

SAMED Guidance Document pertaining to the Management of Indirect Sponsorship and Associated Educational Grants

May 2018 version

Disclaimer: *This Guidance Document and the templates therein have been prepared by SAMED as a suggested guide only for medical technology companies and third party grant recipients be they (1) a third party conference organiser or (2) another appropriate third party (such as a training institution, hospital, medical or other professional association, educational foundation, or similar entity that supports the training and education of Healthcare Professionals (HCPs) and should not be construed as legal advice for any particular facts or circumstances. Use of this document or any parts thereof shall be at the sole discretion and risk of the user parties. SAMED shall not be held liable for any loss or damage that may result from use of this document or any parts thereof. SAMED reserves the right to change or amend the document or any parts thereof at any time without notice.*

This document has been created by SAMED to assist both its member companies and third party grant recipients in the implementation of Indirect Sponsorships and the Management of Associated Educational Grants.

Contents

Criteria for Companies' support for third party organised educational events	2
Guide: Third Party Selection of Recipients of Grants.....	3
Frequently Asked Questions and Answers	4
Educational Grant Agreement Template	10
Annex I: Grant Request Application Form	14
Guide: Vetting Educational Conference Organisers.....	17

Criteria for Companies' support for third party organised educational events

Third party organised educational events are defined as activities of any type that are planned, budgeted, managed and executed, in whole or in part, by or on behalf of a person or entity other than a medical technology company to fulfil HCPs educational needs.

Under the Medical Device Code of Ethical Marketing and Business Practice, companies can provide an educational grant or donation of funds to support bona fide independent, educational, scientific, and policymaking conferences that promote scientific knowledge, medical advancement and the delivery of effective health care.

Such educational grants can be provided to:

A third party conference organiser or another appropriate third party such as a training institution, medical or other professional association, hospital, educational foundation, or similar entity that supports the training and education of HCPs.

Such educational grants can be used to reduce or defray legitimate conference costs, such as the cost of modest meals, registration, venue rental, and travel and lodging, among other costs.

Effective 1 January 2018, SAMED member companies may no longer directly pay for individual HCPs costs to attend a third party organised educational event. Instead companies may support educational events through educational grants to an appropriate third party that supports the training and education of HCPs and must heed the following criteria aligned with the Medical Device Code of Ethical Marketing and Business Practice, including but not limited to Chapter 1: General Criteria for Events:

1. The event must be primarily dedicated to objective scientific and educational activities
2. 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
3. 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
4. Only the conference organiser or grant recipient (if different) can select the individual HCPs who will receive support to attend the educational conference (see Guide: Third Party Selection of Recipients of Grants, on page 10)
5. The venue must be conducive to the educational program
6. 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
7. Requests for educational grants should reflect the actual, fair market value costs of the intended educational activities
8. 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
9. All support for third party educational conferences should be appropriately documented

Companies may also establish procedures to manage educational grant requests. This could include:

1. A centralized portal or point of contact through which an appropriate third party submits its request for educational grant funding

2. 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.)
3. A company should undertake a due diligence vetting or screening process before paying the educational grant
4. Some companies may establish an internal, independent review committee to evaluate potential educational grant support against objective criteria
5. 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:

1. The selection process should be transparent and fair and ensure that only truly deserving candidates are the recipient of grants
2. The selection process must be documented and available on request by a company
3. Only the third party can select and invite the individual Healthcare Professionals (HCPs) who will receive support to attend the educational conference
4. A company cannot influence the selection of individual HCPs that benefit from the educational grant
5. 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
6. 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 XXX (FIELD OF EXPERTISE).
 - Senior XX (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 XXXXX.
 - 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 XXX 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
7. What about those HCPs who do not belong to a professional association? SAMED urges all societies to publicly advertise on their websites and allow non-members to apply.

Frequently Asked Questions and Answers

- 1. QUESTION: When did the change come into effect i.e. that SAMED members may no longer provide direct sponsorship to HCPs to attend third party organised educational events?**

ANSWER: 1 January 2018

- 2. QUESTION: What is meant by a third party organised educational event**

ANSWER: means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a medical technology company to fulfil HCP medical educational needs.

- 3. QUESTION: Continued medical education of HCPs is important for patient safety and for ensuring patients have access to the best possible care. What is the reason for the change in approach?**

ANSWER: Medical Technology Industry associations in many countries have implemented a prohibition on direct sponsorship in order to preserve and enhance the independence of HCPs decision-making. These changes promote the highest standards of transparency around Industry's interactions with HCPs, while at the same time addressing the clear need for training and education of HCPs in new medical technologies and therapies.

- 4. QUESTION: If companies can no longer provide direct sponsorships to individual HCPs, how may companies support the training and education of HCPs in new medical technologies and therapies?**

ANSWER: Companies can:

- continue to support individual HCPs to attend company arranged educational events;
- provide sponsorship to the relevant third party organisation
- provide direct support for individual HCPs to attend third party organized procedure / hands on training.

