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

WA Statewide Medicines Formulary Guidelines

Version 5.0

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Prepared by Medicines and Technology Unit, Department of Health, Western Australia

health.wa.gov.au

Contents

1. Background

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. MP 0077/18 Statewide Medicines Formulary Policy mandates the initiation of prescribed medicines according to the adult, paediatric and neonatal formularies that make up the SMF. An electronic platform, Formulary One, hosts the SMF and is accessible to WA Health employees via the internet https://formulary.health.wa.gov.au/ and the WA Health intranet https://formulary.hdwa.health.wa.gov.au.

This guideline is intended to be read in conjunction with MP 0077/18 Statewide Medicines Formulary Policy to support public Health Service Providers in developing local policy and procedures for medicines governance.

2. SMF Purpose

The purpose of the SMF is to promote and facilitate the delivery of optimal patient outcomes through a single and equitable list of approved medicines which can be initiated across the WA health system. The SMF is evaluated, implemented and managed in a systemwide approach with expert review by the WA Medicines Evaluation Panel (WAMEP) to support safe, cost-effective, equitable and evidence-based prescribing across the WA health system.

3. SMF Rationale

The SMF contributes to the WA health system achieving the goals outlined in the Australian *National Medicines Policy* and *The National Strategy for Quality Use of Medicines*. The rationale for a statewide approach for evaluating and approving medicines which can be initiated across the WA health system 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 and applying the Council of Australian Therapeutic Advisory Groups (CATAG): Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines where applicable
- 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.

4. Scope

The SMF encompasses medicines used in clinical practice across the WA health system. Medicines are listed on the SMF after undergoing a systematic evidence-based evaluation process by WAMEP that considers the clinical efficacy, safety, cost-effectiveness, equity of access and implementation implications.

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 health service medicine governance authority (referred to as equivalent authority throughout this guideline), or other specialised committees where applicable according to local policies.

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 MP 0077/18 Statewide Medicines Formulary 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.

Figure 1 specifies the medicines and therapeutic products that are deemed to be within and outside 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

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 equivalent authorities (for example, 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

Figure 1. SMF scope

*Refer to Section 18. Definitions

5. Accountability

Figure 2 shows the clinical governance accountability structure of the SMF (refer to Section 6 Roles and responsibilities).

Although WAMEP is a subcommittee of the WA Therapeutics Advisory Group (WATAG), WAMEP operates autonomously to make decisions on formulary listings. WATAG and WAMEP work collaboratively to achieve the goals of both groups and the SMF.

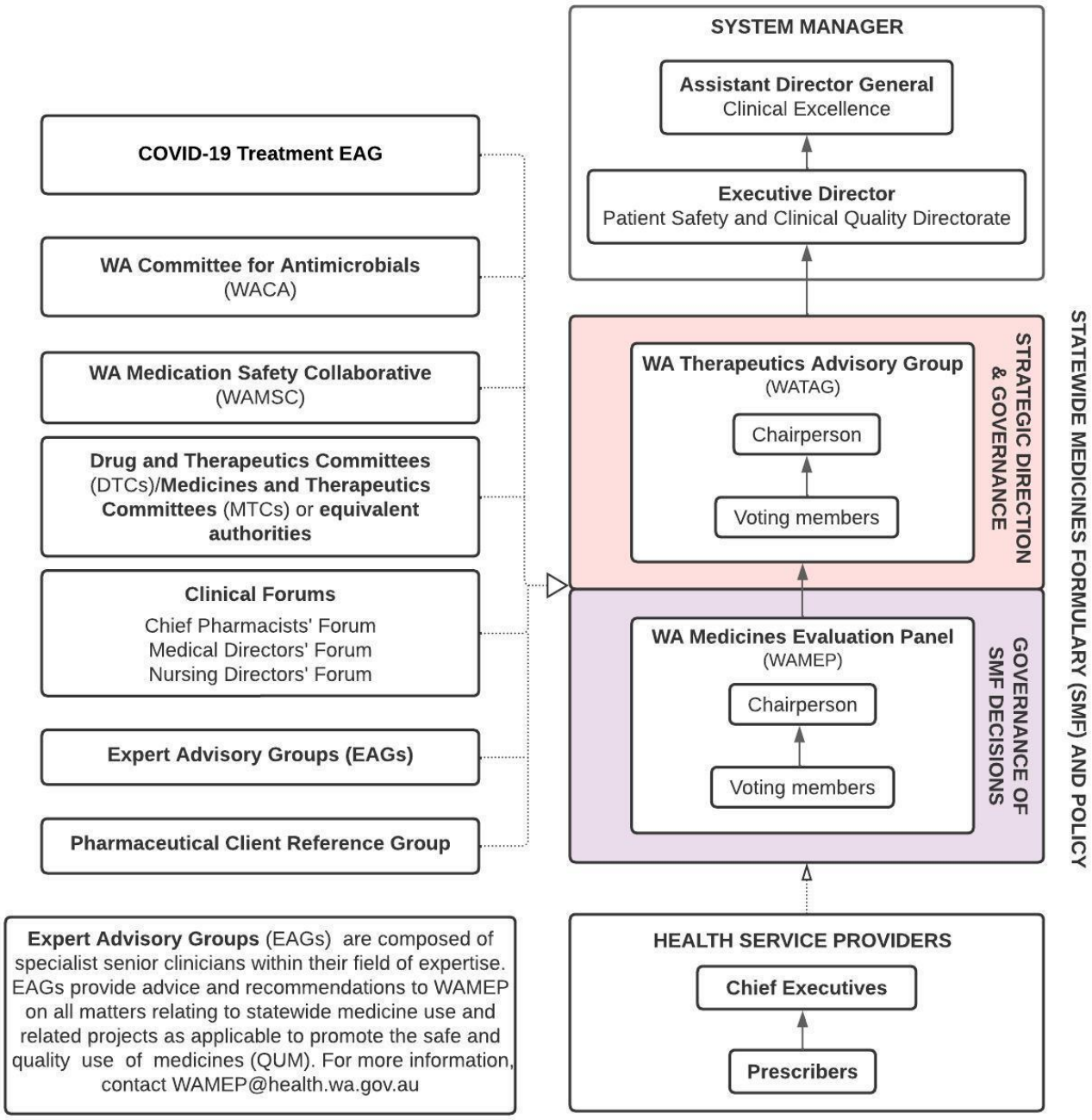

Figure 2. Accountability structure of the SMF

6. Roles and responsibilities

6.1 System manager

Assistant Director General, Clinical Excellence Division

The Assistant Director General, Clinical Excellence Division is the owner of MP 0077/18 Statewide Medicines Formulary Policy.

Executive Director, Patient Safety and Clinical Quality (PSCQ)

The Executive Director, Patient Safety and Clinical Quality (PSCQ) is the representative member for the SMF at the Department Executive Committee (DEC) and the Health Executive Committee (HEC).

WA Therapeutics Advisory Group (WATAG)

WATAG is the committee that is responsible for promoting, supporting and advising on statewide medicine governance and the quality use of medicines across Western Australian (WA) public hospitals. Their role is to:

- facilitate collaboration across WA public hospitals
- promote the consistent and quality use of medicines
- keep consumers central to the delivery of pharmaceutical care
- support and improve compliance with the SMF.

Further details can be found in the WATAG Terms of Reference.

WA Medicines Evaluation Panel (WAMEP)

WAMEP is the committee that governs SMF decisions. The Panel's responsibilities are to:

- maintain the SMF for use across the WA health system. This includes but is not limited to:
    - using a systematic, fair, and transparent evidence-based evaluation process that considers the clinical efficacy, safety, cost-effectiveness, equity of access and implementation implications for additions, amendments, or deletions to the SMF
    - maintaining processes for new listings and review of current listings on the SMF
    - maintaining the Formulary One platform to optimise usability.
- perform robust consultation with key stakeholders
- refer formulary submissions for medicines that are specialised in nature, have therapeutic or safety concerns, or require specialised input to expert advisors
- consult WATAG on decisions that may necessitate state-based change management strategies to mitigate associated risk across the system
- ensure effective and timely communication of decisions to DTCs/MTCs or equivalent authorities and other relevant stakeholders
- monitor and review the use of medicines across the WA health system, including those that are approved on the SMF and those accessed via Individual Patient Approvals (IPAs), to identify medicines or therapeutic areas for WAMEP review with regards to the SMF
- provide advice to DTCs/MTCs or equivalent authorities or Product Evaluation Standardisation Committees (PESCs) about the medicine component of devices
- make recommendations to other state and national bodies as requested.

Further details can be found in the WAMEP Terms of Reference.

6.2 Health service providers (HSPs)

Chief Executives

HSP Chief Executives are responsible for ensuring the implementation of, education, and compliance with MP 0077/18 Statewide Medicines Formulary Policy within their HSP.

Drug and Therapeutics Committees (DTCs)/Medicines and Therapeutics Committees (MTCs) or equivalent authorities

DTCs/MTCs or equivalent authorities own the primary medicine governance role at the local hospital or HSP. In relation to the SMF, DTCs/MTCs or equivalent authorities are responsible for:

- assisting the HSP Chief Executives with the local implementation of and compliance with the SMF and MP 0077/18 Statewide Medicines Formulary Policy. This includes but is not limited to:
    - supporting and communicating formulary related decisions made by WAMEP to relevant stakeholders at their site/area
    - supporting education and training on the rationale for and use of the SMF
    - establishing local processes for the submission, review and assessment of IPA applications
    - garnering the support of hospital executives, managers and heads of departments for the provision and funding of formulary listed medicines (unless precluded by restrictions).
- facilitating formulary submissions to WAMEP by providing local support to applicants
- escalating formulary submissions that are deemed urgent to WAMEP for consideration of a priority review. Priority review requests will be assessed by the WAMEP Chair and the Formulary Management Team (FMT) on a case-by-case basis with consideration of the nature and urgency
- encouraging a formulary submission for a particular medicine and indication that has reached the state IPA limit (refer to Section 12.2 IPA limit and monitoring)
- assessing IPA applications and providing IPA data to WAMEP upon request (refer to Section 12 Individual Patient Approvals (IPAs))
- promptly reporting on all IPAs approved for a specific indication of a medicine to WAMEP by email (WAMEP@health.wa.gov.au) if this requirement is specified on the listing
- providing and/or facilitating information gathering on medicine utilisation and clinical practice reviews to support WAMEP activities upon request
- establishing and maintaining local processes for assessing compliance with the SMF and MP 0077/18 Statewide Medicines Formulary Policy
- referring issues surrounding medicine governance matters to WAMEP if appropriate.

All clinicians

For the purposes of this guideline, clinicians encompass health professionals involved in medicine management within their scope of clinical practice, including but not limited to medical practitioners, nurses, pharmacists, midwives, and allied health professionals. Clinical staff can support HSP compliance with the SMF and MP 0077/18 Statewide Medicines Formulary Policy by:

- maintaining a contemporary medicine knowledge base
- complying with all local and state policies and procedures and legislative requirements for medicine prescribing, dispensing, supply and administration
- taking part in audits and quality improvement projects when relevant
- reporting issues that arise with Formulary One or SMF listings to the FMT via email (WAMEP@health.wa.gov.au).

Prescribers

In relation to the SMF, prescribers are required to:

- ensure that medicines initiated for their patients comply with the requirements of the SMF as well as legislation, local and state policies and procedures and their scope of clinical practice
- complete formulary submissions and provide additional information and feedback to WAMEP as required
- refer medicine governance matters requiring attention to the local DTC/MTC or equivalent authority where appropriate
- facilitate the implementation and adoption of the SMF, Formulary One platform and MP 0077/18 Statewide Medicines Formulary Policy within clinical care teams
- work collaboratively with pharmacists to ensure SMF compliance.

Pharmacists

In relation to the SMF, pharmacists are required to:

- support prescribers to comply with the requirements of the SMF
- assist prescribers with the adoption and use of the SMF, Formulary One platform and MP 0077/18 Statewide Medicines Formulary Policy
- support prescribers with the development of formulary submissions if required
- refer medicine governance matters to the local DTC/MTC or equivalent authority where appropriate.

7. Structure

The SMF encompasses three separate formularies: the adult, paediatric and neonatal formularies. All formularies can be viewed at any time on the Formulary One platform – refer to Section 13 Access via Formulary One.

