

# Guiding Principles for the governance of Medicines Access Programs (MAPs) in Western Australian Public Hospitals

The purpose of these guiding principles is to support Western Australian public hospitals and health service providers with the governance of Medicines Access Programs (MAPs). The guiding principles are intended to assist drug and therapeutics committees (DTCs), health professionals, consumers and pharmaceutical sponsors with the appropriate implementation, management, delegation of authority, provision of information and oversight of MAPs.

MAPs are programs offered by pharmaceutical sponsors to facilitate the cost-free, subsidised or deferred cost, of access to medicines for hospital patients before the relevant funding arrangements are implemented. These programs include, but are not limited to, compassionate use, expanded access, product familiarisation and cost-share programs. These guiding principles will facilitate the implementation of consistent good governance and promote the quality use of medicines\* within MAPs available in Western Australian public hospitals and health service providers.

The overarching guiding principles are:

**Guiding principle 1.** The management and oversight of every MAP should be delegated to a DTC or equivalent.

**Guiding principle 2.** Appropriate advice regarding participation in a MAP should be provided to patients.

**Guiding principle 3.** Prescribers should comply with DTC requirements when participating in a MAP.

**Guiding principle 4.** A formal agreement should exist between pharmaceutical sponsors and hospitals or health service providers when participating in a MAP.

**Guiding principle 5.** Responsibilities of all parties involved in provision of a MAP should be assigned and clear.

\*Quality Use of Medicines (QUM) means judicious selection of treatment options; appropriate choice of medicine when a medicine is required; and safe & effective use of medicines. The National Strategy for Quality Use of Medicines. Canberra: Department of Health and Ageing; 2002.

## Overview

### Purpose

The purpose of these Guiding Principles is to provide guidance to hospital prescribers, patients and DTCs on how to access certain medicines or medicinal products through MAPs. A medicinal product is anything which could be defined as a medicine by the Australian Therapeutic Goods Administration (TGA), including medicines not registered by the TGA, but available under the TGA Special Access Scheme (SAS).

Appropriate governance is recommended to ensure patients, hospitals and health service providers are not unduly exposed to clinical risk of harm (e.g. inappropriate discontinuation of therapy) or financial risk of harm (e.g. unanticipated costs at the cessation of a MAP).

Medicines should only be supplied for use by hospital or health service provider clinicians under approved conditions and structures (e.g. listed on the relevant formulary, approved on an individual patient basis or approved as part of a MAP).

### Scope

These Guiding Principles cover all MAPs offered by pharmaceutical sponsors to facilitate cost-free or subsidised or deferred cost access to medicines for hospital or health service provider **patients before subsidised listing** on the Pharmaceutical Benefits Scheme (PBS), hospital formulary or other relevant funding arrangement.

Pricing agreements as entered into by HSP's and Sponsors after such listing are not within the scope of these guiding principles.

Such MAPs include (but are not limited to) Compassionate Use Programs, Expanded Access Programs (EAPs), Product Familiarisation Programs (PFPs), Cost-Share Programs (CSPs) and other similarly named access programs. For the purpose of this document, all such programs are collectively referred to as MAPs.

These Guiding Principles do not apply to medicines which are being used as part of a registered clinical trial which has been approved by the relevant human research ethics committee (HREC).

\* Note - in WA government services, the (Fees and Charges) Health Service Order limits the fee any patient may be charged. [https://www.legislation.wa.gov.au/legislation/statutes.nsf/main\\_mr\\_title\\_13794\\_homepage.html](https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mr_title_13794_homepage.html)

### Definitions and terminology

#### Medicines Access Programs

MAPs are programs offered by pharmaceutical sponsors to facilitate cost-free, subsidised or deferred cost access to medicines for hospital or health service provider patients before the implementation of relevant funding arrangements.

#### Compassionate Use

Compassionate use is a MAP offered by pharmaceutical sponsors to provide a medicine free of charge for indications which are not already included in a funded scheme (i.e. PBS listed indication, other MAP arrangement or eligible clinical trial).

Compassionate use may be determined for an individual Patient, or as part of a wider program. Compassionate use usually involves patients with serious or life-threatening conditions or rescue treatments.

