

TERMS OF REFERENCE

South Australian Medicines Evaluation Panel (SAMEP)

The South Australian Medicines Evaluation Panel (SAMEP) is a Sub-Committee of the South Australian Medicines Advisory Committee (SAMAC):

1 Aim

The aim of the South Australian Medicines Evaluation Panel (SAMEP) is to increase the efficiency of funding of medications and promote equity of access to medicines for patients in South Australian public hospitals by evaluating high cost medicines for use in the South Australian Public Health Sector.

2 Purpose

The role of the South Australian Medicines Evaluation Panel (SAMEP) is to:

- > evaluate the safety and effectiveness of medicines referred to it that are proposed for inclusion in the Statewide Formulary for High Cost Medicines;
- > initiate reviews to evaluate the safety and effectiveness of high cost medicines which are not registered for use within Australia, for the purpose of providing guidance to local hospital drug committees for individual patient use (IPU) requests;
- > initiate reviews to evaluate the safety and effectiveness of any high cost medicine at their discretion;
- > recommend to the Chief Executive Council of the Department of Health *via* the South Australian Medicines Advisory Group (SAMAC) whether there are sufficient grounds to list any medicine, the conditions of listing, and (if required) guidelines for the use of the medicine;
- > facilitate collaborative monitoring of medicines use in South Australian hospitals with regards to high cost medicines.

3 Operation

- > Submissions to SAMEP are received from a Drugs and Therapeutics Committee (DTC) of any SA public hospital, or in the case of hospitals not supporting such a committee the Chairperson of the Clinical Advisory Committee or equivalent committee. SAMEP may also undertake analysis of medicine use with the SA Public Health Sector and horizon scanning activities to determine medicines suitable for statewide evaluation.
- > Applications to SAMEP are assessed according to pre-defined clinical and economic criteria that will form the basis of a recommendation for or against formulary listing to SAMAC. Positive recommendations are referred to the SA Health Chief Executive Council to ensure affordability and corporate oversight of the recommended high-cost medicine listing. This recommendation and its basis are examined by the SA Health Chief Executive Council and if thought fit, the medicine will be included on the Statewide Formulary for High Cost Medicines.
- > Where a review of a medicine is a SAMEP-initiated evaluation of an unregistered medicine (medicines accessed through the Special Access Scheme (SAS)), SAMEP will forward their recommendations regarding appropriate use to SAMAC for approval. If the recommendation is approved by SAMAC, guidance will be distributed to local hospital drug committees to assist with decision making on receipt of IPU requests for the medicine.
- > A positive recommendation must be approved by SA Health Chief Executive Council for a high-cost medicine to be listed at any public hospital for the specified indication.
- > Applicants may make a formal appeal to SAMAC against unfavourable recommendations as per the process set out in the SAMAC terms of reference.



- > Re-applications may be considered by SAMEP if there is new evidence supporting the application or a change in clinical or reimbursement context that merits reconsideration.

4 Membership

With the approval of SAMAC, membership of the SAMEP may include:

- > 8 senior clinicians with expertise in medicine use (including clinical pharmacology, rheumatology, oncology, haematology, paediatrics, but may include other specialty areas of practice such as microbiology/infectious diseases, immunology, etc);
- > 3 Pharmacy clinicians;
- > 2 Health economists;
- > 2 Consumer representatives;
- > 1 Medical ethicist.

Membership of SAMEP should be broad ranging and include representation from different SA Health hospitals. SAMEP may co-opt additional members for specialist expertise and advice and/or from Working Groups, as required.

4.1 Appointments

Members are selected on their demonstrated interest and expertise, rather than representation. Selection of potential members of SAMEP can be made by SAMAC and invited by the Chair of SAMAC. Members can also be recruited via Expression of Interest processes or at the suggestion of current members to fill the needs of the committee.

The Chairperson is elected by SAMAC.

4.2 Length of Membership

The term of membership for committee members is three years. Membership is revised annually by the Chief Executive of the Department of Health, or his/her delegate, in conjunction with the Chairperson to ensure that there is ongoing renewal of the committee and to ensure that appointment of new members is spread over a period of time.

The term of appointment for the Chairperson is three years.

4.3 Temporary Vacancies/Relevant expertise

Temporary vacancies may be filled at the discretion of the Chairperson and, when called for, the Chairperson may invite persons with relevant expertise to provide input on selected issues.

5 Secretariat

An Executive Officer is provided to the SAMEP by SAMAC. Medicines and Technologies Policy and Programs, SA Health, is responsible for the management of the secretariat and coordination of SAMEP's activities in conjunction with SAMAC.

The SAMEP Executive Officer shall be an *ex-officio* member of the committee. The Executive Officer shall be entitled to attend meetings, and be heard at such meetings, but not entitled to vote. The Executive Officer shall act as Committee Secretary and record and prepare minutes of meetings.

SAMEP also has the authority to commission independent reports on the cost-effectiveness of medicines on its agenda, subject to agreement in principle and funding from the Department of Health. Additional support staff appointments may also be made to support the activities of SAMEP, as required.

6 Reporting Arrangements

SAMEP's Chairperson is responsible to SAMAC and to the SA Department of Health and formally reports on performance to SA Health Chief Executive Council *via* SAMAC.