7.1 Adult formulary

The adult formulary provides the list of medicines that can be initiated within a care setting intended for persons aged 18 years and over. This may include patients under 18 years receiving care in an adult setting, as clinically appropriate.

7.2 Paediatric formulary

The paediatric formulary provides the list of medicines that can be initiated for use in children and adolescents up to 18 years of age. It is a separate list to the adult and neonatal formularies.

For safety, it is recommended that the ‘paediatric’ section of Formulary One is used as the main portal on paediatric wards.

7.3 Neonatal formulary

The neonatal formulary provides the list of medicines that can be initiated for use in neonates from birth to 28 days corrected gestational age. It is a separate list to the adult and paediatric formularies.

For safety, it is recommended that the ‘neonatal’ section of Formulary One is used as the main portal on neonatal wards.

7.4 Formulary terminology

Formulary status and restriction level categories

Medicines are categorised based on the formulary status or restriction level set by WAMEP in the evaluation process, as shown in Table 1. The formulary status or restriction level also determines the level of governance and authorisation required. The prescribing, supply and administration of all medicines listed on the SMF must also comply with legislative requirements, state and local policies and procedures and the prescriber's scope of clinical practice.

Table 1. Formulary status and restriction level category explanations

Category	Explanation	Formulary related authorisation and governance	Example
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; see CATAG: Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines).	None required	Paracetamol, where no formulary restrictions to prescribing apply.
Restricted 	Medicines that can only be initiated according to the criteria stated in the listing (e.g. population, treating specialty, treatment duration, route etc.).	Prescribing that does not comply with the SMF listing will require an Individual Patient Approval (IPA), except if the listing specifies that the indication is not to be initiated via an IPA.	Ivabradine for PBS indications and criteria, and for specific indications under the direction of an Intensivist or Cardiologist. For use in any other circumstances, prescribers must seek an IPA from the local DTC/MTC or equivalent authority before initiation.
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.	Prescribing that does not comply with the SMF listing will require an IPA, except if the listing specifies that the indication is not to be initiated via an IPA.	Linezolid injection requires Clinical Microbiologist or Infectious Disease Physician approval before initiating. Neonatal formulary – Amiodarone injection requires Neonatologist or Cardiologist approval before initiating.

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.	WAMEP may reject the listing with the following IPA clauses: • The medicine or indication may only be initiated via an IPA in exceptional circumstances. Any IPAs granted must be promptly reported to WAMEP via the FMT. **OR** • The medicine or indication cannot be initiated via an IPA.	An extended course of tocilizumab for the treatment of giant cell arteritis in adult patients with pre-existing end-organ damage was reviewed and rejected by WAMEP for listing on the SMF, however WAMEP decided that tocilizumab can still be initiated for this indication via an IPA. Any IPAs granted must be in an exceptional circumstance and be reported to WAMEP via the FMT. Adalimumab injection for the treatment of generalised granuloma annulare in adult patients was reviewed and rejected by WAMEP for listing on the SMF. An IPA may not be granted.
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.	An IPA must be approved by the local DTC/MTC or equivalent authority before initiating. Prescribers may complete a SMF submission form and apply to WAMEP for listing on the SMF if it is deemed that there is a significant clinical need for SMF consideration.	Fish oil capsule is within scope of the SMF but has not yet been reviewed by WAMEP.
Outside the scope of the SMF*	Medicines or therapeutic products that are outside the scope of the SMF as per Section 4 of this document.	DTCs/MTCs or equivalent authorities, or other specialised committees where applicable according to local policies govern these medicines and products. Prescribers should check their local site or HSP policies and consult their local DTC/MTC or equivalent authority, or relevant specialised committee.	Refer to Figure 1. SMF scope.

*Please note that this is not a named category on the Formulary One platform.

Terminology used in SMF listings

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

Table 2. SMF terminology

Terminology	Explanation	Formulary related authorisation and governance	Example
First line	A medicine which has been deemed as the first treatment option for a particular condition.	If a different medicine has been prescribed before a first line option is trialled, it is best practice for the prescriber to document their rationale for use in the patient's clinical notes.	Temazepam tablet is recommended as the first line medicine treatment option for insomnia on the adult formulary.
Preferred	The preferred medicine(s) from a therapeutic class, where there is more than one medicine in that class.	If a different medicine in the therapeutic class is prescribed before the preferred medicine(s), it is best practice for the prescriber to document their rationale for use in the patient's clinical notes.	Pantoprazole injection is listed on the adult formulary as the preferred IV proton pump inhibitor.
PBS indications and criteria	The PBS indications and prescribing criteria apply. Additional restrictions may be included. Refer to the PBS website for details.	Prescribing that does not comply with the SMF listing will require an IPA, except if the listing specifies that the indication is not to be initiated via an IPA.	Olaparib tablet is listed on the adult formulary for outpatients as per PBS indication and criteria for castration resistant metastatic carcinoma of the prostate.
Special Access Scheme (SAS)	The SAS allows certain Australian registered health practitioners to access medicines that are not included in the Australian Register of Therapeutic Goods (ARTG) for an individual patient on a case-by-case basis. Prescribers must meet the requirements for SAS supply and complete the relevant SAS Category A, B or C form prior to prescribing irrespective of the SMF status/restrictions. This is a TGA requirement.	Prescribing that does not comply with the SMF listing will require an IPA, except if the listing specifies that the indication is not to be initiated via an IPA.	Treatment with dinoprost (SAS) injection must meet the requirements for SAS supply for use as per the hospital's protocol for postpartum haemorrhage (PPH).

Authorised Prescriber (AP) scheme	The AP scheme allows authorised medical practitioners to prescribe medicines that are not included in the Australian Register of Therapeutic Goods (ARTG) to a class of patients with a particular medical condition. Medical Practitioners must meet the requirements for AP scheme supply prior to prescribing irrespective of the SMF status/restrictions. This is a TGA requirement.	Prescribing that does not comply with the SMF listing will require an IPA, except if the listing specifies that the indication is not to be initiated via an IPA.	Treatment with allergen immunotherapy kits must meet the requirements for AP scheme supply.
Audit required	Auditing may be stipulated to ensure compliance against the formulary listing. The auditing terms will be determined by WAMEP during the evaluation process and communicated to the DTCs/MTCs or equivalent authorities.	At the request of the FMT, DTCs/MTCs or equivalent authorities will be required to implement the audit and report results to WAMEP via the FMT.	Apixaban for use under the direction of a consultant vascular surgeon post-revascularisation for acute limb ischemia in adult patients where warfarin would be considered unsafe due to non-adherence or barriers to accessing healthcare services was reviewed and approved by WAMEP for listing with an audit requirement.
Provisional listing	A medicine that is pending further assessment and consideration by WAMEP for full approval to the SMF once more robust supporting evidence becomes available.	If approval is granted provisionally, it is due for review after a pre-determined period of time by WAMEP.	Remdesivir injection was provisionally approved by WAMEP for listing on the SMF for the treatment of COVID-19 on advice by a specialist clinician. Further assessment and consideration is required for full approval to the SMF.
Deferred	A medicine or indication that has been evaluated by WAMEP and the Panel has deferred their final decision for SMF listing until more robust supporting evidence is published or a treatment algorithm/guideline is developed.	When further evidence is available, the medicine or indication will be re-evaluated by WAMEP. The medicine or indication may only be initiated via an IPA in exceptional circumstances. Any IPAs granted must be reported to WAMEP via the FMT.	WAMEP deferred its decision for the inclusion of andexanet alfa for reversal of apixaban or rivaroxaban in life threatening bleeding on the adult formulary until published data from a randomised controlled trial and the Council of Australian Therapeutic Advisory Groups (CATAG) position statement are available.

Hosted listing	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 have not been reviewed by WAMEP. Medicines or therapeutic products that are requested to be hosted will be tabled for noting at the next available WAMEP meeting.	Medicines or therapeutic products that are hosted on the SMF are not bound by MP 0077/18 Statewide Medicines Formulary 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.	National Blood Authority (NBA) indications for plasma derived products and recombinant products

8. Prescribing

To provide safe and high quality healthcare, prescribers must be cognisant of the legislative requirements, and state and local policies and procedures which guide their scope of practice. Refer to Scope of clinical practice and the Statewide Medicines Formulary position statement.

8.1 Initiation

Medicines listed on the SMF can be initiated for a patient, provided any relevant prescribing restrictions and/or requirements are met. Refer to Table 1. Formulary status and restriction level category explanations.

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

8.2 Continuation

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.

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.

9. Supply

Supply of SMF approved medicines will be facilitated for admitted inpatients, booked day patients and where applicable outpatients. However not all hospitals will have outpatient supply services and local policies and procedures should be followed for outpatient supply requests (e.g. Individual Patient Usage (IPU) approvals).

In general, hospitals will have limited logistical capability to immediately supply all medicines listed on the SMF. This is particularly the case for sites where the spectrum of clinical services and/or specialties offered is smaller compared to a larger site, thereby limiting the range and type of medicines kept as part of regular inventory.

Furthermore, judicious inventory management necessitates the need to only stock the most commonly used medicines at sites, resulting in the need to specifically order products that are not frequently prescribed.

Prescribers should note that in these cases there may be a delay in supplying some SMF approved medicines. Working in collaboration with the pharmacy team is imperative to optimise the supply of these products. If appropriate, the patient should be involved in these conversations.

Hospitals should develop and implement policies and procedures to facilitate the timely supply of SMF approved medicines that are not kept as part of regular stock on hand.

In the instance whereby a medicine list has been developed to recommend stockholdings, the SMF status and restrictions for prescribing the medicine must be followed.

10. Submissions

Applicants should refer to Figure 3 when considering whether a SMF submission is required.

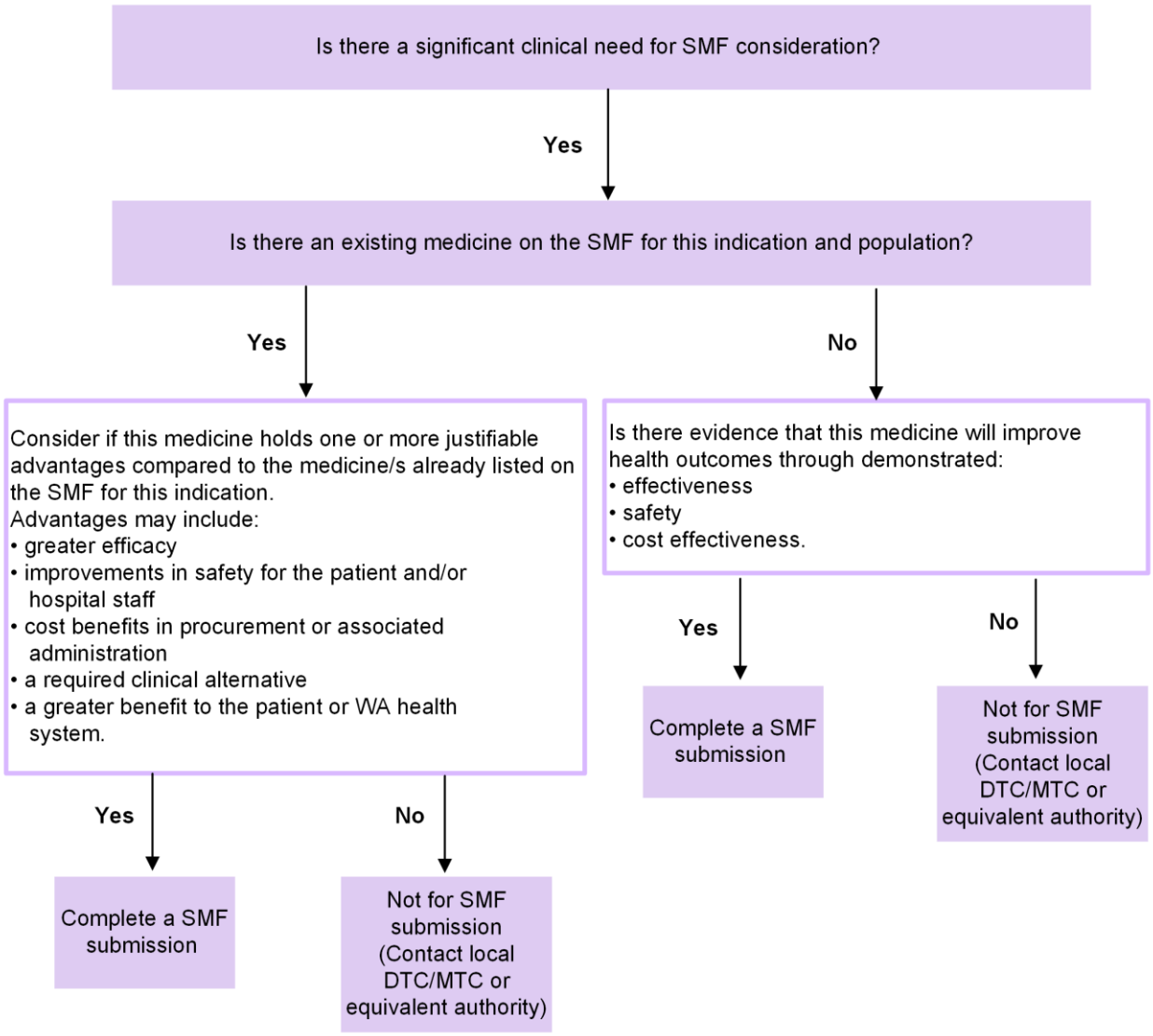

Figure 3. SMF submission decision algorithm

10.1 Eligibility to complete a SMF submission

It is important that there is a clinical need and drive for medicines listed on the SMF. Therefore, 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 authority.