5. QUESTION: What is third party organised procedure / hands on training?

ANSWER: Third party organised procedure / hands on training is a type of educational event that must be held in a clinical setting, focus on skill acquisition and be a stand-alone event (e.g. live surgery observations) and not associated with a third party organised congress.

6. QUESTION: A third party conference has some practical workshops as part of the agenda. Does this mean companies can provide direct sponsorships to individual HCPs to attend this conference?

ANSWER: No. Third party organised hands on training must be a stand-alone educational event and not a subset of a larger meeting. That is the event must be an entirely separate event and not a pre-meeting or symposium of a larger event.

7. QUESTION: Will South Africa be the only country stopping direct sponsorship of HCPs?

ANSWER: No, the other industry associations and regions which are impacted are listed below:

- Medtech Europe - Europe
- MECOMED – Middle East
- APACMed – Asia Pacific
- Advamed China - China
- ABIMED - Brazil
- AMID – Mexico

Note the following industry associations have had in place prohibitions on direct sponsorship which predate the new 1 January 2018 requirements:

- Advamed – USA
- MTAA – Australia
- MTNZ – New Zealand
- Japan
- UCPMP – India

8. QUESTION: Does the prohibition on direct sponsorship of HCPs apply to company organised educational events

ANSWER: No. Companies can continue to provide direct support for individual HCPs to attend company arranged educational meetings.

9. QUESTION: What type of events are affected by the change in rules regarding direct sponsorship?

ANSWER: The change applies to third party organized educational events. That is a conference or meeting that is of a medical, scientific, and/or educational nature, intended to promote scientific knowledge, medical advancement, and/or the delivery of effective healthcare, and organised by a third party e.g. Professional Association, Healthcare Institution, or by a bona fide medical or other professional education provider.

10. QUESTION: Can companies continue to provide sponsorships to event organisers (e.g. to be the Gold sponsors of an event)?

ANSWER: Yes. However, all events supported by a company must comply with the requirements of the Medical Device Code of Ethical Marketing and Business Practice.

11. QUESTION: Can we continue to pay for stand space, advertising costs or to have satellite symposia at third party events?

ANSWER: Yes. However, all events supported by a company must comply with the requirements of the Medical Device Code of Ethical Marketing and Business Practice.

12. QUESTION: Can part of the sponsorship for an event include having the donor / grant recipient invite a number of specific HCP's to its congress on behalf of the company?

ANSWER: Whilst the event agreement can include funds to support a defined number of HCPs to attend the event, the donor / grant recipient is responsible for selecting those HCPs and they cannot invite them "on behalf of" a company", since that could potentially encourage the HCPs to support that particular company's products.

13. QUESTION: I understand that companies can provide grants to event organisers and HCOs for them to use, to support the costs for HCPs to attend third party educational conferences. What is an HCO?

ANSWER: A Healthcare Organisation (HCO) can include the following: professional associations, medical associations and hospitals.

14. QUESTION: Many HCPs are used to going directly to and requesting companies to support their attendance at third party arranged educational events. How are HCPs being informed of this change? What should a company do if an HCP asks for support to attend a congress?

ANSWER: SAMED has a campaign in place to advise all relevant stakeholders of the change. Companies can direct the HCP to the HCOs/Conference organisers to which they can request a grant to support their attendance. The company must make it clear that while they may donate funds to these third party entities, they have no role in deciding who receives a grant.

15. QUESTION: Can companies contact hospitals to offer grants to support the attendance of their HCP/Allied Professional employees to third party organised educational events?

ANSWER: Yes, however the company may have no influence on the selection of the grant recipient and this process needs to be well documented.

16. QUESTION: A hospital has submitted a grant request to support the attendance of one of their employees to a third party arranged educational event. The hospital does not have the facilities to arrange travel. Can a company arrange the travel on behalf of the hospital?

ANSWER: No. Companies are not permitted to make logistics arrangements for individual HCPs attending or speaking at third party educational events. They can provide financial support to the hospital but the hospital must make all arrangements themselves.

17. QUESTION: A hospital has requested a grant to support the attendance of one of their employees to a conference. The conference requires expert knowledge and the company is concerned that the hospital may send someone too junior to benefit from the course. Can a company provide the grant on the provision that they must send the Head of Department only?

ANSWER: No. Because a HOD is too specific, refer to Guide: Selection Criteria on page 4.

18. QUESTION: A training hospital has requested support to send employees to a local conference. Can companies provide the grant conditional to them only sending trainee surgeons and not qualified surgeons?

ANSWER: Yes, if there are a large number of trainee surgeons, and the company is not thereby influencing the selection such that it points to one particular individual.

19. QUESTION: A HCP-owned clinic has submitted a request for a grant to support the attendance of an unnamed employee to an Orthopaedic conference. The HCP owner is the only Orthopaedic surgeon. Can this request be approved?

