

# Policy Directive: compliance is mandatory

## Interaction between SA Health and the Therapeutic Goods Industry Policy Directive

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### Summary

The updated Interaction between SA Health and the Therapeutic Goods Industry Policy Directive provides greater clarity and direction to SA Health staff and health services about interaction with Industry including sponsorship, attendance by industry representatives at health care facilities and conflicts of interest. It aims to 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.

### Keywords

Therapeutic Goods, Industry, Pharmaceuticals, Ethics, Probity, Interaction, Payments, Sponsorships, Travel, Donations, Conflict of Interest, Representatives, Medicines, Interaction between SA Health and the Therapeutic Goods Industry Policy Directive

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Is this a new policy? *N*  
Does this policy amend or update an existing policy? *Y*  
Does this policy replace an existing policy? *N*  
Interaction between SA Health and the Therapeutic Goods Industry Policy Directive v1.0

### Applies to

*All SA Health Portfolio*

### Staff impacted

*All Staff, Management, Admin, Students; Volunteers*

### EPAS compatible

*NA*

### Registered with Divisional Policy Contact Officer

*Yes*

### Policy doc reference no.

*D0267*



SA Health

## Version control and change history

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1.0	15/12/11	01/05/15	Original version
2.0	1/06/2015	current	Updated version



Interaction between SA  
Health and the Therapeutic  
Goods Industry  
Policy Directive

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Date	Version	Who approved New/Revised Version	Reason for Change
01/06/2015	V2	Portfolio Executive approved; reviewed and updated version	Formally reviewed in line with 1-5 year scheduled timeline for review.
15/12/2011	V1	Portfolio Executive approved original version	

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# Interaction between SA Health and the Therapeutic Goods Industry Policy Directive

## 1. Objective

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This Policy Directive outlines the requirements for all SA Health employees (which includes contractors and consultants) when interacting with the Therapeutic Goods Industry (referred to as 'Industry' hereafter). The policy also outlines the expectations of Industry when interacting with SA Health, employees and any SA Health hospital or health service.

This policy aims to 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.

Additionally, the purpose of this policy is to protect:

- > The wellbeing of the individual patient
- > The fiduciary nature of the health professional-patient relationship
- > The legal interests of SA Health.

## 2. Scope

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This policy directive applies to all SA Health Portfolio and covers all interactions with Industry.

## 3. Principles

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This policy recognises that interactions between health practitioners and Industry are a necessary and legitimate part of improving the lives of South Australians through the provision of specialised product information and ensuring that patients have access to medicines, medical devices and other treatments to promote quality care. It is acknowledged that Industry interacts with hospitals and health services, individual health professionals and other SA Health employees in areas such as clinical trials, research and development, staff education, meetings and travel sponsorship, and procurement.

Patients need to be supported to make well-informed decisions about their healthcare which extends to knowing about their health care provider interactions and involvement with Industry. To ensure that patient care takes precedence and that the trust placed in SA Health is not subject to undue influence by Industry, consideration must be given to the appropriateness of all interactions.

SA Health employees must be aware that many interactions between Industry representatives and SA Health are likely to have a promotional intent. While it is unrealistic and inappropriate to prohibit contact between health practitioners and Industry, it is important to recognise those activities that enhance clinical practice and those that potentially damage the relationship with patients. Unbiased prescribing, product selection and acquisition of medicines, medical devices and other therapeutic goods is essential. This policy describes due consideration to be given to the appropriateness of interactions with Industry.

## 4. Detail

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### Requirements for SA Health employees when interacting with Industry

