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

Western Australian Medicines Evaluation Panel (WAMEP) Terms of Reference

Name

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

Purpose

WAMEP is a multidisciplinary body that governs the Western Australian Statewide Medicines Formulary (SMF) decisions. WAMEP supports safe, cost-effective, equitable, and evidence-based prescribing across the WA health system through evaluating, approving, and maintaining medicine listings on the SMF.

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), an 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. 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.

Panel responsibilities

The panel's responsibilities are to:

- ensure a systemwide approach for systematic, fair, and transparent evidence-based evaluation processes that consider the clinical efficacy, safety, cost-effectiveness, equity of access and implementation implications for additions, amendments, or deletions to the SMF
- consult with expert advisory groups and other clinical experts to inform the evaluation process
- consult Western Australian Therapeutics Advisory Group (WATAG) on decisions that may require 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 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
- provide recommendations to other State and National bodies as requested.

WAMEP's evaluation principles and processes are detailed in the WA Statewide Medicines Formulary Guidelines.

Membership

Member's identity will be confidential to external stakeholders.

Chair

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

Deputy Chair

The Deputy Chair will be nominated and elected from the membership of WAMEP.

Voting Members

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

- at least one senior medical specialist from:
    - 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 doctor in training 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 medication safety representative
- at least one pharmacologist or pharmacology registrar
- one representative from the Department of Health.

Members may represent 2 positions on WAMEP but are limited to a single vote 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.

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.

At a minimum WAMEP shall have at least one corresponding member that are:

- CAHS Neonatal Coordinating Group (CNCG) corresponding member (CM)
- public health practitioner or epidemiologist
- health economists.

Corresponding members are consulted to review agenda items relevant to their specialty 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.

Proxy members

If a current WAMEP voting member anticipates an absence from meetings they may nominate a proxy who is equivalent in terms of expertise and from the same site.

Proxies accepted by the chair count towards the quorum for a meeting and are entitled to participate in panel discussions and decision-making, with the right to vote autonomously on all issues and motions, including in and out-of-session items.

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, they do not have voting rights and do not assume membership.

On occasion, at the discretion of the chair, observers may be invited to attend a meeting.

Appointments

Members may be appointed in relation to their professional expertise, role, and representation of their health service. Suitable experience and expertise in contemporary medicine management within the public hospital system and highly developed analytical skills to undertake a critical appraisal of evidence for SMF applications is required for appointment. Appointments require WAMEP approval following an expression of interest process.

The Chair and members will be appointed for an initial term not exceeding 3 years, at which point the position will be eligible for renomination and reappointment. Members will be eligible for reappointment provided the member still fulfils their appointed role and their responsibilities as a voting member, as outlined in Section 6.

Members roles and responsibilities

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 must 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.

Deputy chair

In the chair's absence, the deputy chair will fulfil all chair responsibilities.

Acting chair

If both the chair and deputy chair is absent, an acting chair may be elected by members to enable work of the panel to continue.

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.

Voting members are expected to review up to 3 submissions per year and are asked on a rotational basis.

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

Formulary Management Team (FMT)

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, and 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 for 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.

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.

