Formulary Guidelines
- Antimicrobial Stewardship Guidance Document
- Australian Government, Department of Health and Ageing: National Medicines Policy
- Council of Australian Therapeutic Advisory Groups (CATAG): Rethinking Medicines Decision Making: Guiding Principles for the quality use of off-label medicines
- CATAG: Achieving Effective Medicines Governance: Guiding Principles for the roles and responsibilities of Drugs and Therapeutics Committees in Australian public hospitals
- Who Can Prescribe Medicines in Western Australia

7 Definitions
The following definitions are relevant to this Policy.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs and Therapeutics Committee or equivalent authority (DTC)</td>
<td>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 own the primary governance role in relation to the use of medicines at a local hospital level.</td>
</tr>
<tr>
<td>Formulary</td>
<td>A list of approved medicines and indications, which may be used in a hospital including where appropriate dose, formulations, treatment details and prescribing restrictions relevant to each medicine.</td>
</tr>
<tr>
<td>Individual Patient Approval</td>
<td>Medicines not otherwise available on the formulary (or not available for an indication) may be approved for individual patient use by the local DTC when therapeutic need is justified.</td>
</tr>
<tr>
<td>Prescribers</td>
<td>A health professional authorised under the Health Practitioner Regulation National Law, and acting in the lawful practice of their profession, can prescribe medicines. Who and what can be prescribed varies by profession and classification of the medicine.</td>
</tr>
</tbody>
</table>
8 **Policy owner**

**Assistant Director General Clinical Excellence**

Enquiries relating to this policy may be directed to:

Title: Project Coordinator WA Drug Evaluation Panel  
Division: Clinical Services and Research Division  
Email: WADEP@health.wa.gov.au

9 **Review**

This mandatory policy will be reviewed and evaluated as required to ensure relevance and recency. At a minimum it will be reviewed within three (3) years after first issue and at least every three (3) years thereafter.

<table>
<thead>
<tr>
<th>Version</th>
<th>Effective from</th>
<th>Effective to</th>
<th>Amendment(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MP 0077/18</td>
<td>31 January 2018</td>
<td>8 March 2019</td>
<td>Original version</td>
</tr>
<tr>
<td>MP 0077/18 v.1.1.</td>
<td>8 March 2019</td>
<td>31 December 2023</td>
<td>Minor amendment to supporting information link – WA Statewide Medicines Formulary Guidelines</td>
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The review table indicates previous versions of the mandatory policy and any significant changes.

10 **Approval**

This mandatory policy has been approved and issued by the Director General of the Department of Health.

<table>
<thead>
<tr>
<th>Approval by</th>
<th>Dr David Russell-Weisz, Director General, Department of Health</th>
</tr>
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<tbody>
<tr>
<td>Approval date</td>
<td>20 December 2017</td>
</tr>
<tr>
<td>Published date</td>
<td>8 March 2019</td>
</tr>
<tr>
<td>RMR#</td>
<td>F-AA-51861, TRIM ref D-AA-17/83666</td>
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