Policy No.: D0269

Medicine Samples Policy Directive

Version No.: 1.1
Approval date: 19/10/18

Government of South Australia
SA Health

Contents

Medicine Samples Policy Directive

1. Policy Statement

The purpose of this policy directive is to control and manage samples of medicines within SA Health facilities.
Safe, quality use of medicines is well recognised as a key health priority across all health care settings. This policy directive will help to support safe, equitable access for patients to samples of medicines within SA Health hospitals and health services.

2. Roles and Responsibilities

2.1 Chief Executive, SA Health:

- Ensures SA public hospitals and health services are aware of and comply with this policy.

2.2 Director of Medicines and Technology Programs and Out of Hospital Pharmacy Services:

- Establishes this policy; and
- Ensures this policy is maintained and periodically reviewed to ensure consistency with current evidence and nationally agreed best practice.

2.3 Chief Executive Officers of Local Health Networks and statewide services:

- Ensure there is a plan developed for implementing this policy.
- Ensure SA Health employees (including consultants, contractors and students) are aware of, have access to, and comply with this policy. Ensure breaches of this policy are handled appropriately in accordance with SA Health policy.

2.4 Delegate the day-to-day responsibility for complying with this policy to the relevant senior managers. Executive Directors, Directors, Heads of Service/Department and other senior managers:

- Develop, implement and monitor local processes that support the operation of this policy.
- Ensure breaches of this policy are reported via the Safety Learning System (SLS) and other appropriate pathways.

2.5 Directors of Pharmacy (or their delegate) (in addition to the responsibilities outlined in section 2.3):

- Approve the use of samples within their hospitals and health services for medicines listed on the South Australian Medicines Formulary; and
- Oversee dispensing and supply of samples through the hospital or health service Pharmacy Department.

2.6 Drug and Therapeutics Committees (and equivalent committees):

- Approve the use of samples within their hospitals and health services for medicines not listed on the South Australian Medicines Formulary.

2.7 All SA Health employees including consultants, contractors and students):

- Adhere to the principals and aims of this policy.
- Adhere to local processes established to support the operation of this policy.

- Report breaches of this policy in accordance with the local procedures.

3. Policy Requirements

3.1 Background

Evidence suggests that medicine samples influence prescribing behaviour and increase prescribing of a particular product. As such, the potential consequences for the quality use of medicines must be borne in mind[1].

Where supply of samples is not in accordance with this policy it may result in an expectation by the patient that there will be continuing access to treatment with the particular medicine or brand of product which may not be available on the SA Health Medicines Formulary.

3.2 Scope

This policy directive applies to:

- SA Health hospitals and health services
- SA Health employees (including consultants, contractors and students)

This policy covers all samples of medicines, as defined in section 6 of the policy.

3.3 Policy

- The acceptance of samples by prescribers within SA Health is not permitted.
- The provision and use of samples of a medicine, not listed on the South Australian Medicines Formulary, must be approved by the Local Health Network Drug and Therapeutics Committee (or equivalent committee). Samples of medicines already listed on the South Australian Medicines Formulary require approval by the Director of Pharmacy.
- In facilities with a hospital or health service Pharmacy Department/Service, all samples should be received directly by the hospital or health service Pharmacy Department and dispensed or supplied through the Pharmacy Department/Service.
- Hospitals or health services without a Pharmacy Department/Service must have processes in place to manage samples. The processes must be approved by the Local Health Network Drug and Therapeutics Committee (or equivalent committee).
- The requisition and receipt of supply of samples must be documented in accordance with the Medicines Australia Code of Conduct.
- Samples should not be kept in clinics, patient care areas or elsewhere in the hospital or health services for direct supply to patients.
- The availability or acceptance of medicine samples must not influence the choice of medicine prescribed.
- Requesting or use of medicine samples for personal use is not permitted.
- Where there is ongoing supply of medication under a Medicines Access Program, the Medicines Access Programs Policy Directive must be observed.

4. Implementation & Monitoring

It is the responsibility of Local Health Networks to implement the principles of this policy and to monitor the outcomes. This may be achieved by assessing ongoing progress and performance, including utilising SLS reports and reported breaches of policy.

5. National Safety and Quality Health Service Standards

National Standard 1 Governance for Safety and Quality in Health Care	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare associated infections	National Standard 4 Medication Safety	National Standard 5 Patient Identification & Procedure Matching	National Standard 6 Clinical Handover	National Standard 7 Blood and Blood Products	National Standard 8 Preventing & Managing Pressure Injuries	National Standard 9 Recognising & Responding to Clinical Deterioration	National Standard 10 Preventing Falls & Harm from Falls
☐	☐	☐	☒	☐	☐	☐	☐	☐	☐

Please note these National Standards above apply until 31 December 2018.

The National Standards below will be implemented from 1 January 2019.

National Standard 1 Clinical Governance	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare-Associated Infection	National Standard 4 Medication Safety	National Standard 5 Comprehensive Care	National Standard 6 Communicating for Safety	National Standard 7 Blood Management	National Standard 8 Recognising & Responding to Acute Deterioration
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6. Definitions

In the context of this document:

- **Samples** means samples of medicines given without cost to persons providing clinical services under the auspices of SA Health by pharmaceutical representatives. This includes samples in any form (e.g. tablets, creams, lotions, inhalers) of all scheduled medicines and unscheduled medicines.

7. Associated Policy Directives / Policy Guidelines and Resources

7.1 Relevant SA Health policies, procedures and guidelines

Interaction Between SA Health and the Therapeutic Goods Industry Policy Directive

Medicines Access Programs Policy Directive

7.2 Relevant Legislation

- Controlled Substances Act 1984 – under Reg 46 of the Controlled Substances (Poisons) Regulations 2011, samples of narcotics are prohibited
- Health Care Act 2008
- Public Sector Act 2009
- Public Sector (Honesty and Accountability) Act 1995
- State Procurement Act 2004
- Therapeutic Goods Act 1989

7.3 Other Relevant Documentation

- Medicines Australia Code of Conduct

8. Document Ownership & History

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Previous title was 'Samples (Product Starter Packs) Policy Directive'

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Approval Date	Version	Who approved New / Revised Version	Reason for Change
19/10/18	V1.1	Deputy Chief Executive	Minor amendments and formally reviewed in line with 1-5 year scheduled timeline for review. Title has been changed.
15/12/11	V1.0	Portfolio Executive	Original Portfolio Executive approved version.