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# Medicines Access Programs Policy Directive

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Government of South Australia
SA Health

# Contents

# Medicines Access Programs Policy Directive

## 1. Policy Statement

This policy provides guidance and direction to South Australian Local Health Networks, hospitals and health services to ensure that Medicines Access Programs are governed and monitored appropriately. This includes allowing prescribers the opportunity where clinically appropriate, to use, evaluate, and become familiar with a medicine without putting patients and SA Health services at risk of inappropriate discontinuation of therapy or unanticipated costs at the cessation of a program.

Appropriate governance ensures equity of access and protects patients and providers from medicines access arrangements that may unduly expose them to physical or financial risk.

This policy directive applies to:

- SA Health Local Health Networks, hospitals and health services
- SA Health employees, contractors and consultants.

This policy covers all medicines access arrangements offered by the pharmaceutical industry to facilitate deferred cost, cost-free or subsidised access to medicines for public hospital, Local Health Network and health service patients before relevant funding arrangements are implemented. These include compassionate use, expanded access, product familiarisation, cost-share and all other similarly named access programs. For the purpose of this document, all such programs are collectively referred to as Medicines Access Programs (MAP).

This policy does not apply to products used as part of a registered clinical trial approved by the relevant Human Research Ethics Committee (HREC).

Requirements for access to products other than medicines are covered under relevant SA Health procurement, consumable trials, biomedical engineering (BME) and Health Technology Assessment (HTA) processes and policies, including:

- Approval of products or equipment for routine use (e.g. by the SA Health Biomedical Engineering Service and Procurement Product Standardisation Committee)
- Approval of high risk, high cost health technologies (by the SA Policy Advisory Committee on Technology).

Medicines Access Programs (MAPs) provide patients and prescribers with access to medicines that may be unavailable through other usual funding mechanisms.
Medicines may only be supplied for use by clinicians under SA Health approved conditions and structures e.g. listed on the relevant formulary, approved on an individual patient use (IPU) basis, or approved as part of a MAP.

Appropriate governance ensures equity of access and protects patients, Local Health Networks, hospitals and health services from medicines access arrangements that may unduly expose them to physical or financial risk. As such, the following principles must be adhered to:

Principle 1: the management and oversight of all MAP is delegated to the Local Health Network, hospital or health service Drug and Therapeutics Committee (DTC) or equivalent committee.

Principle 2: appropriate advice regarding the supply of medicines within a MAP must be provided to patients

Principle 3: prescribers must comply with the requirements of the authorising DTC (or equivalent committee) when participating in a MAP

Principle 4: a formal agreement must exist between the pharmaceutical company and the Local Health Network, hospital or health service when participating in a MAP

Principle 5: the responsibilities of all parties involved in the provision of a MAP should be assigned and clear.

## 2. Roles and Responsibilities

**2.1 Chief Executive Officers (or their delegate) of SA Health Local Health Networks, hospitals or health services are responsible for:**

- Ensuring all relevant employees, consultants and contractors are aware of and have access to this Policy Directive.
- Ensuring the implementation of appropriate governance and administrative arrangements to reflect this Policy Directive including completion of pharmaceutical company acknowledgement forms, patient information sheets and prescriber acknowledgement forms.

**2.2 Directors of pharmacy (or their delegate) are responsible for:**

- Ensuring medicines accessed under a MAP across SA Health are supplied in accordance with this policy and used in line with their conditions for approval.
- Ensuring the storage, management and dispensing of medicines accessed under a MAP occurs at the relevant Local Health Network, hospital and/or health service pharmacy in accordance with procedures applicable to other medicines, including provision of information to support appropriate use.