#### Expanded Access Programs

EAPs are MAPs offered by pharmaceutical sponsors which provide an investigational product cost-free when associated with prior involvement in a clinical trial. EAPs usually involve patients with serious or life-threatening conditions. An EAP may include patients who do not meet the enrolment criteria for a clinical trial in progress, or those who have been participating in a clinical trial and require continued supply of an investigational product after its conclusion.

Medicines provided under EAPs may often be products not yet registered with the Therapeutic Goods Administration (TGA) for use within Australia.

#### Product Familiarisation Programs

PFPs are MAPs offered by pharmaceutical sponsors which are designed to allow the prescriber to evaluate and become familiar with a product while PBS listing is being sought. Products offered under a PFP must be in accordance with the TGA-approved indications and the indication for which PBS listing is being sought.

#### Cost-Share Programs

CSPs are MAPs offered by pharmaceutical sponsors which offer a medicine commercially at reduced cost. Consideration of the product either individually or as a part of a program should be undertaken as though the drug was simply being marketed at that reduced price.

Treatment costs are shared between a pharmaceutical sponsor and the hospital or health service provider and/or the patient\*. Cost-share arrangements may include deferred costs, subsidised supply of a medicine (e.g. reduced purchase cost) or arrangements in which the supply of a medicine at a reduced price is provided after the purchase of a specified (threshold) amount. However, these CSP approaches are discouraged. - See Comment B under Guiding Principle 1.

## Guiding Principles

The Western Australian Therapeutic Advisory Group recommends that the following guiding principles apply to the conduct of MAPs within Western Australian hospitals and health service providers.

### GUIDING PRINCIPLE 1

***The management and oversight of every MAP should be delegated to a DTC or equivalent.***

It is recommended that MAP approval be delegated to, and obtained from, a DTC with the required authority included in its remit, before enrolment of any patients in the MAP. (e.g. a local or district-based DTC)

The process for approving a MAP must be well defined to provide transparency, propriety and avoid conflicts of interest. Standard criteria for decision-making should be defined and implemented consistently across all MAP formulary decisions, as with all formulary decisions.

The DTC or equivalent should refer to relevant guidelines published by the Council of Australian Therapeutic Advisory Group (CATAG), including:

- [Guiding principle 7 in \*Achieving Effective Medicines Governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals\*; and](#)
- [Rethinking medicines decision-making in Australian hospitals: Guiding principles for quality use of off-label medicines as well as relevant local policies.](#)

The processes for risk assessment and development and implementation of risk mitigation strategies should be conducted by the DTC to ensure no additional risk of harm arises to the patient, hospital or health service provider.

A MAP medicine must be used in line with its conditions of approval. Health professionals and patients involved in the process of supply and use must have access to adequate information to support appropriate clinical use of the product.

Hospitals and health service providers should implement appropriate administrative arrangements, including the use of a pharmaceutical sponsor agreement form, patient consent form and prescriber agreement form (samples shown in Appendix 1).

All MAP medicines must be stored, managed and dispensed through the hospital approved pharmacy in accordance with standard procedures applicable to all other medicines. Standard patient co-payments, if applicable, should be levied.

Acceptance of a MAP does not commit any hospital, health service provider, local health network or the state to subsequently place the medicine on its formulary.

The hospital or health service provider's executive, DTC, director of pharmacy or prescriber(s) may decline to participate in a MAP, depending on local circumstances and resources.

Details of all MAP should be regularly reported to the WA therapeutics advisory group (WATAG).

Additional specific requirements may be applied to any MAP arrangement.

### ***Other considerations for DTC management of MAPs***

#### ***A) Patient enrolment in a Product Familiarisation Program***

A PFP allows an individual healthcare professional to enrol a maximum of 10 patients in a PFP program in accordance with the [Medicines Australia Code of Conduct](#).

The Medicines Australia Code of Conduct does not specifically limit the collective number of patients who may participate in other types of MAPs, but local governance may limit patient numbers if considered appropriate.

If the sponsor has made an application for PBS or other listing, the PFP must conform to the proposed listing and any restrictions which apply.

