

Directive: compliance is mandatory

Statewide Formulary for High Cost Medicines

Objective file number:

Policy developed by: South Australian Medicines Advisory Committee

Approved at Portfolio Executive on: 02 June 2011

Next review due: 02 June 2013

Summary

To establish a High Cost Medicines Formulary to ensure equity of access to High Cost Medicines across SA public hospitals. To establish an expert panel of clinicians, pharmacists, economists, and an ethicist and consumer representative to evaluate the clinical efficacy and cost-effectiveness of High Cost Medicines used within South Australian public hospitals.

Keywords

High Cost Medicines, High Cost Drugs, Statewide Formulary, SAMEP, SADEP, medicines evaluation, drug evaluation, South Australian Medicines Evaluation Panel, Individual Patient Use

Policy history

Is this a new policy? **Y**
Does this policy amend or update an existing policy? **N**
Does this policy replace an existing policy? **N**
If so, which policies?

Applies to

All SA Health Portfolio

Staff impact

All Clinical, Medical, Nursing, Allied Health

PDS reference

D0229

Version control and change history

Version	Date from	Date to	Amendment
1.0	02/06/2011	Current	Original version

1 Definitions

For the purposes of this policy, the following definitions apply:

1.1 High Cost Medicines

Those medicines for which the predicted expenditure is:

- ≥\$10,000 per patient per treatment course or per year; or
- ≥\$100,000 for an individual hospital per year; or
- ≥\$300,000 within the SA public health system per year.

Exemptions:

- medicines to be used in a clinical trial that have been approved by the hospital's Drug and Therapeutics Committee and Ethics Committee and paid for by the sponsor of the clinical trial; or
- medicines funded by a pharmaceutical company as part of a Medicines Access Program for that medicine, which are covered under another SA Health policy; or
- medicines listed under the Pharmaceutical Benefits Scheme (section 85 or section 100) used in accordance with the PBS criteria for subsidy; or
- medicines funded under the Commonwealth's Life Saving Drugs Program; or
- low cost medicines which represent a high cost due to high volumes of use (e.g. sodium chloride for injection).

1.2 Statewide Formulary

A list of High Cost Medicines and their indications and other restrictions, if applicable, specifying which medicines have been approved to be prescribed in South Australian Public Hospitals and Health Services developed based on evaluations of efficacy, safety, and cost-effectiveness of medicines.

2 Policy

A statewide formulary for High Cost Medicines (Formulary) will be established, specifying which High Cost Medicines may be funded for use within South Australian public hospitals.

Medicines currently in use within South Australian public hospitals which meet the definition for High Cost Medicines will be grandfathered onto the initial formulary, subject to a review process. New medicines or new indications for medicines meeting the definition of a High Cost Medicine will be subject to a robust evaluation process to determine Formulary listing. In emergency situations, High Cost Medicines that have not yet been evaluated for a particular indication may be approved for Individual Patient Use. Where a decision has been made to not list a High Cost Medicine on the Formulary for

a particular indication, that medicine may not be funded by SA Health for that indication within any South Australian public hospital.

Individual hospitals will have processes in place to consider a medicine that has not been approved for inclusion on the Formulary for a particular indication or approved for Individual Patient Use (IPU) to be administered to a patient who elects to pay for themselves.

Treatment guidelines for the use of the High Cost Medicine will be specified as part of the evaluation process. The treatment guidelines will be placed on the Department of Health website. Having treatment guidelines readily available on the website will facilitate equitable access to the medicines that are included in the Formulary.

2.1 Purpose

The implementation of a Statewide Formulary for High Cost Medicines aims to address the four key concerns about use of High Cost Medicines in South Australian Public Hospitals:

- Ensuring equity of access to South Australians in the public health system
- Ensuring that cost-effective medicines are used within SA Health
- Ensuring there is less duplication of effort in assessing High Cost Medicines
- Ensuring that High Cost Medicines are used in accordance with specific guidelines

3 Background

Quality use of medicines is fundamental to good health care. Appropriate use of medicines can improve the quality of life as well as prolong life. However over recent decades with advances in pharmaceutical science, the range of medicines, their indications for use, and in certain instances, their costs have increased. High cost medicines present a significant cost pressure for South Australian Public Hospitals. This pressure has increased over the last decade and is unlikely to diminish in the face of development of new High Cost Medicines and the emergence of new indications for existing High Cost Medicines.

