WA Statewide Medicines Formulary
Frequently Asked Questions (FAQ)

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What is the WA Statewide Medicines Formulary (SMF)?

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. Its composition is evidence-based and considers the clinical efficacy, safety and cost-effectiveness of medicines. The SMF governs the initiation of prescribed medicines to ensure effective, equitable and consistent clinical care is provided across the WA health system.

Why do we have a Formulary?

The rationale includes:

- providing a single list of approved medicines with appropriate restrictions and decision support
- ensuring consistency and equity of access to medicines across the WA health system
- optimising the quality use of medicines by supporting safe and evidence-based prescribing
- ensuring that quality use and cost-effective medicines are prescribed across the WA health system
- facilitating effective monitoring, reporting and review of medicine usage and clinical outcomes to support decisions
- creating a transparent and consistent submission evaluation process
- establishing a single medicines formulary for integration into electronic systems associated with the management, administration, or governance of medicines such as the Western Australian Individual Patient Approval System (WAIPAS)
- reducing process duplication for Drug and Therapeutics Committees (DTCs)/Medicines and Therapeutics Committees (MTCs) or equivalent authorities and creating capacity for effective site-level medicine governance.

Who does the SMF apply to?

The formulary is applicable to all Health Service Providers (HSPs) 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.

It is also applicable to contracted health entities, to the extent they provide health services to the State.

How do I access the SMF?

The SMF is accessible via Formulary One, an electronic platform available via the internet https://formulary.health.wa.gov.au/ and the WA Health intranet https://formulary.hdwa.health.wa.gov.au.

Refer to the guide on how to create a shortcut to the Formulary One site on the home screen of your smart phone for step-by-step instructions.

Who maintains the SMF?

The WA Medicines Evaluation Panel (WAMEP) is responsible for maintaining the SMF.

What do the SMF status and restriction level categories mean?

Medicines are categorised based on the formulary status or restriction level set by WAMEP in the evaluation process, as detailed in the table below.

Category	Explanation
Unrestricted 	No formulary restrictions apply to the initiation of the medicine provided that the indication is TGA registered or where off-label use is considered routine (i.e. widely used in clinical practice with an extensive evidence base).
Restricted 	Medicines that can only be initiated according to the criteria stated in the listing (e.g. population, treating specialty, treatment duration, route etc.).
Highly restricted 	Approval from the indicated specialty prescriber type must be obtained before initiating the medicine. For example, this category may be used for highly restricted antimicrobials and selected high risk medicines at the discretion of WAMEP.
Not approved by WAMEP 	A medicine or indication that has been evaluated by WAMEP and has been rejected for listing on the SMF. A WAMEP formulary note outlining the rationale for rejection will be uploaded to the medicine monograph on Formulary One.
Not reviewed by WAMEP	A medicine or indication that is within the scope of the SMF but has not yet been reviewed by WAMEP for listing on the SMF. **Note:** Medicines and indications that have not been reviewed by WAMEP may not return search results or be listed under the applicable medicine monograph on Formulary One.

What medicines and therapeutic products are considered within the scope of the SMF?

In Scope

- Medicines included on the Australian Register of Therapeutic Goods (ARTG), where not listed as out of scope
- Medicines not included on the ARTG that require access via the Special Access Scheme (SAS) or Authorised Prescriber (AP) scheme, where not listed as out of scope
- Medicine indications, doses or frequencies that are not licensed for a TGA-registered medicine ('off-label' use) where there is sufficient evidence for use and no alternative medicine registered
- Medicines produced by an Australian TGA-registered manufacturing facility, where TGA-registered or SAS medicine alternatives are unavailable
- Extemporaneously compounded medicines in the following situations:
  - Adult formulary: products produced by complex compounding*, where a proprietary product does not exist and there are no suitable alternatives
  - Paediatric and neonatal formularies: all extemporaneously compounded medicines, where a proprietary product does not exist and there are no suitable alternatives
- Non-prescription medicines (including over the counter (OTC) medicines, herbal and complementary medicines) that have an accepted place in contemporary clinical care, and/or are associated with significant efficacy, safety, or cost-effectiveness concerns
- Other medicines at the discretion of the WAMEP Chair that are associated with significant efficacy, safety or cost concerns

