SA Health

Policy

Interaction between SA Health and the Therapeutic Goods Industry

Version 3.0

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Government of South Australia

SA Health

1. Name of Policy

Interaction between SA Health and the Therapeutic Goods Industry

2. Policy statement

This policy provides the mandatory requirements for SA Health employees when interacting with the Therapeutic Goods Industry ('Industry').

3. Applicability

This policy applies to all employees and contracted staff of SA Health; that is all employees and contracted staff of the Department for Health and Wellbeing (DHW), Local Health Networks (LHNs) including state-wide services aligned with those Networks and SA Ambulance Service (SAAS).

4. Policy principles

SA Health's approach to interactions between SA Health and Industry is underpinned by the following principles:

- We will act in the public interest.
- We will ensure that all interactions between SA Health and Industry serve the primary interest of patient health and well-being and promote the practice of evidence-based, conflict-free medicine.
- We will ensure unbiased prescribing, product selection and acquisition of medicines, medical devices, and other therapeutic goods.
- We will support patients in making well-informed decisions about their healthcare which extends to knowing about their health care provider interactions and involvement with Industry.
- We will ensure that patient care takes precedence and that the trust placed in SA Health is not subject to undue influence by Industry.
- We will ensure transparency and accountability in decision making.
- We will ensure the fiduciary nature of the health professional-patient relationship and legal interests of SA Health are protected.

5. Policy requirements

Conflicts of Interest

- Employees must disclose any conflict of interest as outlined in Appendix 1: Conflict of Interest Disclosure Mandatory Instruction.
- Managers must ensure that all staff are aware of the need to identify and declare their interest as relevant to the context of the Declaration and Management of Interest Policy. Where unsure whether a conflict of interest exists, employees must discuss it with their relevant line manager, health service Chief Executive Officer (CEO), Executive Director (ED) or delegate for assistance in determining if there is a conflict of interest to be declared.
- Once a conflict is declared, the line manager, health service CEO/ED or delegate must ensure the conflict is appropriately managed.
    - It is not improper for a SA Health employee to have a conflict of interest, but it must be identified, declared, and managed appropriately.

Industry Funding

- Payments or funding from Industry must only be received by the hospital or health service and administered in accordance with Income and Receivables Policy
    - Employees must not accept direct payments or funding from Industry.
- Any Industry funding must only be used for the purposes covered in this Policy or approved by the health service CEO or their delegate.

Sponsored Meetings and Events at SA Health Facilities

- Industry sponsorship must not be sought or accepted for meetings or events held by SA Health services within SA Health facilities.
- SA Health employees must only attend Industry led educational events in accordance with the Guidelines for Suppliers – Educational Event Request for SA Health.

Industry Sponsored Research Projects and Clinical Trials

- Sponsored research projects and clinical trials must obtain approval in compliance with the Research Ethics and Governance Policy.
- The Human Research Ethics Committee (HREC) must be informed of financial arrangements for clinical trials, including proposed payments to researchers and research participants and the provision of other resources required to carry out the study, inclusive of travel to investigators' meetings.
- Funds provided for the purpose of research and clinical trials must only be for the conduct of the project and not involve direct personal payment to individual employees.
    - If funds are used for payment within award regulations for the time and expertise of employees involved in a formal contract directly relevant to the Industry sponsor, it must be publicly recorded.
    - The amount of compensation must be administered under a formal contractual arrangement with Industry, which is open to scrutiny and can only be undertaken as per the Delegations of Authority.
- All funds must be deposited into an appropriate SA Health bank account and administered in accordance with the Income and Receivables Policy
- In the case of a medicine trial, the relevant pharmacy department or pharmacist providing pharmacy services must be informed of the conduct of the trial.
    - Information regarding the trial, as approved by the HREC, must be forwarded to the pharmacy department or pharmacist providing pharmacy services.

Travel and Accommodation Sponsorship

- Industry sponsored travel or accommodation for SA Health employees must comply with the requirements of the Overseas Travel Policy and the Domestic Travel Policy.
    - Sponsorship must not be approved unless it is related to the legitimate need for research that has a tangible benefit to the state of South Australia, or involves active participation in educational activities related to the employees' professional speciality.
- Employees must fully utilise any allowances or otherwise available funding allocated for professional development, as outlined in the relevant enterprise bargaining agreement, prior to accepting any Industry sponsored travel.
- Accepting travel sponsorship from Industry for a spouse, family member or partner must not permitted.

