



Government of **Western Australia**  
Department of **Health**

# WA Statewide Medicines Formulary Guideline

# Contents

<b>1</b>	<b>Introduction</b>	<b>3</b>
<b>2</b>	<b>Governance</b>	<b>6</b>
<b>3</b>	<b>Key components of the SMF</b>	<b>10</b>
<b>4</b>	<b>Listing medicines on the SMF</b>	<b>14</b>
<b>5</b>	<b>Monitoring and review</b>	<b>22</b>
<b>6</b>	<b>Communication</b>	<b>23</b>
<b>7</b>	<b>Formulary One</b>	<b>26</b>
<b>8</b>	<b>Acquisition of medicines</b>	<b>26</b>
<b>9</b>	<b>Evaluating the SMF</b>	<b>27</b>
<b>10</b>	<b>Supporting documents</b>	<b>28</b>
<b>11</b>	<b>Definitions</b>	<b>29</b>
<b>12</b>	<b>Document History</b>	<b>30</b>
	<b>Appendix A. Expert Advisory Group Participants</b>	<b>31</b>

# 1 Introduction

## 1.1 Background

The increasing number of available medicines and indications for use and overall cost in recent times has placed significant pressure on hospital budgets and medicine governance systems. Added to this is increased complexity in prescribing and administration of medicines, variability in resourcing allocated to medicines management and a warranted drive for equity of access to health care across metropolitan and country services.

A formulary is a list of medications which may be used in a hospital; the list may also include the approved indications, dose formulations, treatment details and prescribing restrictions relevant to each medicines. It is a tool that can be used to provide governance to medicines use, guide safe, cost-effective and equitable prescribing and control increasing expenditure on medications. Medicines available in the public system should aim to maximise therapeutic outcomes and public monies by providing safe, clinically efficacious and cost-effective therapeutic options.

To date three states in Australia have implemented a statewide formulary; South Australia's Medicines Formulary, Queensland's List of Approved Medications and the Electronic Tasmanian Medicines Formulary.

In 2014 the WA Therapeutics Advisory Group (WATAG) began formally pursuing a Statewide Medicines Formulary (SMF); the Statewide Medicines Formulary - Development and Implementation Project Plan was endorsed by then A/Director General, Professor Bryant Stokes and the State Health Executive Forum – Operations Review Committee (SHEF-ORC) in August 2014.

In February 2015 the SMF Guideline was endorsed by the A/Director General and SHEF-ORC and the initial review and listing of medicines on the SMF began. Since the initial listing process started over 2000 medicines have been considered utilising the expertise of over 120 Consultant Specialists and Senior Pharmacists from across the state, a list of participants can be found in Appendix A.

## 1.2 Vision

The vision of the Western Australian SMF is:

“To deliver optimal patient outcomes in an equitable manner through a single list of approved medicines for the WA health system; evaluated, implemented and managed in a statewide approach”

### 1.3 Rationale

A statewide medicines formulary will be a step towards achieving the goals outlined in the National Medicines Policy<sup>1</sup> and the Quality Use of Medicines principles<sup>2</sup>. With unprecedented change in the WA health system's existing sites and commissioning of new hospitals, increasing expenditure on medicines and a change to Activity Based Funding, quality in medicines use is now more urgent than ever. The SMF will:

- support efficiencies in the management of medicine use and costs,
- facilitate efficiencies in human resources by reducing duplication of resource intense processes,
- improve uniformity, governance and transparency in medication management, formulary listing and prescribing approval,
- promote the safe and quality use of medicines,
- increase the opportunity for effective monitoring, reporting and review of medicine use and clinical outcomes to facilitate decision support and compliance with medicine standards, and
- provide a single medicines formulary for integration into Electronic Medicines Management Systems in hospitals.

### 1.4 Objectives

The objectives of the SMF are:

- To provide a single list of approved medications with appropriate restrictions and guidance for all Health Service Providers (HSPs).
- To apply the principles guiding the Quality Use of Medications for all patients to the WA health system.
- To promote medication safety by reducing prescribing errors, improving continuity of care and standardising medication use procedures and protocols.
- To facilitate efficiencies in the evaluation of medicines by reducing duplication of Drug and TC processes and in turn freeing human resources for more effective governance of medication use.

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<sup>1</sup> National Medicines Policy. Australian Government, Department of Health and Ageing. Accessed October 2017, available online at:  
[http://www.health.gov.au/internet/main/publishing.nsf/content/B2FFBF72029EEAC8CA257BF0001BAF3F/\\$File/NMP2000.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/B2FFBF72029EEAC8CA257BF0001BAF3F/$File/NMP2000.pdf)

<sup>2</sup> The National Strategy for Quality Use of Medicines. Australian Government, Department of Health and Ageing. Accessed October 2017, available online at:  
[http://www.health.gov.au/internet/main/publishing.nsf/Content/8ECD6705203E01BFCA257BF0001F5172/\\$File/natstrateng.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/8ECD6705203E01BFCA257BF0001F5172/$File/natstrateng.pdf)

- To foster a prescribing environment that takes into account and makes decisions based around the value of medicines in everyday clinical activity.
- To identify and exploit any benefits of an increase in public hospitals' pharmacy purchasing power for acquisition costs.
- To create an accountable and transparent system for medication evaluation, access and use in the public health system.
- To create a guideline for strategic alignment with EMMS and E-prescribing priorities.

## 1.5 Scope

The SMF encompasses all medicines which may be used in clinical practice in the WA health system. Medicines within the scope of the SMF and this Guideline will include but are not limited to:

- Pharmaceutical agents registered by the Therapeutic Goods Administration (TGA) as registered medicines for use in Australia.
- Medicines not listed by the TGA but used in an accepted "off-label" manner including Special Access Scheme (SAS) medicines.

Medicines outside the scope of the SMF and this Guideline will come under the governance of local Drugs and Therapeutics Committee or equivalent authority (DTC) or hospital policies, these include:

- Investigational medicinal products for use in a clinical trial
- Blood or blood derived products which are not a scheduled pharmaceutical product
- Medicines supplied for use in a Medicines Access Program

Non-therapeutic items which may be procured and distributed by pharmacy such as sundries and consumables are outside the scope of the SMF and the DTC.

### 1.5.1 Document Scope

This Guideline will encompass the processes and procedures for the application, evaluation, listing and review of formulary items. The document will also outline the governance surrounding the formulary and compliance evaluation.

## 1.6 Risks

The implementation of the SMF will result in statewide change, as with any change; perceptions, attitudes, system capability and structural and procedural barriers may limit progression and the opportunity for smooth transitions. For example, the perceived reduction in clinician and hospital autonomy and restrictions to medicines otherwise available may result in disengagement and discontent. Likewise, the addition of the SMF may place extra administrative and financial burden on smaller hospitals, or may cause delays to medicines due to lengthy approval processes. Efficient communication and timely reliable access to decisions will require IT infrastructure and statewide system capability.