*Complex compounding: The Pharmacy Board of Australia defines complex compounding as 'the preparation and supply of a single 'unit of issue' of a therapeutic product that is intended for supply for a specific patient and that requires or involves special competencies, equipment, processes or facilities.[1] Examples are sterile preparations and preparations containing ingredients that pose an occupational health and safety hazard (such as cytotoxics or hormones), micro-dose single-unit dosage forms containing less than 25mg (or up to 25 per cent by weight or volume) of active ingredient, and sustained-release or other modified-release preparations.[1]

[1]Pharmacy Board of Australia. Guidelines on compounding of medicines. Cited January 2024, available online at https://www.pharmacyboard.gov.au/codes-guidelines.aspx.

What medicines and therapeutic products are considered outside the scope of the SMF?

Medicines and therapeutic products outside the scope of the SMF fall within the remit of individual hospital and health service medicines governance bodies such as the DTC/MTC or equivalent authority, or other specialised committees where applicable according to local policies.

Out of Scope

- Investigational medicines used in a clinical trial
- Medicines supplied for use under a Medicines Access Program (MAP)
- Diagnostic agents except if the agent is used for a therapeutic indication
- Surgical antiseptics and applications
- Parenteral nutrition products
- Large volume fluids, including but not limited to intravenous infusion fluids, irrigation fluids, dialysis solutions and cardioplegia solutions are out of scope, except in the following situations:
  - Products that have a specific treatment indication e.g. mannitol infusion for ophthalmology use
  - Paediatric formulary: high risk large volume fluids[#] for paediatric use are within the scope of the SMF
- Enteral nutrition products except if indicated for a metabolic disorder
- Extemporaneously compounded medicines in the following situation:
  - Adult formulary: products produced by simple compounding[^] (this includes all compounding that does not fit the definition of complex compounding)
- Sundries and consumables that are non-therapeutic
- Non-National Blood Authority (NBA) indications for blood products
- Medical devices that do NOT contain medicines
- Medical devices that contain medicines. Note: WAMEP can provide advice to DTCs/MTCs or Product Evaluation Standardisation Committees (PESCs) about the medicine component of the device on a case-by-case basis at the discretion of the WAMEP Chair.

Hosted Listings
(Outside the scope and not subject to WAMEP review or the SMF Policy)

- NBA indications for plasma derived and recombinant blood products
- Highly Specialised Therapies (HSTs) that have been reviewed and approved through established governance processes such as Medical Services Advisory Committee (MSAC) and WA Policy Advisory Committee on Health Technology (WAPACT)
- Other medicines or therapeutic products at the discretion of WAMEP

[#]High risk large volume fluid includes those containing potassium or those that are significantly hyper or hypo-osmolar.

[^]The Pharmacy Board of Australia defines simple compounding as 'the preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need.[1] It routinely involves the compounding of products from formulations published in reputable references such as the Australian Pharmaceutical Formulary and Handbook (excluding the preparation of sterile products from these formulations, which is considered complex compounding), or using other formulations for which information confirming quality, stability, safety, efficacy and rationality is available.[1]

What are hosted listings?

Where appropriate, WAMEP may agree to host medicines or therapeutic products that are outside the scope of the SMF on the Formulary One platform for visibility and clarity for clinical staff. However, these will be clearly noted as being outside the scope of the SMF and not subject to WAMEP review.

Medicines or therapeutic products that are hosted on the SMF are not bound by the SMF Policy and come under the governance of the local DTC/MTC or equivalent authority, or other national, state, or specialised committees where applicable according to local policies.

Medicines or therapeutic products that are requested to be hosted will be tabled for noting at the next available WAMEP meeting.