#### 4.1 Conflicts of Interest

- i. Section 27 of the *Public Sector (Honesty and Accountability) Act 1995* creates a legal onus on public sector employees to disclose pecuniary or personal interests if they conflict or potentially conflict with the employee's duties. As this is a legal onus on employees, failure to do so constitutes as grounds for termination of employment in the public sector, or other disciplinary action.
- ii. The onus is on SA Health employees to disclose and manage any conflict of interest that may arise at any time throughout their employment. In relation to this policy such conflicts may arise when:
  - a) receiving Industry funding or sponsorship
  - b) acting as an Industry consultant
  - c) known financial interests in Industry exist
  - d) receiving Industry research or educational funds
  - e) procuring or acquiring therapeutic goods
- iii. SA Health managers must ensure that all employees involved in a relevant process understand their obligation to declare a conflict of interest, either actual, potential or perceived.
- iv. An employee unsure whether a conflict of interest exists is advised to discuss it with their relevant line manager, health service CEO/ED or Delegate for assistance to determine if there is a conflict of interest to be declared. Once the conflict is declared the onus then falls on the line manager, CEO/ED or Delegate to manage the conflict appropriately.
- v. It is not improper for a SA Health employee to have a conflict of interest, but it must be identified, declared and managed appropriately.

#### 4.2 Industry Funding

- i. Any Industry funding must only be used for corporate purposes approved by the CEO/Delegate.
- ii. Any payments received for such purposes must be made to the hospital or health service and administered in accordance with any relevant SA Health finance policies.
- iii. Payments must not be made directly to SA Health employees.

#### 4.3 Sponsored Meetings and Events at SA Health Facilities

There shall be no Industry sponsored events at SA Health facilities; Industry sponsorship is not sought or accepted for meetings or events held by SA Health services within SA Health facilities.

#### 4.4 Industry Sponsored Research Projects and Clinical Trials

- i. Sponsored research projects and clinical trials require Human Research Ethics Committee (HREC) approval and must adhere to HREC guidelines.
- ii. The 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. This would include details of travel to investigators' meetings.
- iii. Funds provided must be for the conduct of the project and not involve direct personal payment to individual employees.

- iv. Funds may be used for payment within award regulations for the time and expertise of employees involved in a formal contract directly relevant to the Industry sponsor and 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.
- v. All funds are required to be deposited into an appropriate SA Health account and administered in accordance with the relevant policies.
- vi. 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.

#### 4.5 Gifts

- i. SA Health employees (including contractors and consultants) are not to accept gifts and benefits from Industry where they can be, or may be seen to be, a means of influence that can compromise or appear to compromise neutrality and integrity.
- ii. SA Health employees have legal obligations in regard to gifts and benefits under the Code of Ethics for the South Australian Public Sector including:
  - a) the acceptance of any gifts or benefits by public sector employees has the potential to secure the influence or favour of an employee. The public expects the public sector and its employees to be impartial and not to be improperly influenced in the performance of their duties
  - b) public sector employees will not, for themselves or others, seek or accept gifts or benefits that could be reasonably perceived as influencing them
  - c) all employees will comply with any health service requirements in relation to accepting, declaring and/or recording the receipt of gifts or benefits
- iii. Under no circumstances are employees and/or their families to accept money.
- iv. Refer to the SA Health Policy Directive on *Supplier Interaction and Engagement Protocols* for further information on gifts.

#### 4.6 Travel and Accommodation Sponsorship

- i. All travel must be in accordance with relevant SA Health policies including the SA Health Policy Directives on *Overseas Travel Policy and Procedures*, *Travel Diary and Travel Reimbursements* and the SA Health Guideline on *Absence on duty for medical officers to attend to professional commitments* and must be by economy class only, unless otherwise approved by the CEO or Delegate.
- ii. Industry sponsored travel or accommodation for SA Health employees must be approved by the relevant CEO/ED or Delegate and a register kept in accordance with the above policies considering any fringe benefits tax (FBT) requirements. Sponsorship will 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 (e.g. presentation at a conference).
- iii. Employees are encouraged to access 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. It is noted that SA Health supports health practitioner employee access to continuing professional development through various means including enterprise agreements, allowances and specific grant programs.
- iv. SA Health employees must ensure the transparency of any sponsored travel arrangements; sponsorship must be declared to the relevant CEO or Delegate and

approval obtained in the first instance. Accepting travel sponsorship from Industry for a spouse, family member or partner is not permitted.