#### ***B) Considerations for Cost-Share Programs***

CSPs should be discouraged. It is preferable that price reductions are negotiated with the sponsor through the appropriate procurement process. Negotiations at a state level are also preferred to ensure equity of access across WA Health.

CSPs requiring an initial full-price purchase of product as a pre-requisite to subsequent provision of free or subsidised supply should not be approved.

Where subsidised supply is offered, the reduced purchase price shall be maintained for the life of the program (e.g. X% cost reduction) to ensure patient equity.

There may be instances when a patient wishes to pay for their own treatment under a CSP. Enrolment of patients in CSPs should comply with relevant regulations and policies regarding patient self-funding of medicines.

[https://www.legislation.wa.gov.au/legislation/statutes.nsf/main\\_mrtitle\\_13794\\_homepage.html](https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13794_homepage.html)

Even if a patient chooses to self-fund the medicine, the processes for risk assessment, and the development and implementation of risk mitigation strategies, should be conducted by the DTC to ensure no additional risk of harm arises to patient, hospital or health service provider.

**GUIDING PRINCIPLE 2**

***Appropriate advice regarding participation in a MAP should be provided to patients.***

Patients and their carers must have access to appropriate information to inform their decision to accept a medicine within a MAP arrangement, as they would for any other medicine.

Patients must also be fully informed that the medicine is not routinely available from that hospital or health service provider and that continuing supply from that institution is dependent on continuance of the MAP at the hospital or health service provider and that the patient’s participation in the MAP occurs under these conditions.

This information should inform the patient’s agreement to participate in a MAP.

This agreement should be documented in the patient’s medical record.

A patient consent form (see sample Form B in Appendix 1) should be completed and retained in the medical record.

Sample Form B records the patient’s consent to participation in the specified MAP.

Sample Form B is not consent to treatment and must be used in conjunction with an appropriate record of the patient’s consent to treatment.

If a guardian or other authorised person gives consent on behalf of a patient the details of the authority should be obtained and recorded with the patient consent form.

Sample Form B also records the patient’s consent to the use and disclosure of their medical information for the purposes of the MAP.

The patient must be clearly told how their information will be handled, the purposes for which it will be used and the implications of providing or withholding consent. The consent should be as specific as possible.

After the conclusion of a MAP, further supply of the medicine through the hospital or health service provider will be subject to the medicine being listed on the formulary or otherwise approved for use in the hospital or health service provider. Ongoing patient management must not be compromised by cessation of a MAP.

If the medicine is not made available or ceases to be available through the hospital or health service provider, transfer to another medicine or private

