



Western Australian Medicines Evaluation Panel (WAMEP) Terms of Reference

1. Name

The committee is known as the Western Australian Medicines Evaluation Panel, (WAMEP).

2. Purpose

WAMEP is a multidisciplinary body that governs the Western Australian Statewide Medicines Formulary (SMF) decisions. WAMEP considers the clinical efficacy, effectiveness, safety, cost-effectiveness, equity of access and implementation implications of medicines for SMF listing.

WAMEP will support the purpose of the SMF:

‘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. 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. The scope of the SMF is detailed in the WA Statewide Medicines Formulary Guidelines.

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 Drug and Therapeutics Committee (DTC)/Medicines and Therapeutics Committee (MTC) or equivalent authority, or other specialised committees.

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 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.

4. Panel Responsibilities

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 (see [Western Australian Statewide Medicines Formulary Expert Advisory Groups Terms of Reference](#) for more information)
- consult Western Australian Therapeutics Advisory Group (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 Product Evaluation Standardisation Committees (PESCs) about the medicine component of devices
- make recommendations to other State and National bodies as requested.

5. Membership

Member's identity will be confidential to external stakeholders.

5.1 Chair

The Chair will be appointed by the Executive Director, Patient Safety and Clinical Quality (PSCQ), Department of Health.

5.2 Deputy Chair

The Deputy Chair will be nominated and elected from the membership of WAMEP. Nominations are required to be endorsed by two voting members. Nominations are then reviewed and voted on by WAMEP members and consensus is required to be supported by the majority of voting members in attendance at the meeting. WATAG endorsement is also required for appointment.

If no WAMEP member is nominated, an appointment may then be made by the WATAG Chair.

5.3 Voting Members

WAMEP membership consists of at least 15 voting members. Voting member composition should include, where possible:

- at least one **senior medical prescriber** (registrar or consultant) from each of the following:
 - Fiona Stanley Hospital
 - Royal Perth Hospital
 - Sir Charles Gairdner Hospital
 - WA Country Health Service (WACHS)
 - Perth Children’s Hospital
 - a general or specialist hospital(s) in the Perth metropolitan area
- at least one **junior medical officer** representative (from any Health Service Provider)
- at least one **senior pharmacist** from each of the following:
 - Fiona Stanley Hospital
 - Royal Perth Hospital
 - Sir Charles Gairdner Hospital
 - WA Country Health Service (WACHS)
 - Perth Children’s Hospital
 - a general or specialist hospital(s) in the Perth metropolitan area
- at least one **senior nursing clinician with prescribing rights** (from any Health Service Provider)
- at least one member from the **Medicines and Technology Unit (MTU)**, Department of Health
- at least one **medication safety** representative
- at least one **pharmacologist** or **pharmacology registrar**
- at least one **consumer advocate**.

Members may represent two positions on WAMEP but are limited to a single vote at the discretion of the Chair. Additional members may be opted in on an ad-hoc basis for specific subspecialties and expertise at the discretion of the Chair. Balanced membership from across Health Service Providers will be sought to ensure equity of representation. Although best efforts are made to ensure all positions are filled, there may be instances where specialist Panel positions may be vacant due to no suitable candidates.

5.4 Corresponding Members

The Chair, in consultation with members, may establish a network of corresponding members to provide expert opinions and recommendations on specialised areas to the Panel.

Corresponding members may be representative of service areas which may require ad-hoc involvement in Panel discussions. At a minimum WAMEP shall have at least one corresponding member from the following:

- CAHS Neonatal Coordinating Group (CNCG) corresponding member (CM)
- Public health practitioner or epidemiologist
- Health economist(s).

Corresponding members are consulted to review agenda items relevant to their specialist area and are invited to attend meetings when requested by the Chair to participate in discussions. They do not have voting rights and may raise agenda items as required.

5.5 General Proxy Members

If a current WAMEP voting member anticipates they will be absent for **two or more consecutive meetings**, they must nominate a general proxy who is equivalent in terms of expertise and from the same site. A general proxy will have the right to vote autonomously on all issues and motions, including in and out-of-session items. The nominating Panel member retains the right to resume their WAMEP voting role at any time and end the proxy membership, including if the substantive member resigns. General proxies must be approved by the WAMEP Chair.

