

Interaction between SA Health and the Therapeutic Goods Industry

SA Health has implemented a policy directive on *Interaction between SA Health and the Therapeutic Goods Industry* to ensure that the primary objective of professional interactions with the Therapeutic Goods Industry (Industry) is the promotion of patient health and wellbeing. The policy outlines requirements for SA Health Staff as well as the expectations of Industry when interacting with SA Health or any SA Health hospital/health service.

Who is covered by this Directive?

All SA Health Staff and incorporated hospitals and health services. This includes all South Australian public hospitals and health services.

The Therapeutic Goods Industry (Industry) refers to all companies involved in the supply, manufacture &/or promotion of medicines, medical devices and other therapeutic goods.

If a healthcare professional works at a mix of public and private hospitals in SA, would they be considered staff for the purposes of this Directive?

Any healthcare professional who is employed by SA Health is considered staff for the purposes of the Directive, regardless of hours worked.

Some provisions relate to activities specifically within the hospital/health service and would not apply to private practice (eg sponsored meetings and events, donations of equipment, supply of medicines samples).

However, provisions relating to individual staff are applicable to all SA Health employees, regardless of when these activities take place (eg 10.6-Gifts to staff members, 10.7-Travel Sponsorship, 10.9-SA Health Staff Members Acting as Industry Consultants, 10.10-Financial Interests).

Can funding/payments be provided to SA Health staff or units?

Any funding or sponsorships from Industry must be provided into a SA Health special purpose fund account and only be used for approved corporate purposes (eg support of professional visitors, research fellowships, staff continuing education or other such purposes) and must also be declared.

Payments to staff may only be made for time and expertise (eg for participation in research or acting as an Industry consultant) at fair market value for the service provided.

Can gifts be provided to SA Health Staff from Industry (10.6)?

No. SA Health staff may not accept any gifts from Industry. This includes small gifts such as pens or calendars and educational items such as medical textbooks and anatomic models which are provided directly to staff members.

Can Industry Sponsor SA Health meetings or events (10.2)?

Industry sponsored events are not encouraged. However, if Industry sponsored events are held on any SA Health premises or in association with any SA Health entity, they must be arranged in consultation with the relevant CEO or Delegate. These events must not provide public opportunities for industry to promote their products.





This provision relates to any Industry events conducted at SA Health sites as well as hospital-run meetings or events which include any sponsorship/funding from Industry.

Who should obtain approval for an Industry sponsored meeting or event (10.2.1)?

The SA Health staff member/unit arranging the funding should also arrange the approval. The Industry sponsor would be required to provide details of the event.

What is an Industry sponsored lunch or meal during working hours (10.2.3)?

This provision includes specific meals as well as the provision of any food or refreshments at any meetings, journal clubs, grand rounds, educational events, inservices (day-to-day product training), etc held during working hours, including the provision of meals such as breakfast or lunch that coincide with a break in the work day or immediately before/after work.

This would not apply to the provision of modest refreshment as part of the approved program of all-day training sessions.

What are "public opportunities to promote products" (10.2.2)?

Public opportunities to promote products include the promotion of products at any forum which is attended by clinical staff and/or external participants.

Is there a process for inviting SA Health staff to Industry sponsored educational events (10.2 & 10.7)?

There is no official process at this stage; however it is requested that any invitations are only sent for Industry sponsored educational events which comply with the

Directive (eg no offers of sponsorship for attendance only).

Can travel sponsorship be provided to SA Health employees for attendance at a conference for educational purposes?

Sponsorship may only be provided for active participation at a conference such as presentation or for research activities. Professional development funding can be used to support educational activities designed to improve patient outcomes, QUM principles, etc.

All travel must be in accordance with relevant SA Health travel policies and Industry Codes including provisions regarding acceptable standards of travel and accommodation.

Does the provision relating to 'donations of equipment' (10.8) apply to trials &/or samples of equipment?

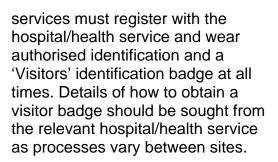
Donations of equipment samples/trials must be subject to evidence of safety, efficacy and cost-effectiveness and identified clinical need. All negotiations regarding donations must be undertaken by an approved negotiator.

Donations may only be made to the hospital/health service and not to individual staff members.

What are the requirements regarding industry representatives attending SA public hospitals and health services?

Industry representatives may attend SA public hospitals/health services by appointment only and must familiarise themselves with and abide by all hospital/health service policies. Industry representatives are not permitted to enter patient care areas (unless as specified under section 11.2.

In addition, Industry representatives attending SA public hospitals/health



Is there a process companies should be aware of before engaging SA healthcare professionals as consultants (10.9)?

It is the responsibility of SA Health employees to obtain appropriate management approval prior to engaging in any outside employment, including acting as an Industry consultant.

Where can I obtain a visitor's badge?

The exact location to obtain a visitor's badge varies between sites. Visitors' badges are generally obtained at the *engineering & building services* reception (or similar) or at the *security desk* if out of hours access is required. Visitors' badges may be obtained at the *front reception* desk I hospitals without an *engineering & building services* reception.

Can I meet with SA Health Staff?

Industry representatives must register with the hospital/health service before contacting individual staff members (ie arrangement with the relevant superior).

Appointments must not interfere with usual work or patient care.

How can patient consent be obtained for participation in a hospital procedure (11.1.1 i)?

Patient consent for attendance in theatre can be obtained by the surgeon/hospital via usual patient consent process.

How can Industry representatives obtain approval to attend surgical procedures?

For industry representatives to attend surgical procedures, they must first submit a document containing a brief outline of the service they would be providing, their background and expertise for providing the service, and the endorsement of the surgeon who will be performing the procedure. This document will require approval by the Director of Surgical Services and/or General Manager of the Hospital/Health Service.

Will approval to attend surgical procedures be provided on a blanket basis or is approval required for every procedure (11.1.1 ii)?

Approval for representatives to routinely attend surgical procedures may be granted by the Director of Surgical Services &/or General Manager for a specific service to be provided at that hospital/health service. If any aspects of the approval change (eg service to be provided, surgeon responsible for the procedure &/or location) then a new approval would be required.

What should I do if I am aware of a breach of the Directive?

It is recommended that you report the breach to the relevant hospital/health service CEO or their delegate.

For more information

South Australian Medicines Advisory Committee SA Health

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