<p><b>GUIDING PRINCIPLE 3</b>  <b><i>Prescribers should comply with DTC requirements when participating in a MAP.</i></b>          The prescriber means an authorised health professional who has the appropriate authority to prescribe the medicine.</p> <p>Prescribers treating hospital or health service provider patients must have the approval and support of the hospital or health service provider, DTC and director of pharmacy to participate in a MAP.</p> <p>A prescriber agreement form must be completed and returned to the DTC before participating in a MAP (see sample Form C in Appendix 1).</p> <p>Prescribers involved with a MAP must declare any actual, potential or perceived conflict of interest to the DTC for each MAP.</p> <p>Prescribers and other health professionals involved in supply or use of medicines within a MAP must have access to adequate information to support safe and effective use of the medicine and compliance with these guiding principles.</p>	<p>Each individual prescriber must limit their enrolment of patients to a maximum of 10 patients for each MAP/PFP, or as approved locally by the DTC for other MAP.</p> <p>Prescribers must submit reports to the hospital DTC or delegate at agreed intervals and/or a final report at the end of the MAP and/or when application is made for formulary listing.</p> <p>MAP reports must provide:</p> <ul style="list-style-type: none"> <li>• the number of patients enrolled</li> <li>• details of all adverse events experienced</li> <li>• effectiveness measures and clinical outcomes of the treatment</li> <li>• costs of treatment, including associated and incidental costs and cost savings compared with usual treatment</li> <li>• an assessment by participating prescribers of the medicine and comments on their experience with the medicine</li> <li>• the final report must be co-signed by all participating prescribers.</li> </ul>
<p><b>GUIDING PRINCIPLE 4</b>  <b><i>A formal agreement should exist between pharmaceutical sponsors and hospital or health service providers when participating in a MAP.</i></b>          MAPs should be subject to a formal agreement (see Sample Form A in Appendix 1) between the hospital or health service provider and the sponsor supplying the medicine to ensure supply is uninterrupted and free of charge by the sponsor (or as otherwise agreed with the hospital or health service provider), for as long as the prescriber considers there is a clinical benefit for the patient, and no equivalent or tolerated therapeutic alternative for the patient remains available in Australia.</p>	<p>The pharmaceutical sponsor agreement form (which may include sponsor necessitated documentation) should be between the hospital or health service provider and the pharmaceutical sponsor as per relevant tiers and delegations within those organisations - and received by the DTC before medicine is supplied to any patient.</p> <p>The pharmaceutical sponsor should acknowledge that supply to the patient, as indicated above, will continue until the medicine is available through a formal funding mechanism, such as the PBS or the relevant formulary.</p>
<p><b>GUIDING PRINCIPLE 5</b>  <b><i>Responsibilities of all parties involved in the provision of a MAP should be assigned and clear.</i></b>          WATAG recommends that the following responsibilities be assigned to ensure the appropriate conduct of MAP within hospitals and health service providers.</p>	<p>Appropriate governance and/or oversight should be in place in all facilities. There must be a supportive governance process in place to ensure the following responsibilities are enacted, where applicable. Otherwise, participation in the MAP is not advised.</p>

Guiding Principle 5 - Responsibilities of parties	
PARTY	RESPONSIBILITIES
Senior hospital and health service executives	<p>Ensure all prescribing and pharmacy staff are aware of, and have access to, these Guiding Principles.</p> <p>Ensure the implementation of appropriate governance and administrative arrangements to reflect these Guiding Principles, including application and completion of pharmaceutical sponsor agreement forms, patient consent forms, and prescriber agreement forms.</p>
Drug and therapeutics committee (or equivalent)	<p>Provide appropriate governance for access to, and appropriate use of, medicines through the MAP within its jurisdiction, ensuring prescribers follow the approval requirements and recommendations of these Guiding Principles.</p> <p>Approve MAPs within their hospital or health service provider.</p> <p>Ensure administrative requirements for MAPs are met.</p> <p>Ensure that their hospital pharmacy department agrees with, and has the resources to support, participation in MAPs.</p>
Director of pharmacy (or delegate)	<p>Ensure medicines used at their hospital or health service provider under a MAP are supplied in accordance with these guiding principles and used in line with the indications specified at the time of a MAP approval and in line with local DTC provisions for information and education of health professionals and patients about appropriate use of the medicine.</p> <p>Ensure that their hospital pharmacy department has the resources to support participation in a DTC-approved MAP.</p>
Hospital pharmacy department (or suppliers)	<p>Ensure the processes of storage, management and dispensing of medicines accessed under a MAP through the hospital pharmacy are undertaken in accordance with procedures applicable to other medicines, including the provision of adequate information about appropriate use.</p> <p>Ensure medicines accessed under MAPs and dispensed at their hospital or health service provider are used in line with the approval for use within the MAP.</p>
Prescriber	<p>Follow the requirements outlined in these Guiding Principles.</p> <p>Complete a prescriber agreement form. See sample Form C: Prescriber Agreement Form in Appendix 1.</p> <p>Inform patients that the medicine is <u>not routinely available from the hospital or health service provider</u>, and that continuing supply from that institution is dependent on continuance of the MAP at the hospital or health service provider.</p> <p>Obtain the patient's agreement to these conditions and obtain a signed patient consent form before participation in the MAP commences. See sample Form B: Patient Consent Form in Appendix 1 Document that agreement with the patient in the patient's medical record</p> <p>Obtain the patient's consent to treatment in a separate consent to treatment process and document this consent in the patient's medical record - this must be done in addition to the consent to participation in the MAP.</p> <p>Declare any actual, potential or perceived conflict of interest to the DTC (or equivalent) for each MAP.</p> <p>Limit enrolment in PFP to a maximum number of 10 patients (allowing familiarisation with the medicine) and as otherwise DTC-approved for other MAPs.</p> <p>Submit reports at agreed intervals and/or a final report (at the DTC's prerogative) at the end of the MAP, or when application is made for formulary listing, via the hospital or health service provider's DTC or delegate.</p> <p>Report adverse drug events to the TGA through the Australian Adverse Drugs Reactions System (ADRS) and to the hospital DTC (or equivalent).</p>
WATAG	Provide oversight and governance for access to medicines within WA Health, when applicable.