Substantive Panel members who have elected a general proxy and are absent for a period greater than 12 months, will be asked to relinquish their position. The general proxy member will be given the opportunity to take the substantive position after this time.

5.6 Limited Proxy Members

A limited proxy who is equivalent in terms of expertise and from the same site may be nominated by a Panel member to act on their behalf for **up to two consecutive meetings**. This may include reading the Panel member's comments or reviews of agenda items or voting on the Panel member's behalf in or out-of-session. The limited proxy holder must cast the member's vote and represent the member in any other way as stipulated by the nominating Panel member. Limited proxy members must be approved by the WAMEP Chair.

5.7 Formulary Management Team

The Formulary Management Team (FMT) is part of the PSCQ Directorate. Secretarial duties are provided by the FMT. The FMT will attend meetings in an ex officio capacity but will not have voting rights.

5.8 Other participants

At the discretion of the Chair, other persons may participate in WAMEP's activities where relevant to an agenda item for expertise and advice. However, such persons do not have voting rights and do not assume membership.

5.9 Appointments

Members may be appointed in relation to their professional networks, expertise, experience and knowledge and represent their area health service. Suitable experience and expertise in contemporary medicine management within the public hospital system and highly developed research and analytical skills to undertake a critical appraisal of evidence for SMF applications is required for appointment. Potential members may be identified by the Chair, WAMEP members, WATAG or WATAG subcommittees, Expert Advisory Groups, Heads of Department, Health Networks or expression of interest sought by advertisement. Appointments will be reviewed and voted on by the members of WAMEP and consensus is required to be supported by the majority of voting members in attendance at the meeting.

The Chair and members will be appointed for a term not exceeding 3 years, at which point the position will be eligible for renomination and reappointment. After a first 3 year term, the member will be notified of membership expiry and will be afforded the opportunity to renominate for a further 3 year term provided the member still fulfils their appointed role (e.g. junior medical officer) and their responsibilities as a voting member as outlined in [Section 6](#). If the member is now employed in a different position (e.g. junior medical officer now a senior medical officer), the member is given the opportunity to nominate for a different position within WAMEP and their original position will be opened to expressions of interest. After a second consecutive 3 year term, the member will be notified of membership expiry and expressions of interest will be opened for the position; the incumbent member is invited to re-apply for the position via expressions of interest.

6. Members roles and responsibilities

6.1 Chair

The Chair is responsible for providing leadership, open communication to all stakeholders, and working with the FMT secretariat to ensure WAMEP's responsibilities are carried out optimally. In the circumstance whereby the Chair has to vacate a meeting, the Deputy Chair or Acting Chair may assume control of the meeting, however all decisions are required to be ratified by the Chair out-of-session.

6.2 Deputy Chair

In the Chair's absence, the Deputy Chair will fulfil all Chair responsibilities.

6.3 Acting Chair

If both the Chair and Deputy Chair are absent, an Acting Chair may be elected by members to enable work of the Panel to continue.

6.4 Voting Members

Voting members are required to actively participate in all meetings and decision making including out-of-session items, gather and share information and represent the SMF processes and governance in practice. They are required to review the agenda and supporting materials independently and submit their vote for out-of-session items where applicable prior to the scheduled meeting.

Members are likely to be asked to review two to three submissions per year and are asked on a rotational basis (with the exception of the consumer representative).

If a member is planning to go on leave and will be unavailable for WAMEP activities, they should inform the FMT in advance. If a member nominates a proxy, the proxy must be equivalent in terms of expertise and from the same site. Refer to Section [5.5 General Proxy Members](#) and [5.6 Limited Proxy Members](#) for further details.

Meeting attendance will be reviewed annually and attendance at less than two thirds of the meetings in any 12 month period without justification will result in loss of membership.

