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The meeting is being recorded for record purposes, by participating you consent to the recording thereof.

Competition law reminder and conflict of interest

The meeting is held with no intent to collude or engage in any matter that might contravene competition law. Conflicts of interest must be declared and if required, members recuse themselves, either before or during the meeting, as and when they become apparent.

Disclaimer

The content i.e. presentations, views , opinions, advice expressed within the context of this event by invited speakers are theirs and not those of SAMED and as such does not imply an endorsement by SAMED of either the content or the speaker. The content is not a substitute for appropriate legal advice and is not binding on SAMED. SAMED, its board members, committees, employees and members, will not be responsible for any inaccuracies or omissions, or, liable for any damages or loss of whatsoever nature suffered by any person as a result of relying on or using the content provided.



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SAMED Competition Law Guidelines: Do's and Don'ts

Don't

Don't reach understandings or agreements or even hold discussions with a competitor (or even a potential competitor) on commercially sensitive topics such as selling or purchase prices, trading or credit terms (including delivery charges, minimum purchase quantities or interest rates) or billing practices, production, inventory, supply volumes, sales, costs, future business plans, budgets, upcoming tender or bids, or individual suppliers or customers.

Don't attend meetings with competitors or any industry body without written agenda or clear indication of the purpose.

Don't attend unscheduled gatherings with competitors or any industry body unless you know that they are for a bona fide purpose or that they are purely social gatherings.

Don't discuss business related topics at social functions.

Don't accept written non-public information or agree to the exchange of oral non-public information with Members who manufacture, market or sell (or could manufacture, market or sell) competing products.

Don't exchange any current or future information with your competitors (what your company intends to charge or do).

Don't participate in market surveys, or benchmarking exercises that allow access to any competitive information of any individual company. Any data published pursuant to a market survey must be aggregated and contain only aggregated/average data for at least 5 competitors.

Don't engage in joint negotiations, joint sales or joint buying without legal advice.

Don't agree to exclude competitors or engage in collective boycotts of suppliers or customers.

Do

Do read the SAMED Competition Law Compliance Guidelines as contained in the [SAMED Committee SOPs](https://samed.org.za/about-samed/our-committees/) (<https://samed.org.za/about-samed/our-committees/>)

Do discuss public policy, education, scientific developments, regulatory matters of general interest, general industry trends, appropriately aggregated and non-individualized (statistical) market surveys or benchmarking projects, publicly available information and historical information, but be prepared to terminate the discussion and record your disagreement if anyone mentions any of the subjects listed in the "Don't" list above.

Do insist that your company's individual, commercial information is kept confidential by anyone conducting a survey.

Do inform SAMED if you disagree with any of its decisions and keep a copy for your files of any such correspondence.

Do return commercially sensitive information you receive from any competitor, without keeping copies, and explain in writing that you do not wish to obtain such information.

Do inform your company counsel of any approaches seeking to exchange non-public information or coordinate conduct on the market.

Do ask SAMED to have counsel attend SAMED meetings if you or your company has any doubts.



MEMBER FORUM

FORUM 3 OF 4 ON THE CODE UPDATES

Medical Device Code Forum: What does compliant grant management entail?

8 November 2023, 14:00 - 16:00, Virtual

Medical technology companies are often approached to support the continued professional development of healthcare professionals in their field. Join us as we cover updates around indirect educational grants and HCP support.

Please make use of the chat function to send us your questions or raise your hand and the moderator will call on you to speak.



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Chapter Five: Educational grants and support to HCP participation in Events

A few important definitions

“Delegate”

means Healthcare Professionals that attend an event neither as Faculty, nor as Healthcare Professionals providing services to member companies for the specific event.

“Educational Grants”

means provision of funding, member company or third-party products or other in kind support to a Healthcare Organisation by or on behalf of a member company solely for the support and advancement of genuine medical education of HCPs, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the member company is interested and/or involved and where such support is provided solely for a specified intended purpose within this category.

“In Kind”

means the provision of Grants, Charitable Donations and other types of support in the form of goods or services other than money, including the provision of labour, lent or donated goods, or lent or donated services (e.g. catering services for events, provision of venue space, company products and other services).