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## Glossary

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**Adverse drug reaction:** a drug response which is noxious and unintended and which occurs at doses normally used or tested in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.<sup>1</sup>

**Adverse drug event:** an incident in which harm resulted to a person receiving healthcare.<sup>1</sup>

**Conflict of interest:** a situation in which an individual or organisation is involved in multiple interests, one of which could possibly corrupt the motivation for an act in the other. Conflict of interest includes situations in which a perceived, potential or actual conflict exists. It is sometimes the perception of a conflict of interest which may be important whether such conflict materially exists or not, as such perceptions adversely affect relationships within and outside the organisation.

**Drug and therapeutics committee (DTC):** the group assigned responsibility for governance of the medication management system, and for ensuring the safe and effective use of medicines in the hospital or health service provider.<sup>2</sup> These may also be known as a medicines advisory committee, pharmacy and therapeutics committee, drug committee, drug and therapeutics advisory committee or quality use of medicines committee.

**Formulary:** a continually updated list of medications and related information, reflecting the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis or treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medicines and medicine-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organisational guidelines.<sup>3</sup>

**Health service provider:** a constituted health service which is responsible for the clinical governance, administration and financial management of one or more service units providing healthcare. A service unit involves a grouping of clinicians and others working in a systematic way to deliver healthcare to patients and can be in any location or setting, including hospital pharmacies, clinics, outpatient facilities, hospitals, practices and clinicians' rooms.<sup>1</sup>

**Medicine:** 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 route of administration - may be included.<sup>1,4</sup>

**Patient:** a person receiving healthcare. Synonyms for patient include consumer and client.<sup>1</sup>

**Pharmaceutical sponsor<sup>6</sup>:** a person or company who does one or more of the following:

- exports therapeutic goods out of Australia
- imports therapeutic goods into Australia
- manufactures therapeutic goods for supply in Australia or elsewhere
- arranges for another party to import, export or manufacture therapeutic goods.

### References

1. Australian Commission on Safety and Quality in Health Care. National safety and quality health service standards. Sydney: ACSQHC; 2011.
2. Australian Commission on Safety and Quality in Health Care. Safety and quality improvement guide. Standard 4: Medication safety. Sydney: ACSQHC; 2012.
3. American Society of Health-System Pharmacists. ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. American Journal of Health-System Pharmacists 2008; 65:166-75.
4. Australian Pharmaceutical Advisory Council. Guiding principles for medication management in the community. Canberra: Commonwealth of Australia; 2006.
5. Therapeutic Goods Act 1989. Canberra: Commonwealth of Australia.
6. Therapeutic Goods Act 1989 section 3(1)

### Acknowledgements

These guiding principles were developed from the Council for Australian Therapeutic Advisory Groups (CATAG) publication: Managing Medicines Access Programs. Guiding principles for the governance of Medicines Access Programs in Australian hospitals. CATAG, 2015.

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# Guiding Principles for the governance of Medicines Access Programs (MAPs) in Western Australian Public Hospitals

## Appendices

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**APPENDIX 1:** These forms are provided as samples only and must be reviewed and amended as appropriate by the relevant hospital or health service organisation before use in any MAP. The hospital or health service organisation is responsible for ensuring compliance with all statutory and policy requirements including the WA Health Consent to Treatment Policy.