6.5 Formulary Management Team

The FMT is the secretariat for WAMEP and is responsible for:

- undertaking and maintaining the business, communication, and administrative functions of the Panel including meeting coordination, minute taking, circulation of relevant information, coordinating out-of-session items
- assessing SMF submissions for completeness, eligibility and robustness and liaising with applicants if further information or clarification is required
- supporting applicants in the submission process
- gathering and providing additional relevant information from various sources where required to WAMEP members to support and facilitate decision making
- liaising with the Chair in the preparation of meeting agenda, out-of-session items, minutes and papers
- maintaining a log of all formulary submissions and the Panel's decisions
- coordinating the review of formulary listings with an audit requirement specified
- periodically monitoring and recording the state's total IPAs via WAIPAS
- coordinating the appeals process as required
- communicating WAMEP's decisions to the applicant and to other relevant stakeholders according to the SMF Guidelines document.

7. Accountability

WAMEP is responsible for the ongoing maintenance of the SMF. The SMF governance and accountability structure is illustrated in [Figure 1](#).

The Western Australian Therapeutic Advisory Group (WATAG) is responsible for promoting, supporting and advising on statewide medicine governance and the quality use of medicines across Western Australian (WA) public hospitals. WATAG is accountable to the Assistant Director General, Clinical Excellence Division via the

Executive Director, Patient Safety and Clinical Quality Directorate. See [WATAG Terms of Reference](#) for more information. Although WAMEP is a subcommittee of 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.