Risks to the SMF will be mitigated by:

- Ensuring that the needs of the patient are central to all decisions
- A robust, relevant guideline that is regularly reviewed
- A transparent and consistent decision making process and governance structure
- Timely and thorough consultation and engagement with relevant stakeholders representing all areas of the health system
- An effective communication strategy to ensure end users are well informed and timely and reliable access to the SMF through the IT application
- Clear pathways for submission, review and appeal
- An effective and equitable Individual Patient Application (IPA) process
- Careful planning of the initial establishment of the SMF to limit large and immediate changes to practice and procedures

It is recognised that the SMF will not always be reflective of individual patient clinical needs and it must be emphasised that the SMF should not replace judicious prescribing, sound clinical judgement and common sense.

## **2 Governance**

### **2.1 Key stakeholders' roles and responsibilities**

#### **2.1.1 Chief Medical Officer**

The Chief Medical Officer (CMO) is the executive sponsor of WATAG and the SMF project. The CMO will be the representative member for the SMF at the Department Executive Committee (DEC) and the Health Executive Committee (HEC).

#### **2.1.2 Health Service Provider Boards,**

HSP Boards will be responsible for ensuring the implementation of, and compliance with, the Statewide Medicine Formulary Policy within their HSP.

#### **2.1.3 WA Therapeutics Advisory Group**

The WATAG is the state's peak medicines advisory committee. WATAG's role is to:

- provide administrative support and expert advice when required for the function of the SMF,
- advocate to executive members of the WA health system via the CMO,
- review appeals against formulary decisions, and
- be available for consultation with WA Drug Evaluation Panel (WADEP) and/or consider for endorsement, items which are of high-cost, high-impact, require large practice change or may be of significant risk.

Subcommittees of WATAG such as the WA Committee for Antimicrobials (WACA), the WA Psychotropic Drugs Committee (WAPDC) and the WA Medication Safety Group (WAMSG) will provide advice to WADEP and WATAG and be available for consultation on formulary matters particular to the group's expertise.

#### **2.1.4 WA Drug Evaluation Panel**

WADEP will take the role as the peak formulary review committee. In this role, the Panel's responsibilities will be to:

- implement a fair and transparent process for evaluation and review of medicines considered for formulary listing,
  - assess submissions of medicines for formulary listing in a considered and consistent approach underpinned by evidence based practice and clinical and cost-effectiveness, utilising external expertise and or working groups as required,
  - facilitate robust consultation with expert advisors, lead clinicians, HSPs and the Department of Health.,
  - ensure effective and timely communication of Panel decisions,
  - develop best-practice standards and guidelines for medicines use, and
- consult and seek endorsement from WATAG on decisions which are expected to have high-cost, high-impact, require large practice change or may pose significant risk to any level of the WA health system.

#### **2.1.5 Formulary Management Team**

The Formulary Management Team (FMT) sits within the Patient Safety and Clinical Quality in the Department of Health. The FMT will be responsible for supporting the formulary including:

- coordinating and providing administrative support for WADEP and Expert Advisory Groups (EAGs),
- support the cost-effectiveness review of medicines on or submitted to the SMF
- executing the SMF and WADEP communication strategy including maintaining and updating Formulary One, the Electronic Platform that hosts the SMF and makes it easily available to users,
- reporting deliverables to DEC and the DG via the CMO,
- liaising and engaging hospital staff in particular hospital DTCs,
- supporting drug use evaluation and quality use of medicines activities related to the SMF, and
- other functions for the effective administration of the SMF.

#### **2.1.6 Drug and Therapeutics Committees**

Hospital or area DTCs (or equivalent authorities) have historically been responsible for decisions regarding the formulary listing of medicines. The SMF Policy impacts DTCs by decreasing resource intense and often duplicated medicine evaluations. With regards to the formulary, the expectation is for the DTC to take responsibility for:

- the local implementation of the formulary including but not limited to:
  - supporting and communicating decisions made by WADEP, WATAG and DEC regarding evaluated medicines and associated guidelines, and
  - garnering the support of hospital executives, managers and heads of departments for the financial provision of all formulary items (unless restrictions preclude this requirement),
- providing local information on drug utilisation and clinical practice to WADEP,
- supporting the provision of SMF information to relevant staff including the communication of the availability and functionality of Formulary One,
- taking part in evaluations and review processes where necessary,
- facilitating submissions to WADEP and supporting applicants,
- assessing IPAs and provision of IPA data to WADEP as per section 3.7 (page 14) of this Guideline.

DTCs will thus own the primary governance role in relation to the use of medicines at a local hospital level.

DTCs will refer any formulary submissions to WADEP and will no longer have sole autonomy over formulary inclusions/exclusions at the hospital level. DTCs will be given the opportunity to be represented on WADEP according to the WADEP Terms of Reference to permit harmonisation of drug access between sites.

### **2.1.7 Clinical staff**

For the purpose of this Guideline, clinical staff encompasses all staff involved in the medication management system including prescribers, pharmacists and nurses. Clinical staff can support their HSP with its compliance of the SMF policy by:

- submitting new medication or change requests to the FMT and assisting in the review process
- prescribing medicines according to any restrictions placed on those medicines by the SMF, available on Formulary One, maintaining an appropriate knowledge base on the prescription, access and use of medications, policies and procedures relevant to their area of practice,
- taking part in auditing and quality improvement projects when relevant,
- reporting issues that arise with Formulary One, the SMF listing or this Guideline to the FMT or WADEP, and
- complying with all other requirements of medication prescription and supply.

### **2.1.8 Pharmacy staff**

As the primary gatekeepers to medicine inventory and supply, the SMF will rely on the Chief Pharmacists of public hospitals and their respective pharmacy departments to provide the day-to-day governance and support. The pharmacy's role will be to:

- facilitate the implementation and adoption of the SMF, Formulary One and this Guideline,
- support prescribers by identifying, clarifying and communicating to them when items are prescribed outside the SMF,
- keep minimal stock of medicines not listed on the SMF, and
- refer matters to the local DTC or WADEP where appropriate.

If an item has not been prescribed according to the SMF, the pharmacist must discuss this with the prescriber. Substitution will not occur without the prescriber’s permission.

## 2.2 Governance overview

It is important that a robust, transparent and relevant governance structure is defined for the application process and day to day function of the SMF. Figure 1 provides an overview of this governance structure.