**2.3 Drug and Therapeutics Committees (DTCs) (or equivalent committees) are responsible for:**

- Appropriate governance for access and appropriate use of medicines via MAP within their Local Health Network, hospital or health service.
- Approval of MAP within their Local Health Network, hospital or health service.
- Ensuring prescribers follow the approval requirements described in this policy.
- Ensuring that their hospital pharmacy department agrees with and has the resources to support participation in a MAP.
- Reporting all MAP applications considered to SAMAC in a timely manner usually within 4-6 weeks to enable noting at the next SAMAC meeting.
- Collecting relevant MAP reports from prescribers and forwarding these to SAMAC.
- Ensuring administrative requirements for MAP are met.

**2.4 Prescribers are responsible for:**

- Following the requirements outlined in this Policy Directive.
- Informing patients that the medicine is not routinely available from the Local Health Network, hospital or health service, and that continuing supply is dependent upon continuance of the MAP at the Local Health Network, hospital or health service.
- Advising the patient on the medicine and the MAP. This may include, where appropriate, advising the patient that the medicine is not yet registered with the Therapeutics Good Administration (TGA) for use within Australia.
- Discussing with the patient details of the medicine including dose, frequency, potential adverse effects, duration of treatment and matters such as potential benefits and nature and extent of monitoring (including imaging and invasive procedures).
- Obtaining the patient's written informed consent to the stated conditions of the MAP before the commencement of treatment.
- Documenting the agreement with the patient in their medical record.
- Declaring any actual, potential or perceived conflict of interest to the DTC (or equivalent committee) for each MAP.
- Submitting reports as detailed in this policy.

- Limiting enrolment into a Product Familiarisation Program (PFP) to a maximum of 10 patients and as otherwise approved by the Drug and Therapeutics Committee for other MAP.
- Reporting adverse drug reactions to the TGA through the Australian Adverse Drug Reaction Reporting System (the ADRS) and through the Local Health Network, hospital or health service adverse drug reaction reporting procedure.
- Completing the *Medicines Access Program Prescriber Acknowledgement Form*.

**2.5 The South Australian Medicines Advisory Committee (SAMAC) is responsible for:**

- Recording a register of MAP in use within SA Health.
- Providing oversight and governance of access to medicines within SA Health, when applicable.

## 3. Policy Requirements

### 3.1 Management and Oversight

3.1.1 Any MAP must be approved by the Local Health Network, hospital or health service DTC (or equivalent committee) before commencement. Before approving a MAP, the DTC (or equivalent committee) must be satisfied that the program complies with the provisions outlined in this policy, in particular section 3.2 (Conditions for Approval).

Clinicians are encouraged to discuss with the Local Health Network, hospital or health service DTC (or equivalent committee) prior to commitment of the proposed MAP treatment to the patient.

3.1.2 The Local Health Network, hospital or health service Executive, DTC (or equivalent committee), Director of Pharmacy or prescriber may decline to participate in a MAP depending on local circumstances and available resources.

3.1.3 An *Individual Patient Use (IPU) Medicine application* may be required by the Local Health Network, hospital or health service DTC (or equivalent committee).

### 3.2 Conditions for Approval

3.2.1 Any MAP is subject to a formal agreement between the Local Health Network, hospital or health service DTC (or equivalent committee)and the sponsor (the supplying pharmaceutical company) to ensure uninterrupted supply, free of charge (or as otherwise approved by the DTC [or equivalent committee]) until the product is made available through a formal funding mechanism (e.g. Pharmaceutical Benefits Scheme (PBS) or formulary listing), for as long as the patient's treating clinician determines that there is a clinical benefit and, the medicine remains available in Australia.

- This agreement must be documented by completing the *Medicines Access Programs Pharmaceutical Company Acknowledgement Form*. The completed form must be returned to the Local Health Network, hospital or health service DTC (or equivalent committee) prior to supply of medicine to the patient.

3.2.2 If the medicine is a chemotherapy medicine being used for the treatment of cancer, additional governance processes may be required. Please refer to the *SA Health Cancer Drug Committee* and the *Cancer Services – State-wide Cancer Chemotherapy Policy Directive*.