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

WAMEP will not accept formulary submissions directly from pharmaceutical companies or sponsors.

10.2 Submission categories

The nature of the submission will affect the level of information required in the SMF submission form and the way in which it is evaluated. There are three submission categories detailed in Table 3. 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/. For requests to delist a SMF medicine, contact the FMT via email (WAMEP@health.wa.gov.au).

Table 3. SMF submission categories

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. **Note:** An application is required to be submitted for WAMEP to review PBS medicines for inclusion on the SMF. A PBS application can be submitted for medicines that have had a positive PBAC recommendation prior to PBS listing. If approved by the Panel, the SMF will be updated once the medicine is listed on the PBS.
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 FMT and WAMEP Chair, minor change submission requests that are associated with significant efficacy, safety, cost, or other concerns may require a full submission.

10.3 Submission process

Applicants should consider the following when developing their submissions:

- 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.)
- medicine 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.

In order to aid workflow and ensure clinical relevance, the applicant should complete the six steps listed in Figure 4.

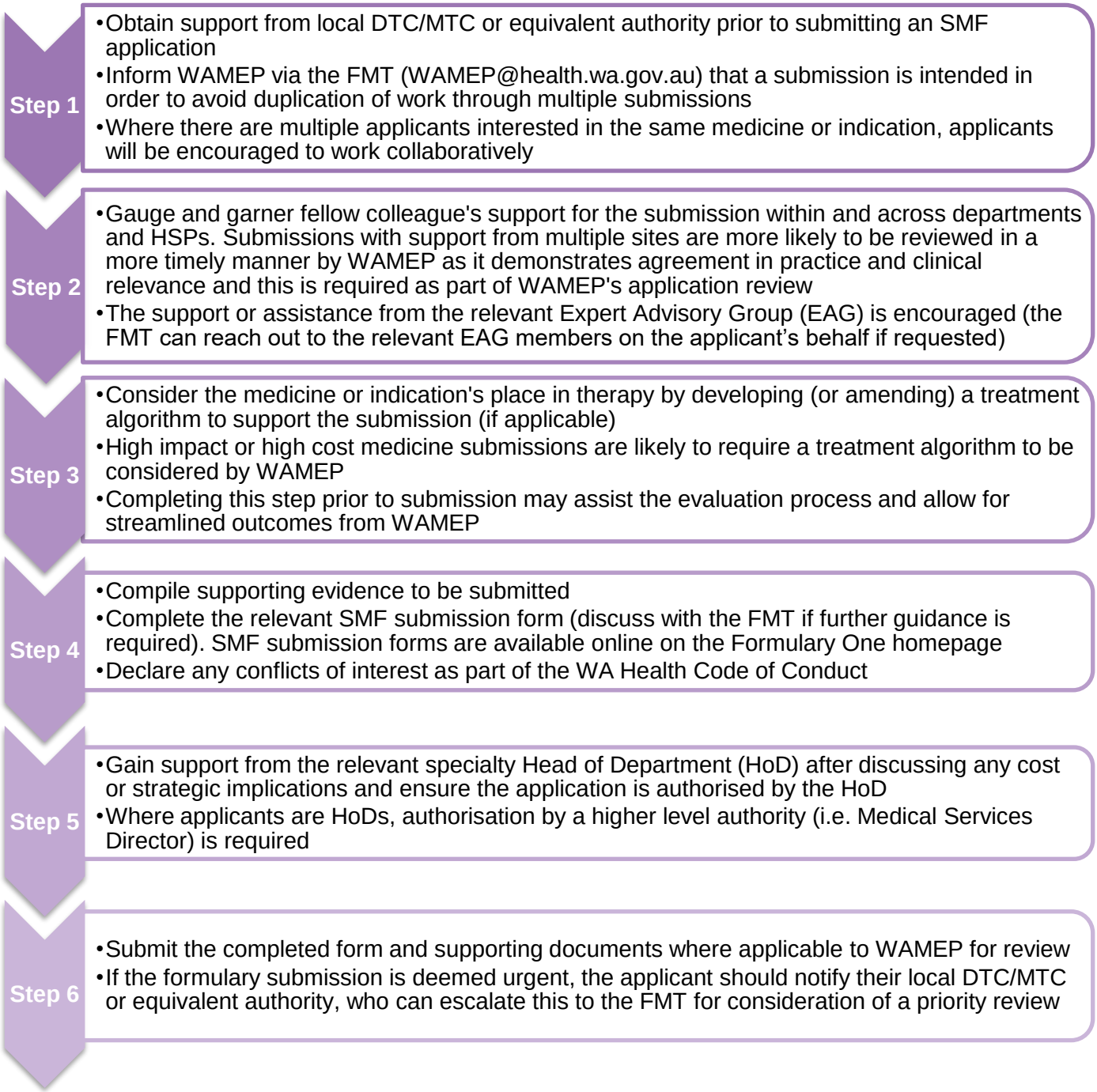

Figure 4. SMF submission process

10.4 Quality assurance

Upon receipt of the submission, the FMT will independently review each submission to ensure it is eligible, complete and of an appropriate standard required for WAMEP to make an accurate evaluation and informed decision. If further information or clarification is required, the FMT will liaise with the applicant and recommend what is required to strengthen their application. The FMT may wish to seek expert opinion or advice on a submission.

10.5 Pharmaceutical sponsors

WAMEP will only provide general advice or information to pharmaceutical representatives. WAMEP will not accept submissions, appeals or resubmissions from pharmaceutical company representatives.

Applicants may obtain information from the manufacturer for a submission; however they must declare any pharmaceutical sponsor involvement in the submission, any conflicts of interest as per MP 0124/19 Code of Conduct Policy.

10.6 Communication of submissions received

The FMT will publish details of the formulary submissions that have been received on the Formulary One homepage and in the SMF newsletter that is circulated to DTCs/MTCs and the Chief Pharmacists' Forum (CPF) group.

11. Evaluation

Submissions for additions, amendments or deletions to the SMF are evaluated by WAMEP based on the guiding principles outlined in Figure 5.

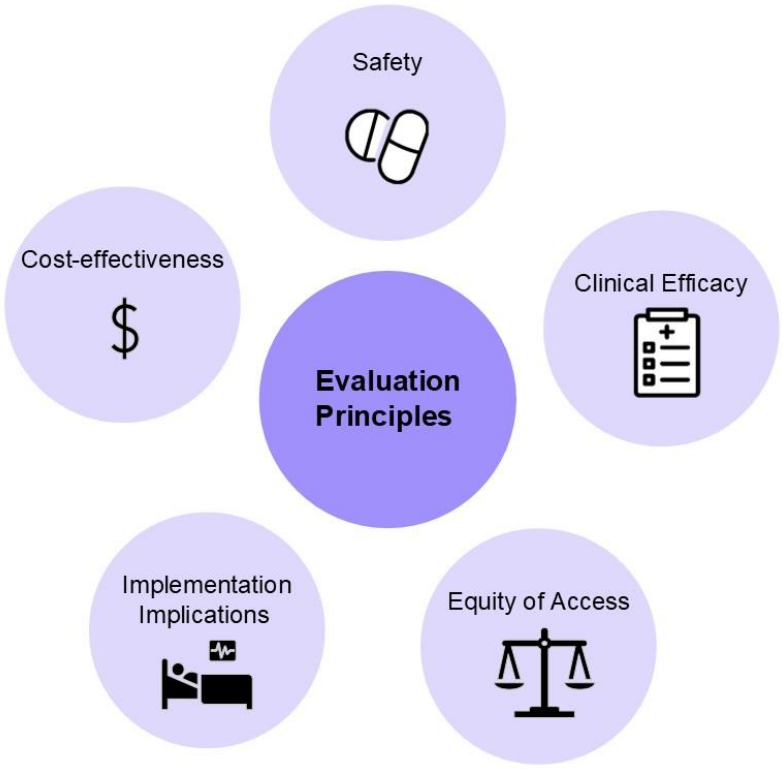

Figure 5. Evaluation principles[1]

[1]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.

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.

A component of the evaluation is the assessment of a medicine's 'value' to the community. WAMEP reviews the economic impacts of medicine listings based on the direct acquisition costs of the medicine to the WA health system. However, compelling societal perspective cost-effectiveness evidence may be submitted for consideration where relevant.

Outcomes may also be affected by national or international factors such as decisions from other review bodies or jurisdictions and medicine shortages. The submission evaluation process is detailed in Figure 6.

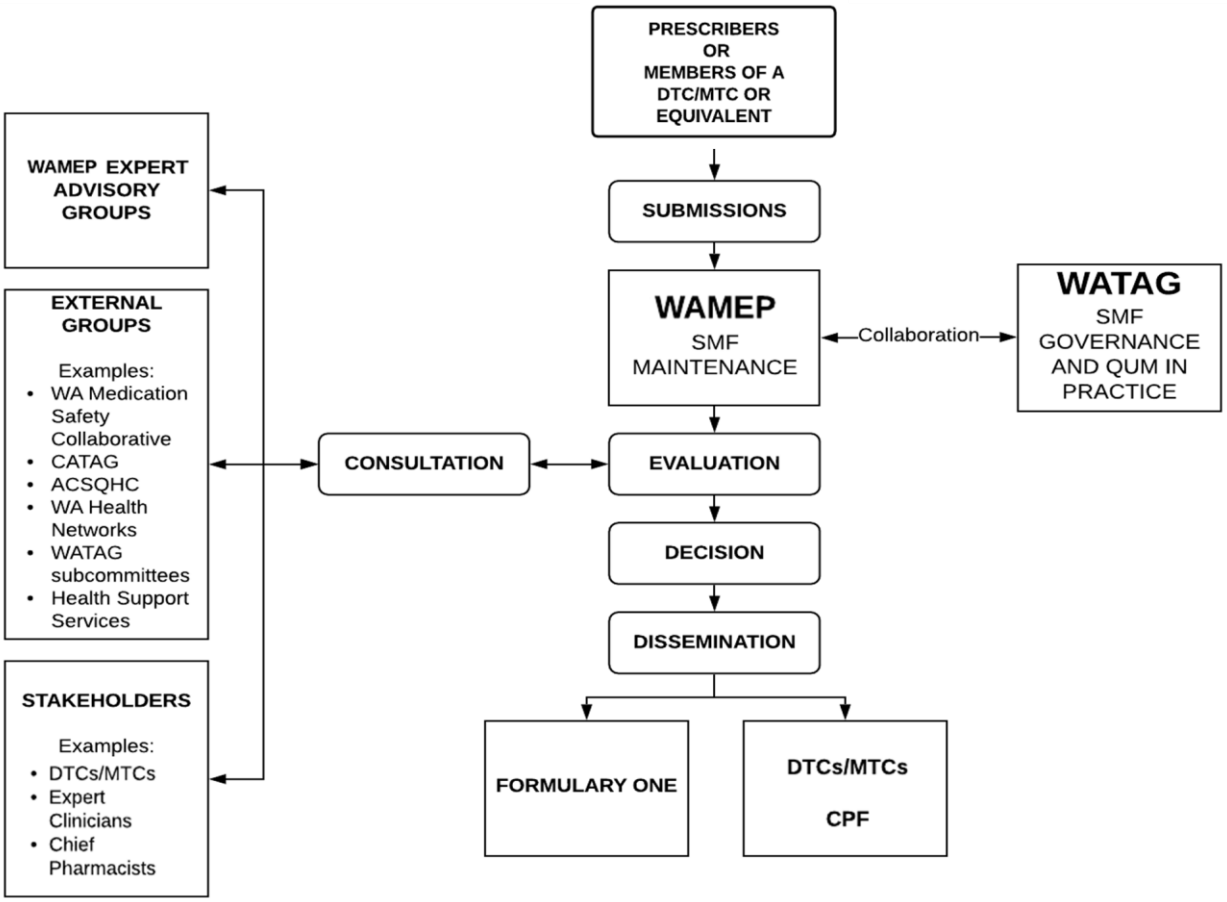

Figure 6. Functional diagram of submission evaluation process

11.1 Adult and Paediatric formulary submissions evaluation

Adult and Paediatric formulary submissions follow the evaluation pathways as specified for each of the submission categories listed below. Applicants from the Child and Adolescent Health Service (CAHS) should seek endorsement from the CAHS DTC before submission to WAMEP.