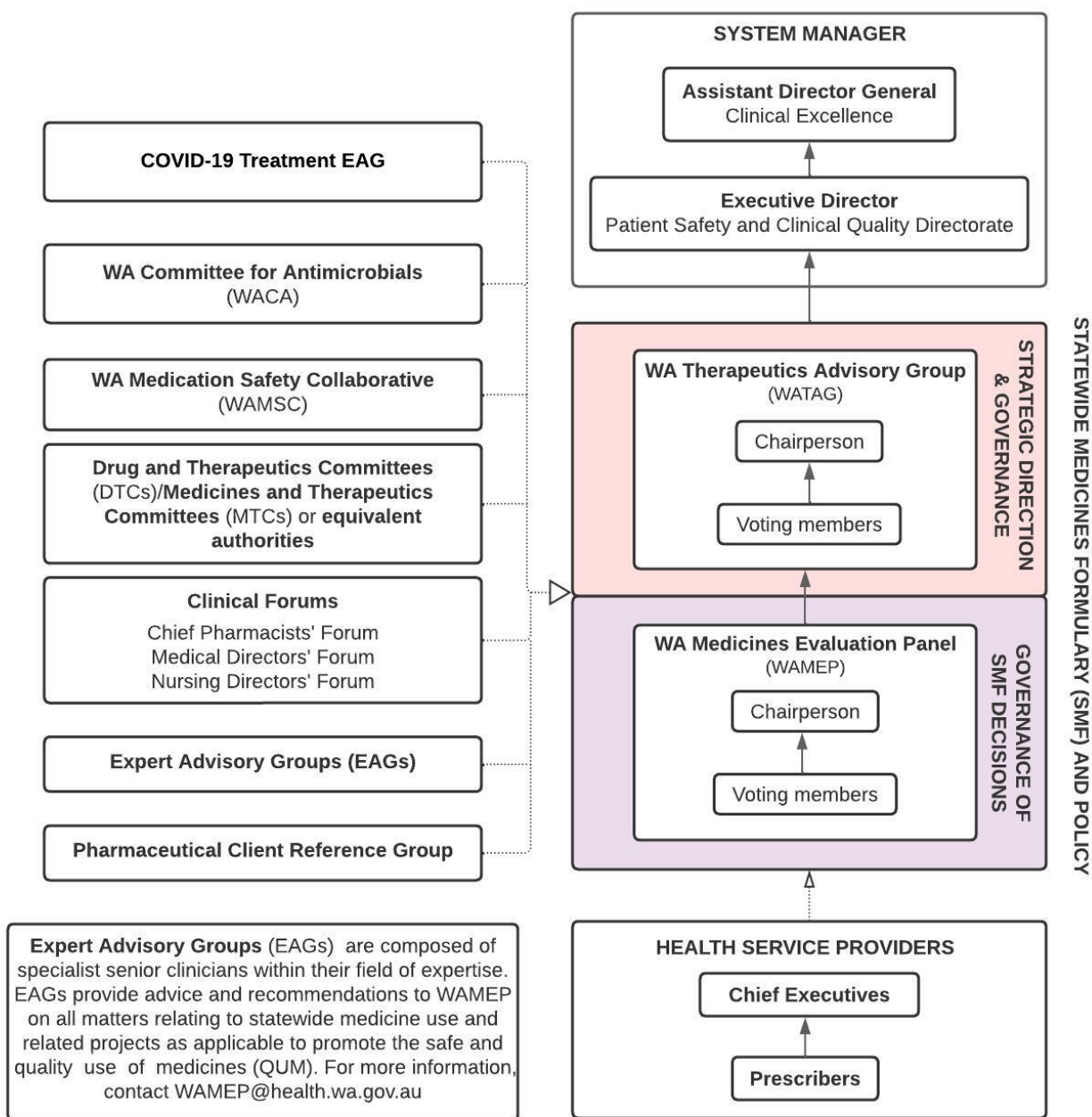


Figure 1. Accountability structure of the SMF

7.1 Annual report

The FMT, in consultation with the Chair and MTU manager, will provide an annual report on the activities of WAMEP at the end of each calendar year to the Assistant Director General Clinical Excellence Division.

7.2 Health Executive Committee (HEC) reporting

The FMT, in consultation with the Chair and MTU manager, will provide a report on the activities of WAMEP every six months to the Health Executive Committee (HEC).

8. Meetings

8.1 Frequency, duration and location

WAMEP meets approximately every six weeks or at the discretion of the Chair for a duration of 1.5 hours. Meetings are held by teleconference unless otherwise advised by the FMT. Meeting dates and times will be set before the first meeting of each year. Members are required to review information circulated by the FMT, provide feedback and vote on out-of-session items prior to the scheduled meeting.

8.2 Quorum

Quorum is required to be met before the meeting can be commenced. Quorum is attained when half the number of voting members plus one is in attendance. If quorum is not met, the following will occur:

- the Chair will confirm if the meeting is to proceed or if the meeting is to be adjourned to a later date and time
- if the meeting proceeds, all recommendations will be preliminary. Preliminary recommendations require out-of-session voting or discussion at the next scheduled meeting at which quorum is present to formalise decisions.

8.3 Decisions and recommendations

The Panel will review, discuss and provide a decision based on a vote. Provided that quorum is met, decisions and recommendations will be passed if consensus is supported by the majority of voting members in attendance. If quorum is not met, preliminary recommendations require confirmation at a later time through out-of-session voting or discussion at the next meeting at which quorum is present to formalise decisions.

8.3.1 Voting

All voting members/approved proxies including the Chair have a single vote (regardless of the number of positions the member holds on the committee). Members must be present to vote with voting being conducted anonymously. In the case of an equality of votes, the Chair has a casting vote.

8.3.2 Out-of-session resolutions

The Chair may elect to determine WAMEP's position by an out-of-session vote. Refer to [Section 9 Out-of-session items review and decision](#) for further information.

8.4 Agenda

The FMT in consultation with the Chair will prepare the agenda for each meeting. The FMT will circulate the agenda and supporting materials to members via email at least one week prior to the scheduled meeting. Members may contribute to an agenda no less than two weeks prior to the meeting.

8.5 Minutes

The FMT will write the minutes of a WAMEP meeting and the Chair and manager of MTU will review the first draft before circulation to the Panel for review and comments. Two voting members will confirm and approve the minutes at the following meeting before circulating to DTCs/MTCs, CPF and WATAG.

The FMT is responsible for the record keeping of the minutes and all official documents of WAMEP in accordance with the [Information Retention and Disposal Policy](#).