Examples of hosted listings include:

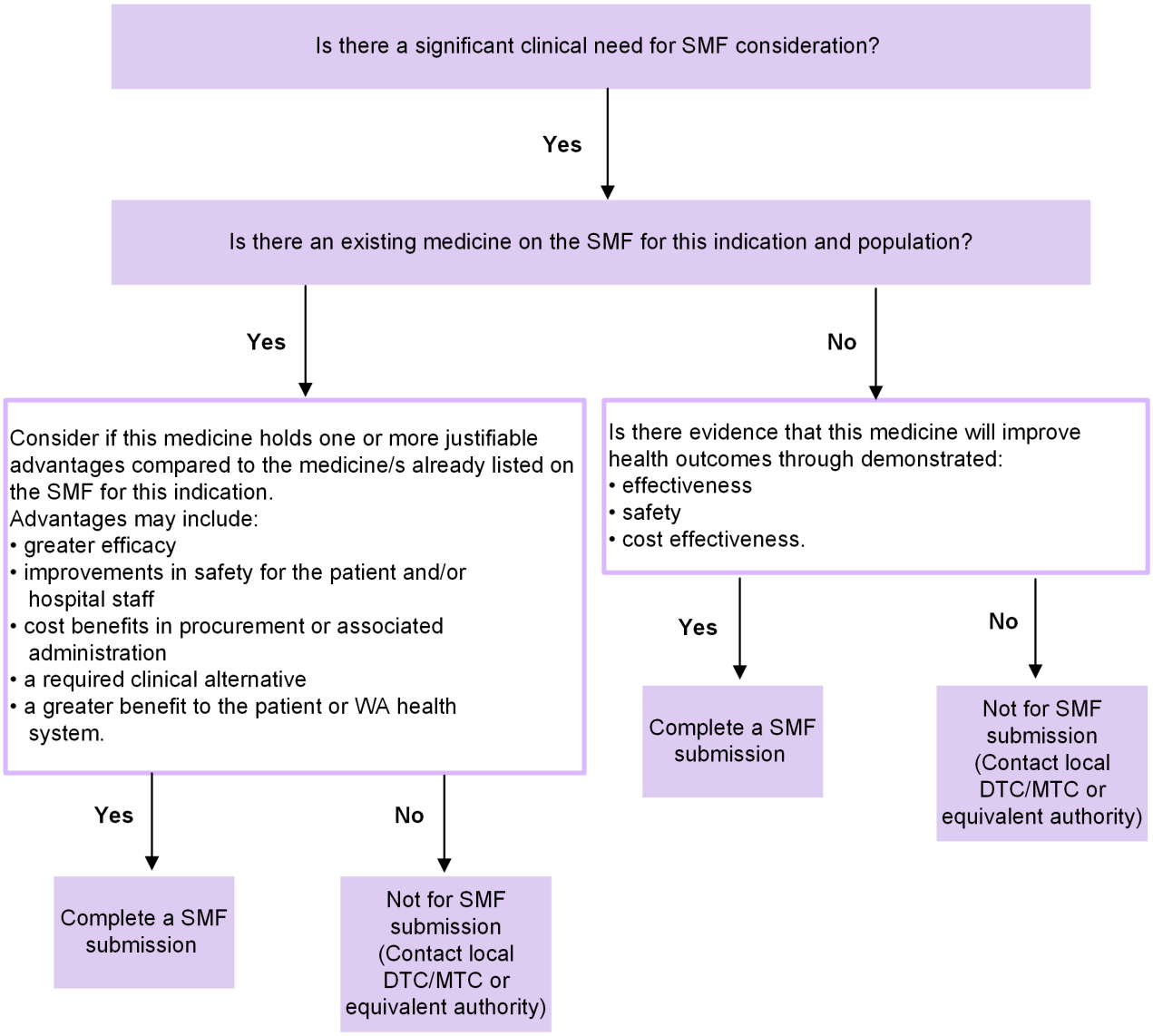
- NBA indications for plasma derived and recombinant blood products
- Highly Specialised Therapies (HSTs) that have been reviewed and approved through established governance processes such as Medical Services Advisory Committee (MSAC) and WA Policy Advisory Committee on Health Technology (WAPACT)

I can't find a medicine, or the indication is not approved on Formulary One – What should I do?