Provision of Staff or Equipment

- Donations of equipment or consumables, or funds for the purchase of equipment or consumables must be subject to evidence of safety, efficacy and cost-effectiveness and identified clinical need as well as the Charitable Gifts and Donations Policy.
- Negotiations must only be undertaken by a designated negotiator versed in the practical and legislative requirements in relation to such donations and free of any potential conflict of interest. Decisions must be endorsed by the relevant oversight Committee.
- Donations of equipment or funds for the purchase of equipment must be made to the health service and not to individual employees. Any donated gifts must comply with the *Health Services Charitable Gift Act 2011* and the Charitable Gifts and Donations Policy.
- Donations must not be accepted for potentially ongoing commitments if ongoing funding is not available.
- The health service CEO or delegate must only approve funds to be used to employ staff for specific service functions following consideration of any potential conflicts of interest and cessation of services on staff employed for such service functions.
- Donations of equipment in excess of market value of $100 must be disclosed in relevant health service public communications. The SA Health Fixed Asset Team must be notified where donations of equipment are received in excess of market value of $10,000.

Gifts, Benefits, Financial and Personal Interests

- Employees must act in accordance with the:
    - Gifts and Benefits Policy
    - Probity in SA Health Procurement Policy, and,
    - Code of Ethics for the South Australian Public Sector.
- Employees must ensure the interests of family members, friends or associates do not influence the performance of their duties and their role as a SA Health employee. Where a known financial interest in a relevant Industry exists, this interest must be declared in writing to the health service CEO or delegate at the earliest available opportunity.
    - Financial and personal interests must also be disclosed on any occasion where they present an actual or potential conflict of interest, including disclosure to the patient for whom the product is to be used.
- Employees must be aware that financial interests in Industry are likely to influence professional judgement.
- In circumstances where there is a known financial or personal interest relating to a medicines formulary application or the acquisition or application of new devices or therapeutic goods, the employee must, before entering into any discussions regarding procurement or use of the medicine/device/technology, declare their interest to the appropriate authorised Committee or delegate, including:
    - Drug and Therapeutics Committee (DTC)
    - South Australian Medicines Evaluation Panel (SAMEP)
    - South Australian Policy Advisory Committee on Technology (SAPACT), and/or
    - Hospital or health service CEO or delegate.

- In cases where a conflict of interest is declared by the person most informed about a specific medicine or technology or device, then the relevant Director Medical Services or senior staff member delegated by the hospital or health service CEO or delegate must be involved in all decisions surrounding the approval or procurement of the medicine or technology or device.

Acquisition of Therapeutic Goods and Medicines

- Procurement of any therapeutic goods must be undertaken in accordance with the SA Health Internal Procurement Framework, Procurement and Contract Management System (PCMS) Policy, Probity in SA Health Procurement Policy and Treasurer's Instructions 18 - Procurement.
- All procurement above $55,000 (inc GST) must be recorded in the Procurement and Contract Management System in accordance with the Procurement and Contract Management System (PCMS) Policy.
- All medicine deliveries for Special Access Scheme (SAS) and Medicines Access Programs (MAP) must be accompanied by a purchase order. In hospitals and health services where there is a pharmacy, such deliveries must be made directly to the pharmacy department and dispensed accordingly.
- Management of medicines at hospitals and health services must be in accordance with the authorised statewide medicines formulary and processes for non-Formulary medicines.
- SA Health hospitals and health services and employees must not be under any obligation to Industry which could result in the inclusion of a particular company's products on the formulary, with the exception of formal procurement contracts.

Medicine Samples

- The control and management of medicine samples within SA Health must be in accordance with Appendix 2: Control and Management of Medicines Samples Mandatory Instruction.

Requirements for Interacting with Industry Representatives

- The requirements for employees interacting with industry representatives must be in accordance with Appendix 3: Requirements for Interacting with Industry Representatives Mandatory Instruction.
- Appointments with Industry Representatives
    - All appointments made by Industry Representatives must be in accordance with the process outlined in Appendix 4: Process of Appointments with Industry Representatives Mandatory Instruction.

Policy Breaches

- Policy breaches must be managed as outlined in Appendix 5: Management of Policy Breaches Mandatory Instruction.

6. Mandatory related documents

The following documents must be complied with under this Policy, to the extent that they are relevant:

- Code of Conduct
- Code of Ethics for the South Australian Public Sector
- *Controlled Substances Act 1984*
- *Controlled Substances (Poisons) Regulations 2011*
- Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy
- Declaration and Management of Interests Policy

- Domestic Travel Policy
- *Fringe Benefits Tax Assessment Act 1986*
- Gifts and Benefits Policy
- *Health Care Act 2008*
- *Health Services Charitable Gifts Act 2011*
- Income and Receivables Policy
- Medicines Access Programs (MAP) Policy
- Overseas Travel Policy
- Probity in SA Health Procurement Policy
- Procurement and Contract Management System (PCMS) Policy
- *Public Sector (Honesty and Accountability) Act 1995*
- *Public Sector Act 2009*
- Research Ethics and Governance Policy
- SA Health (Health Care Act) Human Resources Manual
- SA Health Internal Procurement Framework
- *State Procurement Act 2004*
- *The Therapeutic Goods Act 1989 & the Poisons Standard*
- Treasurer's Instructions 18 - Procurement