“Healthcare Organisation (HCO)”

means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, university or other teaching institution or learned or professional society (except for patient organisations), or through which one or more HCPs provide services.

“Healthcare Professional (HCP)”

means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services. **Note:** unless otherwise stipulated the term, HCP includes and is applicable to HCOs.

Requirements for Educational Grants

- May provide Educational Grants for the advancement of medical education.
- Shall document all Educational Grants.
- Shall specify the intended purpose of the Educational Grant in the Grant agreement.
- Shall ensure that the Educational Grant agreement with the recipient organisation includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose.

Member Companies may provide Educational Grants for the following (non-exhaustive) purposes:



Support for HCP Participation at Third-party Organised Educational Events



Support for Third-party Organised Events via commercial organisations not involved in the organisation of the Event (or of all of the Events)



Scholarships and Fellowships



Educational Grants for general medical education topics



Grants for Public Awareness Campaigns

A few more important definitions

“Product and Procedure Training and Education Event”

means a type of company event that is primarily intended to provide HCPs with genuine education, including information and/or training on:

- The safe and effective use of medical technologies, therapies and/or related services, and/or
- The safe and effective performance of clinical procedures, and/or
- Related disease areas.

In all cases the information and/or training directly concern a member company’s medical technologies, therapies and/or related services.

“Third-party”

in the context of educational events and grants, means national, regional, or specialty medical associations or societies, hospitals, professional conference organizers, training institutions (such as medical schools and teaching hospitals), patient organizations or accredited continuing medical education providers. Legal entities established by HCPs in private practice are not considered compliant under the definition of a third-party as such entities serve the self-interest of the HCP’s, does not allow for unbiased selection criteria, and fails to safeguard the anonymity of potential beneficiaries due to the generally small size of the pool of potential beneficiaries.

“Professional Conference Organizer (PCO)”

means a for-profit company or organisation which specialises in the management of congresses, conferences, seminars, and similar events.

“Third-party Organised Educational Event”

means activities of any type that are planned, budgeted, managed, and executed in whole, or partly, by or on behalf of a person or entity other than a member company to fulfil HCPs medical educational needs.

“Third-party Organised Educational Conferences”

means a type of third-party organised educational event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, professional conference organisers (PCOs), patient organisations or accredited continuing medical education providers.

“Third-party Organised Procedure Training”

means a type of third-party organised educational event that is primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

- Specific therapeutic, diagnostic, or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies).
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.
- For the avoidance of doubt, proctorship and preceptorship are not considered to constitute third-party organised procedure training.



Support for HCP Participation at Third-party Organised Educational Events

- The Healthcare Organisation receiving the grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written grant agreement.
- Members should not proactively seek to receive the names of the HCPs benefiting from the educational grant.
- When required by law or for the purposes of auditing, compliance and monitoring, a member may request and receive the names of the HCPs and their respective HCO, who have benefited from the educational grant provided by the member post the event.



Support for Third-party Organised Events via commercial organisations not involved in the organisation of the Event

- Bear in mind that certain compliance risks may rise from working with intermediary companies for the management of Educational Grants and member companies must therefore take all necessary actions to mitigate these risks.
- Agreements must provide the member the right to monitor and audit the activity of the companies managing the Educational Grants.
- Where selection will be made by the managing entity, ensure that the managing company has sufficient experience and expertise to make an appropriate selection.
- Member companies may not provide an Educational Grant or funds for education to a third-party travel agency directly.
- Member companies must include in all of the contractual arrangements appropriate and specific compliance-related criteria and conditions for the HCO/PCO to outsource travel arrangements to a third-party travel agency, which should include appropriate provisions to allow effective monitoring and control of the activity of the third-party travel agency

“Scholarships and Fellowships”

means educational grants provided to an HCO by or on behalf of a member company to support fellowships or scholarships offered by the HCO. Scholarships in this context means an educational grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g., medical training after a residency). “Scholars” and “Fellows” shall be understood accordingly.