#### **4.7 Provision of Staff or Equipment**

- i. 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 relevant SA Health policies and procedures (e.g. asset register, Work Health Safety policies, biomedical engineering policies, radiation safety procedures, health technology assessment requirements).
- ii. Negotiations may 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 Committee (e.g. Medical Imaging Advisory Committee, Clinical Reference Group, ICT Steering).
- iii. 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 relevant SA Health Finance policies.
- iv. Donations must not be accepted for potentially ongoing commitments if recurrent funding is not available.
- v. Donated equipment becomes the property of the health service and is subject to SA Health policies and procedures relating to receipt and handling. This includes policies relating to the introduction of new technologies and/or products.
- vi. The CEO or Delegate may approve funds to be used to employ staff for specific service functions. However, consideration must be given to any potential conflicts of interest and cessation of services on staff employed for such service functions.
- vii. Donations of equipment in excess of market value of \$100 should 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.

#### **4.8 Medicines Access Programs**

- i. All SA Health employees must refer to and comply with the requirements of the SA Health *Medicines Access Programs (Product Familiarisation Programs and Expanded Access Programs)* Policy Directive. Medicines Access Programs include compassionate use, expanded access programs, product familiarisation programs, cost-share programs and all other similarly named access programs.

#### **4.9 Financial and Personal Interests**

- i. SA Health employees must ensure the interests of family members, friends or associates do not influence the performance of their duties and their role as a public sector 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 (e.g. disclosure to the patient in whom the product is to be used).
- ii. Employees should be aware that financial interests in Industry are likely to influence professional judgement.
- iii. 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 declare their interest to the appropriate authorised Committee, (i.e. Drug and Therapeutics Committee (DTC), the South Australian Medicines Evaluation Panel (SAMEP), the South Australian Policy Advisory Committee on Technology (SAPACT), and/or the hospital or health service CEO or Delegate before entering into any discussions regarding procurement or use of the medicine/device/technology.



- iv. 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. This is to uphold transparency of process and clinical best practice.

#### **4.10 Acquisition of Therapeutic Goods and Medicines**

- i. Appropriate consultation with clinical units and/or users must take place. This includes adherence to relevant SA Health policies and procedures for the introduction of new technology and or products.
- ii. The choice of therapeutic goods for acquisition must be based on evidence of safety, efficacy and cost effectiveness, and identified clinical need.
- iii. Procurement of any therapeutic goods must be undertaken in accordance with the SA Health *Procurement, and Contract Management System Policy, Probity in SA Health Procurement Policy* and the *State Procurement Act 2004*.
- iv. During any formal procurement process, employees must not discuss the progress of acquisition with Industry representatives or other interested parties, unless specifically authorised to do so by SA Health's Procurement and Supply Chain Management. Employees must not discuss the offers of any other tenders with a supplier.
- v. 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.
- vi. Management of medicines at hospitals and health services must be in accordance with the authorised medicines formulary. The health service DTC and the South Australian Formulary Committee (SAFC) recommend medicines for inclusion in the formulary following consideration of applications from senior medical staff. Approval is in accordance with quality use of medicines (QUM) principles for appropriate and cost-effective prescribing.
- vii. 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.

#### **4.11 Samples/Starter Packs**

- i. All SA Health employees must refer to and observe the *Samples (Product Starter Packs) Policy Directive*.

### **Requirements for Industry Representatives Interacting with SA Health**

#### **4.12 Industry representatives attending SA Health facilities**

In addition to SA Health Policies and procedures, Industry representatives must also abide by the *Medicines Australia Code of Conduct* and medical technology representatives must abide by the *Medical Technologies Association of Australia (MTAA) Code of Practice* in all interactions with SA Health employees.

- i. Industry representatives attending any SA Health facility must abide by all relevant SA Health policies, including this policy.
- ii. Attendance at a SA Health facility is by appointment only. Appointment times and locations should not interfere with employees' usual work or patient care requirements.
- iii. Authorised identification and 'Visitors' identification badge must be worn at all times while at a SA Health facilities.