7. Supporting information

- Supplier Interaction and Engagement Factsheet
- Guidelines for Suppliers – Educational Event Request for SA Health

8. Definitions

For the purpose of this policy, the following definitions apply:

- **Employee** means: SA Health employees, contractors and consultants employed under the *Health Care Act 2008* or the *Public Sector Act 2009*.
- **Gift** means: anything of value offered to an employee above their normal salary or employment entitlements. Gifts can be a token value, such as a box of chocolates, or of a significant value, such as a holiday. A public sector agency may also offer a gift, for example, to a visiting delegation or speaker. Gifts are generally tangible and include items such as consumer goods, promotional materials, samples, discounts on goods and services and cash.
- **Hospital and/or health service** means: means the DHW, an incorporated hospital established under the *Health Care Act 2008*, SAAS or a health service as defined under that Act. This includes all LHNs, their sites and the health services provided by or through them.
- **Industry** means: those organisations supplying medicines, medical devices and other therapeutic goods as defined in the *Therapeutic Goods Act 1989* (Cth). The Therapeutic Goods Industry is referred to as 'Industry'.
- **Medicines Access Program** means: programs offered by the pharmaceutical industry to facilitate deferred cost, cost-free or subsidised access to medicines for public hospital patients prior to the implementation of relevant funding arrangements, including compassionate use, expanded access programs, product familiarisation programs, cost-share programs and all other similarly named access programs.

- **Samples** means: medicines given by pharmaceutical representatives without cost to persons providing clinical services under the auspices of SA Health. This includes samples in any form (such as tablets, creams, lotions, inhalers) of any scheduled medicines and unscheduled medicines.
- **Special Access Scheme** means: TGA arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. With the exception of drugs of abuse where the manufacture, possession, sale or use is prohibited by State or Territory law, any unapproved therapeutic good can potentially be supplied via the SAS.
- **Therapeutic Goods** means: goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use (Therapeutic Goods Act 1989).
- **Therapeutic Goods Industry** means: See Industry.
- **Statewide services**: includes Statewide Clinical Support Services, Prison Health, SA Dental Service, BreastScreen SA and any other statewide services that fall under the governance of the Local Health Networks.

9. Compliance

This policy is binding on those to whom it applies or relates. Implementation at a local level may be subject to audit/assessment. The Domain Custodian must work towards the establishment of systems which demonstrate compliance with this policy, in accordance with the requirements of the Risk Management, Integrated Compliance and Internal Audit Policy.

Any instance of non-compliance with this policy must be reported to the Domain Custodian for Clinical Governance, Safety and Quality Policy Domain and the Domain Custodian for the Risk, Compliance and Audit Policy Domain.

10. Document ownership

Policy owner: Domain Custodian for the Clinical Governance, Safety and Quality Policy Domain

Title: Interaction between SA Health and the Therapeutic Goods Industry Policy

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11. Document history

Version	Date approved	Approved by	Amendment notes
3.0	01/10/2024	Deputy Chief Executive, Clinical System Support & Improvement	Transfer to new Policy Framework template and requirements.
2.0	01/06/2015	Portfolio Executive	Updated version
1.0	15/12/2011	Portfolio Executive	Original Version

12. Appendices

1: Conflict of Interest Disclosure Mandatory Instruction

2: Control and Management of Medicines Samples Mandatory Instruction

3: Requirements for Interacting with Industry Representatives Mandatory Instruction

4: Process for Appointments with Industry Representatives Mandatory Instruction

5: Management of Policy Breaches Mandatory Instruction

Appendix 1: Conflict of Interest Disclosure Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. *Conflict of Interest Disclosure*

- Employees must disclose any conflict of interest that may arise at any time during their employment, in accordance with Section 27 of the *Public Sector (Honesty and Accountability) Act 1995 (SA)* and the Declaration and Management of Interests Policy, including (but not limited to):
  - receiving Industry funding or sponsorship;
  - acting as an Industry consultant;
  - known financial interests in Industry exist;
  - receiving Industry research or educational funds; and/or
  - procuring or acquiring therapeutic goods.