Scholarships and Fellowships

- Only HCOs where HCPs are in training shall be eligible to request and/or receive this type of Educational Grants.
- Member companies shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual HCPs.
- Similarly member companies shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant
- Member companies may not additionally pay for, or reimburse, the travel or other participation costs incurred by a Scholar or Fellow.



Educational Grants for general medical education topics

- The topic must directly relate to the Member's area of business, medical technologies, therapies or related services.
- The Event must be conducted in accordance with, and meet the other requirements of Part 1: Interactions with HCPs, Chapter 1: General Criteria for Events of the Code.
- Members can also support genuine medical training on general healthcare-related topics through Company-organised Product and Procedure Training and Education Events.



Grants for Public Awareness Campaigns

- Must be for the legitimate purpose of providing information, promoting awareness and/or educating patients, carers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Member company is interested and/or involved.
- May provide an Educational Grant to support the provision of high-quality information, promoting awareness and/or educating patients, carers, and the public about health and disease provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Member is interested and/or involved.
- Such awareness campaigns must not, however, be designed or used to promote the use of Member therapies, technology, products, or specific HCOs. I.e. they must be “brand-agnostic”
- Supported programme/activity should genuinely aim to improve patient safety and/or clinical outcomes.
- It is not appropriate to support the routine or administrative capacity of a hospital i.e. it must go above and beyond supporting normal hospital capacity and capability, considering the primary purpose of the hospital.

The following table provides a summary of allowed versus prohibited / not allowed support by member companies to HCP participation in events.

ANNEX VI Direct support to HCP participation in Events

Event	Setting	Direct Support for HCP attendance		
		Faculty /Speaker	Delegates	
Third Party Organised Educational Conference	Main Event / Independent Scientific Program	Not allowed	Not allowed	
	Satellite Symposium	Allowed (consulting agreement required)	Not allowed	
	Booth	Allowed (consulting agreement required)	Not allowed	
Third Party Organised Procedure Training meeting*		Allowed	Allowed	
*The criteria for a Third Party Organised Procedure Training meeting can be found in Q&A 18				
Company Events	Product and Procedure Training and Education Event	NOT taking place at or about the same time as a Third Party Organised Educational Event	Allowed	
		Taking place at or about the same time as a Third Party Organised Educational Event	Not allowed	
	Sales, Promotional and Other Business Meeting	NOT taking place at or about the same time as a Third Party Organised Educational Event	Allowed (consulting agreement required)	Not allowed (except for demonstration of non-portable equipment)
		Taking place at or about the same time as a Third Party Organised Educational Event	Allowed	Not allowed

TPOE vs Company Event

In order to determine whether an event is a Third-party organised event (TPOE) or a Company Event, the following aspects should be taken into account:

- Open events (not only Company's customers) are typical of a TPOE, and in this case, it is a third-party who chooses which HCPs attend or HCPs self-select.
- Who is the primary initiator of the Event: To what extent is the third party vs. the Member Company involved and who is determining the agenda?
- CME accreditation is an indication of a TPOE.
- TPOE generally have a broader focus than one or only a few products.
- Single-sponsored events are often Company Events.

Important to Remember...

- All educational grants must be appropriately documented by the Member Company.
- No educational grant shall be provided until a written agreement documenting the terms of this is signed by both parties
- A Company may provide Educational Grants to training institutions (such as medical schools and teaching hospitals) and to other third-party entities in support of their legitimate educational and training programs and activities.
- **A Company may not make an Educational Grant to individual HCPs or individual HCPs-in-training (prohibition of direct sponsorship since Jan 2018)**



Addendum One: Guidance pertaining to the Management of Indirect Sponsorship and Associated Educational Grants

Addendum 1 should be reviewed in conjunction with Chapter 5



Criteria for Companies' support for third-party organised educational events



Guide: Vetting Educational Conference Organisers



Educational Grant Agreement Template (to use and complete)



Guide: Third-party Selection of Recipients of Grants



Frequently Asked Questions and Answers (for reference and review)



Annex I: Grant Request Application Form (to use and complete)