Sample Form A: Pharmaceutical Sponsor Agreement Form

Sample Form B: Patient Consent Form

Sample Form C: Prescriber Agreement Form

Contact the WATAG office for a Word document Version of these forms if required<sup>#</sup>.

# File Reference W:\PAQ\EPG\Med and Tech\WATAG Committees\WATAG\WATAG Projects\Medicines Access Programs (MAP)\Appendix to MAP A B C in Word Version

# Medicines Access Programs -Appendix

## Form A: Sample Pharmaceutical Sponsor Agreement

Medicines Access Program name: \_\_\_\_\_

Pharmaceutical Sponsor: \_\_\_\_\_

Medicine generic name: \_\_\_\_\_ Medicine Brand name: \_\_\_\_\_

Type of Medicines Access Program \_\_\_\_\_  
(Compassionate use, Expanded Access Program, etc.)

TGA approved indication (if applicable): \_\_\_\_\_

PBS/formulary indication being sought (if applicable): \_\_\_\_\_

Maximum number of patients which may be engaged in the Medicines Access Program by the hospital or health service organisation \_\_\_\_\_ (Default being 10 patients, or 10 patients per Prescriber, unless otherwise approved)

Any other relevant information: \_\_\_\_\_

I, \_\_\_\_\_ representing \_\_\_\_\_  
(Name of Pharmaceutical Sponsor representative) (Pharmaceutical Sponsor)

agree and acknowledge that the above Medicines Access Program is offered to

\_\_\_\_\_ under the following conditions:  
(hospital or health service organisation)

1. The Medicines Access Program must be considered and approved by the hospital or health service organisation Drug and Therapeutics Committee or other delegated person or body before commencement;
2. The pharmaceutical sponsor agreement form (which may include sponsor necessitated documentation) should be between the hospital or health service organisation and the pharmaceutical sponsor as per tiers and delegations, and this is to be received by the DTC before medicine is supplied to any patient.
3. The Medicines Access Program Medicine(s) must be stored, managed and dispensed through the hospital approved pharmacy in accordance with procedures applicable to other medicines;
4. Inclusion criteria are for Therapeutic Goods Administration (TGA) approved indications and within the requested Pharmaceutical Benefits Scheme (PBS) indications being sought where applicable;
5. The Pharmaceutical Sponsor will provide adequate information to enable safe and effective use of the Medicine and compliance with the Guiding Principles for the Governance of Medicines Access Programs (MAP) in Western Australian Public Hospitals;
6. The Medicine will continue to be provided uninterrupted and free of charge by the Pharmaceutical Sponsor to the hospital (or as otherwise agreed) for as long as the patient is judged to benefit clinically from the treatment, the Medicine remains available in Australia and while no equivalent or tolerated therapeutic alternative for the patient is available in Australia. Supply will continue until the Medicine is available to those patients through a formal funding mechanism, such as PBS or the relevant formulary;
7. Acceptance of this Medicines Access Program does not commit the hospital to subsequently place the Medicine on the hospital formulary.
8. Should the sponsor become aware of additional information regarding the safe use of the Medicine, during or after completion of the MAP, the sponsor will undertake all reasonable actions to inform the Prescriber and the relevant DTC.

Medicines Access Programs –Sample Agreements

These forms are provided as samples only. A suitable document should be developed at each site and for each MAP as appropriate by the relevant hospital or health service organisation, who are responsible also for ensuring compliance with statutory and policy requirements including the WA Health Consent to Treatment Policy.

**FOR PHARMACEUTICAL SPONSOR:**

Signed: \_\_\_\_\_

Name: \_\_\_\_\_  
(block letters)

Title: \_\_\_\_\_

For: \_\_\_\_\_  
(Pharmaceutical sponsor represented)

Date: \_\_\_\_\_

**FOR HOSPITAL OR HEALTH SERVICE ORGANISATION:**

Signed: \_\_\_\_\_

Name: \_\_\_\_\_  
(block letters)

Title: \_\_\_\_\_

For: \_\_\_\_\_  
(Hospital or health service organisation represented)

Date: \_\_\_\_\_

SAMPLE

# Medicines Access Programs - Appendix

## Form B: Patient Consent To Participate in MAP

The purpose of this form is to set out the terms on which the Medicine will be provided to the patient and to record to the patient's consent to the collection, use and potential disclosure of personal and confidential information for the purposes of the Medicines Access Program.