If you wish to initiate a medicine or indication that is not listed on the SMF, or outside the SMF specified criteria, you will need to apply to your local DTC/MTC or equivalent authority for approval via the Individual Patient Approval (IPA) process in accordance with local policies and/or procedures.

Consider applying to WAMEP to have this medicine or indication evaluated for listing on the SMF if it is deemed that there is a significant clinical need. Refer to the figure below when considering whether a SMF submission is required.

Note: A submission for SMF inclusion that has not yet been reviewed by WAMEP does not permit the prescriber to initiate treatment until WAMEP has approved the medicine for inclusion on the SMF and the listing is displayed on Formulary One.



Who is eligible to complete a SMF submission?

Submissions may only be completed by the following WA Health employees:

- Prescribers (within their scope of clinical practice)
- Members of a DTC/MTC or equivalent

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.

Where can I find the SMF submission forms?

SMF submission forms are available online on the Formulary One homepage at https://formulary.health.wa.gov.au/ or https://formulary.hdwa.health.wa.gov.au/.

What are the SMF submission categories?

There are three submission categories detailed in the table below.

Submission Category	Criteria
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). **Note:** For PBS items, refer to the PBS submission category explanation below.
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.
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. **Note:** new indications require a full submission. • Review of a current medicine listed on the SMF 'as per PBS indications and criteria', where the medicine has changed on the PBS to the General Schedule. • Paediatric formulary: A medicine and requested indication that has been evaluated and approved for listing on the adult formulary provided it is registered for paediatric use by the TGA and is PBS-listed for paediatric use. • Addition of vaccines that are listed in the Australian Immunisation Handbook, National Immunisation Program Schedule, WA Immunisation Schedule or as per WA Communicable Disease Control Directorate (CDCD) guidance. **Note:** this excludes travel vaccines. **Note:** At the discretion of the Formulary Management Team (FMT) and WAMEP Chair, minor change submission requests that are associated with significant efficacy, safety, cost, or other concerns may require a full submission.

What is the process to add a new medicine or indication to the SMF?

If you wish to make a formulary submission to WAMEP, please complete the following steps:

Step 1
- Obtain support from local DTC/MTC or equivalent authority prior to submitting an SMF application
- Inform WAMEP via the FMT (WAMEP@health.wa.gov.au) that a submission is intended in order to avoid duplication of work through multiple submissions
- Where there are multiple applicants interested in the same medicine or indication, applicants will be encouraged to work collaboratively

Step 2
- Gauge and garner fellow colleague's support for the submission within and across departments and HSPs. Submissions with support from multiple sites are more likely to be reviewed in a more timely manner by WAMEP as it demonstrates agreement in practice and clinical relevance and this is required as part of WAMEP's application review.
- The support or assistance from the relevant Expert Advisory Group (EAG) is encouraged (the FMT can reach out to the relevant EAG members on the applicant's behalf if requested)

Step 3
- Consider the medicine or indication's place in therapy by developing (or amending) a treatment algorithm to support the submission (if applicable)
- High impact or high cost medicine submissions are likely to require a treatment algorithm to be considered by WAMEP
- Completing this step prior to submission may assist the evaluation process and allow for streamlined outcomes from WAMEP

Step 4
- Compile supporting evidence to be submitted
- Complete the relevant SMF submission form (discuss with the FMT if further guidance is required). SMF submission forms are available online on the Formulary One homepage.
- Declare any conflicts of interest as part of the WA Health Code of Conduct

Step 5
- Gain support from the relevant specialty Head of Department (HoD) after discussing any cost or strategic implications and ensure the application is authorised by the HoD
- Where applicants are HoDs, authorisation by a higher level authority (i.e. Medical Services Director) is required

Step 6
- Submit the completed form and supporting documents where applicable to WAMEP for review
- If the formulary submission is deemed urgent, the applicant should notify their local DTC/MTC or equivalent health service medicine governance authority, who can escalate this to the FMT for consideration of a priority review

What factors should I consider when developing a SMF submission?