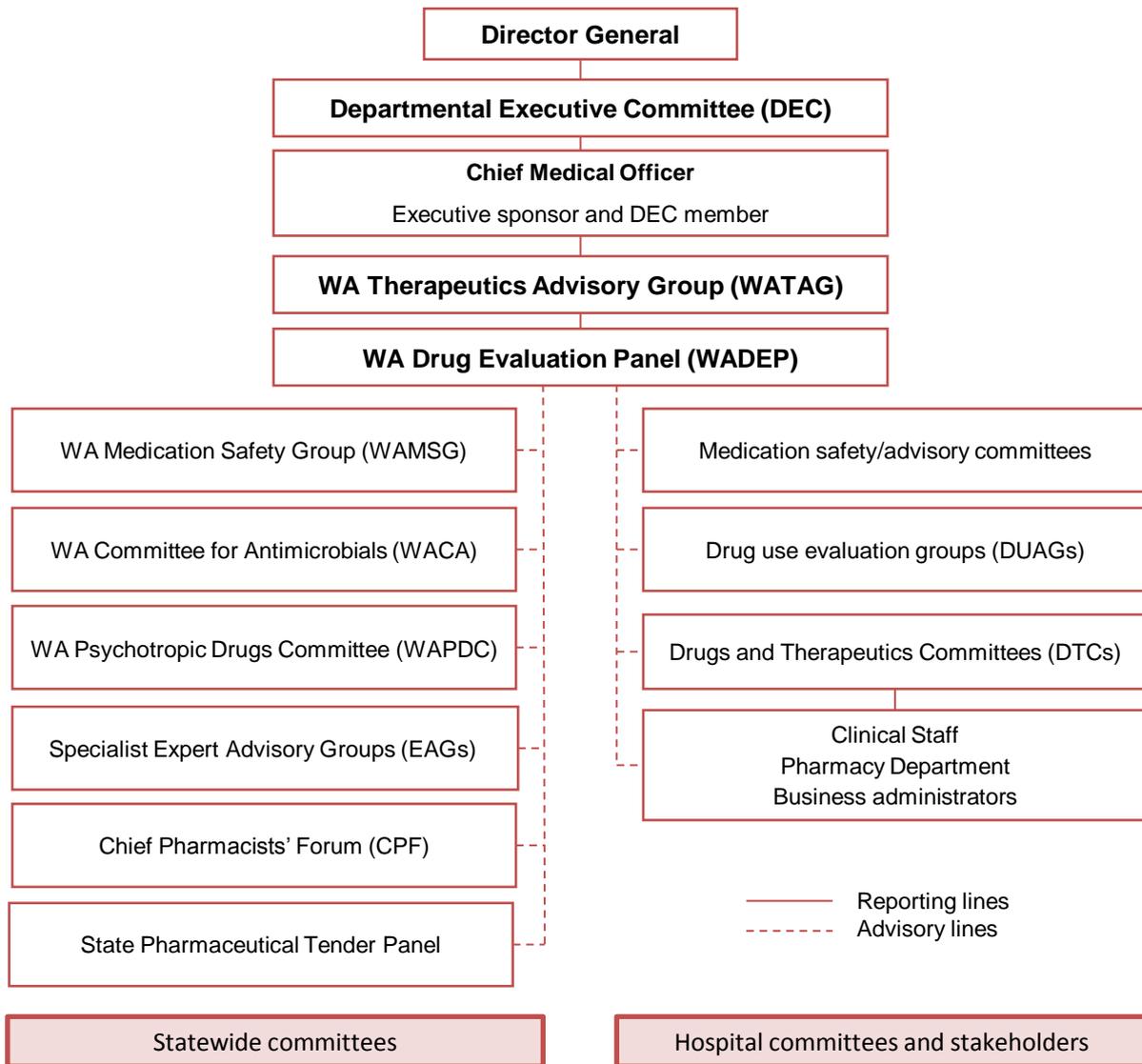


Figure 1. WA Statewide Medicines Formulary governance structure.

## 3 Key components of the SMF

### 3.1 Access to the SMF

The SMF will be maintained by the Department of Health’s Office of Patient Safety and Clinical Quality and made available via Formulary One, an electronic application available via the internet and the Health intranet at <https://formulary.health.wa.gov.au/> and <https://formulary.hdwa.health.wa.gov.au/>.

### 3.2 Understanding the SMF

The SMF will aim to be clear in prescribing requirements and rather than being a set of rules looks to provide decision support, guidance and enable the quality use of medicines. Pivotal to the success of the SMF will be the level of understanding, engagement and cooperation from prescribers.

#### 3.2.1 SMF Classifications

For easy referencing, each medication will be placed into a category depending on the restrictions set by WADEP in the evaluation process, described in Table 1; this classification will also determine the level of governance and authorisation required. The prescribing, administration and supply of all medicines must comply with standard local and state procedures and legislative requirements.

Table 1. Classifications for SMF medications

Category	Explanation	Authorisation / governance	Example
<b>Unrestricted</b>	No restrictions <sup>3</sup>	None required	Paracetamol where no restrictions to prescribing or access apply.
<b>Restricted</b>	Medications which must be used according to restrictions stated (e.g. population, specialty, treatment length, treatment site)	Use that does not comply with the SMF listing will require prescribers to provide justification on an individual patient basis to the local DTC. Pharmacy may choose to refer the prescriber to the DTC before dispensing however the prescriber will	Omalizumab for PBS indications and according to the WA Treatment Algorithm for chronic idiopathic urticaria. Any prescriber using omalizumab for any other indication must seek Individual Patient Approval from the local DTC before prescribing. Amikacin must be prescribed by or

<sup>3</sup> It is generally expected that prescribing is limited to TGA licenced indications or when off-label use is considered routine (i.e. with a high level of evidence; see CATAG Guiding Principles for the Quality Use of Off-label Medicines)

Category	Explanation	Authorisation / governance	Example
		first be contacted.	in consultation with an Infectious Disease Physician or Microbiologist.
<b>Not listed</b>	The medication has been evaluated by WADEP and has been rejected for listing on the SMF OR Medication has not been considered by WADEP for listing on the SMF	The local DTC must give approval for IPA use. Patient may continue on treatment if started before hospital admission.	Fampridine is not listed on the SMF. All prescribers must seek an IPA before prescribing for any indication.

Further detail may be added to the listing to give more information about the level of restriction and requirements for prescribing; this is described in Table 2.

In most instances if there is no information available for a particular agent, it can be assumed the agent has not been evaluated for listing. To prescribe treatment which has no information available the local DTC must be approached for an IPA.

Table 2. SMF prescribing requirements

Nomenclature	Requirements	Authorisation / governance
<b>First line</b>	An agent which has been deemed first line for a particular indication.	If a different agent has been prescribed before a first line agent is trialled, the prescriber may be required to justify that choice.
<b>Preferred agent</b>	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.

Nomenclature	Requirements	Authorisation / governance
<b>PBS indications only</b>	<p>The PBS indications and prescribing criteria apply to inpatient and outpatient use.</p> <p>This includes PBS medicines that are restricted benefit.</p> <p>Additional restrictions may be included.</p>	<p>If used outside the listed indications the local DTC must give approval.</p>
<b>Pending</b>	<p>A medication which is pending evaluation.</p> <p>If noted, a medication may be permitted for use until a final decision has been made.</p>	<p>If approval for use is not noted, the local DTC must give approval for IPA use.</p>
<b>Audit required</b>	<p>Auditing may be stipulated to ensure compliance against formulary listing.</p>	<p>Local DTCs will have governance over audit requirements and reporting</p>
<b>Outcome reporting required</b>	<p>Reporting of clinical outcome measures may be required for some medications.</p>	<p>Local DTCs will have governance over outcome reporting.</p>
<b>Special Access Scheme (SAS)</b>	<p>All prescribers must complete SAS Category A, B or C form prior to prescribing irrespective of the SMF category/restrictions.</p> <p>This is a TGA requirement.</p>	<p>Pharmacy departments may have specific requirements for access to SAS medicines.</p>

### 3.3 Paediatric sub-formulary

The paediatric sub-formulary provides the list of medicines for use in children and adolescents up to 18 years old. The paediatric sub-formulary is a separate list to the adult formulary due to the differences in practice, requirements and evidence availability. Where available specific prescribing and administration information (drug monographs) will be provided however may not always be available or contain the required information for use in paediatrics. Clinicians are advised to seek out alternative, reliable sources of information as necessary.