9. Out-of-session items review and decision

Members may be requested to review and vote on items out-of-session. A written proposal will be circulated via email to members with a time and date for responses to be returned. The timeframe will be made at the discretion of the Chair on a case-by-case basis with consideration of the nature and urgency. For out-of-session voting to be valid, half the number of voting members plus one is required to respond. The decision will be passed if consensus is supported by the majority of responding voting members. In the case of an equality of votes, the Chair has a casting vote, or the Chair may decide to defer the item for discussion at the next scheduled meeting. Members will be promptly advised by the FMT via email of the outcome.

10. Conflicts of interest (COI)

Each member of WAMEP shall abide by the WA Health [Code of Conduct Policy](#) and [Managing Conflicts of Interest Policy](#) and declare any perceived, potential or actual conflicts of interest (COI) in personal or professional matters of concern. When in doubt, members should declare a conflict even if it does not seem significant. Refer to the table below for definitions as per the [Managing Conflicts of Interest Policy](#).

Table 1. COIs definitions¹

Term	Definition
COI	A situation arising from conflict between the performance of public duty and private or personal interests. Conflicts of interest may be actual, or be perceived to exist, or potentially exist at some time in the future.
Actual COI	There is a real conflict between a Department of Health employee or Health Service Provider staff member's public duties and private interests. Where a person's duties as a member of staff (that is the principal goals of the profession or activity, the duties of public office, the protection of clients, the health of patients, or the integrity of research) may be unduly influenced by a secondary interest (such as a personal or competing professional interest, including secondary employment or office).

¹[Managing Conflicts of Interest Policy](#)

Perceived COI	The public or a third party could form the view that a Department of Health employee or Health Service Provider staff member has a private interest that could improperly influence their decisions or actions, now or in the future, whether or not this is in fact the case.
Potential COI	A Department of Health employee or Health Service Provider staff member has private interests that could conflict with their public duties. This refers to circumstances where it is foreseeable that a conflict may arise in future and steps should be taken now to mitigate that future risk.

10.1 Types of COIs and identifying a COI

Refer to the [Managing Conflicts of Interest Information document](#) for further details about the types of COIs and identifying a COI.

10.2 COIs classification

For the purpose of WAMEP, COIs are classified as either minor or major.

Examples of minor COIs include but is not limited to:

- Previously attended meal/education event paid for by the Sponsor of the medicine under review in the preceding 6 months.

Examples of major COIs include but is not limited to:

- Personal involvement in SMF submission (e.g. applicant, contributor, Head of Department approver).
- Receiving money from the Sponsor of a medicine under review.
- Investigator for clinical trials funded by the Sponsor of the medicine under review.
- Previous employment by a pharmaceutical company for the medicine under review.
- Shares in a pharmaceutical company for the medicine under review.

10.3 COIs declaration

Members are required to:

- complete and sign a declaration of conflicts of interest before the commencement of each meeting on matters pertaining to the prepared agenda, and
- verbally alert the Chair of any other potential conflicts of interest that may arise during the course of a meeting, or in writing for out-of-session matters.

Invited guests, proxies, or other attendees will be required to complete a sign a declaration of conflicts of interests before the commencement of the meeting.

COIs will be recorded by the FMT and reported to the Chair for review.

10.4 Evaluating and managing COIs

The Chair will assess all declared perceived, potential or actual conflicts of interest (COI) and decide on the most appropriate action to take, including developing and documenting a management plan, in accordance with the [Managing Conflicts of Interest Policy](#). Members who declare a COI are required to propose if, and how, the conflict can be managed at the time of declaration. If applicable, once a strategy has been identified the details should be agreed between the member who has the conflict and the Chair. In the instance whereby the Chair has declared a COI, this will be reviewed by the deputy Chair to decide on the most appropriate action. If a COI is declared during a meeting, the Chair will decide on a strategy for dealing with the COI immediately.

10.4.1 Minor COI

Members deemed to have a minor COI may, at the Chair's discretion, receive information pertaining to the relevant agenda item/s and participate in discussions but may not participate in decision making or voting. At the discretion of the Chair, a proxy who is equivalent in terms of expertise and from the same site as the member may be nominated to attend the meeting to enable quorum to be met.