Criteria for Companies' support for third-party organised educational events

- The event must be **primarily dedicated** to objective **scientific and educational activities**.
- The conference **organiser or grant recipient** must be able to **show the donor** that the grant will only be used for a genuine educational purpose. For example, the grant may not be used to defray costs related to entertainment, social activities or partners accompanying HCPs.
- **Industry** should not have any control or responsibility for the **selection** of program content, faculty, educational methods, and materials of the third-party organised event.
- Only the **conference organiser or grant recipient** (if different) can **select** the individual HCPs who will receive support to attend the educational conference.
- The **venue must be conducive** to the **educational** program.
- Companies **cannot** provide educational **grants as a quid pro quo** or with the intention to **influence** any decision to purchase, order, recommend, or market a product.
- Requests for educational grants should reflect the actual, fair market value costs of the intended educational activities.
- A company may not provide an educational grant/donation to influence the recipient's decision to purchase, order, recommend, or market any product or medical technology.
- All support for third-party educational conferences should be appropriately documented.



Criteria for Companies' support for third-party organised educational events

Establish procedures to manage educational grant requests could include:

- A **centralized** portal or point of contact through which an appropriate third-party submits its request for educational grant funding.
- Requesting that the educational grant request include detailed information on the event, including agenda, content, venue, faculty, budgets, etc., and information about the conference organiser or grant recipient (qualification, history of requests, and organizational structure, etc.).
- A company should undertake a due diligence vetting or screening process before paying the educational grant.
- Some companies **may establish an internal, independent review committee to evaluate** potential educational grant support against objective criteria.
- Company agreements with conference organisers or grant recipients, if different, should contain some **standard provisions prohibiting the use of funds to support entertainment** and recreation, requiring compliance with applicable laws or Codes, and requiring organisers to provide companies with fund usage details.



Guide: Third-party Selection of Recipients of Grants

SAMED urges third parties to heed the following in relation to selection of recipients of grants:

- The selection process should be transparent and fair and ensure that only truly deserving candidates are the recipient of grants.
- The selection process must be documented and available on request by a company.
- Only the third-party can select and invite the individual Healthcare Professionals (HCPs) who will receive support to attend the educational conference.
- A company cannot influence the selection of individual HCPs that benefit from the educational grant.
- All individuals / members of the relevant professional association interested in a sponsorship should apply in writing to the organisers of the event / professional association and their written applications should include:
 - Personal details and a CV;
 - Details of the meeting they require sponsorship to;
 - Motivation for sponsorship; and
 - Proof of membership of the relevant association if applicable



Guide: Third-party Selection of Recipients of Grants

The following (not necessarily all) criteria for selection of grant recipients is suggested:

- Field and years of **experience**;
- HCPs assisting in the management of the organisation and the promotion of the discipline of XXXX (FIELD OF EXPERTISE).
- Senior XXXX (example orthopaedist) that have promoted the discipline of XXXX (example orthopaedics) and has rendered a service to XXXX (example orthopaedics) for some time.
- Active members of the society/associations that have assisted in the management, the organisation and attended meetings on a regular basis.
- HCPs that have been actively involved in their own original research and presentations to promote the discipline of XXXX.
- HCPs that have published peer reviewed articles or that have presented peer reviewed presentations at meetings.
- HCPs that have been regular speakers at meetings and that have been actively involved in the Continued Professional Development in XXX of other healthcare professionals.
- HCPs that have been presenters at industry / association meetings.
- HCPs who share knowledge with other HCPs and should after sponsored meetings organise and present the knowledge gained at the sponsored meeting with other HCPs at XXXX organised regional or national meetings.
- Previous sponsorship should always be considered as an exclusion criteria for HCPs, to ensure that others also be considered for sponsorship.
- A full Curriculum Vita could assist in the allocation of sponsorship as it could assist in determining the merit of certain members as well as identify specific interests of certain members to attend certain important meetings that could relate to their interest and expertise.
- Other factors such as historically disadvantaged individual's status, gender, geographical location in terms of rural and inaccessible locations, young practitioners and developing.

SAMED urges all societies to publicly advertise on their websites and allow non-members to apply.