Variable and inconsistent decision making by individual hospitals (due to variation in the assessment process, variation in evidence requirements for clinical effectiveness and cost effectiveness, and pressures to approve medicines for individual patient use) can result in some hospitals providing access to certain High Cost Medicines while other hospitals do not. Additionally, local decision making results in duplication of efforts and is often lacking in optimal resources to perform a robust High Cost Medicine evaluation. Patient access to clinically-appropriate and cost-effective High

Cost Medicines should not be dependent on which hospital the patient attends.

Development and maintenance of a Statewide Formulary for High Cost Medicines (Formulary) is seen as the most appropriate mechanism for addressing these concerns.

4 Scope

Only High Cost Medicines that are listed on the Formulary or approved for emergency Individual Patient Use under the provisions outlined in this policy will be able to be funded by SA Health for use within South Australian Public Hospitals.

5 Responsibility

5.1 SA Department of Health will be responsible for:

- Providing recurrent annual funding to Pharmaceutical Services and Strategy, SA Health, to support strategic SA Health medicines committees including the South Australian Medicines Advisory Committee (SAMAC) and the South Australian Medicine Evaluation Panel (SAMEP).

5.2 The Chief Executive, SA Department of Health will be responsible for:

- Approving the initial Formulary;
- Issuing instruction to SA public hospitals and health services indicating whether or not specific High Cost Medicines may be used and what restrictions and conditions there are on its use.

5.3 Portfolio Executive (PE), SA Department of Health will be responsible for:

- Considering the proposed initial Formulary;
- Assessing the affordability within the SA Public Health System of High Cost Medicines recommended for inclusion on the Formulary by SAMAC
- Determining inclusion of new medicines on the Formulary based on the recommendations of SAMAC. Making a final decision on affordability and formulary inclusion.

5.4 Pharmaceutical Services and Strategy (PSS), SA Department of Health will be responsible for:

- Coordinating the compilation of the initial Formulary;
- Overseeing the communications regarding the Formulary;
- Providing secretariat support to SAMEP and SAMAC;

- Reviewing the overall Statewide Policy on High Cost Medicines after two years of operation.
- 5.5 The South Australian Medicine Evaluation Panel (SAMEP) will be responsible for:
- Recommending the initial Formulary list;
 - Considering applications of medicines proposed for listing on the Formulary;
 - Performing evaluations of new medicines considered for listing on the Formulary and provision of recommendations to SAMAC;
 - Considering treatment guidelines for medicines listed on the Formulary;
 - Establishing and maintaining WebPages for the Formulary in conjunction with the Department of Health;
 - Overseeing a statewide database for individual patient use approvals of high cost medicines;
 - Biannual reviews of medicines included on the Statewide Formulary for High Cost Medicines (or earlier if appropriate);
 - Biannual reviews of the process for listing of new medicines on the Statewide Formulary for High Cost Medicines.
- 5.6 The South Australian Medicines Advisory Committee (SAMAC) will be responsible for:
- Considering SAMEP recommendations for medicines proposed for inclusion on the Statewide Formulary for High Cost Medicines and providing recommendations to PE.
- 5.7 The Chief Medical Officer, SA Health will be responsible for:
- Considering Individual Patient Use (IPU) requests for the use of High Cost Medicines referred by SA public hospital DTCs.
- 5.8 The Chief Pharmacist, SA Health will be responsible for:
- Considering Individual Patient Use (IPU) requests for the use of High Cost Medicines referred by SA public hospital DTCs;
 - Leading a review of the Policy on a *Statewide Formulary for High Cost Medicines*.
- 5.9 The Communications Division, SA Department of Health will be responsible for:
- Assisting PSS in the communications regarding the Formulary and decisions reached by SAMEP;
 - Assisting the CE, SA Health, in issuing instruction to SA public hospitals and health services indicating whether or not specific High Cost Medicines may be used and what restrictions and conditions there are on its use.

- 5.10 SA Public Hospital Chief Executive Officers will be responsible for:
- Developing site specific auditable procedures regarding access to High Cost Medicines on the Formulary.
- 5.11 SA Public Hospital/Regional Drug and Therapeutics Committee/Clinical Advisory Committee Chairpersons will be responsible for:
- Referring applications for medicines proposed for inclusion on the Formulary SAMEP;
 - Considering Individual Patient Use (IPU) applications for High Cost Medicines not listed on the Formulary;
 - Contacting the Chief Medical Officer or Chief Pharmacist, SA Department of Health, for IPU approval High Cost Medicines in the case of a fourth request for a specific indication or the cost of the medicine exceeds \$50,000 per patient per treatment course or per year;
 - Providing 6 monthly reports to SAMEP of all High Cost Medicines used within their hospital/health service(s).