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- iv. Meetings between SA Health employees and Industry representatives should not occur in the presence of patients. Appropriate areas such as private offices, meeting rooms or staff facilities may be used for interviews where prior arrangements have been made.
- v. Where a visitor or observer may or will participate in any capacity in a procedure, they must obtain the appropriate consent from the relevant Director Medical Services or Delegate and abide by relevant SA Health policies and procedures including operating theatre procedures and the *SA Health Credentialing and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy*. Participation must only occur with the consent of the patient(s) involved.
- vi. For Industry representatives to attend surgical procedures, they must first obtain approval from the Director of Surgical Services and/or General Manager of the hospital or health service. To obtain approval the Industry representative must submit written documentation outlining the service to be provided (e.g. 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.
- vii. Products or indications that have not been registered by the TGA must not be promoted nor should any printed material be disseminated for these by Industry, unless explicitly requested by a SA Health employee.

#### **4.13 Appointments with Industry Representatives**

- i. Appointments with medical employees: authorisation must first be obtained from the most senior medical officer within the individual unit (or delegate). Industry representatives may not normally meet with resident staff unless a consultant is present. Pre-authorisation is required prior to every individual meeting.
- ii. Appointments with pharmacy employees: authorisation must first be obtained from the most senior pharmacist within that hospital or health service. Pre-authorisation is required prior to every individual meeting.
- iii. 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 is required prior to every individual meeting.
- iv. 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 is required prior to every individual meeting.

### **Policy Breaches**

#### **4.14 Policy breaches by SA Health employees**

- i. Employees that become aware of any breach of this policy must report this to their line manager or to the SA Health health service facility CEO or Delegate as appropriate. Policy breaches by employees must be managed in accordance with the SA Health (*Health Care Act*) Human Resources Manual.
- ii. In cases where it is unclear if a breach of this policy has occurred, or where an employee seeks clarification about a particular interaction or conflict of interest that might result in a breach of this policy, the matter must be referred to the relevant line manager or SA Health facility CEO or Delegate as appropriate, for consideration.

#### **4.15 Policy breaches by Industry Representatives**

- i. Where a SA Health employee becomes aware of a breach of this policy by an Industry representative, the employee must report the breach to the 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 CEO or Delegate has discretion, after discussion with the reporter, as to whether a formal warning is required.
- ii. Where the 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 to the reported breach. A written warning must also be sent to the relevant company.
  - iii. 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.
  - iv. Following a further written report, the Industry representative must be warned by the CEO or Delegate of the hospital or health service. A formal warning in writing must be sent to the relevant company.
  - v. 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.

## 5. Roles and Responsibilities

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- 5.1 All SA Health Staff (including contractors and consultants) are responsible for:**
- i. Understanding and abiding by the requirements of this policy
  - ii. Reporting breaches of this policy by employees or Industry representatives as outlined in the policy.
- 5.2 Chief Executive Officers (CEOs) of LHNs, the Chief Executive of SA Health and Executive Directors (EDs) of South Australian public hospitals and health services or SA Health Divisions are responsible for:**
- i. Ensuring effective implementation of this policy
  - ii. Investigating and managing policy breaches as described in the [SA Health \(Health Care Act\) Human Resources Manual](#) and the [Public Sector Act 2009](#) (SA).
- 5.3 Drug and Therapeutics Committees (DTCs) (and equivalent committees) are responsible for:**
- i. Investigating and following up on policy breaches as outlined in the [SA Health \(Health Care Act\) Human Resources Manual](#) and the [Public Sector Act 2009](#) (SA).

## 6. Reporting

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SA Health employees are required to engage with the CEO or Delegate to declare and obtain approval for interaction with Industry, including but not limited to:

- > Industry sponsored meetings or events (noting these are discouraged);
- > Industry sponsored travel and accommodation
- > Engaging in outside employment as an Industry consultant
- > Where known personal or financial interests exist
- > Receiving research or education funds
- > Reporting policy breaches.