The following factors should be considered when developing a SMF submission:

- clinical effectiveness, appropriateness and comparative benefits
- level and quality of available evidence
- magnitude of clinical need across the WA health system
- presence of alternative treatment options and place in therapy
- patient and staff safety concerns (including adverse events and the potential for abuse or resistance in the case of antimicrobials)
- cost-effectiveness and affordability to the WA health system and the patient (i.e. in the absence of SMF listing)
- impact on clinical practice (administration, change in staff resourcing, monitoring requirements etc.)
- medicines management implications (e.g. storage, cold chain)
- equity of access and continuity of care in the outpatient setting (if applicable)
- practicality of supply such as procurement and supply chain management.

When will my submission be evaluated by WAMEP?

As part of due process to ensure an appropriate WAMEP evaluation, time is required to compile an overview for the application (including but not limited to local consultation on usage, national and international guidance, other state and territory formulary listings, clinical evidence, cost-effectiveness etc) as well as providing WAMEP reviewers adequate opportunity to review and seek further information from the applicant prior to an evaluation and decision from WAMEP.

If the formulary submission is deemed urgent, the applicant should notify their local DTC/MTC or equivalent health service medicine governance authority, who can escalate this to the FMT for consideration of a priority review. Priority review requests will be assessed by the WAMEP Chair and the FMT on a case-by-case basis with consideration of the nature and urgency.

How are SMF submissions evaluated?

Submissions for additions, amendments or deletions to the SMF are evaluated by WAMEP based on the guiding principles outlined in the figure[2] below.

In addition to the guiding evaluation principles outlined above, WAMEP also considers the following factors when evaluating medicines for listing on the SMF:

- current and proposed use and indications
- published evidence
- current best practice guidelines
- presence in national and international guidelines
- place in therapy and alternative treatment option/s
- IPA outcomes
- expert opinions
- review by other Australian state and territory medicines formularies
- impacts the listing may have on existing therapies on the SMF.

[2]The evaluation principles figure has been developed with reference to other Australian jurisdiction medicine formularies resources including Queensland Health Medicines Advisory Committee (QHMAC) 5 Pillars Decision Support Tool and NSW Medicines Formulary Committee Formulary Submission Framework.

I would like to prescribe a medicine that my patient was already on prior to the episode of care – Does the SMF requirements apply?

The SMF applies to the initiation of medicines only and not the continued use of medicines started prior to the episode of care. Provided the medicine has been clinically reviewed in the context of the presenting complaint and the treatment deemed appropriate, hospitals have a duty of care to maintain the continuity of care, regardless of formulary status.

Are the adult SMF restrictions applicable when a paediatric patient transitions to adult services?

If a medicine is initiated for a paediatric patient as per the paediatric formulary restrictions, adult formulary restrictions are not applicable when the patient transitions to adult services, i.e. an IPA is not required

Are combination products listed on the SMF?

Unless otherwise specified, combination products that contain medicines that have been individually approved for SMF listing may not be visible on Formulary One but are able to be prescribed for initiation.

However, it is up to the individual Health Service Provider whether it is appropriate to procure combination products. Consult with your local pharmacy department to find out whether a combination product is available at your local site.

How is the imprest functionality on Formulary One updated?

Formulary One automatically pulls imprest data from iPharmacy once daily after hours. Allow at least one working day for any changes to imprest lists to come into effect on Formulary One.

Version Control

Version	Version date	Review date	Author	Rationale
1.0	26/02/2024	26/02/2026	Formulary Management Team - Medicines and Technology Unit	First version for publication
1.1	07/05/2024	07/05/2026	Formulary Management Team - Medicines and Technology Unit	Minor update, to include information regarding formulary status of combination products; and Formulary One imprest function