

WATAG Advisory Note

WATAG Medicines Access Programs (MAPs) Guidelines

1. Background

Evidence-based, cost-effective therapies are provided at WA health sites in an approved formulary. For compassionate, commercial and other reasons, pharmaceutical companies (sponsors) may seek to subsidise supply of non-formulary items to WA Health clients through various 'medicines access programs' (MAPs).

MAPs may cover expensive treatments which yet lack evidence of efficacy and MAPs may be used by pharmaceutical companies to introduce medicines that may have future impacts on health expenditure.

MAPs are resource intensive to manage, with a workload required that approximates that of running a clinical trial. While MAPs can yield benefits for WA Health clients, there is a need for a consistent approach to the approval and conduct of MAPs in WA Health.

The Western Australian Therapeutic Advisory Group (WATAG) has previously endorsed '**Guiding Principles for the Governance of Medicines Access Programs (MAPs) in Western Australian Public Hospitals**' (available at <http://www.watag.org.au>). The Guiding Principles were adapted from the Council of Australian Therapeutic Advisory Groups (CATAG) 'Guiding Principles for MAPs in Australian Hospitals'.

The 'Medicines Australia' Code of Conduct Edition 18 requires that pharmaceutical companies must be familiar with and comply with the CATAG Guiding Principles for MAPs in Australian Hospitals and that pharmaceutical companies must be aware of State and individual institutional requirements for Product Familiarisation Programs in hospitals and particularly the requirements for management and distribution of a product within an institution.

This guideline outlines recommendations for implementation of MAPs at WA Health sites. More detailed information is offered in the Guiding Principles document.

2. Definition and Scope

MAPs are programs offered by sponsors to facilitate deferred cost, cost-free or subsidised access to medicines for hospital patients before the implementation of relevant community (usually PBS subsidy) funding arrangements.

The Guiding Principles cover medicines access arrangements including expanded access, product familiarisation and other similarly named access programs.

MAPs may include non-TGA registered products.

The Guiding Principles do not apply to products used as part of a registered clinical trial.

Neither are 'Compassionate Use' programs applying to an individual patient included in the scope. 'Cost-share' arrangements may be discussed with pharmaceutical companies who supply medicines to individual patients on a compassionate basis. The Guiding Principles outline the limitations and drawbacks of these

3. Principles guiding MAPs

- Provision of medicines to WA Health patients through the approved formulary is preferred to ensure efficacy and cost-effectiveness have been adequately considered.
- MAPs should be approved by a Drugs and Therapeutics Committee (DTC) or Chief Pharmacist, according to local hospital guidelines, when they are satisfied that there is a clinical or compassionate imperative for supply of a medicine that is not suitable for formulary listing.
- Conduct of MAPs in WA Health should be informed by the **WATAG Guiding Principles for the governance of Medicines Access Programs in Western Australian Public Hospitals**.
- WA Health sites should generally fully recover the cost of managing a MAP from the pharmaceutical sponsor. Cost recovery should include the cost of the drug and costs associated with the implementation and subsequent management of the MAP including staffing costs for the dispensing and subsequent administration of the drug.
- MAPs approved by one tertiary DTC should generally be reciprocally accepted at other WA Health sites. Notwithstanding this, individual site Chief Pharmacists and/or DTCs retain the discretion of not participating in a MAP initiated at another site. For example, implementation of a MAP may not be feasible at a general hospital or WACHS site, even if cost recovery has been agreed at a larger site.
- MAPs are subject to a formal agreement between the hospital management and the pharmaceutical sponsor of the medicine which ensures uninterrupted supply, free of charge from the Company, for as long as the patient's treating prescriber judges that there is a clinical benefit (and that there is no equivalent or tolerated alternative for the patient and the medicine remains available in Australia). Uninterrupted supply includes ongoing provision of the medicine when patients move to other sites for continuation of the MAP.
- The sponsor company should acknowledge that supply, as indicated above, will continue until the medicine is available to those patients through a formal funding mechanism, such as PBS or the Statewide Medicines Formulary.
- Ongoing clinical assessment of MAPs should be required by DTCs (such as review of the MAP approval at regular intervals) to ensure that the MAP remains an acceptable alternative to formulary approved treatments.

4. Implementation and flexibility of MAPs

The **WATAG Guiding Principles for the governance of Medicines Access Programs in Western Australian Public Hospitals** provide endorsed tools for implementation of this guideline including a i) Pharmaceutical company acknowledgement form, ii) Patient consent form and iii) Prescriber acknowledgement form.

These MAP agreements may be amended, with approval of the Chief Pharmacist, at the site of the approving DTC, subject to the above principles being adhered to. These minor amendments may include, for example in the case of MAPs for specific patients, an individual addendum outlining specific terms and conditions. Chief Pharmacists, in negotiation with clinical stakeholders, should exercise discretion in relation to recovery of the costs associated with MAPs to prevent patient disadvantage.