

COUNCIL OF AUSTRALIAN THERAPEUTICS ADVISORY GROUPS

Guiding Principles for Managing Use of Medication Samples in Australian Public Hospitals

Purpose

To provide a guide for hospital policy makers and clinical staff on managing medication samples (also referred to as product starter packs) in Australian public hospitals.

Scope

These guidelines apply to all medication samples, all clinical staff, and to all patients attending a public hospital (including inpatients, outpatients, and patients seen in the Emergency Department only). Medication samples are medicines that are provided by a pharmaceutical company representative at no (or minimal) cost. They may include tablets, creams, lotions, inhalers and other presentations of both scheduled and unscheduled medicines.

Background

Medication samples are part of the marketing strategy of pharmaceutical companies to promote new medicines. Samples have no or little advantage for patients in public hospitals and should not be supplied directly to them.

All clinical staff should be aware that medication samples have been associated with:

- patient confusion and medication errors because of inadequate labeling and patient instructions;
- poor quality assurance because of insufficient checks on medicine expiry and storage requirements;
- inadequate opportunity for pharmacy to review safety and efficacy;
- poor ability to track and recall medicines;
- supply of inappropriate quantities to an individual;
- unfairly raising patient expectations that there will be continuing access to the treatment, which may not be approved on the PBS, or State or hospital formulary.

These disadvantages outweigh any cost or convenience advantage to the patient or the hospital from direct supply of medication samples to patients.

Prescribers who wish to initiate a new medicine can apply to the hospital Drugs and Therapeutic Committee for individual patient use or to add a new medicine to the formulary. This process ensures that new medicines are assessed for safety, efficacy, convenience and cost against alternatives on the hospital formulary. If approved by the Drugs and Therapeutic Committee, the hospital Pharmacy Department will supply the medicine to the patient, which ensures that the medicine is stored, labeled and supplied correctly with adequate instructions for the patient. This process also ensures that supply of the new medicine can be tracked.

Guiding Principles

- Hospitals should manage samples in the same way as other medicines (see below) or have a 'no samples' policy;
- Doctors or other clinical staff who are offered samples by pharmaceutical representatives should refer the representative to the hospital Pharmacy Department;

- All medication samples should be received directly by the hospital Pharmacy Department or Service and dispensed or supplied through the hospital Pharmacy Department or Service;
- The provision of medication samples directly to hospital staff who provide clinical services (including medical, nursing and other clinical staff) should not be allowed;
- The provision and use of samples of a medicine, not listed on the relevant hospital medicines formulary, should be approved by the hospital's Drugs and Therapeutics Committee. Samples of medicines already listed on the hospital formulary should be reviewed on a regular basis by the Director of Pharmacy or equivalent;
- Medication samples should not be kept in clinics, patient care areas or elsewhere in the hospital for direct supply to hospital patients;
- Medication samples should not be made available during displays and education sessions;
- The availability of a medication sample on a hospital formulary should not influence the choice of medicine prescribed;
- Requesting or use of medication samples for personal use should not be permitted;
- The requisition and receipt of supply of medication samples should be documented in accordance with the relevant Medicines Australia Code of Conduct;
- Medication samples intended for use in non-hospital patients should not be delivered to staff on hospital grounds;
- Supply of medicines under a Medicines Access Program must abide by relevant hospital policies or guidelines. (see CATAG *Guiding Principles for Medicines Access Programs in Australian Public Hospitals*, July 2012)

Responsibilities

Health Service Chief Executives:

- Ensure that all persons providing clinical services under their authority are aware of, and have access to, these Guiding Principles or an equivalent local policy; and
- Ensure that medication samples are used in accordance with the provisions outlined in these Guiding Principles or an equivalent local policy.

Directors of Pharmacy (or their delegate):

- Consider approval of medication samples for use within their hospital for medicines that are listed on the hospital formulary; and
- Oversee the dispensing and supply of medication samples through the hospital Pharmacy Department or Service.

Drugs and Therapeutics Committees (or equivalent):

- Consider approval of medication samples for use within its hospital for medicines that are not listed on the hospital formulary.

Persons providing clinical services (doctors, nurses, pharmacists and other clinical staff):

- Doctors or other clinical staff who are offered samples by pharmaceutical representatives should refer the representative to the hospital Pharmacy Department;
- Comply with the principles of these Guidelines regarding the use of medication samples in public hospitals and health services.