Appendix 2: Control and Management of Medicines Samples Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. *Control and Management of Medicines Samples*

- The provision and use of samples of a medicine, not listed on the South Australian Medicines Formulary, must be approved by the LHN Drug and Therapeutics Committee (or equivalent committee). Samples of medicines already listed on the South Australian Medicines Formulary must be approved by the Director of Pharmacy.
- In facilities with a hospital or health service pharmacy department/service, all samples must 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 LHN 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 must 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.
- Medicine samples must not be requested or utilised for personal use.
- Where there is ongoing supply of medication under a Medicines Access Program, the Medicines Access Programs Policy must be observed.

Appendix 3: Requirements for Interacting with Industry Representatives

The following Instruction must be complied with to meet the requirements of this policy.

1. *Requirements for Interacting with Industry Representatives*

- Employees must ensure, Industry representatives abide by the Medicines Australia Code of Conduct and medical technology representatives abide by the Medical Technologies Association of Australia (MTAA) Code of Practice in any interactions with SA Health.
- Employees must ensure industry representatives attending any SA Health facility must abide by all relevant SA Health policies and procedures, including this policy.
- Employees must ensure industry representative attendance at a SA Health facility is by appointment only. Appointment times and locations must not interfere with an employee's usual work or patient care requirements.
- The business unit within the SA Health facility authorising the visit must provide an identification badge to the industry representative or ensure one is worn at all times while at SA Health facilities.
- Meetings between SA Health employees and Industry representatives must not occur in the presence of patients. Appropriate areas such as private offices, meeting rooms or staff facilities must be used for interviews.
- Employees must ensure that where a visitor or observer may or will participate in any capacity in a procedure, the appropriate approval must be obtained from the relevant Director Medical Services or Delegate. Participation of visitors or observers must only occur with the consent of the patient(s) involved in accordance with Consent to Health Care and Medical Treatment Policy
- For Industry representatives to attend surgical procedures, employees must ensure industry representatives first obtain approval from the Director of Surgical Services and/or General Manager of the hospital or health service.
    - Approval for the Industry representative to attend a procedure must only be granted following a written submission outlining the service to be provided (such as advice or instruction on operating a device), their credentials in providing the service, and the endorsement of the surgeon who will be performing the procedure. The surgeon will assume responsibility for all aspects of the surgical procedure, including those aspects provided by the Industry representative.
- Employees must ensure products or indications that have not been registered by the TGA must not be promoted nor any printed material be disseminated for these by Industry, unless explicitly requested by a SA Health employee.

Appendix 4: Process for Appointments with Industry Representatives Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. *Process for Appointments with Industry Representatives*

- Appointments with medical employees: authorisation must first be obtained from the most senior medical officer within the individual unit (or delegate). Industry representatives must not normally meet with resident staff unless a consultant is present. Pre-authorisation must occur prior to every individual meeting.
- Appointments with pharmacy employees: authorisation must first be obtained from the most senior pharmacist within that hospital or health service. Pre-authorisation must occur prior to every individual meeting.
- Appointments with nursing and midwifery employees: authorisation must first be obtained from the Director of Nursing/Midwifery (or delegate) within that hospital or health service. Pre-authorisation must occur prior to every individual meeting.
- Appointments with allied health employees: authorisation must first be obtained from the most senior member of that allied health profession within that hospital or health service. Pre-authorisation must occur prior to every individual meeting.

Appendix 5: Management of Breaches Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. *Management of Policy Breaches*

- Policy breaches by SA Health employees
    - Employees that suspect or become aware of any breach of this policy must report this to their line manager or to the SA Health service facility CEO or delegate as appropriate. Breaches of this policy may result in disciplinary action.
- Policy breaches by Industry Representatives
    - Where a SA Health employee becomes aware of a breach of the Medicine Australia Code of conduct or the Code of practice of MTAA by an Industry representative in their interaction with SA Health, the employee must report the breach to the health service CEO or Delegate of the health service. The report must outline details of the breach and include the company and Industry representative(s) names. The health service CEO or Delegate has discretion, after discussion with the reporter, as to whether a formal warning is required.
    - Where the health service CEO or Delegate deems a formal warning is to be given, the Industry representative is to be advised in writing and afforded the opportunity to respond. A written warning must also be sent to the relevant company.
    - Depending upon the nature and severity of the breach, this may also be progressed to an official complaint and request for sanctions under the Medicines Australia Code of Conduct if it is a medicines issue, or the MTAA Code of Practice if it is an issue relating to medical devices and other therapeutic goods.
    - Following receipt of a second notification of a breach, the Industry representative must be warned by the health service CEO or Delegate of the hospital or health service. A formal warning in writing must be sent to the relevant company
    - If a third breach occurs by an Industry representative, the relevant company must be notified and the matter referred to them for resolution with a recommendation that they prohibit the representative from attending any SA Health premises. Further infringement may jeopardise future business dealings with SA Health.