10.4.2 Major COI

Members deemed to have a major COI will not receive any information pertaining to the relevant agenda item/s and will not participate in discussions or vote on the matter. The member will be asked to step out of the meeting for the entirety of the item discussion and this will be recorded in the meeting minutes. At the discretion of the Chair, a proxy who is equivalent in terms of expertise and from the same site as the member may be nominated to attend the meeting to enable quorum to be met. If there is a major ongoing COI that affects a member's ability to contribute and participate in WAMEP processes, they may be required to resign.

10.4.3 Recording and record keeping

All COIs will be recorded in the meeting minutes and the minutes will include details relating to the nature of the conflict, how the conflict was managed and if applicable the times that the member was absent from the meeting due to the conflict.

The FMT will be responsible for the record keeping of the minutes, COI declaration forms and correspondences about the management plan for declared COIs in accordance with the [Information Retention and Disposal Policy](#).

10.5 COI not disclosed

If a COI is found that should have been disclosed for a previous decision made by the Panel, this decision will be re-tabled for deliberation following the COI management plan determined by the Chair.

11. Confidentiality

Each member of WAMEP must be mindful of and respect the confidentiality and/or commercial sensitivity of any information discussed at WAMEP meetings, or in out-of-session communications. Members are required to:

- A. complete and sign a confidentiality statement prior to each WAMEP meeting, and
- B. verbally alert the Chair of any potential breaches of confidentiality that may arise during the course of a meeting, or in writing for out-of-session matters.

Members must make reasonable efforts to prevent the disclosure of any WAMEP meeting or out-of-session content, discussions, or decisions to non-WAMEP members until the meeting minutes have been confirmed by the Panel members, and the FMT has communicated outcomes to all applicants and relevant stakeholders. The FMT will inform members when this has occurred.

Member votes and opinions, and material marked 'confidential' must not be discussed or circulated beyond the WAMEP membership at any time unless approved by the Chair.

The Chair will alert WAMEP members of potential or actual breaches of confidentiality that are reported. The Chair, in consultation with members, will decide on an appropriate action to take following a reported confidentiality breach.

Invited guests, proxies, or other attendees will be required to complete a sign a confidentiality statement before the commencement of the meeting.

12. Communication

Correspondence to WAMEP members is usually by electronic means.

WAMEP decisions may only be communicated following the ratification 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. The FMT will then notify DTCs/MTCs or equivalent authorities and the Chief Pharmacist Forum (CPF) group who may then circulate this information to relevant clinical specialties. A SMF newsletter will also be published on the Formulary One homepage and circulated to DTCs/MTCs and CPF summarising WAMEP's decisions as well as details of the formulary submissions that have been received.

13. Adoption and amendment

The Terms of Reference will be endorsed by WAMEP every second year and updated when necessary. Amendments shall be ratified by WATAG.