3.2.3 Patients must be informed that the medicine or treatment is being provided under a MAP and that it is not routinely available from the Local Health Network, hospital or health service. Patients must also be informed that if the MAP ceases and the medicine is no longer available through the Local Health Network, hospital or health

service they may be required to transfer to an alternative treatment, or to obtain ongoing private supply from another source.

- Patients are required to agree to treatment under these conditions. The agreement must be documented in their medical record by completing the *Medicines Access Program Patient Consent Form*. The form includes space for patient and if needed a witness signature. A witness may be required in the case of guardianship (for children).
- Patient consent must be obtained and retained in the patient's medical records.

3.2.4 Prescribers must declare any actual, potential or perceived conflict of interest to the Local Health Network, hospital or health service DTC (or equivalent committee) for each MAP in which they are involved. Prescribers must have the approval of the Local Health Network, hospital or health service DTC (or equivalent committee) to participate in a MAP.

- This agreement must be documented by completing the *Medicines Access Program Prescriber Acknowledgement and Declaration Form*. The form includes space for doctor and if needed a witness signature. A witness may be required in the case of guardianship (for children).
- An application for a MAP must be completed by a consultant. The prescription may be written by the consultant or a qualified delegate.

3.2.5 Clinicians who have outstanding MAP outcome reports (section 3.6) that have not been submitted to the relevant approval committee may not be granted approval for future MAP until the report(s) have been submitted.

### 3.3 Additional requirements applicable to specific medicines access program

3.3.1 **Product Familiarisation Programs (PFP)**: Any applications for a PFP within the Local Health Network, hospital or health service must conform to the proposed PBS listing and any restrictions within the requested indication.

As per the *Medicines Australia Code of Conduct* individual prescribers are limited to enrolling a **maximum of 10 patients** into a PFP. Other MAP do not usually have a limit on the number of patients that may participate in a program however local governance may limit patient numbers if deemed appropriate

3.3.2 **Cost-share programs (CSP)** should not be encouraged. It is preferable that a price reduction is negotiated with the supplier by the relevant SA Health procurement area. Negotiations at a state wide level are preferred to ensure equity of access for all South Australians.

Any cost-share program requiring an initial purchase of product prior to the provision of cost-free or subsidised supply should not be approved. If subsidised supply is offered, this must be via a reduced purchase price for the life of the program.

3.3.3 **Self-funding by patients**: It is noted that there may be instances where a patient wishes to fund their own treatment under a cost-share program. Such arrangements should comply with relevant regulations and SA Health policies. If a patient chooses to self-fund the medicine, a risk assessment and the development and implementation of risk mitigation strategies must be conducted by the Local Health Network, hospital or health service DTC (or equivalent committee) to ensure no additional risks to the Local Health Network, hospital or health service.

### 3.4 Access and Storage of Medicines Approved under a MAP

3.4.1 All medicines accessed under a MAP must be used in accordance with the conditions for approval.

3.4.2 MAP medicines must be stored, managed and dispensed through the Local Health Network, hospital or health service pharmacy in accordance with procedures and legislation applicable to other medicines. Medicines provided under a MAP cannot be supplied directly to the treating clinician by the sponsor company. Standard patient co-payments, where applicable, should be levied.

### 3.5 Continued use of medicines accessed under a MAP

3.5.1 Ongoing patient management must not be compromised by cessation of a MAP. Medicines accessed under a MAP must not be considered part of standard care unless they have been approved for routine use in the Local Health Network, hospital or health service by the relevant approval committee (e.g. listed on the formulary). This includes the presence of any MAP medicine on state-wide clinical guidelines or local protocols.

3.5.2 Acceptance of a MAP does not commit any Local Health Network, hospital, health service or SA Health to approve any future use of that product, including formulary listing or IPU approval.

3.5.3 When medicines accessed under a MAP are considered for routine use (e.g. listed on the formulary), the full price of that medicine must be considered, rather than any discounted price obtainable under a MAP.

3.5.4 Reports of MAP (section 3.6) should be used to inform decisions relating to continued supply of that product outside of the MAP (e.g. for consideration on the formulary).