Full submissions

Full submissions follow the general evaluation process outlined in Figure 7. A more detailed description can be found in Appendix 1.

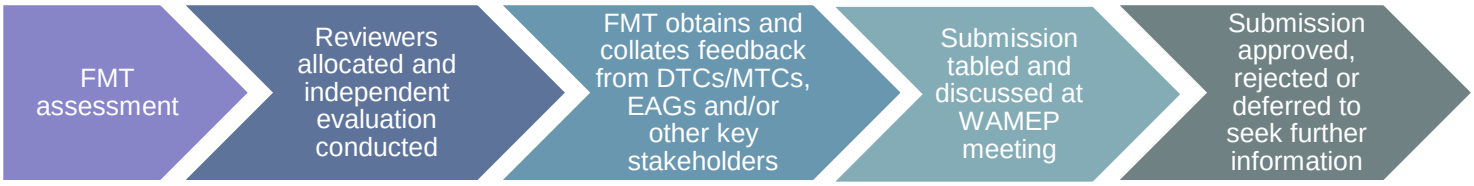

Figure 7. Adult and Paediatric full submission evaluation process

PBS submissions

PBS submissions follow the general evaluation process outlined in Figure 8. A more detailed description can be found in Appendix 2.

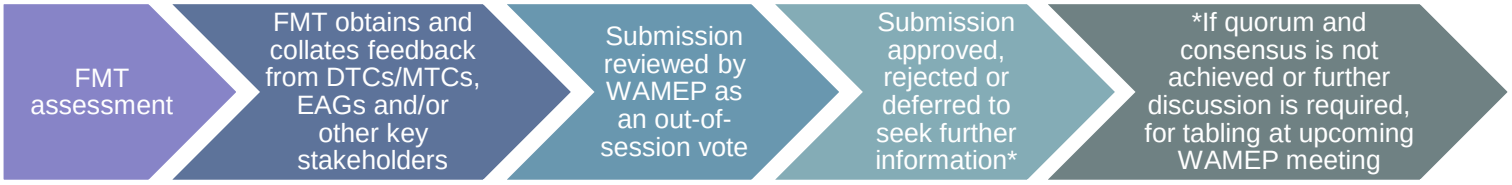

Figure 8. Adult and Paediatric PBS submission evaluation process

Minor submissions

Minor change submissions follow the general evaluation process outlined in Figure 9.

If deemed low risk, the minor change will be included in the upcoming WAMEP meeting agenda pack for noting. If deemed high risk, the minor change request will be reviewed by WAMEP as an out-of-session vote to determine whether the change is approved, rejected, or deferred to seek further information. If quorum cannot be achieved out-of-session or it is identified that further discussion is required, the submission will be tabled at the upcoming WAMEP meeting.

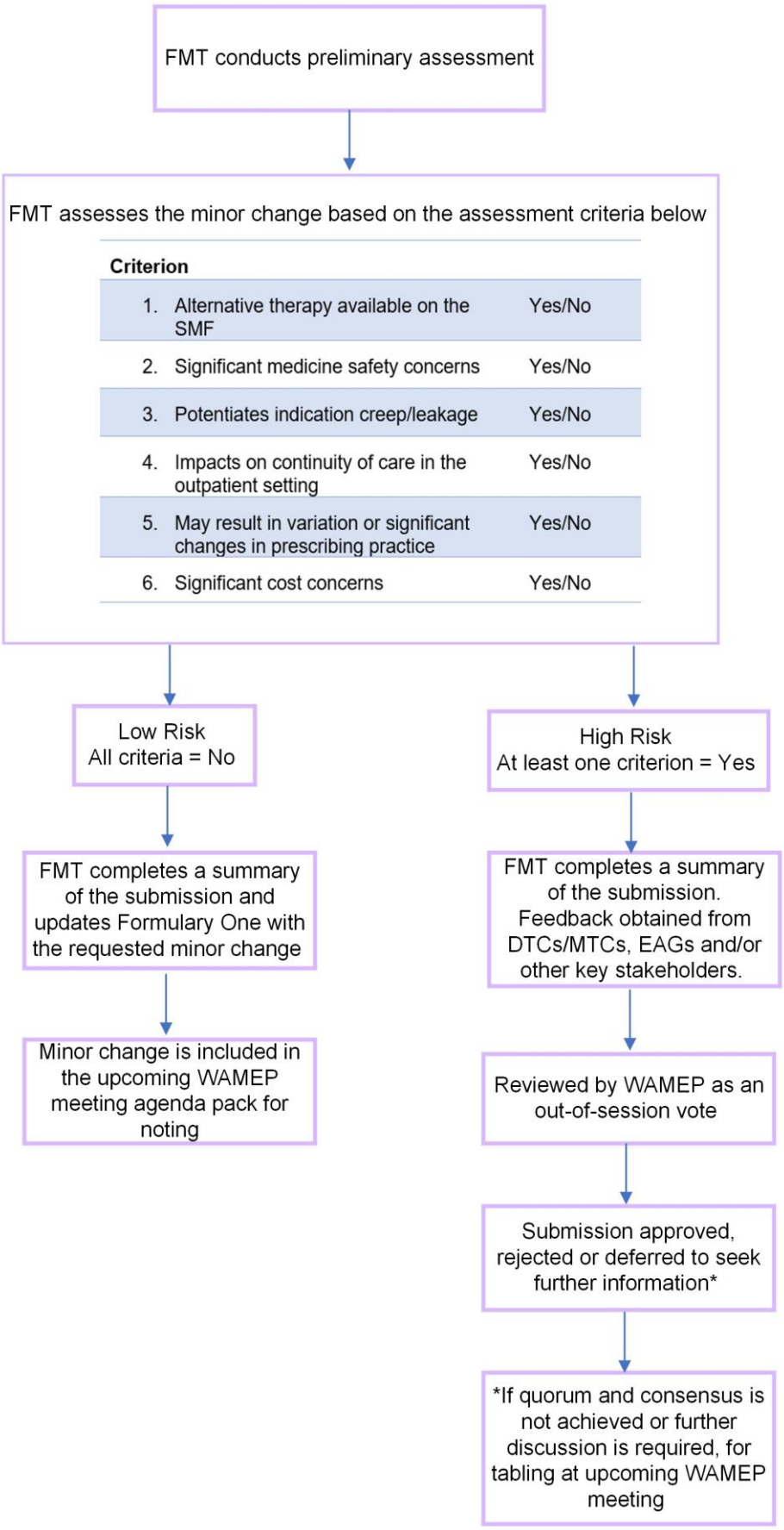

Figure 9. Adult and Paediatric minor submission evaluation process

11.2 Neonatal formulary submissions evaluation

Specific considerations for the neonatal population are required due to the complexities in obtaining high quality evidence for clinical use, due to difficulty in conducting clinical trials and the common need for off-label and unlicensed medicine use. Neonatal formulary submissions follow the same evaluation processes as the adult and paediatric submissions but with the addition of the CAHS Neonatal Coordinating Group (CNCG) corresponding member (CM).

The CAHS Neonatal Coordinating Group (CNCG) corresponding member (CM) will:

- coordinate stakeholder consultation on the submission and any relevant protocols, guidelines and policies. Stakeholders include but are not limited to:
    - Neonatology representative from either King Edward Memorial Hospital (KEMH) MTC or Child and Adolescent Health Service (CAHS) DTC
    - Fiona Stanley Fremantle Hospitals Group DTC
    - WA Country Health Service (WACHS).
- collate feedback for circulation to WAMEP members
- independently and confidentially evaluate the submission
- make a recommendation on the outcome of the submission
- present full neonatal submission to WAMEP
- attend the relevant WAMEP meeting to answer any questions about neonatal submissions.

Full submissions

Neonatal full submissions follow the general evaluation process outlined in Figure 10. A more detailed description can be found in Appendix 3.

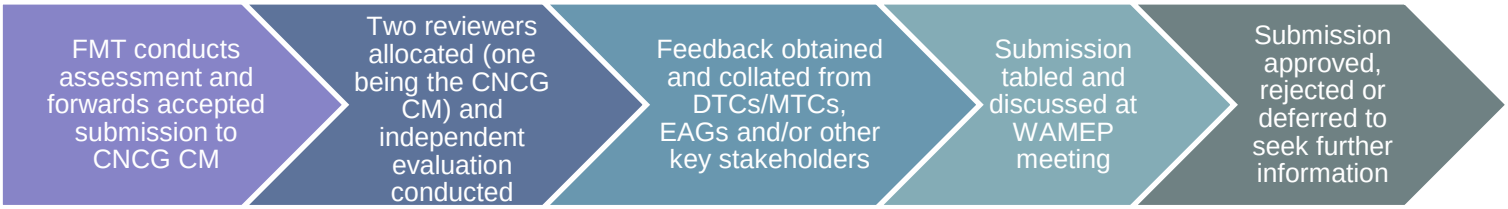

Figure 10. Neonatal full submission evaluation process

PBS submissions

Neonatal PBS submissions follow the general evaluation process outlined in Figure 11. A more detailed description can be found in Appendix 4.

Figure 11. Neonatal PBS submission evaluation process

Minor submissions

Neonatal minor change submissions follow the general evaluation process outlined in Figure 12.