The paediatric sub-formulary can be viewed via Formulary One at any time. On paediatric wards it is recommended that this sub-formulary is used as the main portal.

### 3.4 Neonatal sub-formulary

The neonatal sub-formulary provides the list of medicines for use in neonates from birth to 1 month old. The neonatal sub-formulary is a separate list to the adult and paediatric formulary due to the very specific requirements for administration. Where available guidelines for common medicines used in this population from King Edward Memorial Hospital's and Fiona Stanley Hospital's neonatal units will be attached as an external link.

In order not to create unnecessary delays in treatment in uncommon circumstances, medications listed on the paediatric sub-formulary may be used in the neonatal setting when under the direction of both a Specialist Consultant and a Neonatologist.

The neonatal sub-formulary can be viewed via Formulary One at any time. On neonatal wards it is recommended that this sub-formulary is used as the main portal.

### **3.5 Availability of medications**

With regards to the availability and supply of medicines, hospitals are limited in the amount of stock that can be held or the services that are funded. Sites that do not provide services, such as for outpatients, will be restricted in their provision of medicines within that service. However, it is encouraged that policies and procedures are put in place to avoid disadvantaging or compromising patient treatment.

- The decision on local stock holdings is the responsibility of the DTC (or equivalent authority) and pharmacy department and should take into account local services, demographics and procedures.
- Pharmacy departments should endeavour to make medications appropriate for their site available when required, whether by an order/transfer process or held on stock. These requirements do not refer to the supply of medications outside the provision of service or that are restricted to specialist sites.
- Prescribers should note that not all medications will be immediately available at their practising site and should adjust their practice if required.
- Patients should be made aware either by pharmacy or their prescriber if a required medication is not held on stock and the local procedures or arrangements for supply.

### **3.6 Patients taking medications not listed on the SMF**

There will be instances when patients come into hospital on a medication not listed on the SMF. This includes the following scenarios, patients 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 such patients, it is encouraged that their treatment is reviewed. Prescribers are encouraged to consider the safety, efficacy and cost-effectiveness of treatment and if clinically appropriate to do so, should consider switching to the preferred or first-line alternative listed on the SMF. Prescribers should discuss this decision with the patient and/or their carer and if relevant the initiating prescriber.

Where the patient is stable and there are no clinical reasons for change, treatment may be continued; this should be indicated on the prescription, medication chart and in the patient's notes.

### **3.7 Individual patient approvals**

There will be limitations to the SMF as all medication options for all conditions cannot necessarily be assessed in a timely manner. New medicines or new clinical evidence, rare diseases, patients who lie outside the assessed population, last-line or rescue therapy are examples of when an alternative pathway to access medicines not on the SMF may be important.

For such cases prescribers will be able to apply to the local DTC with an IPA to access medicines not listed on the SMF. The request must have justified clinical need with evidence or expert advice supporting the agent's use.

The application process for IPAs may differ between hospitals and local policies and procedures should be followed.

#### **3.7.1 Role of the DTC**

The DTC has governance over the IPA system and may place caveats, limit or refuse an application.

At a minimum the DTC is expected to:

- request outcome reports from the prescribing doctor,
- have systems in place for high-cost applications to be given additional authorisation from the Head of Department, Clinical Service Manager and/or Business Manager,
- report all IPAs to the WADEP via the FMT for regular review,
- be aware of medicines close to reaching the state IPA limit (as reported by the FMT) and instruct prescribers to submit a formulary application once the limit has been reached,
- limit IPAs for medicines rejected by WADEP to instances where exceptional need has been justified and all other options exhausted.

For more information, see local DTC policies and procedures.

#### **3.7.2 State IPA limit**

The SMF policy states that procedures should be in place for WADEP to receive de-identified information on IPAs. Once 10 IPAs have been submitted to WADEP from across the State for a particular medication and indication, Consultants will be approached by the FMT to submit an application to WADEP for listing the medication on the SMF.

## **4 Listing medicines on the SMF**

### **4.1 Principles for Listing**

Medications will be listed on the SMF based on the following attributes: the current and proposed use and indications, published evidence, expert opinion, national and international guidelines, alternative treatment options and patient safety. Applicants should ensure that medicines submitted for listing, compared to those already listed on the SMF, should be:

- more effective,
- safer for the patient or clinical staff,
- less expensive (to purchase or administer),
- a required clinical alternative, or
- of greater benefit to the patient or WA health system.

The factors that guide the evaluation process and therefore the application include:

- Clinical effectiveness, appropriateness and comparative health gain (including toxicity)
- Evidence of need
- Severity and extent of medical condition and presence of effective alternative options
- Patient safety (including the potential for abuse or resistance in the case of antimicrobials)
- Cost-effectiveness
- Cost implications and affordability to the WA health system and the patient (i.e. in the absence of SMF listing)
- Impact on clinical practice (dosing, administration, change in staff resourcing etc.)
- Equity and continuity-of-care
- Practicality of supply such as procurement and supply chain management

A major component of a formulary and medicines management system is for the assessment of a medication's "value" to the community. Part of the assessment of "value" is the economic evaluation and analysis of cost-effectiveness. The SMF economic evaluation process aims to be consistent with the Pharmaceutical Benefit Advisory Committee's (PBAC) approach in that decisions will take into account the cost to achieve additional health outcomes with the evaluated medication in the hospital context.

## 4.2 Process for listing new medicines

### 4.2.1 Submission process

Submissions can be categorised as:

- A) Full submission: medicine to be added to the SMF or new indication for an existing medicine listed on the SMF.
- B) 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.

Submissions for additions or change to the SMF can be made by using the [SMF Submission Form for Full and PBS submissions](https://formulary.health.wa.gov.au/) or the [Minor change form](https://formulary.hdwa.health.wa.gov.au/), available from Formulary ONE at <https://formulary.health.wa.gov.au/> or <https://formulary.hdwa.health.wa.gov.au/>.

It is important that there is a clinical need and drive for medicines listed on the SMF therefore submissions may be initiated by the following individuals or groups:

- Prescribers who work in the WA health system
- DTCs who have identified a medicine for listing
- WATAG or a subcommittee
- The IPA limit, see 4.4

In order to aid work flow and ensure clinical relevance, the applicant should complete the six steps listed in Figure 2.