6 Risks

Delays in the decision making process for listing of High Cost Medicines on the Formulary may result in a high number of Individual Patient Use requests. This risk can be mitigated by ensuring a timely decision making process and by horizon scanning for new High Cost Medicines likely to impact on South Australian public hospitals.

Unfavourable decisions not to list certain medicines on the Formulary may result in perceived inequities for patients wanting to access High Cost Medicines. This risk will be mitigated by ensuring a robust and transparent evaluation process, and a bi-annual review of medicines listed on the formulary

7 Detail

7.1 High Cost Medicines Already in Use in South Australian Public Hospitals

Medicines meeting the above definition of a High Cost Medicines that are currently being used in South Australian Public Hospitals (either on an individual patient basis or in a specific patient group) will be included in the initial formulary subject to review. Pharmaceutical Services and Strategy will oversee the compilation of the initial formulary by the South Australian Medicine Evaluation Panel (SAMEP).

The proposed Formulary will be submitted to the Portfolio Executive for consideration. The Chief Executive would approve the Formulary before it is published.

7.2 Accessing High Cost Medicines

The process for accessing High Cost Medicines is summarised in **Appendix 1**. A list of medicines included on the Formulary and their treatment guidelines will be placed on the SA Health website (see 6.7). Having treatment guidelines readily available on the website will facilitate equitable access to the medicines that are included in the Formulary.

Each facility/hospital will be required to develop auditable site specific procedures regarding the access to High Cost Medicines listed on the Formulary.

If a High Cost Medicine is not listed on the Formulary, a prescriber may submit a request for Individual Patient Use (IPU) of the medicine (see section 7.3) and/or an application for the medicine to be listed on the Formulary (see section 7.5).

Under the National Healthcare Agreement Rules, SA public hospitals are only permitted to charge Medicare eligible patients (public or private) for pharmaceuticals upon discharge or for outpatients.

Under exceptional circumstances where a patient wishes to self-fund the cost of their own medicine, a hospital may consider the administration of a medicine to a patient for whom an IPU request has not been granted provided due processes have been followed to ensure that it is safe and appropriate to do so.

7.3 Individual Patient Approvals for Use of High Cost Medicines

Where a High Cost Medicine is to be used in an emergency on an individual patient basis there will be the ability for the Chair of the relevant regional/hospital Drug and Therapeutics Committee, or their delegate, to consider use of the medicine, as summarised in **Appendix 1**. Applications will be made on the standard *Request for Individual Patient Use (IPU) High Cost Medicines Form*. Requests should be forwarded to the secretary of the hospital Drug and Therapeutics Committee, and if the request is urgent, it should be immediately forwarded to the committee Chair. If the request for use is not urgent, the application for individual patient approval will be considered by the hospital Drug and Therapeutics Committee.

It should be noted that a rejection for the emergency use of a High Cost Medicine in an individual patient, does not preclude the prescriber making a separate application for the medicine to be considered through the standard submission process for the addition of new High Cost Medicines to the statewide formulary as outlined below.

After the third approval for emergency use of individual patient use for a High Cost Medicine is made for a specific indication within SA Health, or the cost of the medicine exceeds \$50,000 per patient per treatment course or per year, approval must be sought from the Chief Medical Officer or the Chief Pharmacist of the Department of Health, or their delegate, prior to use of the High Cost Medicine for any further emergency individual use.

In addition, the issue should be referred to SAMEP for consideration for statewide evaluation.

A database will be established to include all individual patient requests for High Cost Medicines within all SA Public Health facilities.

7.4 South Australian Medicine Evaluation Panel

The South Australian Medicines Evaluation Panel (SAMEP) will perform evaluations of High Cost Medicines proposed for listing on the Formulary and provide reports of these evaluations to South Australian Medicines Advisory Committee (SAMAC).

SAMEP will comprise members with clinical and medicine evaluation expertise and a consumer representative. The Executive Officer will provide administrative support for SAMEP. Advice from experts may be required and may be obtained on a consultancy basis. All members of SAMEP must ensure any potential conflicts of interest are declared. The Chair will make sure these are documented, and will determine whether a member should participate in the evaluation based on the determinations of conflict of interest as outlined in the *SAMAC guidelines for determining conflict of interest*.