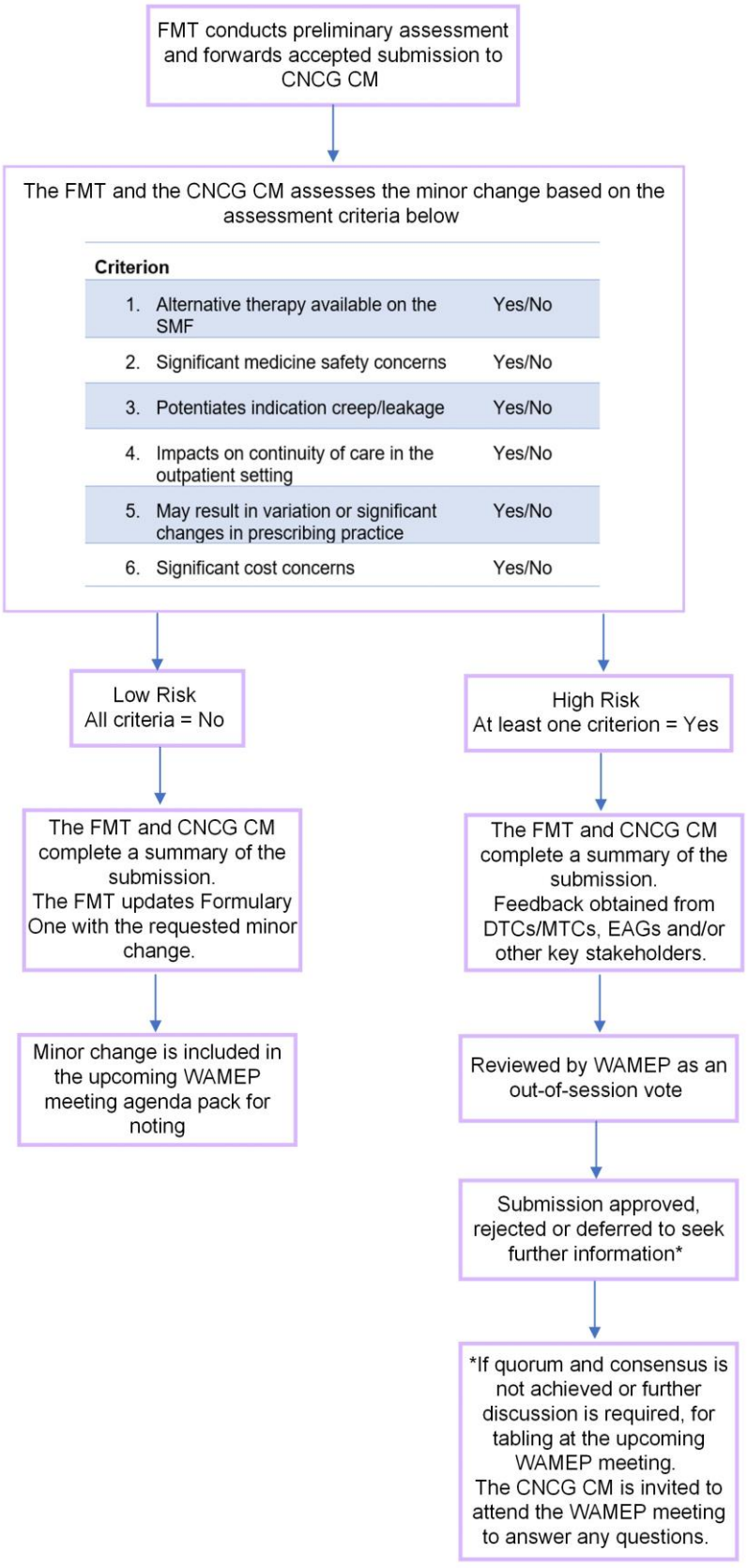

Figure 12. Neonatal minor submission evaluation process

11.3 Sources of advice

The FMT on behalf of WAMEP may wish to seek expert opinion or recommendation on a submission; the sources for this advice may stem from multiple sources including, but not limited to:

- WA Committee on Antimicrobials for anti-infective medicines
- WA Medication Safety Collaborative for medication safety concerns
- Expert Advisory Groups (EAGs)
- WA Health Networks and specialist committees
- Lead clinicians and specialists
- Relevant specialty Heads of Service
- Chief Pharmacists' Forum (CPF)
- Medical Directors' Forum.

11.4 Communication of WAMEP decisions

WAMEP decisions may only be communicated following the confirmation of the WAMEP meeting minutes by the Panel members. The applicant of the SMF submission will be notified via email of WAMEP's decision first by the FMT and subsequent changes will be uploaded onto Formulary One. The FMT will then notify DTCs/MTCs or equivalent authorities and the CPF group via email who may then circulate this information to relevant clinical specialties. A SMF newsletter will also be published on the Formulary One homepage summarising WAMEP's decisions.

11.5 Resubmissions

For full SMF submissions, WAMEP will not accept resubmissions for a rejected medicine and associated indication until at least 6 months after the date of WAMEP's decision. Supporting evidence is required to be provided which directly addresses the reasons for WAMEP previously rejecting the listing.

11.6 Appeals

Outcomes of the application process may be subject to appeal by the original applicant or affected prescribers. The process for appeals is outlined in Figure 13.

If an applicant wishes to appeal a decision made by WAMEP, they must first have relevant and demonstrable grounds for appeal. Grounds for appeal may include:

- a claim that WAMEP have misinterpreted the provided evidence
- a claim that WAMEP have overlooked submitted evidence or have taken factor(s) into account that may not be relevant to the submission.

Notice of intention to lodge an appeal must be submitted to the FMT via email (WAMEP@health.wa.gov.au) within 20 business days of the applicant's receipt of WAMEP's decision.

Supporting evidence for the appeal, which directly addresses the reasons for submission rejection as provided by WAMEP, must be received by the FMT via email (WAMEP@health.wa.gov.au) within 10 business days of receival of the notice of intention to appeal.

WAMEP will undertake a review of the appeal and decide whether to approve or reject the appeal. If the appeal is to proceed, the applicant will be given an opportunity to justify their stance in person at the next most suitable WAMEP meeting. WAMEP will make a decision according to the group's Terms of Reference. This decision will be final for WAMEP.

If the applicant does not accept the outcome of the appeal, WAMEP can refer the appeal to WATAG. WATAG will review the decision according to the group's Terms of Reference to make a final decision.

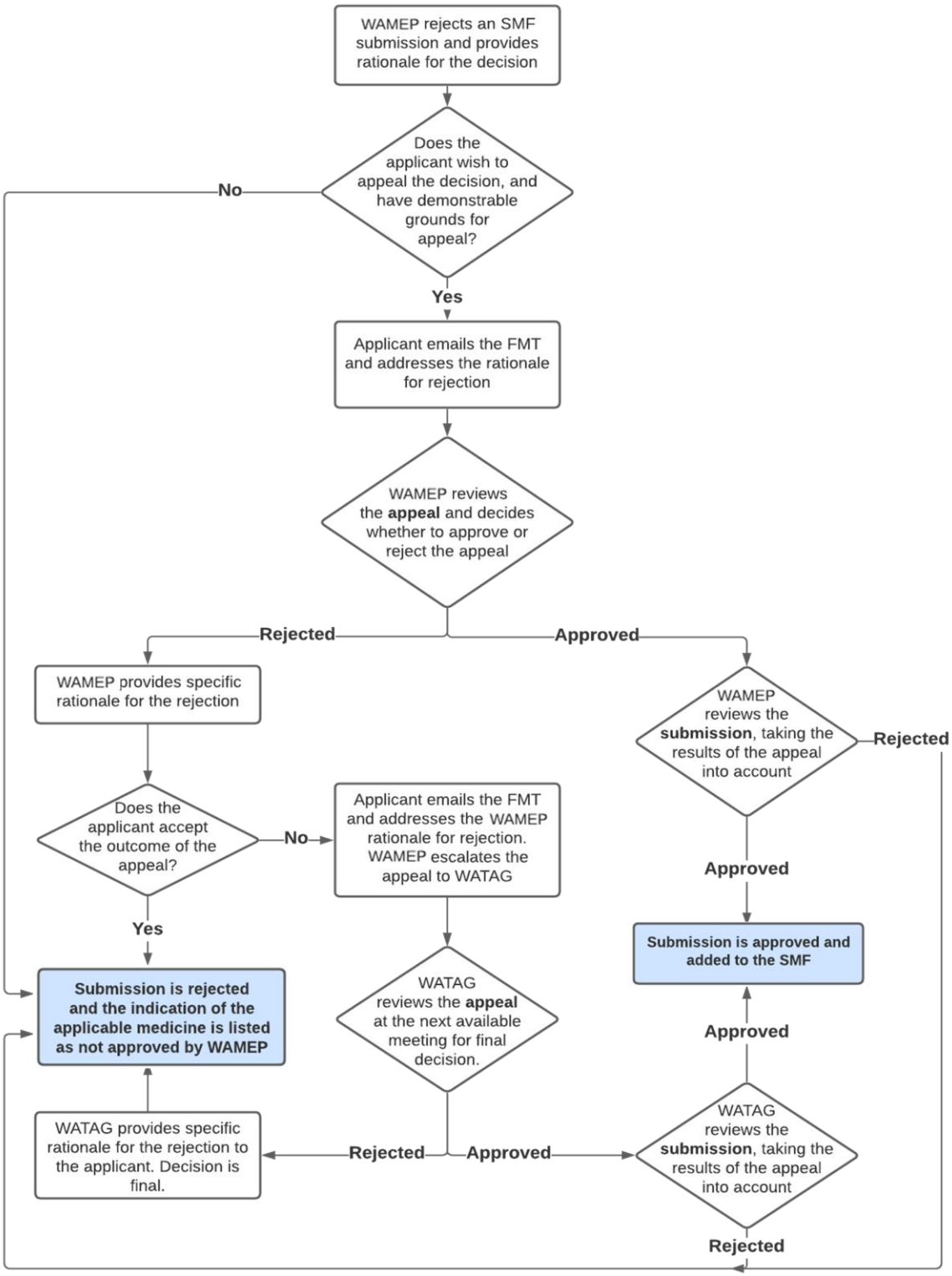

Figure 13. SMF submission appeals process

11.7 Compromise to the independence of WAMEP

Actions or events that may result in compromise to the independence of WAMEP may include but is not limited to:

- direct communications from the applicant or submission contributors to the Panel members about their submission
- direct communications from pharmaceutical sponsors or their representatives to Panel members regarding submissions or medicine listings on the SMF
- failure of a WAMEP member or a FMT member to disclose a conflict of interest both verbally and in writing for an evaluation they are involved in
- any other event that results in a breach of accepted WAMEP processes.

Where there has been an action or event that could compromise the ability of the Panel to ensure evaluations and decisions are independent and due process is observed, the Panel will conduct a vote to decide whether:

- WAMEP may proceed with the evaluation, or
- to refer the evaluation to WATAG for review.

Any member of WAMEP, the Medicines and Technology Unit at the Department of Health, or the Executive Director of PSCQ may request a vote to take place, as above.

WAMEP to proceed with the evaluation

WAMEP will continue to evaluate the submission as per the group's Terms of Reference.

Evaluation referred to WATAG

If a submission is referred to WATAG, the applicant, WAMEP Chair and WAMEP reviewers (if applicable) will be given the opportunity to address WATAG at the evaluation meeting. A decision will be made as per the group's Terms of Reference.

12. Individual Patient Approvals (IPAs)

For the purposes of this guideline, IPAs are defined as 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 specified criteria. The request must have justified clinical need with evidence or expert advice supporting use as well as predicted cost of treatment. IPA processes are governed by the hospital or area DTCs/MTCs or equivalent authorities.

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.

The application and assessment processes for IPAs may differ between hospitals and HSPs and local policies and procedures should be followed. For more information, refer to the local DTC/MTC or equivalent authority policies and procedures and the Individual Patient Approval (IPA) Guideline for the WA Individual Patient Approval System (WAIPAS).

The transfer of IPAs between HSPs is a local policy matter for the HSPs. For more information, contact your local DTC/MTC or equivalent authority.

Note: medicines or therapeutic products that are outside the scope of the SMF are not bound by MP 0077/18 Statewide Medicines Formulary Policy and come under the governance of the local DTC/MTC or equivalent authority, or other specialised committees where applicable according to local policies. Refer to the Individual Patient Approval (IPA) Guideline for the WA Individual Patient Approval System (WAIPAS) for further information.

According to local requirements, some sites may utilise similar processes for Individual Patient Approvals (IPAs) for other types of patient medicine approvals. As an example, Individual Patient Usage (IPU) approvals may be required for supply of expensive medicines listed on the SMF but not usually stored in the local pharmacy inventory for financial oversight. This decision should be made in accordance with existing policies and local risk assessment practices (refer to Section 9 Supply).

12.1 IPA reporting

HSPs 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 as per MP 0077/18 Statewide Medicines Formulary Policy. This is to be reported through a WA Health approved electronic IPA system (such as WAIPAS). If the data is not readily available to the FMT via a WA Health approved electronic IPA system, DTCs/MTCs or equivalent authorities are to forward IPA data to the FMT quarterly (at the end of March, June, September, and December).

Provision of IPA data from sites allows for the identification of a required formulary submission based upon state IPA demand by WAMEP.

In the circumstance whereby a medicine or indication is evaluated by WAMEP and rejected for SMF listing but can still be initiated via an IPA, details of these IPAs must be promptly reported to WAMEP via the FMT by email (WAMEP@health.wa.gov.au) as per the formulary note.