## 7. EPAS

Not applicable











## 8. Exemption

Not applicable

## 9. Other

Not applicable

## 10. National Safety and Quality Health Service Standards

 <a href="#">National Standard 1</a> <a href="#">Governance for Safety and Quality in Health Care</a>	 <a href="#">National Standard 2</a> <a href="#">Partnering with Consumers</a>	 <a href="#">National Standard 3</a> <a href="#">Preventing &amp; Controlling Healthcare associated infections</a>	 <a href="#">National Standard 4</a> <a href="#">Medication Safety</a>	 <a href="#">National Standard 5</a> <a href="#">Patient Identification &amp; Procedure Matching</a>	 <a href="#">National Standard 6</a> <a href="#">Clinical Handover</a>	 <a href="#">National Standard 7</a> <a href="#">Blood and Blood Products</a>	 <a href="#">National Standard 8</a> <a href="#">Preventing &amp; Managing Pressure Injuries</a>	 <a href="#">National Standard 9</a> <a href="#">Recognising &amp; Responding to Clinical Deterioration</a>	 <a href="#">National Standard 10</a> <a href="#">Preventing Falls &amp; Harm from Falls</a>
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## 11. Risk Management

Failure of SA Health employees and Industry representatives to comply with this policy may compromise patient outcomes and the reputation and legal interest of SA Health

## 12. Evaluation

SA Health employees and Industry representatives are required to report breaches of this policy as outlined in section on Policy Breaches.

Additionally, the South Australian Medicines Advisory Committee will liaise with the Local Health Networks regarding uptake and compliance with this policy directive.

## 13. Definitions

**In the context of this document:**

**Employee** means: SA Health employees, contractors and consultants employed under the [Health Care Act 2008](#) or the [Public Sector Act 2009](#).

**Gift** means: free item(s) or hospitality exceeding common courtesy that are offered to employees in association with their work. They may be enduring or consumable. They range in value from nominal to significant and may be given for different reasons.

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**Hospital and/or health service** means: for the purposes of this policy, 'hospital/health service' means the Department of Health, an incorporated hospital established under the *Health Care Act 2008*, SA Ambulance Service (SAAS) or a health service as defined under that Act. This includes all Local Hospital Networks, 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 shall be referred to as 'Industry' for the purposes of this document.

**Medicines Access Program (MAP)** 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. MAP include compassionate use, expanded access programs, product familiarisation programs, cost-share programs and all other similarly named access programs.

**Samples/Product Starter Packs** means: samples of medicines given by pharmaceutical representatives, without cost to persons providing clinical services for SA Health. This includes samples in any form (e.g. tablets, creams, lotions, inhalers, etc.) of all scheduled medicines and unscheduled medicines

**Special Access Scheme (SAS)** 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*.

## Acronyms

CEO	Chief Executive Officer
DTC	Drug and Therapeutics Committee
ED	Executive Director
HREC	Human Research Ethics Committee
MAP	Medicines Access Program
MTAA	Medical Technologies Association of Australia
PBS	Pharmaceutical Benefits Scheme
PFP	Product Familiarisation Program
SAMAC	South Australian Medicines Advisory Committee
SAS	Special Access Scheme
TGA	Therapeutic Goods Administration

## 14. Associated Policy Directives / Policy Guidelines

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- > Absence on duty for medical officers to attend to professional commitments (Policy Guideline)
- > Credentialing and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy (Policy Directive)
- > Medicines Access Programs (Product Familiarisation Programs and Expanded Access Programs) Policy (Policy Directive)
- > Overseas Travel Policy and Procedures (Policy Directive)
- > Probity in SA Health Procurement Policy (Policy Directive)
- > Samples (Product Starter Packs) Policy (Policy Directive)
- > SA Health (Health Care Act) Human Resources Manual
- > Supplier Interaction and Engagement (Policy Directive)
- > Travel Diary and Travel Reimbursements (Policy Directive)
- > Supplier Interaction and Engagement Protocols (Directive)

## 15. References, Resources and Related Documents

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- > *Health Care Act 2008 (SA)*
- > *Health Services Charitable Gift Act 2011*
- > *Public Sector Act 2009 (SA)* and Code of Ethics for the South Australian Public Sector.
- > *Public Sector (Honesty & Accountability) Act 1995 (SA)*
- > *State Procurement Act 2004 (SA)*
- > *Fringe Benefits Tax Assessment Act 1986 (Cwlth)*
  
- > Medicines Australia Code of Conduct
- > Medical Technologies Association of Australia (MTAA) Code of Practice