I, \_\_\_\_\_ hereby agree, or I \_\_\_\_\_  
(name of patient) (name of person with legal authority to give consent on behalf of patient\*)

give consent on behalf of, \_\_\_\_\_, to participation in  
(name of patient)

the specified Medicines Access Program:

Name of Medicines Access Program: \_\_\_\_\_

Pharmaceutical Sponsor: \_\_\_\_\_

Hospital/Health Service Organisation: \_\_\_\_\_

Medicine name: \_\_\_\_\_

Start Date: \_\_\_\_\_ Stop Date: \_\_\_\_\_

Please note that the Medicines Access Program may cease prior to the planned stop date.

*I confirm that the following has occurred (please tick box if applicable):*

- I have been given clear information by my/the Patient's doctor or the prescriber about the Medicines Access Program and the details of the Medicines Access Program including the reasons for participation in the Medicines Access Program and the limits of the Medicines Access Program.
- I have had an opportunity to ask my/the Patient's doctor or the prescriber questions relating to the Medicines Access Program and discussed alternatives to participation in the Medicines Access Program.

*I understand and consent to participate in the Medicines Access Program under the following conditions (please tick box if applicable):*

- The hospital is not expected to subsidise the cost of the Medicine at the end of the Medicines Access Program.
- The Medicine is not currently subsidised under the Pharmaceutical Benefits Scheme (PBS) and may not be subsidised when the Medicines Access Program ends.
- If the Medicine is not subsidised by the PBS, the cost of the Medicine may be high.
- If the Medicine is not subsidised by the PBS or included on the Hospital Formulary at the end of the Medicines Access Program, it may be necessary to change to a suitable alternative medicine that is subsidised.
- The usual hospital medication charges will apply to all items supplied under the Medicines Access Program.
- If the Medicines Access Program or treatment is terminated for safety or clinical reasons, the Medicine may be available from an alternate source, such as a local pharmacy, and should I/the Patient wish to obtain the Medicine I/they may be responsible for the cost.

Medicines Access Programs –Sample Agreements

These forms are provided as samples only. A suitable document should be developed at each site and for each MAP as appropriate by the relevant hospital or health service organisation, who are responsible also for ensuring compliance with statutory and policy requirements including the WA Health Consent to Treatment Policy.

- Supply through the hospital may continue in the event that the Medicine is listed on the formulary or otherwise approved for use in the hospital.

*I understand and consent to disclosure of the following information related to my participation in the Medicines Access Program (please tick box if applicable):*

- I understand and acknowledge that the Medicine is being provided as a part of the Medicines Access Program which may involve the collection, use and disclosure of **deidentified** information, which relates to my/the Patient's participation in the Medicines Access Program, medical history and response to the Medicine.
- I consent to information concerning my/the Patient's medical condition and treatment, limited to deidentified information, being disclosed to the Pharmaceutical Sponsor and/or the hospital Drug and Therapeutics Committee for the purposes of the Medicines Access Program. Information that may be used and disclosed may include the following:  
(eg Age, Gender, Condition, Progress) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- I understand that the information disclosed to the Pharmaceutical Sponsor and/or the hospital Drug and Therapeutics Committee is for the following purposes:  
(eg Research) \_\_\_\_\_  
\_\_\_\_\_

- I am aware that the Pharmaceutical Sponsor and the Drug and Therapeutics Committee are under a legal obligation not to disclose my/the Patient's confidential information without specific consent or some other legal authorisation.

- Should any specific collection, use or disclosure be required which is not addressed in this form, additional consent to such collection, use or disclosure shall be requested for the purposes of providing information about my/the Patient's participation in this Medicines Access Program.

- Further, I understand that if I/the patient, or the Prescriber, or the Sponsor, consider that disclosure of any personal information and/or confidential information is warranted/unavoidable/ in the best interests of me/the patient, that a separate and specific Patient Consent Form will be developed, and also approved by the DTC, and if appropriate, the hospital or health service provider's Human Research Ethics Committee.