12.2 IPA limit and monitoring

Once 10 IPAs have been approved across the state during a 12 month period for a particular medicine and indication, WAMEP will approach DTCs/MTCs or equivalent authorities via the FMT to recommend that a formulary submission is completed. The FMT will also periodically monitor and record the state's total IPAs via WAIPAS.

13. Access via Formulary One

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.

Formulary One:

- allows timely access to the SMF for WA Health employees
- shows all listing particulars such as the approved formulary indication/s, prescribing restrictions and requirements
- provides links to guidelines and procedures related to that medicine and/or indication where available
- clearly identifies the generic name (international non-proprietary name), strength and formulation of the medicine
- shows or links to medicine safety alerts where applicable
- indicates preferred proprietary brand if applicable
- integrates with i.Pharmacy and shows medicine availability on wards and their location via the imprest functionality
- links to the PBS website information and other relevant online resources
- provides links to relevant SMF documents and SMF submission forms
- provides SMF updates including the newsletter, announcements and planned WAMEP meeting dates on the homepage.

Local DTCs/MTCs or equivalent authorities are the first point of contact for enquiries about how to use the Formulary One platform.

Where available, specific prescribing and administration information (medicine monographs and clinical protocols) will be provided within a paediatric and neonatal formulary listing, however these may not always be available or contain the required information for use in paediatrics and neonates. Clinical staff are advised to seek out alternative reliable sources of information as necessary.

13.1 Uploading or linking to documents on Formulary One

Local site documents

Any request to upload or link to a local site medicine related policy, procedure or guideline on Formulary One must be endorsed by the site's DTC/MTC or equivalent authority. Once endorsed, these may be added to the relevant medicine monographs directly on Formulary One. It is the HSP's responsibility to ensure the document and link provided is current and relevant, and the FMT is informed of updates accordingly. Information within any of the documents must align with formulary listings and restrictions where applicable.

External documents

Where there are requests to upload or link to external documents, it is the responsibility of the HSP to house this document on the HSP's intranet site and provide a link which can be added to Formulary One. It is the HSP's responsibility to make sure the document and link remains current and relevant, and the FMT is informed of updates accordingly. Information within any of the documents must align with formulary listings and restrictions where applicable.

13.2 Reporting of bugs or performance issues

For issues relating to information displaying incorrectly or not appropriately on Formulary One, the FMT should be contacted via email (WAMEP@health.wa.gov.au) and informed of the issue. It is the FMT's responsibility to escalate bugs or performance issues to the software vendor.

13.3 Enhancements and other modifications

Stakeholders may request a modification to the Formulary One platform that will impact the functionality of the application (change request). To maintain governance, functionality, and integrity of the platform, change requests require significant engagement with the vendor and stakeholders across the WA health system, before they are considered by WAMEP for endorsement and appropriate approvals for funding sought.

The process for the submission, review and evaluation of change requests is outlined in Figure 14.

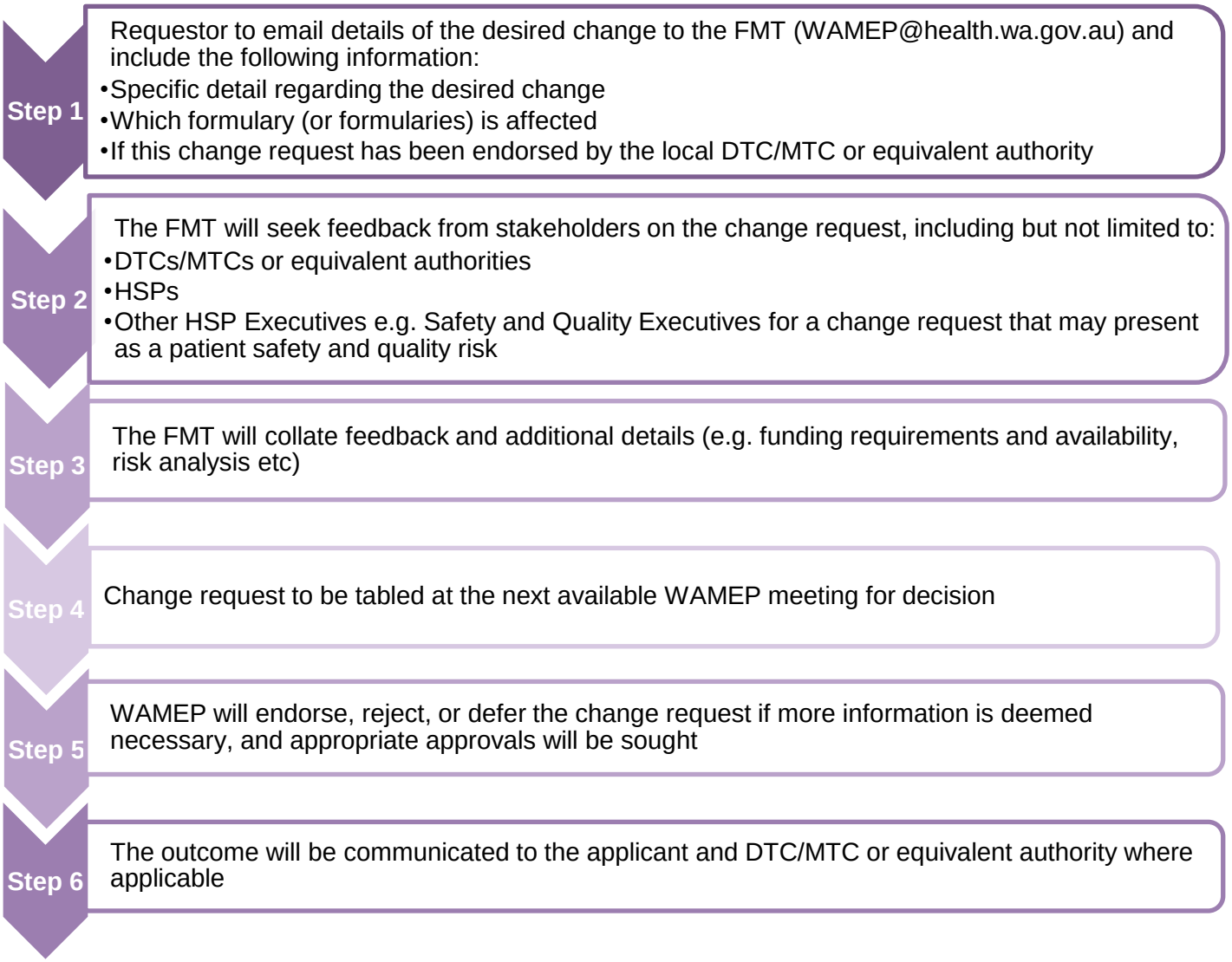

Figure 14. Change request process

14. Procurement of medicines

The SMF provides an opportunity to consider coordinated statewide purchasing of medicines. WAMEP will remain independent of the procurement process.

WAMEP will work closely with the Chief Pharmacists' Forum (CPF) and the Pharmaceutical Client Reference Group with the aim to:

- inform these groups of changes to the SMF
- obtain feedback about SMF submissions so that implications, if any, for more cost-effective medicines acquisition can be determined
- identify preferred medicine brand
- provide clinical input into purchasing considerations, when required
- encourage statewide agreement in medicine procurement
- support these groups with negotiations with pharmaceutical suppliers when required, however WAMEP will remain external to the procurement process.

In turn, DTCs/MTCs or equivalent authorities, members of the CPF and the Pharmaceutical Client Reference Group will inform WAMEP of changes in the market, pricing and reimbursements that may affect the comparative cost benefits of an individual item (this may include original and new cost of the product and site utilisation data to inform decisions on formulary status/restrictions). WAMEP may use this information to review previously evaluated medicines or indications.

15. Risks

Maintaining and administering a medicines formulary carries the following potential risks:

- poor adherence due to differing perceptions, attitudes, system capability and procedural requirements
- efficient communication and timely reliable access to decisions requires information technology (IT) infrastructure and statewide system capability.

To address these risks, the following points are central to the operation and administration of the SMF:

- the needs of the patient are central to all decisions
- robust and relevant policy and guideline documents that are regularly reviewed
- a transparent and consistent submission evaluation 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
- timely and reliable access to the SMF through the IT application
- clear pathways for submission, evaluation and appeal
- an effective and equitable IPA process governed by local DTCs/MTCs or equivalent authorities
- compliance auditing as requested by WAMEP to ensure use is as intended.

16. Assessment of the SMF

To understand the impact on HSPs, DTCs/MTCs and equivalent authorities, pharmacy departments and clinical staff, the indicators in Table 4 may be monitored. These indicators will help to assess areas of efficiency gain, impact on workload and workflow, and the effectiveness of the electronic system and the communication strategy.

The Medicines and Technology Unit, on behalf of the System Manager, will request access to reports and data from HSPs at the end of each financial year or on an as needed basis to ensure SMF compliance as per MP 0077/18 Statewide Medicines Formulary Policy.

HSPs, usually via their DTCs/MTCs or equivalent authorities and pharmacy departments are recommended to assess compliance to the SMF as part of local medicine management governance. Due to the limitations of i.Pharmacy and other current ICT healthcare software and the need to extract data from multiple paper record sources, compliance can be broadly measured at the hospital level using the best data available.

Table 4. SMF use assessment examples

Objective	Indicator(s)	Method(s)
Maintain a single statewide medicines formulary **1. standardised protocols/ procedures** **2. equity of access**	• Discrepancies in medicine use and availability across the WA health system • Number of protocols, procedures and guidelines for medicines across the state • Number of IPAs	• Survey of DTC/MTC members • Review 3 monthly IPA reports
Facilitate efficiencies in medicine evaluations	• Number of IPA submissions per quarter per DTC/MTC	• Survey of DTC/MTC members
Accountability and transparency in medicine evaluations	• Availability of information about SMF decisions • Clinical staff opinion and trust of the SMF processes • Reasonable and accepted timeframe for SMF evaluation and listing	• Information about SMF decisions published on Formulary One (e.g. SMF newsletter and formulary notes) and communicated to key stakeholders • Clinical staff survey • Review of WAMEP listing time
Promote cost-effective use of medicines	• Total cost of medicines • Cost considered in prescribing and decision making	• Monitor trends in cost from i.Pharmacy, procurement data and other dispensing databases • Clinical staff survey
Promotion of medication safety	• Reported medicine errors • Number of medicines with safety information available • Patient information availability	• Pharmacy and Datix-CIMS data • Available safety data • Available patient information

17. Supporting documents

The following documents support this guideline:

1. Australian Government, Department of Health and Aged Care: National Medicines Policy
2. Council of Australian Therapeutic Advisory Groups (CATAG): Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines
3. CATAG: Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals
4. CATAG: Guiding Principles for Medicines Stewardship Programs
5. Individual Patient Approval (IPA) Guideline for the WA Individual Patient Approval System (WAIPAS)
6. Scope of clinical practice and the Statewide Medicines Formulary position statement
7. MP 0084/18 Credentialing and Defining the Scope of Clinical Practice Policy

18. Definitions

The following definitions are relevant to this document:

Authorised Prescriber (AP) Scheme: The AP scheme allows authorised medical practitioners to prescribe medicines that are not included in the Australian Register of Therapeutic Goods (ARTG) to a class of patients with a particular medical condition.[2] For further information refer to: https://www.tga.gov.au/products/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-multiple-patients-authorised-prescriber.

Biological medicine: The TGA defines a biological medicine as 'a medicine (other than an antibiotic) that is: a vaccine, a peptide, a protein, a polysaccharide; and derived from a human, animal or other organism, or produced through recombinant technology or biotechnology; and of a kind specified in item 1 of Part 1 of Schedule 10; or but does not include a 'biological' within the meaning of section 32A of the Act.' [3]

Biosimilar medicine: The TGA defines a biosimilar medicine as 'a version of an already registered biological medicine that has a demonstrable similarity in physiochemical, biological and immunological characteristics, efficacy and safety, based on comprehensive comparability studies.'[3] Biosimilars are not a generic version of the biological product.

Clinicians: For the purposes of this guideline, clinicians encompass health professionals involved in medicine management within their scope of clinical practice, including but not limited to medical practitioners, nurses, pharmacists, midwives, and allied health professionals.