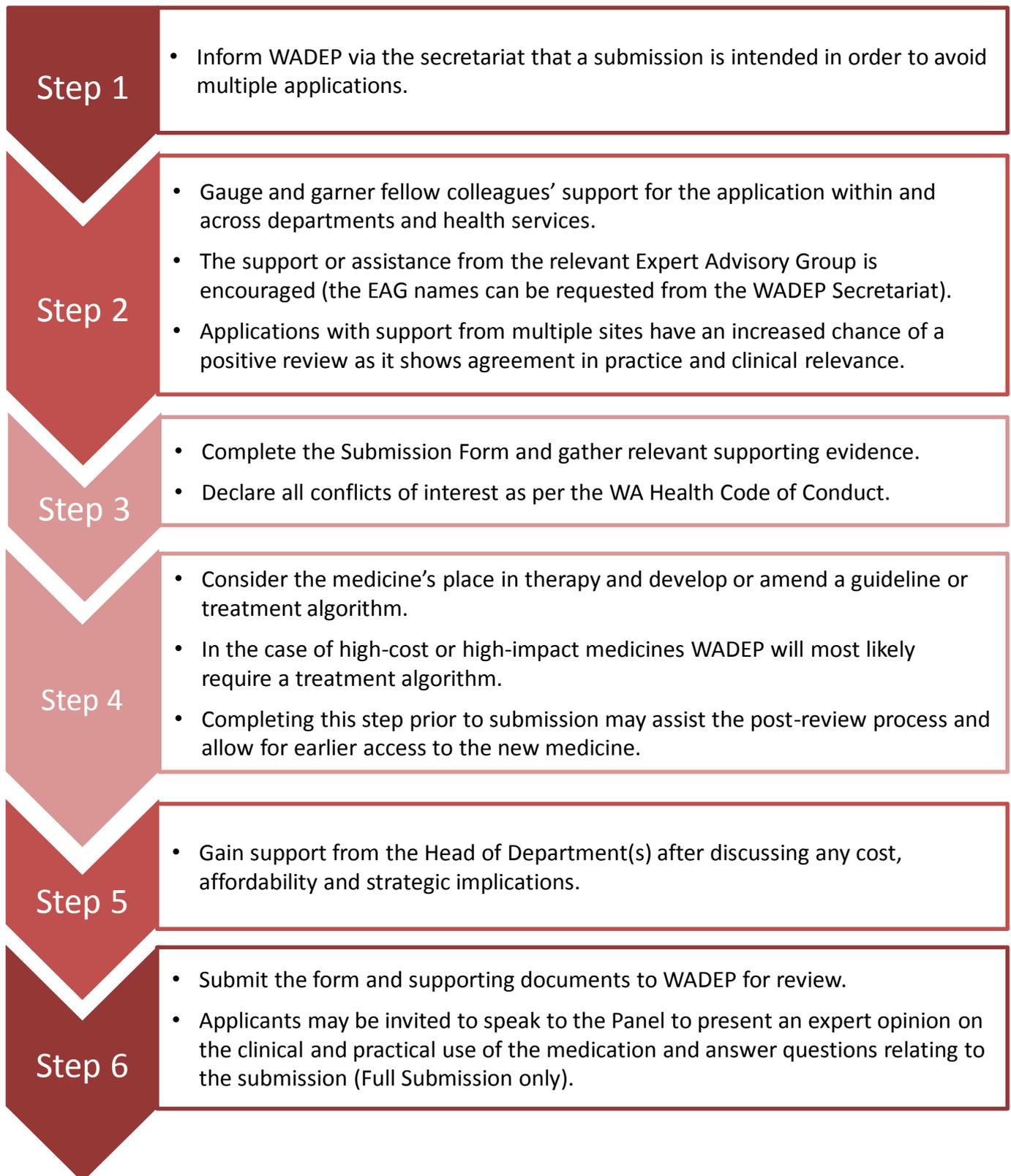


Figure 2. The application process for new medicines or changes to the SMF.

## 4.2.2 WADEP submission review process

The process following the acceptance of a submission is described in Figure 3.

Once a submission has been received the FMT will independently review and summarise the evidence and practical implications of the medicine. The FMT will also be available to support applicants in the submission process and may contact the applicant for more information or clarification on the submission.

Two reviewers will independently and confidentially review the submission guided by the SMF Reviewer Report document. Reviewers may be WADEP members, EAG members or invited expert reviewers.

WADEP will be presented with the following completed documents one week prior to the scheduled meeting:

1. SMF Submission Form plus supporting evidence and documents
2. Medicine Summary Document completed by the FMT
3. Reviewer Report A and B
4. EAG recommendation.

WADEP members will discuss, review and provide a decision on the formulary listing status of the medicine based on a vote (as per the WADEP Terms of Reference). The following outcomes may be made by WADEP:

- A. Medication for unrestricted inclusion on the SMF
- B. Medication for inclusion on SMF with specified restrictions
- C. Medication for recommendation to WATAG and HEC
- D. Medication not for inclusion on SMF

WADEP may or may not make a final decision at the initial meeting; decisions may be deferred until further evidence of clinical/cost-effectiveness is provided. Outcomes may also be affected by national/international factors such as decisions from another review body or jurisdiction.

### 4.2.2.1 Sources of advice

WADEP may wish to seek expert opinion or recommendation on a submission; the sources for this advice may stem from multiple sources including, but not exclusively:

- WA Psychotropic Drugs Committee for psychotropic and mental health medicines
- WA Committee on Antimicrobials for anti-infective medicines
- WA Medication Safety Group for medication safety concerns
- EAGs
- WA Health Networks and specialist committees
- Lead clinicians and specialists
- Chief Pharmacist's Forum
- University representatives

- Council of Australian Therapeutic Advisory Group members
- Other HSPs

#### **4.2.2.2 Paediatric and neonatal sub-formulary review process**

Submissions for the paediatric or neonatal sub-formularies should follow the same submission process described in 4.2.1. For medicines proposed for use solely in paediatrics FMT and or WADEP may approach paediatric representatives of the relevant EAGs for advice if necessary. For medicines proposed for use solely in neonates the FMT and or WADEP may approach the neonatology EAG for advice if necessary.