To be completed by the Patient or person with legal authority to give consent on behalf of the patient:

\_\_\_\_\_  
(signature) (Print name) (Date)

To be completed by the witness:

\_\_\_\_\_  
(signature) (Print name) (Date)

\* If a guardian or other authorised person gives consent on behalf of a patient the details of the authority should be obtained and recorded with the consent.

Medicines Access Programs –Sample Agreements

These forms are provided as samples only. A suitable document should be developed at each site and for each MAP as appropriate by the relevant hospital or health service organisation, who are responsible also for ensuring compliance with statutory and policy requirements including the WA Health Consent to Treatment Policy.

## Medicines Access Programs - Appendix Form C: Sample - Prescriber Agreement

I, \_\_\_\_\_ (print name) hereby accept responsibility for  
prescribing the Medicine \_\_\_\_\_ (medicine name)  
under the specified Medicines Access Program.

Medicines Access Program name: \_\_\_\_\_

Pharmaceutical Sponsor: \_\_\_\_\_

Hospital/Health Service Organisation: \_\_\_\_\_

Start date: \_\_\_\_\_ Stop date: \_\_\_\_\_

*I agree to prescribe the Medicine under the following conditions (please tick the following boxes):*

- The Medicine may not be subsidised by the Pharmaceutical Benefits Scheme (PBS) for my patients at the conclusion of the Medicines Access Program.
- The hospital will not subsidise the cost of the Medicine at the end of Medicines Access Program unless it is approved for use on the hospital formulary or the hospital's Drugs and Therapeutics Committee has approved non-formulary use in an individual patient.
- In the situation where the Medicine is not subsidised by the end of the Medicines Access Program, the Medicine may need to be switched over to a suitable subsidised alternative. I will ensure that each patient understands this and discuss alternative treatments with them.
- Where the Medicine does not have PBS listing at the conclusion of the Medicines Access Program, I will consider the use of a private prescription, or ensure that I obtain the required health service organisation approval to continue prescribing the Medicine for my patients. Alternatively, where possible, I will switch the patient to a suitable subsidised alternative. I will organise the request for approval or the changeover to a suitable alternative in a timely manner.
- I will limit enrolment to a maximum number of 10 patients for each Product Familiarisation Program, or as approved locally by the hospital Drug and Therapeutics Committee for other Medicines Access Program.
- I will submit reports to the hospital Drug and Therapeutics Committee or delegate at agreed intervals and/or a final report at the end of the Medicines Access Program and/or when application is made for formulary listing.

*I undertake to do the following (please tick boxes):*

- provide information about the Medicine and the Medicines Access Program to each patient and/or the person giving consent on behalf of each patient that I enrol.
- obtain consent from each patient or the person giving consent on each patient's behalf to participation in the Medicines Access Program, prior to prescribing the Medicine under the Medicines Access Program.
- obtain separately a consent from each patient or the person giving consent on each patient's behalf to treatment, prior to prescribing the Medicine under the Medicines Access Program.
- Upon learning of additional information relating to the safety of the medicine, either during the MAP or after the completion of the MAP, will make all reasonable actions to inform each patient, and will provide this information to the DTC
- make each patient aware that usual hospital charges will apply to Medicine(s) dispensed under the Medicines Access Program.
- advise each patient that they may be required to pay for the Medicine if they wish to receive it beyond the parameters of the Medicines Access Program.
- make each patient aware of any actual, potential or perceived conflicts of interest I have in relation to the Medicines Access Program.

Medicines Access Programs –Sample Agreements

These forms are provided as samples only. A suitable document should be developed at each site and for each MAP as appropriate by the relevant hospital or health service organisation, who are responsible also for ensuring compliance with statutory and policy requirements including the WA Health Consent to Treatment Policy.

*Declaration of conflict of interest:*

I certify that I do not have any actual, potential or perceived conflict of interest which may arise in respect of the Medicines Access Program

OR

I may have a conflict of interest for the following reason/s: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Prescriber's Signature

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
If signing on behalf of a consultant, please write the consultant's name