

## **Guiding Principles for Product Familiarisation Programs in Australian Public Hospitals**

### **Introduction**

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 Pharmaceutical Benefits Scheme (PBS) listing, or prior to implementation of other relevant funding arrangements. Such programs may be variably named (eg Product Familiarisation Programs or Expanded Access Programs) but for the purpose of this document, such programs will be referred to collectively as Product Familiarisation Programs (PFP). (Special Access Scheme drugs and other medicines not registered by the Therapeutic Goods Administration [TGA] would not usually be covered by these Principles.)

### **Aim**

The aim of the Principles is to ensure that PFPs allow public hospital doctors the opportunity to use, where clinically appropriate, evaluate, and become familiar with, a TGA registered medicine without putting patients or hospitals at risk of inappropriate discontinuation of therapy or unanticipated costs at the cessation of a Program.

### **Guiding Principles**

The conduct of a PFP within a public hospital in Australia should reflect the following principles.

- **Management and oversight:**
  - All PFPs must be accepted by the hospital Drug and Therapeutics Committee or other delegated person or body before commencement. Details of all PFPs must be reported to the State or Territory Drug and Therapeutics Committee, Therapeutic Advisory Group or other nominated agency on a regular basis, and information from all States or Territories will be compiled annually.
  - Acceptance of a PFP does not commit any hospital, State or Territory to subsequently place the drug on its formulary.
  - All PFP medicines must be stored, managed and dispensed through the hospital pharmacy in accordance with procedures applicable to other drugs. Standard patient co-payments, where applicable, should be levied.
  - A PFP medicine must be used in line with its TGA approved indications. If an application for PBS or other listing has been lodged, the indication under the PFP must conform to the proposed listing.
  - Local jurisdictions should implement the appropriate administrative arrangements to reflect these principles including Patient Acknowledgement Forms, Company Acknowledgement Forms and Doctor Acknowledgement Forms.

- **Patients:**
  - Ongoing patient management must not be compromised by cessation of PFPs.
  - Patients must be fully informed that the drug is not routinely available from that hospital, that continuing supply from that institution is dependent on continuance of the PFP 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.
  
- **Doctors:**
  - Prescribers involved with a PFP must declare any potential conflict of interest to the Drug and Therapeutics Committee for each PFP.
  - Each individual clinician would usually be expected to limit enrollment to a maximum number of patients to allow familiarisation with the medicine. The number recommended is no more than 10 patients.
  - Reports at agreed intervals and/or a final report at the end of the PFP 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 doctors and comments on their experience with the medicine.
    - The final report must be co-signed by all participating doctors.
  
- **Companies:**
  - PFPs should be subject to a formal agreement between the hospital management and the supplier of the drug 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 doctor judges that there is a clinical benefit (and that there is no equivalent or tolerated alternative for the patient and the drug 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.

\*\*\*\*\*