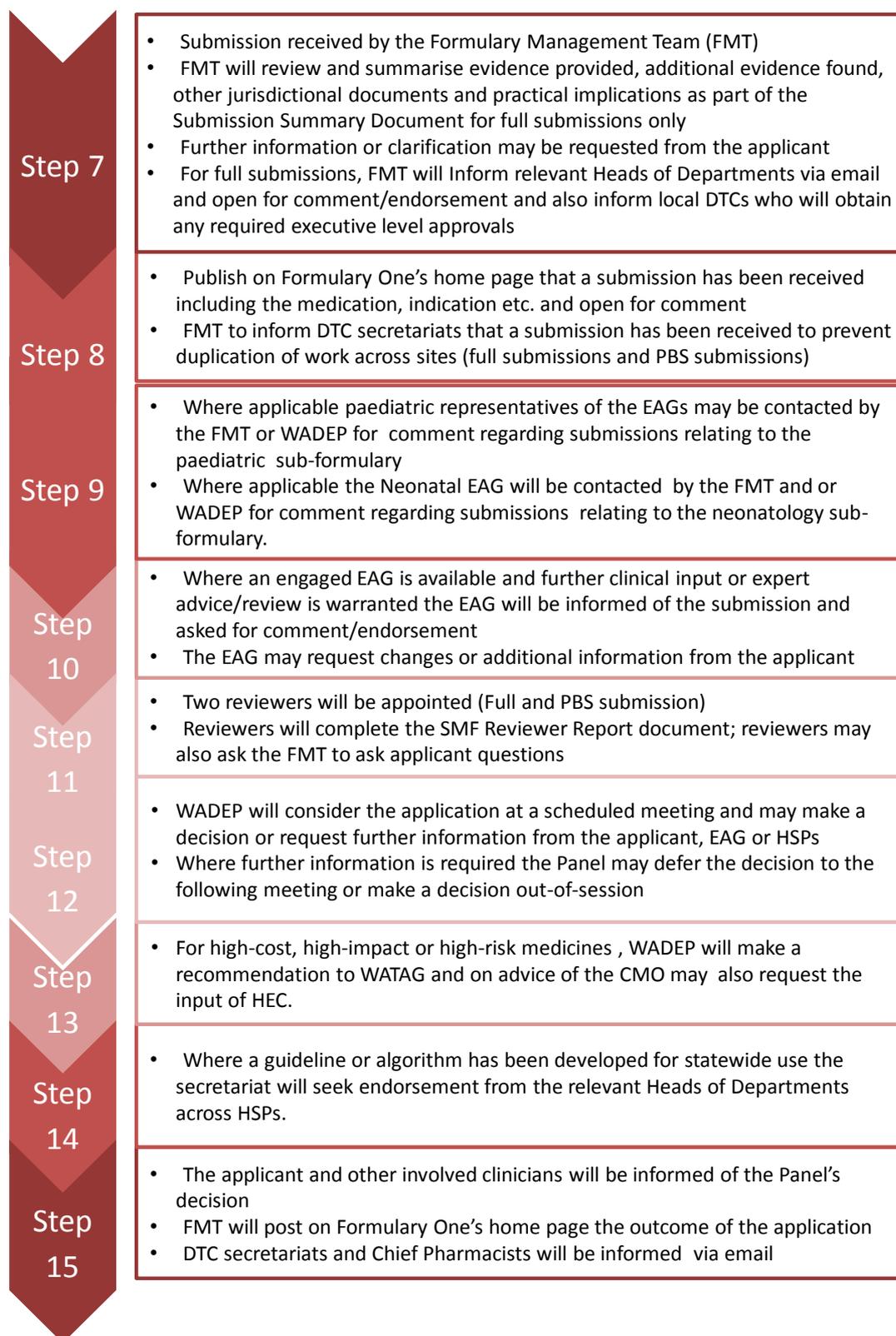


Figure 3. Process for submissions once received by WADEP.

### 4.3 Products excluded from the SMF listing process

Products that are not a medicinal product will not be included on the SMF. These medicines are not uniformly purchased, stocked or distributed by pharmacy departments

Extemporaneous products are resource intensive and their make-up is often specific to the prescriber or patient. The availability of these products in a hospital will be determined by the local DTC and Pharmacy Department in order for local resourcing to be taken into account.

Schedule 2 and schedule 3 products as per the *Standard for the Uniform Schedule of Medicines and Poisons (SUSMP)* will be subject to the same principles as other scheduled medicines.

### 4.4 Process for appeal

Outcomes of the application process, whether positive or negative, may be subject to appeal by the original applicant or affected prescribers.

1. Appeals can be made directly to WATAG via the WATAG Secretariat ([WATAG@health.wa.gov.au](mailto:WATAG@health.wa.gov.au)), or via the FMT ([WADEP@health.wa.gov.au](mailto:WADEP@health.wa.gov.au)). Appeals can also be made as a letter addressed to the WATAG Chair outlining the rationale for appeal.
2. WATAG will preliminarily review the case; it is at the discretion of the WATAG Chair and its members as to whether there are grounds to proceed the appeal.
3. If the appeal is to proceed, both the appellant and WADEP will be given an opportunity to justify their stance in writing or in person at the next most convenient WATAG meeting.
4. WATAG will make a decision according to the Group's Terms of Reference. This decision will be final and if negative prescribers will have the option to apply to their local hospital DTC for an IPA.

It is not considered an appeal if the applicant wishes to submit new supporting data or reapply for an alternative indication. In the case of reapplications, WADEP will assess each case on an individual basis; applications may be required to repeat the submission process.

### 4.5 Pharmaceutical sponsors

WADEP does not accept formulary applications directly from pharmaceutical companies and does not negotiate with pharmaceutical sponsors. WADEP will only provide general advice or information to pharmaceutical representatives. WADEP or WATAG will not accept appeals or reapplications from pharmaceutical company representatives.

Applicants may obtain information from the manufacturer for the submission, however they are expected to declare all conflicts of interest and follow the WA Health Code of Conduct.

**Supporting document(s):** *MP 0031/16 - Code of Conduct. Available from:* [http://www.health.wa.gov.au/circularsnew/circular.cfm?Circ\\_ID=13337](http://www.health.wa.gov.au/circularsnew/circular.cfm?Circ_ID=13337)

## 5 Monitoring and review

### 5.1 Review of existing medicines

All listing outcomes, policies, operational directives, guidelines and procedures will be allocated a review date at the time of endorsement by WADEP or WATAG. Review requirements may differ according to the need determined by WADEP. For example, medicines which are new, have growing clinical evidence or are high-risk or high-cost may be reviewed by the Panel after a shorter timeframe; older medicines with more experience around their use may not require review as often.

Medicines due for review will be assessed by the FMT who will scan for new evidence, assess the impact of alternative treatments and review its place in clinical practice and guidelines from other jurisdictions. Required changes will be presented to WADEP for consideration.

Clinicians, DTCs or members of WATAG or its subcommittees are also able to identify medications which need review prior to the stated review date. This may arise from a submission of an alternative product/therapy, new safety or efficacy data, updates in best practice or changes in acquisition price. WADEP will assess the requirements for each review on a case-by-case basis and may request a full submission for large changes; the FMT will provide support to the applicant and the review process.

#### 5.1.1 Removal of a listed medicine

WADEP may deem that a medicine should be removed from the SMF, after thorough consult, if:

- evidence of unsatisfactory effectiveness becomes available
- evidence of toxicity or patient harm outweighs the benefit to the patient
- treatment is no longer cost-effective or effective in comparison to other treatment options
- supply of the medicine is no longer practical or discontinued in Australia.

### 5.2 Evaluating the quality use of medicines on the SMF

#### 5.2.1 Audits and outcome evaluation

There will be instances where WADEP or WATAG identify medications which require further information regarding efficacy, safety or cost-effectiveness; in such cases an audit or outcome report may be required from the prescriber.

Audits may also be conducted on a medication or group of medications to evaluate utilisation, differences across the State and whether the restrictions/indications of the SMF have been observed.

The aim of these initiatives will be to identify areas of need or improvement, feedback information to WADEP and WATAG on previous decisions, support evidential claims and applicability to the WA population or identify good practice and efficiencies.

## 5.2.2 Drug use evaluation

Drug use evaluation (DUE) is a valuable tool in the measure and improvement of the quality use of medicines. The SMF facilitates DUE in various ways:

- Provides opportunity for statewide initiatives and sharing of experiences which will have greater effect and reach; in particular, will support smaller, regional hospitals that have fewer resources available for such programs.
- Free up resources at the site level for DUE initiatives.
- Provides a single reference point for all clinicians, review bodies (i.e. DTC or quality improvement committees) and organisations.