7.5 Submissions for Addition of New High Cost Medicines to the Formulary

The process for addition of a new High Cost Medicine to the Formulary is summarised in **Appendix 1**.

A prescriber wanting to use a new High Cost Medicine or seeking a change to an existing formulary listing would direct their request to the hospital Drug and Therapeutics Committee (DTC), or in the case of hospitals not supporting such a committee, to the Chairperson of the Clinical Advisory Committee or equivalent committee. The DTC (or equivalent) would refer submissions for Formulary listing to SAMEP for consideration of whether statewide evaluation will be required.

The submissions must be made on the standard *Statewide Formulary for High Cost Medicines Submission Form* and submitted either electronically, or in hard format to the SAMEP Executive Officer.

SAMEP will canvass all hospitals to determine likely or potential use of the medicine. If statewide evaluation is appropriate a statewide evaluation group will be convened.

Medicines which are, or are likely to be marketed at a total cost meeting the definition of a High Cost Medicine should not be purchased by hospitals pending consideration by SAMEP, with the exception of supply to individual patients approved to use the medicines or where the supply will be funded via the PBS, a clinical trial or a compassionate use program. Hospitals should

institute a mechanism to avoid unofficial use of High Cost Medicines outside of the Formulary process.

7.6 Providing a Recommendation to the Department of Health

SAMEP will provide a report of High Cost Medicine evaluations to SAMAC, which includes recommendations for or against Formulary listing a protocol use of the medicines.

After considering the recommendations from SAMEP, SAMAC may seek further information or consideration by SAMEP if appropriate.

A report on the evaluation including a recommendation for, or against inclusion of the medicine on the formulary with details of required restrictions on prescribing and specific indications for use will be provided to Portfolio Executive (PE) for consideration.

Positive recommendations are referred to PE to ensure affordability and corporate oversight of the recommended High Cost Medicine listing. A positive recommendation must be approved by PE for a High Cost Medicine to be listed at any public hospital for the specified indication. Approval by PE does not constitute an offer of additional funding for any institution. Health services and applicants should access internal mechanisms to resolve resource implications of a newly approved and listed medicine.

The Chief Executive, SA Health, will issue an instruction to the hospitals indicating whether or not the medicine can be used and any relevant restrictions and/or conditions there are on its use and this information will be published on the SA Health Website.

Treatment may be continued for patients who are already being treated with a medicine rejected for listing on the Formulary; however no new patients may be commenced.

7.7 Review

In the event that a submission for a High Cost Medicine is not recommended by SAMAC for formulary listing, applicants will have the opportunity to request a review by SAMAC.

A request for review must be from the applicant only and must identify areas where the applicant believes a decision has been incorrectly made. No new information will be considered – if new information is available, a resubmission is recommended. The applicant will have only one opportunity to request a review.

Applicants should note that the review process is distinct from resubmission. The applicant can resubmit an application for review by SAMEP at anytime providing substantial new information becomes available.

7.8 Formulary WebPages

The list of medicines and their approved treatment guidelines that are included on the Formulary will be placed on the SA Health website. SAMEP will be responsible for the administration of the WebPages.

Medicines that have been evaluated by SAMEP and have not been included on the Formulary will also be listed on the SA Health website with reasons why the medicine was not listed.

7.9 Statewide Recording of High Cost Medicines Usage

Details of use of all High Cost Medicines used in South Australian public hospitals are to be recorded by each hospital. Pharmaceutical Services and Strategy aims to assist hospitals to develop existing dispensing software to include functionality for recording details of High Cost Medicines use at each site so that statewide High Cost Medicine usage may be easily monitored. In the interim, hospitals will be required to develop their own systems for recording High Cost Medicine usage.