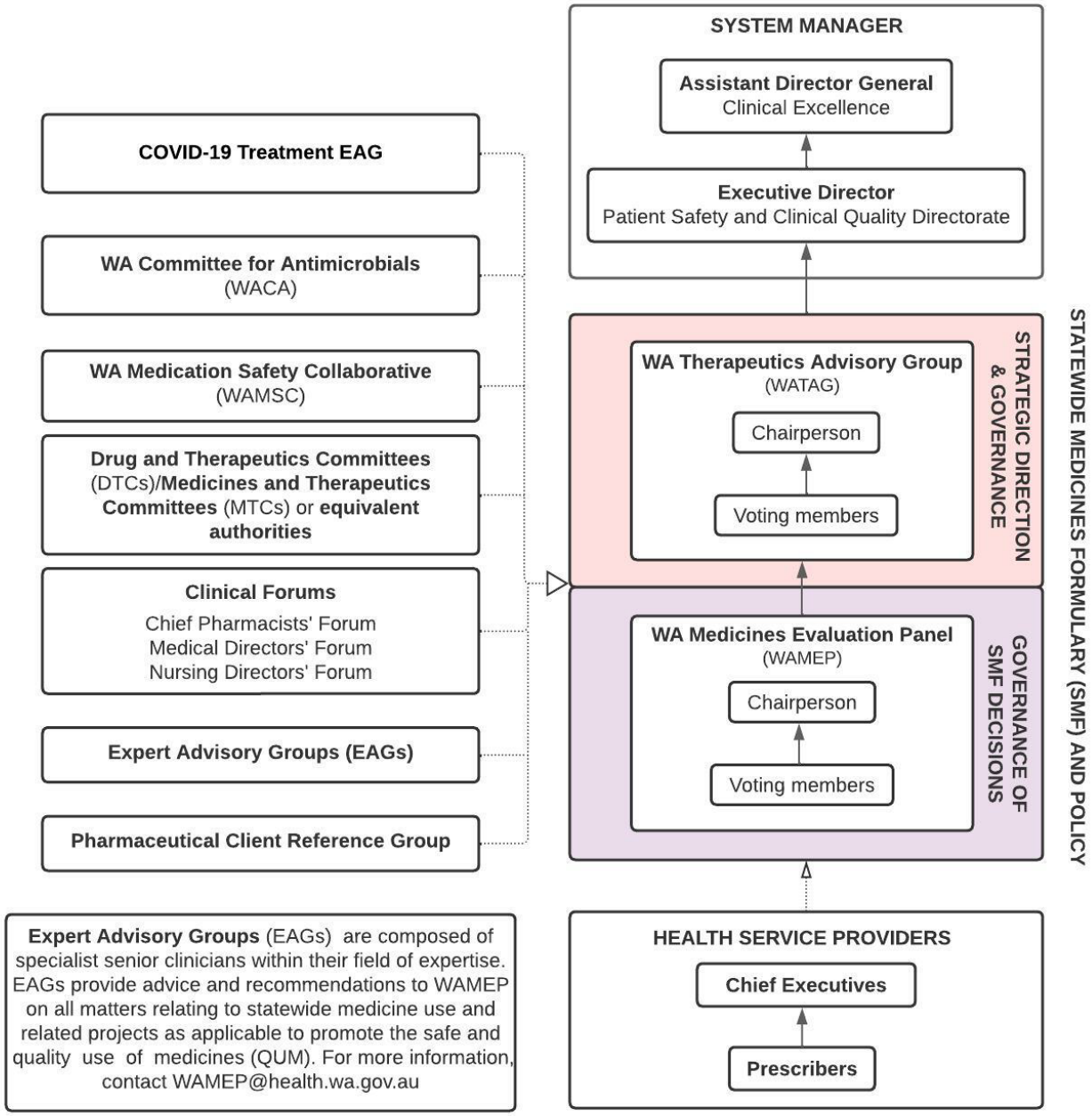
Annual reporting

The FMT, in consultation with the Chair and MTU Manager, will provide an annual summary on the activities of WAMEP at the end of each calendar year to the Executive Director of Patient Safety and Clinical Quality Directorate.

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).

Figure 1. Accountability structure of the SMF



Meetings

Frequency, duration and location

WAMEP meets approximately every 6 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.

Quorum

Quorum is required to conduct the business of the meeting. Quorum is attained when half plus one of voting members are in attendance. If quorum is not met:

- 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 voting at the next scheduled meeting when a quorum is present to formalise decisions.

Decisions and recommendations

The panel will review, discuss, and provide a decision based on voting. Provided that quorum is met, decisions and recommendations will be passed if supported by the majority of voting members in attendance.

Voting

All voting members or approved proxies present at meetings, including the chair, have a single vote (regardless of the number of positions the member holds on the committee). In the case of equal votes, the Chair has a casting vote.

Out-of-session resolutions

The Chair may elect to determine WAMEP's position by an out-of-session vote. Refer to the out-of-session items review and decision section for further information.

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.

Minutes

The FMT will write the minutes of a WAMEP meeting and the Chair and MTU Manager will review the first draft before circulation to the Panel for review and comments. The minutes require endorsement at the following meeting.

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.

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 decision will be passed if quorum is met, and the item is supported by the majority of responding voting members. In the case of equal votes, the Chair has a casting vote, or the Chair may decide to defer the item for discussion at the next scheduled meeting.

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 Table 1 for definitions as per the Managing Conflicts of Interest Policy.

Table 1. COIs definitions[1]

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.

Examples of material COIs pertaining to WAMEP decisions include but are 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.

COIs declaration

Members are required to:

A. complete and sign a declaration of conflicts of interest before the commencement of each meeting on matters pertaining to the prepared agenda, and
B. verbally alert the Chair of any other potential conflicts of interest that may arise during 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.

Evaluating and managing COIs

The chair will assess all declared perceived, potential or actual conflicts of interest (COI) to determine if any action is required including developing and documenting a management plan, in accordance with the Managing Conflicts of Interest Policy. 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.

Members deemed to have a material COI will not receive any information pertaining to the relevant agenda items 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. If there is an ongoing COI that affects a member's ability to contribute and participate in WAMEP processes, they may be required to resign from the panel.

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.

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.

Confidentiality

WAMEP papers and discussions are confidential. Members, proxies, and invited guests are required to:

- complete and sign a confidentiality statement prior to each WAMEP meeting
- alert the chair of any potential breaches of confidentiality.

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.

Communication

WAMEP decisions may only be communicated following the confirmation of the WAMEP meeting minutes by the chair. The applicant of the SMF submission will be notified of the outcome via email. A SMF newsletter will be circulated and published on the Formulary One homepage summarising WAMEP's decisions.

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.

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1. Version control

Version	Date endorsed	Review date	Author	Rationale
2.0	07/05/2026	07/05/2028	Medicines and Technology Unit	Contemporising content
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.

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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

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