Guide: Vetting Educational Conference Organisers

We provide guidance for use by both companies and other entities e.g. Healthcare Organisations / Doctor Societies to **assist them with vetting educational conference organisers** (and/or educational grant recipients, if different) should they manage educational grants received from companies. This list is not exhaustive, and companies may give greater weight to some criteria over others.

1. Whether the conference organiser or grant recipient is an independent entity (via registration certification).
2. Whether the conference organiser or grant recipient has documentation of official government registration, corporate certification, or other necessary qualifications and approvals.
3. The size of the conference organiser or grant recipient and date on which it was formed.
4. Whether the conference organiser or grant recipient operates independently from an individual HCP or is affiliated with or employs an individual HCP, including HCPs who work for hospitals or are influential in the industry.
5. Whether the conference organiser, grant recipient, or any of its subsidiaries or affiliated entities are under common control with, or otherwise related to, medical institutions.
6. Whether the conference organiser or grant recipient, including its principals and the immediate family of its principals, is (a) affiliated with, owned by, or partially owned by the government or government officials and/or (b) recommended by government officials.
7. Whether the conference organiser or grant recipient appears on a list of industry-approved entities (if available) or a government list of restricted entities.
8. Whether the conference organiser or grant recipient is willing to submit to an audit of its books and records upon request.
9. Whether the conference organiser or grant recipient has organized a similar event, and if so, what are the event details and available feedback.
10. Whether information about previous grants provided to the conference organiser or grant recipient raises concerns.

To help ensure companies review and fund educational grant requests in a timely manner, it is important to respond promptly and fully to any request for additional information.









Chapter Six: Supporting Independent Third-Party Research

Supporting Independent Third-Party Research

- **Objectives and Milestones:** A member company may provide support for research that has defined goals, objectives, and milestones. Requests for research grants should be accompanied by clinical protocols that outline these objectives and milestones. Requests for research grants should also document the nature and scope of the research activity, the budget, the approximate duration of the research, and where applicable, the requirements for independent authorizations or approvals.
- **Limitations:** Research grants may include in-kind or monetary support for legitimate, study-related, documented expenses or services and/or reasonable quantities of no-charge product for the limited duration of the research.
- **Member company Involvement:** The recipient of a member company's monetary or in-kind research support should retain independent control over the research.
- **Member Company Review Processes:** A member company should establish controls for reviewing requests for research grants.
- **Sales Involvement:** Sales personnel should not control or unduly influence the decision of who will receive support or the amount of the support. A member company's sales personnel may provide input about the proposed research program or recipient.

Reminder of important dates

-  22 November 2023 Forum: Charitable donations, intermediaries & the enforcement process
-  1 February 2024 Code Version 8 comes into effect
-  1 February 2024 Code certification period opens (existing members)
-  TBC February 2024 Forum: Your questions answered
-  31 July 2024 Code certification period closed (existing members)
-  31 August 2024 Deadline for Annual Declarations



Questions and comments

SAMED 
advancing patient care through MedTech

Thank you for joining us.

Email additional questions to: communication@samed.org.za



MEMBER FORUM

Transformation Forum: Tracking Sectoral Targets

17 November 2023, 09:00 - 11:00, Virtual

Join us as we unpack what sectoral targets will mean for your company and why it will be of vital importance that you maintain accurate records (tracking) of employment data to ensure compliance with legislature.

[REGISTER NOW](#)



MEMBER FORUM

Transformation Forum: SAMED-YES Alumni Platform Launch

21 November 2023, 10:00 - 11:30, Virtual

SAMED and the Yotuh Employment Service (YES) formed a partnership to capacitate medtech one youth at a time. To facilitate further opportunities for the youth that complete a 12 month programme, we now launch the Alumni Programme. Join us for this exciting opportunity to skip the recruitment fees and gain access to YES youth alumni.

[REGISTER NOW](#)



MEMBER FORUM

FORUM 4 OF 4 ON THE CODE UPDATES

Medical Device Code Forum: Donations, intermediaries and enforcement

22 November 2023, 09:00 - 11:00, Virtual

In this forum we take a look a charitable donations, third part intermediaries and the enforcement process as we conclude the series covering the updated Medical Device Code of Ethical Market and Business Practice.

[REGISTER NOW](#)