7 Funding

Recurrent annual funding is provided by the SA Department of Health for each financial year (1 July to 30 June), paid to, and managed by the Medicines and Technologies Policy and Programs Branch of the Department of Health.

8 Meetings

8.1 Meetings Schedule

Meetings are generally held bimonthly (6 times per year), or as determined by the Chairperson and Executive Officer. Issues requiring attention in the interim are addressed by processes determined appropriate by the Chairperson and secretariat. This usually entails email discussion with members, but may include an additional meeting.

8.2 Attendance

Members should table an apology if unable to attend. Attendance by a proxy is not usual practice, but may be at the discretion of the Chairperson.

8.3 Access

SAMEP meetings are restricted to committee members, members of SAMAC, invited guests and committee support staff.

8.4 Conflicts of Interest

Each member of SAMEP shall abide by the *Code of Ethics for South Australian Public Sector* and declare any potential conflict or duality of interest in matters of concern to the committee (or sub-committee). SAMEP members shall:

- a) verbally declare any potential conflicts of interest at the commencement of each meeting on matters pertaining to the prepared Agenda;
- b) alert the Chairperson of any other potential conflicts of interest that may arise during the course of a meeting.

Invited guests or attendees shall complete and sign a Declaration of Potential Conflicts of Interest at the commencement of any meeting attended.

Where a potential conflict of interest has been declared, the Chairperson shall determine how to proceed and advise the meeting accordingly. In the event that the Chairperson has a Conflict of Interest with an item on the agenda a temporary Chairperson may be appointed for that item or meeting.

8.5 Quorum

The quorum exists when half the members are present, including the Chairperson. If a meeting of members does not have a quorum within twenty minutes after the commencement time for the meeting, the meeting may proceed informally or be adjourned to a date and time determined by the Chairperson.

8.6 Chairing of Meeting

The Chairperson may nominate an Acting Chairperson from the membership, or if no arrangement has been made, an Acting Chairperson may be chosen by those members present, to permit the work of the Committee to continue in the Chairperson's absence.

8.7 Resolutions

Recommendations and other resolutions from SAMEP shall be passed by a majority of the members present. A resolution made while a meeting is proceeding informally (see 8.6) shall not be final but will require to be confirmed by a later meeting at which a quorum is present.



8.8 Voting

The Chairperson shall not have an ordinary vote. In case of an equality of votes, the Chairperson shall have a casting vote. The Chairperson may call for a vote on any matter requiring resolution, and may have the vote taken again if in doubt as to the result, or to have the vote counted. Voting will normally be by voice or show of hands, but may be by secret ballot if requested by any member. Members must be present when a question is completely put to be eligible to vote.

8.9 Out-of-session Resolutions

To resolve some matters in a timely manner, the Chairperson may elect to determine the committee's position by way of out-of-session vote. A written proposal(s) will be circulated to members, usually by email and a time and date will be specified for responses to be returned. A resolution shall only be made if supported by a majority of responding members. Voting will be valid only if a minimum of eight members respond. In case of an equality of votes, the Chairperson has a casting vote, or the Chairperson may elect to defer the matter for full discussion at the next regular meeting. Members will be advised promptly of the outcome of any out-of-session resolutions.

8.10 Agenda

Preparation of the Agenda for each meeting shall be prepared by the Chairperson and the Executive Officer. The Agenda for regular meetings shall be made available to members by e-mail at least seven days before each meeting.

Copies of all documents associated with a meeting shall accompany the Agenda or be tabled at the meeting. Documents for information or noting may be circulated to members upon receipt and in advance of a meeting, to be noted during the proceeding of a meeting.

8.11 Minutes

Draft Minutes shall be distributed to members after the meeting where they were recorded. Minutes must include the date, time and place of meeting. Details of attendance and apologies must be recorded accurately. Items will be written in the order in which they appear in the Agenda, irrespective of the order in which they were discussed during a meeting.

Resolutions shall be recorded accurately and numbered sequentially for each calendar year. Any actions to be taken shall also be recorded, together with the initials of the member(s) responsible for completing the action.

Minutes shall be confirmed at the next scheduled SAMEP meeting with a quorum, and stored in accordance with SA Health policies for record storage.

Minutes of all Committee meetings will be recorded, and kept at the SAMAC office. Other SAMEP documents, except accounting records will be maintained at the SAMAC office. Accounting records will be kept with the host organisation.

9 Communication

Usually, committee correspondence will be by electronic means. A database of members' contact details shall be maintained by the Executive Officer.



10 Confidentiality

All papers relating to the activities of SAMEP are confidential. All SAMEP members must sign a confidentiality agreement at the commencement of membership and must not disclose any information discussed at meetings, or otherwise relating to the activities SAMEP. All working documents and papers are for the exclusive use of the SAMEP members and are not to be copied or circulated, with the exception of reports submitted to SAMAC.

11 Annual Report

The Executive Officer and Chairperson shall provide an annual report to SAMAC each year or biennially if approved by the Chair of SAMAC

12 Review

The committee shall review its performance and terms of reference every three years.

For more information

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