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.[4] 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.' [4]

Complementary medicines: are non-prescription medicines and are also known as alternative medicines.[5] They are medicines that primarily contain complementary medicine ingredients that have an established identity and tradition of use such as vitamins, minerals, herbal materials, aromatherapy and homoeopathic preparations.[5]

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[2]Therapeutic Goods Administration (TGA). Unapproved products for multiple patients (Authorised Prescriber). Cited January 2024, available online at https://www.tga.gov.au/products/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-multiple-patients-authorised-prescriber.

[3]Therapeutic Goods Administration (TGA). Acronyms and glossary terms. Cited October 2023, available online at https://www.tga.gov.au/resources/acronyms-and-glossary-terms.

[4]Pharmacy Board of Australia. Guidelines on compounding of medicines. Cited November 2023, available online at https://www.pharmacyboard.gov.au/codes-guidelines.aspx.

[5]Therapeutic Goods Administration (TGA). Complementary medicines. Cited November 2023, available online at https://www.tga.gov.au/topics/complementary-medicines.

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.[6] 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. For further information on the role and operation of DTCs/MTCs, refer to: CATAG: Achieving Effective Medicines Governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals.

Extemporaneous compounding: 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.[4] The practice of compounding is classified in this document as either simple or complex compounding.

Generic medicine: The *Therapeutic Goods Regulations 1990*, Regulation 2, defines a generic medicine as 'a medicine that, in comparison with a registered medicine:

i. has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the registered medicine or previously registered medicine; and
ii. has the same pharmaceutical form; and
iii. is bioequivalent; and
iv. has the same safety and efficacy properties.'[3]

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

Individual Patient Approval (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.

Off-label medicine use: The use of a medicine in ways other than specified in the Australian Therapeutic Goods Administration (TGA) approved product information, including when the medicine is prescribed or administered:

- for another indication
- at a different dose
- via an alternate route of administration
- for a patient of an age or gender outside the registered use.[7]

Medicine: A medicine is defined in this document as a therapeutic product used to prevent, treat or manage a disease or health condition. May also be referred to as a drug or medication.

[6]Council of Australian Therapeutic Advisory Groups. Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals. Cited January 2024, available online at https://catag.org.au/resource/achieving-effective-medicines-governance/.

[7]Council of Australian Therapeutic Advisory Groups (CATAG). Rethinking Medicines Decision Making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines. Cited October 2023, available online at https://catag.org.au/resource/rethinking-medicines-decision-making-in-australian-hospitals/.

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.[8]

Pharmaceutical Benefits Scheme (PBS): The PBS is a Commonwealth scheme for subsidised medicines listed on the PBS Schedule available to all Australian residents who hold a current Medicare card.[9] Overseas visitors from countries with which Australia has a Reciprocal Health Care Agreement (RHCA) are also eligible to access the Scheme.[9]

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.[10]

Simple compounding: 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.[4] 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.'[4]

Special Access Scheme (SAS): The SAS allows certain Australian registered health practitioners to access medicines, medical devices or biologicals that are not included in the Australian Register of Therapeutic Goods (ARTG) for an individual patient on a case by case basis.[11] There are three SAS pathways – Category A, Category B and Category C.[11] For further information refer to: https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-individual-patients-special-access-scheme.

Therapeutic class (therapeutic group): Medicines 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).

Unscheduled medicine: Medicines that are either not included in or are exempted from the schedules of the National Poisons Standard.

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[8]Australian Government Department of Health and Aged Care Pharmaceutical Benefits Scheme. Pharmaceutical Benefits Advisory Committee (PBAC) Membership. Cited January 2024, available online at https://www.pbs.gov.au/info/industry/listing/participants/pbac.

[9]Australian Government Department of Health and Aged Care Pharmaceutical Benefits Scheme. About the PBS. Cited January 2024, available online at https://www.pbs.gov.au/info/about-the-pbs.

[10]MP 0084/18 Credentialing and Defining the Scope of Clinical Practice Policy

[11]Therapeutic Goods Administration (TGA). Special Access Scheme (SAS) Guidance for health practitioners accessing unapproved therapeutic goods version 1. Cited October 2023, available online at https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-guidance-health-practitioners-accessing-unapproved-therapeutic-goods.

WA health system: The WA health system is comprised of:

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.

Western Australian Individual Patient Approval System (WAIPAS): 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 MP 0077/18 Statewide Medicines Formulary 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.

19. Appendices

Appendix 1: Evaluation process for SMF adult and paediatric full submission (detailed)

Full Submission - Adult and Paediatric

FMT assessment

The FMT will:

- Assess the submission for completeness, robustness and eligibility.
- Assess the appropriateness of the submission type.
- Conduct an independent literature review and compile a submission summary document consisting of current evidence and best practice guidelines, comparator treatment(s), a cost analysis (including expected financial impact to the state), a safety review and other relevant information to be provided to WAMEP members.
- Support applicants in the submission process and may contact the applicant for more information or clarification on the submission. It is requested that applicants respond to any queries from the FMT in a timely manner to ensure the submission is tabled at the earliest available meeting.
- Refer to EAGs for advice for submissions that are specialised in nature, have therapeutic or safety concerns or require specialist input.
- In consultation with the WAMEP Chair determine whether the submission is to be tabled at WAMEP and at which meeting.

Reviewers allocated and independent evaluation conducted

When the decision is made to table the submission at WAMEP, two reviewers will independently and confidentially evaluate the submission guided by an SMF reviewer report document.

Reviewers may be WAMEP members or invited experts at the discretion of the Chair.

Reviewers complete the SMF reviewer report document and make a recommendation on the submission outcome and may also request that the FMT asks the applicant further questions.

Reviewers are given at least two weeks to complete their independent evaluation.

Stakeholder Consultation

Submission details are circulated to DTCs/MTCs, Chief Pharmacists' Forum, relevant EAGs, relevant WATAG subcommittees and HoDs for input and recommendations.

Stakeholders are given at least seven days to provide feedback.

Where a treatment algorithm has been developed in relation to a SMF listing, the FMT will seek endorsement from relevant HoDs and EAGs or WATAG subcommittees.

The FMT will collate all feedback and expert recommendations.

Circulation of submission details to WAMEP members prior to scheduled meeting

The FMT will gather and circulate the following information to WAMEP members at least one week prior to the scheduled meeting:

- SMF submission form plus supporting evidence and documents
- Submission summary document completed by the FMT
- Summary of received feedback and recommendations from DTCs/MTCs, Chief Pharmacists, relevant EAGs, relevant WATAG subcommittees and HoDs

WAMEP members review the information independently prior to the scheduled meeting.

Submission tabled and discussed at WAMEP meeting

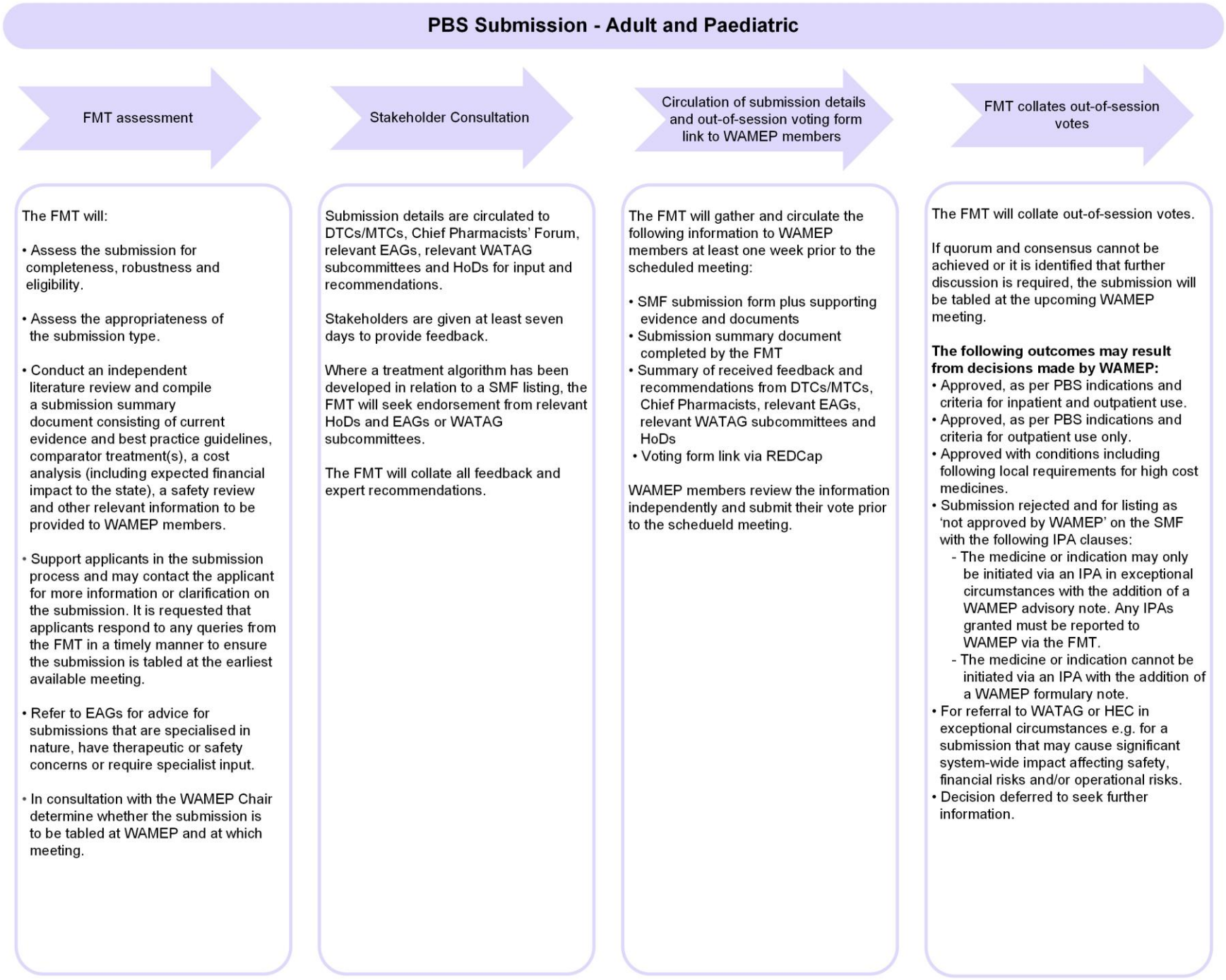
Each reviewer will provide an overview of their critical analysis of the evidence and their final recommendations to the Panel.

The Panel will then discuss, review and provide a decision on the formulary listing status of the medicine or indication based on a vote (as per the WAMEP Terms of Reference). WAMEP meets every 6 weeks or at the discretion of the Chair.

The following outcomes may result from decisions made by WAMEP:

- Approved, unrestricted listing.
- Approved with conditions (i.e. specified restrictions, audit requirement).
- Submission rejected and for listing as 'not approved by WAMEP' on the SMF with the following IPA clauses:
  - The medicine or indication may only be initiated via an IPA in exceptional circumstances with the addition of a WAMEP advisory note. Any IPAs granted must be reported to WAMEP via the FMT.
  - The medicine or indication cannot be initiated via an IPA with the addition of a WAMEP formulary note.
- For referral to WATAG or HEC in exceptional circumstances e.g. for a submission that may cause significant system-wide impact affecting safety, financial risks and/or operational risks.
- Decision deferred until further evidence of clinical, cost-effectiveness or safety is provided.

Appendix 2: Evaluation process for SMF adult and paediatric PBS submission (detailed)



Appendix 3: Evaluation process for SMF neonatal full submission (detailed)

Full Submission - Neonatal

FMT conducts assessment and forwards accepted submission to CNCG CM

The FMT will:

- Assess the submission for completeness, robustness and eligibility.
- Assess the appropriateness of the submission type.
- Forward the submission to the CAHS Neonatal Coordinating Group (CNCG) corresponding member (CM) once accepted.
- Conduct an independent literature review and compile a submission summary document consisting of current evidence and best practice guidelines, comparator treatment(s), a cost analysis (including expected financial impact to the state), a safety review and other relevant information to be provided to WAMEP members.
- Support applicants in the submission process and may contact the applicant for more information or clarification on the submission. It is requested that applicants respond to any queries from the FMT in a timely manner to ensure the submission is tabled at the earliest available meeting.
- Refer to EAGs for advice for submissions that are specialised in nature, have therapeutic or safety concerns or require specialist input.
- Together with the WAMEP Chair and CNCG CM plan when the next most suitable WAMEP meeting will be to table the submission.