### 3.6 Reporting

Reports of MAP are important to promote equity of access through information sharing between Local Health Networks, hospitals or health services DTCs (or equivalent committees). Reports are also helpful to provide understanding and to inform future medicine formulary considerations.

3.6.1 A report must be provided to SAMAC of all MAP considered by the Local Health Network, hospital or health service DTC (or equivalent committee) in a timely manner (usually within 4-6weeks to enable noting at the next SAMAC meeting) and include:

- Local Health Network and hospital or health service name
- MAP type (e.g. Product Familiarisation, Expanded Access)
- Generic product name
- Trade name
- Sponsor
- Indication for use
- Treatment regimen
- Start date of program
- End date (where applicable, e.g. for PFP)
- Approval status (approved/denied) and reason if denied.

3.6.2 Clinicians participating in a MAP must submit report(s) of the MAP to the relevant Local Health Network, hospital or health service DTC (or equivalent committee). DTC (or equivalent committee) will stipulate the timing of the reports, dependent on the duration of the MAP. These reports are to promote safety and quality.
If an application is made for formulary listing, a report must also be provided to the relevant committee (e.g. the SA Formulary Committee, SA Medicines Evaluation Panel or Drug and Therapeutics Committee). Clinicians may not be granted approval for future MAP while they have outstanding reports. MAP reports must provide:

- The number of patients participating in the MAP
- Adverse events experienced
- Effectiveness measures and clinical outcome of the treatment

- The final report must be signed by the lead clinician or delegate.

At times DTCs (or equivalent committee) may use their discretion for requesting the reports where information and approvals exist, e.g. when the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended a medicine for listing on the PBS.

3.6.3 If as part of the MAP a report to the sponsor is required, it is sufficient for the clinician to provide a copy of this report to the Local Health Network, hospital or health service DTC (or equivalent committee).

### 3.7 Risk Management

Failure to comply with this policy and related Local Health Network, hospital and health service protocols and procedures may:

- Compromise patient safety and health outcomes due to the initiation of medicines that are not proven to be safe and/or clinically effective.
- Place pressure on patients, Local Health Networks, hospitals and health services to source funding for the continued supply of a medicine which has ceased to be provided free-of-charge to that patient, before alternative funding arrangements are implemented.
- Compromise the reputation of the clinician, Local Health Network, hospital and health service due to the inappropriate access to products falling within the scope of this policy.

## 4. Implementation & Monitoring

It is the responsibility of Local Health Networks, hospitals or health services, and State-wide Clinical Services to implement this policy and to monitor outcomes. This may be achieved by assessing ongoing progress and performance, including utilising SLS reports and reported breaches of policy.

SA Health employees (including consultants and contractors and students) are required to report breaches of this policy through local reporting structures. Where a breach of the policy relates to conduct of the sponsor the complaint should be considered by the local governance processes. This includes consideration of requirement to progress to an official complaint and consideration of responses to breaches under the *Medicines Australia Code of Conduct* .

## 5. National Safety and Quality Health Service Standards

| National Standard 1<br>Clinical Governance | National Standard 2<br>Partnering with Consumers | National Standard 3<br>Preventing & Controlling Healthcare-Associated Infection | National Standard 4<br>Medication Safety | National Standard 5<br>Comprehensive Care | National Standard 6<br>Communicating for Safety | National Standard 7<br>Blood Management | National Standard 8<br>Recognising & Responding to Acute Deterioration |
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## 6. Definitions

In the context of this document:

**Conflict of Interest** means**:** where an individual or organisation is involved in multiple interests, one of which could possibly corrupt the motivation for an act in the other. It is sometimes the perception of a conflict of interest that may be important, whether or not such conflict actually exists as such perceptions adversely affect relationships within and outside the organisation.

