

Victorian Therapeutics Advisory Group (VicTAG)

Guidelines for Product Familiarisation Programs in Public Hospitals

Aim

These guidelines aim to ensure that Product Familiarisation Programs (PFPs) offered by the pharmaceutical industry provide public hospital patients with the opportunity to access newly approved drugs, during the early prescriber familiarisation phase of the product and prior to possible inclusion on the Pharmaceutical Benefits Scheme listing, without the risks of inappropriate discontinuation of therapy for patients or unanticipated costs to hospitals.

Approval of product familiarisation programs

Following a proposal to conduct a Product Familiarisation Program with hospital clinicians the correct procedure is to discuss the program details with the Director of Pharmacy and seek approval through the Drugs and Therapeutics Committee.

The following requirements must be met:

- 1. Director of Pharmacy** - Approval in principle is required from the Director of Pharmacy for:
 - Adherence to local hospital, pharmacy and Drug and Therapeutics Committee policy matters.
 - Logistical issues (see logistical considerations below).
 - Handling/dispensing fees where relevant.

- 2. The Drug and Therapeutics Committee** – Approval is required from the Drug and Therapeutics Committee for:
 - Drug formulary listing.
 - Policy in relation to the drug prescribing practices, including the designation of patients and clinics to which the program applies.
 - Any proposed costs for the program.
 - Potential future hospital costs following the product familiarisation program – with particular consideration if the drug is not eventually PBS listed or has a limited listing.

- 3. Information Required** for the Drug and Therapeutics Committee should include the usual new drug submission requirements of the hospital including:
 - Evidence of clinical efficacy and safety for the drug.
 - A document outlining the case to justify the use of the drug.
 - Details on the evidence of comparative efficacy and safety with alternative existing drug treatments.
 - Proposed support (including financial), duration of the program and proposed management of patients following the program (see ethical considerations below).

Logistics of product familiarisation programs

All stock must be stored and supplied in a manner that meets all legal requirements and hospital policy.

- All stock is to be delivered to the pharmacy department and supplied via the pharmacy department.
- The dispensing of the medications must meet all safety and legislative requirements, eg. labelling, record of use, etc. and should be carried out by the pharmacy department.

Ethical considerations of product familiarisation programs

Ongoing patient management should not be compromised by access to or cessation of product familiarisation programs.

Patients must be fully informed about the product familiarisation program including any potential implications and be in agreement with future treatment plans if the product familiarisation program ceases. A full discussion with the patient and disclosure of arrangements for ongoing treatment when the program is completed must occur and be documented in the patient's history. Patients should be provided with relevant information in writing.

Participants involved with a product familiarisation programs should declare any potential conflict of interest in the program to the Drug and Therapeutics Committee.

Financial Considerations

Agreements for product familiarisation program must specify that the medication will continue to be provided free of charge by the pharmaceutical company or as otherwise agreed with the hospital until the drug is PBS listed or in the event that the drug is not PBS listed for as long as the patient is judged to benefit clinically from the treatment.

Standard patient co-payments will be levied for drugs issued under product familiarisation programs

Summary

Product familiarisation programs enable patients and medical staff to access new treatments however the process must be managed in a manner that ensures that ongoing patient management and hospital budgets are not compromised and all legal requirements and hospital policy are met.

Additional Information

Further guidelines on the management of product familiarisation programs can be accessed in the Medicines Australia Code of Conduct through the Medicines Australia website at <http://www.medicinesaustralia.com.au>. In particular in the section Research subsection 8.2 Product Familiarisation Programmes.

A sample consent form (courtesy of Austin Health) is attached for those hospitals requiring signed consent from patients participating in product familiarisation programs.

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Patient Consent To Use a Drug Under The Patient Familiarisation or Other Subsidised Drug Program

I, hereby consent to the administration of the drug to the patient (name or 'myself') under the Patient Familiarisation or other subsidised drug program.

Name of program: _____

Start date: _____

Stop date: _____

Please tick box.

- I have been given clear information by Doctor on the reason for using the drug, its nature and known effects, and possible risks.
- I have had an opportunity to ask questions relating to the treatment and discussed alternative treatments.

I understand that:

- The drug is supplied under the Patient Familiarisation or other subsidised drug program and that in order to access this drug, the doctor/hospital may be required to provide certain information about me relating to the use of this drug to the drug company administering the program.
- The hospital is not expected to subsidise the cost of the drug at the conclusion of the Patient Familiarisation or other program.
- The drug is currently not listed on the government's Pharmaceutical Benefits Scheme and may not be subsidised at the conclusion of the Patient Familiarisation or other subsidised drug program.
- The cost of the unsubsidised drug may be quite significant.
- In the situation where the drug is not subsidised at the conclusion of the program, the drug may need to be switched over to a suitable, subsidised alternative.
- The usual hospital medication charges will apply to all items supplied under the Patient Familiarisation or other subsidised drug program.

Based on the information given to me (tick box if applicable):

- If I wish to continue with this drug at the conclusion of the program I am prepared to pay the cost of ongoing therapy, which I will obtain from my local pharmacy.

Patient/agent's name (PLEASE PRINT) Patient/agent's signature Date

Witness' name (PLEASE PRINT) Signature Date

Doctor Acknowledgement For The Patient Familiarisation or Other Subsidised Drug Program

I, hereby accept responsibility for prescribing the drug to the patient under the Patient Familiarisation or other subsidised drug program. is a patient of Austin Health and has been an inpatient here in the previous two years and/or is attending outpatient clinic at Austin Health.

Name of program: _____

Commencement date: _____

Cease date: _____

I understand that (please tick box):

- I must provide information about the drug and program to the patient.
- I am required to obtain patient consent prior to accessing this drug under the Patient Familiarisation or other subsidised drug program.
- The drug may not be subsidised by the Pharmaceutical Benefits Scheme (PBS) at the conclusion of the Patient Familiarisation or other program.
- The hospital is not expected to subsidise the cost of the drug at the conclusion of the Patient Familiarisation or other subsidised drug program unless the drug is approved for formulary listing by the Drug and Therapeutics Committee (DTC) or by the Austin Health non-formulary approval process.
- In the situation where the drug is not subsidised at the conclusion of the program, the drug may need to be switched over to a suitable, subsidised alternative. I will ensure the patient understands this and discuss alternative treatment with him/her.
- Where the drug does not have PBS listing at the conclusion of the Patient Familiarisation or other subsidised drug program, I will ensure that I obtain hospital approval, either via the DTC or the non-formulary approval process in order to continue prescribing the drug for the patient. Failing that, I will switch the patient over to a suitable subsidised alternative. I will organise the request for approval or the changeover to a subsidised alternative in a timely manner.

The patient (please tick box):

- Is aware that usual hospital medication charges will apply to items supplied under the Patient Familiarisation or other subsidised drug program.
- Has indicated that he/she is prepared and able (has the means) to pay for the above mentioned drug if he/she wishes to continue therapy at the conclusion of the program.

Doctor's name (PLEASE PRINT)

Signature

Date

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