7.10 Review

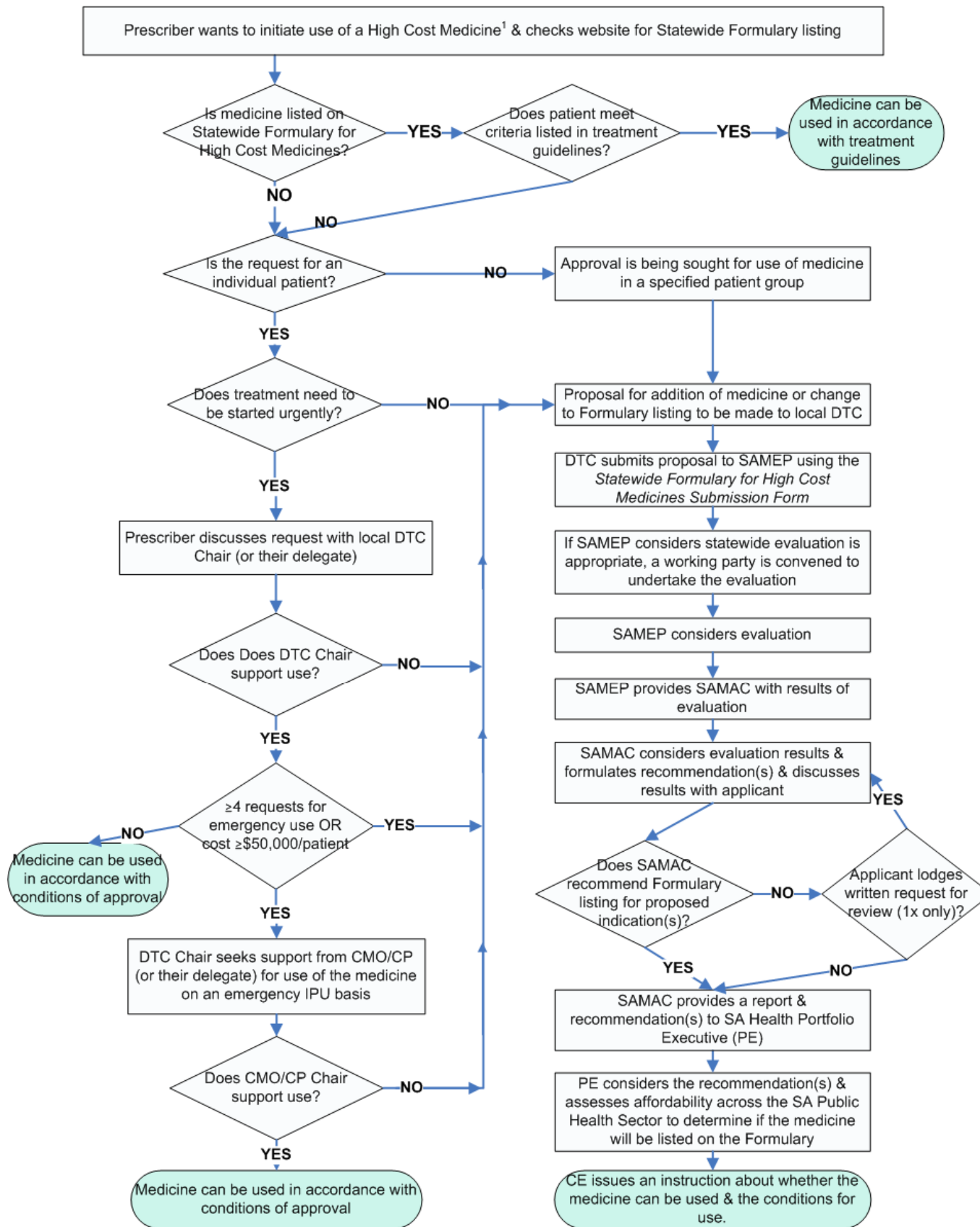
Hospitals using High Cost Medicines will be required to provide a report to SAMEP every six months detailing use of the specific medicine.

SAMEP will undertake a review of the process for listing of High Cost Medicines on the formulary, including stakeholder comments, every two years.

Additions or changes to the Formulary will be reviewed after two years (or earlier if appropriate), if no other source of funding has become available (e.g. section 100 PBS listing) to determine if continued listing is appropriate.

This policy and its operations will be reviewed after two years.

Appendix 1: Process for Accessing High Cost Medicines



¹ **High Cost Medicines** are defined as those medicines for which the expenditure is: $\geq \$10,000$ per patient per treatment course or per year; or $\geq \$100,000$ for an individual health service or hospital per year; or $\geq \$300,000$ within the SA public health system per year. **Exceptions:** medicines being evaluated under a clinical trial with ethics committee approval; medicines used in accordance with PBS approved criteria for subsidy, medicines funded under the Commonwealth's Life Saving Drugs Program.

Abbreviations: CE, Chief Executive; CMO, Chief Medical Officer, CP; Chief Pharmacist; DTC, Drug & Therapeutics Committee; IPU, Individual Patient Use; SAMEP, South Australian medicine Evaluation Panel; SOG, Strategic Operations Group; SAMAC, South Australian Medicines Advisory Committee