As part of ongoing quality and value improvement in the use of medicines, the SMF will hope to engage established site DUE teams and other interested parties to coordinate efforts across the state and inform the medicines review and evaluation process.

# 6 Communication

## 6.1 Communication objectives

Communications objectives that will contribute to the achievement of the SMF goals are:

- To positively change the behaviour of medical practitioners and nurse prescribers in how they approach prescribing medicines.
- To develop effective communication and education information flows to stakeholders most impacted changes to the SMF so as to ensure any changes in working practices are embraced and implemented as effectively as possible.
- To ensure transparency in the decision making process so that all stakeholders understand that the SMF is evidence based, delivering benefits to patients as well as to the WA health system.
- To build trust and develop effective working relationships in the SMF with stakeholders and WA health system employees.
- To secure buy-in from executive and management levels to ensure that the facility will embrace and promote the SMF.
- To remain relevant and maintain momentum and engagement with all WA health staff.
- To harness the networks of key stakeholders to extend the reach of communications.

An avenue for feedback and participation from stakeholders will be important to allow two-way communication and engagement.

## 6.2 Communication methods

The key information to be communicated to stakeholders will include:

- Invitations to participate in consultations for policies, standards and guidelines
- Notifications for new and updated policies, standards and guidelines
- Changes to the formulary listing status of any medicines and/or information pertaining to prescribing requirements and availability of medicines on the formulary

- Changes to the SMF Policy and Guideline
- Implementation of guidelines, policies or procedures relevant to the formulary
- Auditing and outcome reporting requirements and results
- Changes to Formulary One likely to affect users
- SMF assessments as described in section 9. [Evaluating the SMF](#), (p27)

In these communications the message should indicate the rationale behind key decisions, the evidence and consultation process taken and dates for review.

The SMF will use a variety of communication tools and channels to ensure key messages are known, understood and applied. The tools, channels and frequency will be selected based on their appropriateness given:

- The type of information to be conveyed
- The stakeholder who will receive the communication
- The stakeholder who will be responsible for the information or any actions communicated

Care needs to be taken to ensure stakeholders receive messages without alert fatigue. The focus should be on quality communications that inform stakeholders of the key message rather than quantity.

The stakeholders and frequency of communication to be used for the SMF are outlined in Table 3.

### **Direct communication**

Direct communication will be via email direct to the recipient. Formal communications will be via email and in written hardcopy sent via mail. Information for direct communication will be relevant to the recipient and/or their staff and the intent and any requirements should be clearly expressed.

### **Indirect communication**

Indirect communication will be via:

- Formulary One Homepage,
- WATAG weekly e-newsletter
- HealthPoint
- Promotional material/events such as brochures, posters and symposiums

The **SMF Project Communication Strategy** provides a more in-depth description of the communication activities to take place in the implementation phase of the SMF.

**Supporting document:** Statewide Medicines Formulary Project Communication Strategy

Organisation	Type of communication	Regular/as required communication	As required communication	Examples
<b>Department of Health</b>	Direct high-level oversight	Chief Medical Officer	Director General Department Executive Committee (DEC)	High-level and high-impact policy changes Major risks caused by the SMF Major risks to the SMF SMF KPIs and outcomes
<b>Hospital and Health Service Providers (HSP)</b>	Direct high-level policy engagement	DTCs CPF	HSP Boards Chief Executive/ Executive Director Director of Clinical/ Medical Services Director Safety and Quality Health Executive Forum (HEC)	Notifications/invitation for input on high-level policies, standards and guidelines SMF KPIs and outcomes Notifications/invitation for input on changes to the SMF that may have a broad impact on the organisation Requested information
	Direct clinical engagement	WATAG and its subcommittees	Medical co-directors Department Heads Chief Pharmacists EAGs	Notifications/invitation for input on clinical guidelines or standards Notifications/invitation for input on changes to the SMF impacting a clinical area SMF KPIs, outcomes and audit requirements and results specific to a clinical area Requested information
	Indirect communication	Medical, nursing and pharmacy staff		Changes to the SMF Notifications/invitation for input on clinical guidelines
<b>External stakeholders</b>	Direct Communication		Health consumers: Consumer Advisory Committees (CAC) and WA Health Consumers Council (HCC) Interjurisdictional agencies Commonwealth agencies	Invitation for input on policies, standards and guidelines likely to directly impact consumers Requested information

## 7 Formulary One

The [Formulary One User Guide](#) provides a more in-depth description of Formulary One, the Electronic Platform that hosts the SMF and makes it easily available to users.

Formulary One will:

- Allow timely access to the SMF for all WA public hospital staff without creating unnecessary difficulties when prescribing
- Show all listing particulars such as the indication, restrictions and requirements
- Link to guidelines and procedures related to that medication
- Clearly identify the generic name (International Non-proprietary Name), strength, formulation, pack size and cost per pack
- Indicate preferred proprietary brand if required
- Integrate with i.Pharmacy and show stock availability and location
- Link to the PBS website and other relevant online resources

## 8 Acquisition of medicines

### 8.1 Pharmaceutical tender and Chief Pharmacist Forum

Prior to the SMF, purchasing of non-tender items was between individual pharmacy departments and the pharmaceutical supplier. The SMF provides an opportunity to consider statewide purchasing of medications. In particular, medicines which are only deemed by WADEP to be cost-effective below a certain price may require further negotiation with the supplier.

WADEP will remain independent of the procurement process. Instead over the coming years WADEP will focus on fostering a relationship with the Chief Pharmacist's Forum (CPF) and the Pharmaceutical Tender Board. The aim will be to:

- inform CPF of SMF listings so that implications, if any, for more cost effective medicines acquisition can be determined,
- advise on the cost-effective price threshold,
- identify preferred agents,
- provide clinical input into purchasing considerations, when required, and
- encourage statewide agreement in medicine procurement when items not on tender.

In turn, the CPF and Pharmaceutical Tender Board will inform WADEP of changes in the market, pricing, and reimbursements that may affect the comparative benefits of an individual item. WADEP may use this information to review previously evaluated items.

### 8.2 Cost-effective price

The SMF listing process will evaluate the value in each medication which must include consideration of the product acquisition price. In some instances the price of a medication may

be prohibitive to its use in WA. When this is the case, WADEP will attempt to support the Chief Pharmacists or the Pharmaceutical Tender Board when in negotiations with the pharmaceutical supplier.

## 9 Evaluating the SMF

### 9.1 Assessment of the SMF

To understand the impact on HSPs, Pharmacy departments, clinical staff and DTCs, the indicators in Table 4 will be monitored following the implementation of the SMF.

These indicators will help to assess areas of efficiency gain, impact on workload and work flow and effectiveness of the electronic system, the communication strategy and this Guideline.