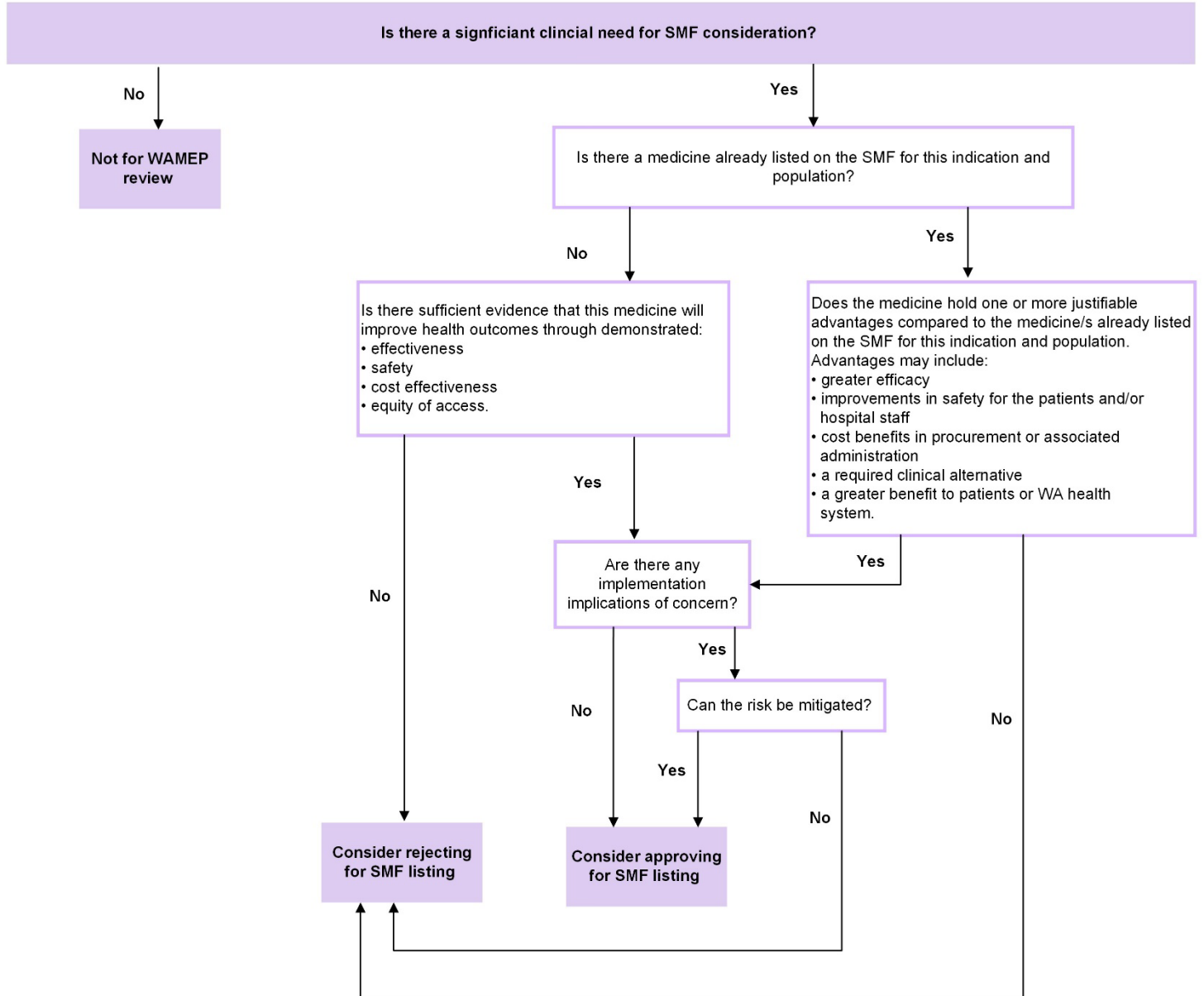
14. Appendix A: Evaluation principles

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



²The 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.

15. Appendix B: Decision framework for evaluating SMF submissions



16. Version control

Version	Date endorsed	Review date	Author	Rationale
1.9	21/03/2024	21/03/2026	Medicines and Technology Unit	Review of voting member positions to address gaps. Update to section 5.9 to clarify appointment requirements.
1.8	23/02/2024	23/02/2026	Medicines and Technology Unit	Name change from WADEP to WAMEP. SMF Governance and Procedures 2021 document superseded with SMF Guidelines 2024. Updated to be in line with the SMF Guidelines 2024 and overall review to ensure relevance and recency.
1.7	2023		Medicines and Technology Unit	Expansion of voting member position options and redefining 'secretariat' to 'Formulary Medicines Team'
1.6	2022		Medicines and Technology Unit	Addition of voting member participation expectations, expansion of voting member position options.
1.5	03/12/2020		Medicines and Technology Unit	Addition of conflict of interest management process details, addition of confidentiality process details.
1.4	28/03/2019		Medicines and Technology Unit	Re-branding with WADEP logo, amendments to WADEP scope.
1.3	16/08/2018		Medicines and Technology Unit	Accountability framework updated.
1.2	12/10/2017		Medicines and Technology Unit	Expansion of voting member positions.
1.1	02/02/2017		Medicines and Technology Unit	Expansion of voting member positions.
1.0	11/02/2016		Medicines and Technology Unit	N/A