Section 27 of the *Public Sector (Honesty and Accountability) Act 1995* creates a legal onus on public sector employees to disclose pecuniary or personal interests if they conflict or potentially conflict with the employee's duties. As this is a legal onus on employees, failure to do so constitutes as grounds for termination of the employees employment in the public sector, or other disciplinary action.

**Local Health Network, hospital and/or health service** means: the Department of Health, an incorporated hospital established under the Health Care Act 2008, SA Ambulance Service (SAAS) or any health service as defined under that Act. This includes all Local Hospital Networks, their sites and the health services provided by or through them.

**Medicine** means: a chemical substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease, or otherwise improving the physical or mental welfare of people. Prescription, non-prescription and complementary medicines, irrespective of their administration route, are included.

**Medicines Access Program (MAP)** means: programs offered by the pharmaceutical industry to facilitate deferred cost, cost-free or subsidised access to medicines for public hospital patients prior to the implementation of relevant funding arrangements. MAP include compassionate use, expanded access, product familiarisation, cost-share programs and all other similarly named access programs:

- **Compassionate Use Program** – where a sponsor offers to provide a medicine free of charge for indications that are not already included in a funded scheme (i.e. other MAP arrangement or eligible clinical trial). Compassionate use may be determined on an individual patient basis or as part of a wider program. Compassionate use usually involves patients with serious or life-threatening conditions or rescue treatments.

- **Cost-Share Program** – where a sponsor offers a medicine commercially at a reduced price. Use of the product either individually or as a program should be considered as if the drug was simply being marketed at that reduced price. This may have the effect that treatment costs are shared between a company and the Local Health Network, hospital or health service and/or the patient. Cost-share arrangements may include deferred cost, subsidised supply of a medicine (e.g. half price) or arrangements where supply of a medicine at a reduced price is provided after the purchase of a specified (threshold) amount.
  Note: Cost Share Programs should not be encouraged. It is preferable that price reductions are negotiated with the sponsor via the appropriate procurement process. Negotiations at a system level are also preferred to ensure equity of access within the local health system. Enrolment of patients in CSP should comply with relevant regulations and policies about patients paying for their medicines.

- **Expanded Access Program** – the cost-free provision of an investigational product by a sponsor with access expanded after participation in a clinical trial. EAP usually involve patients with serious or life-threatening conditions. This may include patients who do not meet the enrolment criteria for a clinical trial in progress or continued supply of an investigational product to patients who have been participating in a clinical trial, following its conclusion. Medicines provided under EAP are often not yet registered with the TGA for use within Australia.

- **Product Familiarisation Program** – programs offered by a sponsor designed to allow the medical profession to evaluate and become familiar with a product while PBS listing is being sought. Products offered under a product familiarisation program must be in

accordance with the TGA approved indications for the medicine and indications for which PBS listing has been sought.

**Patient** means**:** a person receiving healthcare. Other terms for 'patient' include consumer and client.

**Pharmaceutical Company** means: organisations supplying medicines, as defined in the *Therapeutic Goods Act 1989.*

**Sponsor** means**:** the pharmaceutical company or organisation supplying (exports and/or imports and/or manufactures, or arranges these functions through another party) therapeutic goods for supply in Australia.

## 7. Associated Policy Directives / Policy Guidelines and Resources

**Associated Policy Directives:**

- Interaction between SA Health and the Therapeutic Goods Industry Policy (Directive)
- Medicine Samples Policy Directive
- Health Technology Assessment Policy Directive
- Management of Biomedical Technology Policy (Directive)
- Probity in SA Health Procurement Policy Directive

**References, resources and related documents:**

- Council of Australian Therapeutic Advisory Groups (CATAG), Managing Medicines Access Programs: *Guiding Principles for the governance of Medicines Access Programs in Australian hospitals* (June 2018)
- Medicines Australia Code of Conduct
- *Health Care Act 2008 (SA)*
- *Public Sector (Honesty & Accountability) Act 1995 (SA)*
- *Therapeutics Goods Act 1989 (Cth)*

## 8. Document Ownership & History

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