COUNCIL OF AUSTRALIAN THERAPEUTIC ADVISORY GROUPS

Guiding Principles for Medicines Access Programs in Australian Public Hospitals

Purpose

The purpose of these Guiding Principles is to ensure that Medicine Access Programs (MAP) allow public hospital prescribers the opportunity to use, where clinically appropriate, evaluate, and become familiar with, a medicine without putting patients or hospitals at risk of inappropriate discontinuation of therapy or unanticipated costs at the cessation of a Program.

Scope

These Guiding Principles cover all programs offered by the pharmaceutical industry to facilitate deferred cost, cost-free or subsidised access to medicines, which are included on the Australian Register for Therapeutic Goods, for public hospital patients prior to subsidized listing on the Pharmaceutical Benefits Scheme (PBS), hospital formulary or other relevant funding arrangement. Such programs include Product Familiarisation Programs (PFP), Expanded Access Programs (EAP) and other similar arrangements. For the purpose of this document, these programs are collectively referred to as Medicines Access Programs (MAP).

Guiding Principles

The Council of Australian Therapeutic Advisory Groups recommends that the conduct of a MAP within a public hospital in Australia should reflect the following principles.

- **Management and oversight:**
  - All MAP must be accepted by the hospital Drugs and Therapeutics Committee (DTC) or equivalent before commencement. Details of all MAP should be regularly reported to the State or Territory Therapeutics Advisory Group or other nominated agency. Details of state or territory MAP activity may be reported to CATAG for compilation of national data.
  - Acceptance of a MAP does not commit any hospital, State or Territory to subsequently place the medicine on its formulary.
  - All MAP medicines must be stored, managed and dispensed through the hospital pharmacy in accordance with procedures applicable to other medicines. Standard patient co-payments, where applicable, should be levied.
  - A MAP medicine must be used in line with its conditions of approval. If the sponsor has made an application for PBS or other listing, the MAP must conform to the proposed listing and any restrictions that apply.
  - Local jurisdictions should implement the appropriate administrative arrangements to reflect these principles including a Company Acknowledgement Form, Patient Acknowledgement Form and Prescriber Acknowledgement Form.
- **Patients:**
  - Ongoing patient management must not be compromised by cessation of a MAP.
  - Patients must be fully informed that the medicine is not routinely available from that hospital, that continuing supply from that institution is dependent on

continuance of the MAP at the hospital, and agree to treatment under these conditions.

- Thereafter, supply through the hospital will be subject to the medicine being listed on the formulary or otherwise approved for use in the hospital.
- If the medicine is not made available through the hospital, transfer to another medicine or private supply from another source will be required.

- **Prescribers:**
  - Prescribers involved with a MAP must declare any actual, potential or perceived conflict of interest to the Drugs and Therapeutics Committee for each MAP.
  - Each individual clinician would usually be expected to limit enrollment to a maximum number of 10 patients to allow familiarisation with the medicine.
  - Reports at agreed intervals and/or a final report at the end of the MAP or when application is made for formulary listing must be submitted to the hospital DTC or delegate. These reports must provide,
    - The number of patients included;
    - Details of all adverse events experienced;
    - Effectiveness measures and clinical outcome of the treatment;
    - Costs of treatment, including associated and incidental costs and cost savings compared to usual treatment;
    - An assessment by participating prescribers and comments on their experience with the medicine.
    - The final report must be co-signed by all participating prescribers.

- **Companies:**
  - MAP should be subject to a formal agreement between the hospital management and the supplier of the medicine which ensure uninterrupted supply, free of charge from the Company (or as otherwise agreed with the hospital), 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).
  - 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 relevant formulary.

Responsibilities

CATAG recommends that the following responsibilities be assigned to ensure the appropriate conduct of MAP with public hospitals and health services.

- **Senior hospital and health service executives are responsible for:**
  - Ensuring all prescribing and pharmacy staff are aware of, and have access to these Guiding Principles;
  - Ensuring the implementation of appropriate administrative arrangements to reflect this policy directive including Pharmaceutical Company Acknowledgement Forms, Patient Consent Forms, and Prescriber Acknowledgement Forms.

- **Directors of Pharmacy (equivalents or their delegate) are responsible for:**
  - Ensuring medicines used at their hospital under a MAP are supplied in accordance with these Principles and used in line with their TGA approved indications.

- **Drug and Therapeutics Committees (DTC), and equivalent committees, are responsible for:**
  - Approving MAP within their hospital or health service;
  - Notifying their state or territory Therapeutics Advisory Group (TAG) (or equivalent) of MAP within their hospital or health service.

- **Hospital Pharmacy Departments are responsible for:**
  - The storage, management and dispensing of medicines accessed under a MAP through the hospital pharmacy in accordance with procedures applicable to other medicines;
  - Ensuring medicines accessed under MAP dispensed at their hospital are used in line with its approval for use.

- **Prescribing staff are responsible for:**
  - Following the requirements outlined in these Guiding Principles;
  - Informing patients that the medicine is not routinely available from the hospital, that continuing supply from that institution is dependent on continuance of the MAP at the hospital. Patients must agree to these conditions before treatment may be commenced by signing a patient consent form;
  - Declaring any actual, potential or perceived conflict of interest to the Drug and Therapeutics Committee or equivalent for each MAP;
  - Limiting enrolment to a maximum number of 10 patients to allow familiarisation with the medicine;
  - Submitting reports at agreed intervals and/or a final report at the end of the MAP or when application is made for formulary listing to the hospital DTC or delegate;
  - Reporting adverse drug reactions (ADR) to the Therapeutic Goods Administration (TGA) through the Australian Adverse Drug Reaction Reporting System and hospital DTC.

- **The state or territory TAG is responsible for:**
  - Maintaining a register of MAP in use within their jurisdiction.

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