HSPs, usually via their DTCs and Pharmacy departments will be required to assess compliance to the SMF as per the WA Statewide Medicines Formulary Policy. Due to the limitations of i.Pharmacy, the Pharmacy Management System and lack of e-prescribing, differences in medicines initiated and continued from primary care, the prescribing team and the indications for prescriptions will not be exact. Therefore compliance can only be broadly measured at the hospital level using trends and estimates of:

Table 4. SMF implementation assessment

Objective	Indicator	Method
<b>Create a single statewide formulary</b> – <b>standardised protocols/procedures</b> – <b>equity of access</b>	<ul style="list-style-type: none"> <li>• Number of different formularies across WA</li> <li>• Discrepancies in medicine use and availability across WA</li> <li>• Number of Statewide protocols, procedures and guidelines for medicines</li> <li>• Number of IPAs</li> </ul>	<ul style="list-style-type: none"> <li>• Survey of DTCs and pharmacies</li> <li>• Review quarterly IPA reports</li> <li>• Review of hospital formularies</li> </ul>
<b>Facilitate efficiencies in medicines evaluation</b>	<ul style="list-style-type: none"> <li>• Number of formulary evaluations per quarter per DTC</li> <li>• Hours spent per reviewer per submission</li> </ul>	<ul style="list-style-type: none"> <li>• Survey of DTC members</li> <li>• Review of DTC minutes</li> </ul>
<b>Increase pharmacy purchasing power</b>	<ul style="list-style-type: none"> <li>• Acquisition cost of medicines</li> </ul>	<ul style="list-style-type: none"> <li>• Use pharmacy data to compare acquisition prices at different sites and across time</li> <li>• Number of recommendations provided by WADEP to the Pharmaceutical Tender Board</li> </ul>

Objective	Indicator	Method
		<ul style="list-style-type: none"> <li>Number of recommendations provided by the Pharmaceutical Tender Board to WADEP</li> </ul>
<b>Accountability and transparency in medication evaluation</b>	<ul style="list-style-type: none"> <li>Availability of decision process to public</li> <li>Clinician opinion and trust in the system</li> <li>Length of time for formulary listing</li> </ul>	<ul style="list-style-type: none"> <li>Availability of public information about medicine formulary decisions</li> <li>Clinician survey</li> <li>Review of DTC and WADEP listing time</li> </ul>
<b>Promote “valuable” use of medicines</b>	<ul style="list-style-type: none"> <li>Total cost of medicines</li> <li>Cost-considered in prescribing and decision making</li> </ul>	<ul style="list-style-type: none"> <li>Monitor trends in cost from iPharmacy</li> <li>Clinician survey</li> </ul>
<b>Promotion of medication safety</b>	<ul style="list-style-type: none"> <li>Reported prescribing errors</li> <li>Number of medications with safety information available</li> <li>Patient information availability</li> </ul>	<ul style="list-style-type: none"> <li>Pharmacy and Datix-CIMS data</li> <li>Available safety data</li> <li>Available patient information</li> </ul>

## 9.2 Cost-savings

It is expected that the SMF will create efficiencies in the use of medicines across WA. One measure of the formulary’s effectiveness will be in the costs saved in medicine expenditure.

The impact of the SMF on expenditure in the WA public hospital system will be evaluated on a regular basis by WADEP; this will be aided by dispensing data collected in i.Pharmacy. Baseline data will be collected during the development and implementation of the formulary.

## 10 Supporting documents

The following document(s) informed this Guideline:

- WA Drug Evaluation Panel Approach to Biosimilars
- Council of Australian Therapeutic Advisory Groups (CATAG): Rethinking Medicines Decision Making: Guiding Principles for the quality use of off-label medicines. Available online: <http://www.catag.org.au/wp-content/uploads/2012/08/OKA9963-CATAG-Rethinking-Medicines-Decision-Making-final1.pdf>
- CATAG: Achieving Effective Medicines Governance: Guiding Principles for the roles and responsibilities of Drugs and Therapeutics Committees in Australian public hospitals. Available online: <http://www.catag.org.au/wp-content/uploads/2012/08/OKA9964-CATAG-Achieving-Effective-Medicines-Governance-final1.pdf>

# 11 Definitions

The following definitions are relevant to these Guidelines.

**Biological:** The TGA define biological medicines (biologics) as a therapeutic good derived from biological sources and are regulated as registered medicines.<sup>4</sup>

**Biosimilar:** A biosimilar is a version of a registered off-patent biological medicine that has demonstrable similarity in physiochemical, biological and immunological characteristics efficacy and safety. These properties must be based on comparability studies; biosimilars are not a generic version of the biological product.

**Drugs and Therapeutics Committee or equivalent authority (DTC):** 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.<sup>5</sup>

**Generic equivalent medicines (or generic):** Generic medicines are medicines which share the following properties with a registered, off-patent medicine:

- the same quantitative composition of a therapeutically active substance,
- the same pharmaceutical form,
- has the same therapeutic response and bioequivalence, and
- has the same safety and efficacy properties.<sup>1</sup>

**High-cost medicine:** A high-cost medication is defined as those with a cost of more than \$250,000 annually within the WA health system.

**Individual Patient Approval (IPA):** 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.

**Pharmaceutical Benefits Advisory Committee (PBAC):** The PBAC is an independent expert body whose primary role is to recommend new medicines for listing on the PBS.

**Pharmaceutical Benefits Scheme (PBS):** The PBS is a Commonwealth scheme for subsidised medications listed on the PBS Schedule available to all Medicare card holders.

**Therapeutic class (-therapeutic group):** Medications in a therapeutic group are considered to share similar scientific and pharmacologic properties, chemical structure, mechanism of action, physiological effect or similar safety and health outcomes. (i.e. proton-pump inhibitors such as pantoprazole and esomeprazole or antiarrhythmic such as amiodarone and verapamil).

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<sup>4</sup> Therapeutic Goods Administration (TGA). Acronyms and glossary. Cited September 2014, available online at <https://www.tga.gov.au/acronyms-glossary>

<sup>5</sup> Australian Commission on Safety and Quality in Health Care. National safety and quality health service standards. Sydney:ACSQHC; 2011

## 12 Document History

NB. Versions 1.0-2.0 known as Statewide Medicine Formulary Framework.

Version number	Version Date	Sponsor	Document Writer	Next Review Date
<b>1.0</b>	1/12/2014	Office of the Chief Medical Officer (OCMO)	Rebecca Godfrey Project Coordinator	1/12/2016
<b>1.1</b>	14/04/2015	Office of the Chief Medical Officer (OCMO)	Rebecca Godfrey Project Coordinator	1/12/2016
<b>1.2</b>	2/07/2015	Office of the Chief Medical Officer (OCMO)	Rebecca Godfrey Project Coordinator	1/12/2016
<b>2.0</b>	1/01/2017	Office of the Chief Medical Officer (OCMO)	Rebecca Godfrey Project Coordinator	1/01/2019
<b>3.0</b>	04/12/2017	Assistant Director General, Clinical Excellence	Cale Padgett, Project Coordinator	04/12/2020

## Appendix A. Expert Advisory Group Participants

Participant	Position	Participant	Position
<b>Anaesthetics</b>			
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Yan Peng	Senior Pharmacist, FSH	Mark Williams	Cons Anaesthetist, FHS and OPH
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Cathy Mews	Paediatric Gastroenterologist, PMH		

Participant	Position	Participant	Position
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