Reviewers allocated and independent evaluation conducted

When the decision is made to table the submission at WAMEP, two reviewers will independently and confidentially evaluate the submission guided by an SMF reviewer report document.

One of the reviewers will be the CNCG CM, the other reviewer may be a WAMEP member or an invited expert at the discretion of the Chair.

Reviewers complete the SMF reviewer report document and make a recommendation on the submission outcome and may also request that the FMT asks the applicant further questions.

Reviewers are given at least two weeks to complete their independent evaluation.

Stakeholder Consultation

The FMT and CNCG CM will together coordinate stakeholder consultation on the submission and any relevant protocols, guidelines and policies.

Stakeholders include but are not limited to: DTCs/MTCs, Chief Pharmacists' Forum, relevant EAGs, relevant WATAG subcommittees and HoDs for input and recommendations.

Stakeholders are given at least seven days to provide feedback.

Where a treatment algorithm has been developed in relation to a SMF listing, the FMT and CNCG CM will seek endorsement from relevant HoDs and EAGs or WATAG subcommittees.

The FMT and CNCG CM will together collate all feedback and expert recommendations.

Circulation of submission details to WAMEP members prior to scheduled meeting

The FMT will gather and circulate the following information to WAMEP members at least one week prior to the scheduled meeting:

- SMF submission form plus supporting evidence and documents
- Submission summary document completed by the FMT
- Summary of received feedback and recommendations from stakeholders

WAMEP members review the information independently prior to the scheduled meeting.

Submission tabled and discussed at WAMEP meeting

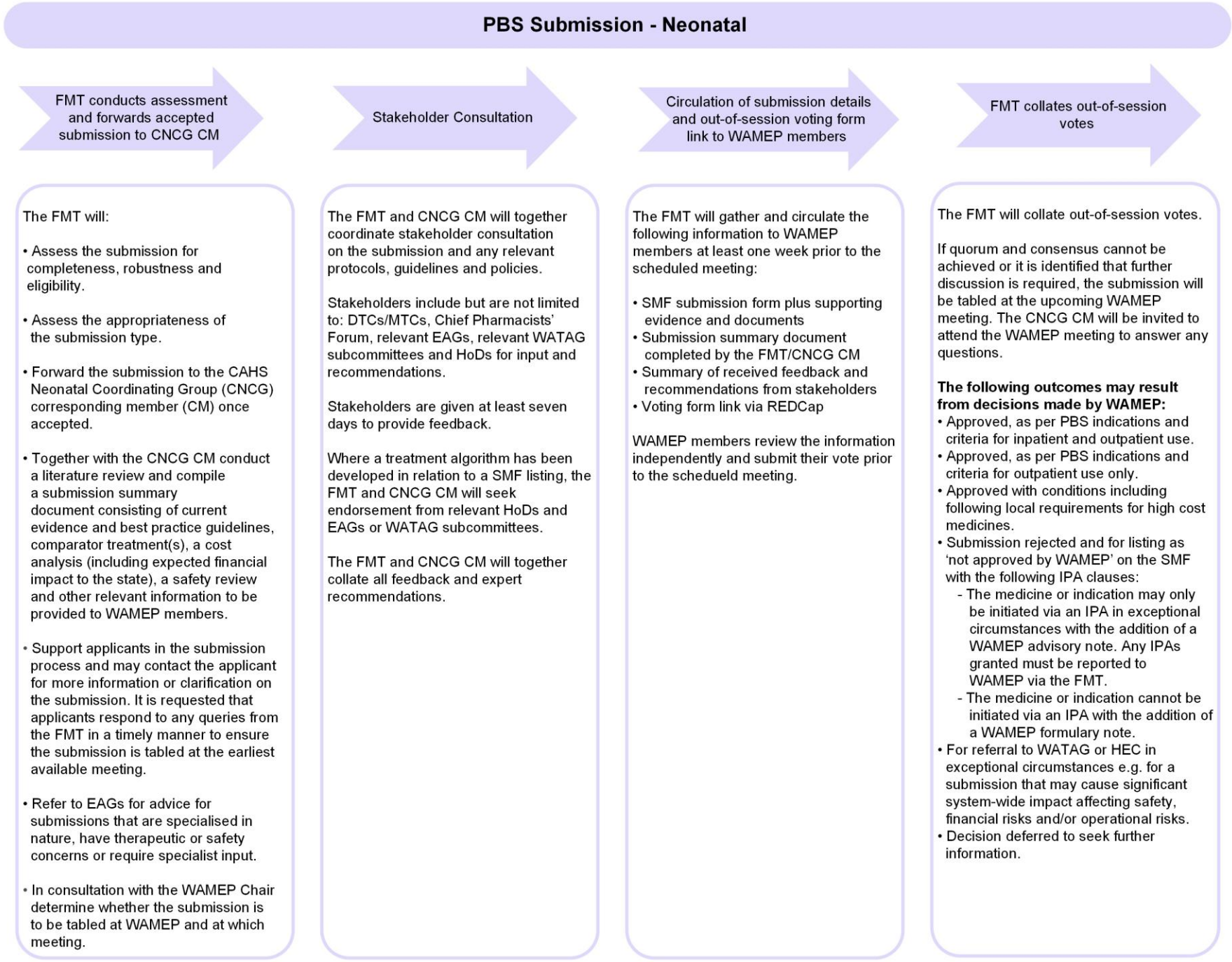
Each reviewer will provide an overview of their critical analysis of the evidence and their final recommendations to the Panel.

The Panel will then discuss, review and provide a decision on the formulary listing status of the medicine or indication based on a vote (as per the WAMEP Terms of Reference). WAMEP meets every 6 weeks or at the discretion of the Chair.

The following outcomes may result from decisions made by WAMEP:

- Approved, unrestricted listing.
- Approved with conditions (i.e. specified restrictions, audit requirement).
- Submission rejected and for listing as 'not approved by WAMEP' on the SMF with the following IPA clauses:
  - The medicine or indication may only be initiated via an IPA in exceptional circumstances with the addition of a WAMEP advisory note. Any IPAs granted must be reported to WAMEP via the FMT.
  - The medicine or indication cannot be initiated via an IPA with the addition of a WAMEP formulary note.
- For referral to WATAG or HEC in exceptional circumstances e.g. for a submission that may cause significant system-wide impact affecting safety, financial risks and/or operational risks.
- Decision deferred until further evidence of clinical, cost-effectiveness or safety is provided.

Appendix 4: Evaluation process for SMF neonatal PBS submission (detailed)



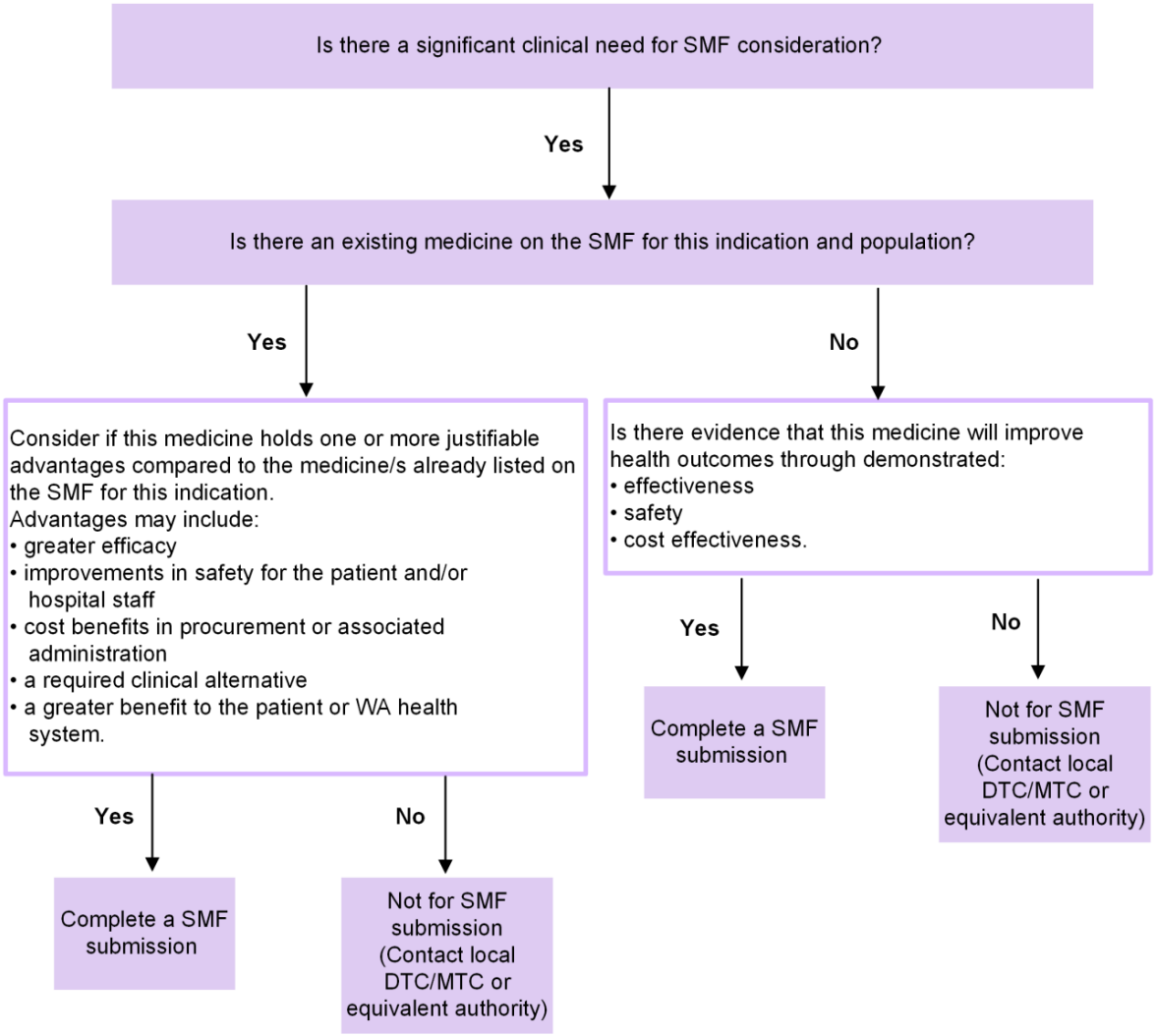
Appendix 5: FAQ

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 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.



If you wish to make a formulary submission to WAMEP, please refer to Figure 4. SMF submission process for a detailed step-by-step guide.

20. Version Control

Version number	Version Date	Sponsor	Document Writer	Review Date
1.0	1/12/2014	Office of the Chief Medical Officer (OCMO)	Rebecca Godfrey Project Coordinator	1/12/2016
1.1	14/04/2015	Office of the Chief Medical Officer (OCMO)	Rebecca Godfrey Project Coordinator	1/12/2016
1.2	2/07/2015	Office of the Chief Medical Officer (OCMO)	Rebecca Godfrey Project Coordinator	1/12/2016
2.0	1/01/2017	Office of the Chief Medical Officer (OCMO)	Rebecca Godfrey Project Coordinator	1/01/2019
3.0	04/12/2017	Assistant Director General, Clinical Excellence	Cale Padgett, Project Coordinator	04/12/2020
4.0	03/12/2021	Assistant Director General, Clinical Excellence	Holly Signal, Project Coordinator Andrew Campbell, Senior Project Officer	01/12/2023
5.0	03/04/2024	Assistant Director General, Clinical Excellence	Mirna Dorkhom, Senior Pharmacist Bianca Vincent, Senior Pharmacist	03/04/2026

Note: Versions 1.0 to 2.0 known as the Statewide Medicines Formulary Framework
Version 3.0 known as the Statewide Medicines Formulary Guidelines
Version 4.0 known as the Statewide Medicines Formulary Governance and Procedures

Any broken or misdirected links can be reported by email to WAMEP@health.wa.gov.au

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