ANSWER: No. In reality this would be a direct sponsorship as there is no separation between the provider of the grant (company) and the ultimate beneficiary (the HCP).

20. QUESTION: An HCP is attending a third party organized educational event as faculty and has asked a company to support his expenses (travel, accommodation and registration). The event organisers selected him as a faculty member but they are not covering these costs. Is it acceptable for the company to provide this support?

ANSWER: No. The ban applies to all HCPs attending third party organized educational events, whether as a delegate or as faculty. Companies cannot pay for, organise or otherwise reimburse the expenses for any individual HCP to attend a third party organized educational event.

21. QUESTION: An event organiser has contacted a company and asked them to arrange the travel and accommodation for a named faculty member at a forthcoming conference. Can the company organise and pay for the travel and accommodation if the event organiser sends a written request?

ANSWER: No. The ban prohibits companies from covering the costs for any individual HCP to attend an event. In this case the request from the event organiser relates to one specific named HCP and by arranging the travel and accommodation there is a direct link between the company and the HCP.

22. QUESTION: An event organiser has contacted a company and asked them to provide a grant to support the travel and accommodation costs for faculty members at a forthcoming conference. Is this acceptable?

ANSWER: Yes. If the event organiser requests a monetary grant to support the travel and accommodation costs for their (unnamed) faculty members, and the money is paid to the event organiser, then this would be permissible.

23. QUESTION: An event organiser has asked a company to recommend faculty for an upcoming event. The company knows a surgeon who will be a great speaker. Are they allowed to provide his name to the event organisers?

ANSWER: Yes. Companies are allowed to recommend faculty members but cannot select or influence the selection of faculty.

24. QUESTION: A company is organising a satellite symposium at an international third party organized conference. Can they select faculty for their symposium?

ANSWER: Yes.

25. QUESTION: Can the company pay consulting fees and expenses for an HCP to participate as faculty at the company satellite symposium at a third party organized conference?

ANSWER: Yes. They can pay consulting fees (at fair market value) to the HCP for providing services at a satellite symposium in accordance with the Medical Device Code and Ethical Marketing Business Practice.

If the HCP only attends the satellite symposium, then they can pay their travel expenses and any accommodation and meal costs associated with their attendance at the satellite meeting.

However, if the HCP also attends the third party organized conference associated with the satellite symposium, then the company cannot pay any associated travel expenses, with the exception of local transportation between the conference and the satellite symposium and also not for any accommodation and meal costs directly associated with the third party conference.

26. QUESTION: Can companies directly support travel and/or accommodation or other expenses of individual HCPs as a delegate at company organised education events / satellite symposia, happening during or around a third party organised event?

ANSWER: No, as of 1 January 2018, member companies cannot directly support travel and/or accommodation or other expenses of individual HCPs passively participating i.e. delegates at company organised education events which take place during, around, or at the same time and in the same approximate location as a third party organised event.

Company events, for example Advisory Boards; Clinical Investigator meetings; but not Sales, Promotional and other Business Meetings, may be organised at or around a third party organised event for reasons of convenience, given the attendance of HCPs at that third party organised event. In such circumstances, the member company may only pay for the contractual remuneration and expenses agreed for the provision of the services by the HCP at the company organised education event. Under no circumstances may a member company pay for a registration fee, travel, accommodation or any other costs associated with the third party organised event.

27. QUESTION: Can a company's third party intermediaries (including consultants, distributors, sales agents, brokers and suppliers) support the direct sponsorship of HCPs to third party events after the ban comes into effect?

ANSWER: No. The ban on direct sponsorship applies to third party intermediaries (including consultants, distributors, sales agents, brokers and suppliers).

28. QUESTION: How should a company record grants for HCOs to support HCP attendance at third party organised educational events? How will HCOs know that they can request these grants from a company? How will HCPs know if grants are available?

ANSWER: Companies should document grants and contracts in relation to grants. It is the responsibility of the HCOs to promote their grant offerings. In response to questions from HCPs it is acceptable to tell the HCPs that the company has grants available but companies must explain that they have no role in the selection of recipients of the awards.

29. QUESTION: A company has received a request from a medical society to provide a grant of R100 000 to support the attendance of two of their members (unnamed) to a local conference. How do they know if this is a reasonable amount to pay?

ANSWER: Companies should establish guidance on the fair market value costs for supporting HCPs to different categories of events in their market. This guidance should be available in the event of a complaint. See the section on fair market value in the Medical Device Code of Ethical Marketing and Business Practice.

30. QUESTION: The company would like to provide a grant to an International Conference Organiser to enable them to support the attendance of HCPs from South Africa to their annual conference. They want to ensure the grant is used to support HCPs who will most benefit from the event. Is it acceptable to provide selection criteria?

ANSWER: Yes. For grants to congress organisers or societies it is acceptable to provide recommended criteria, providing the ultimate decision on recipient suitability rests with the event organisers. Based on the educational objectives of the event, criteria can include, but are not restricted to:

- Speciality
- Country of residence of the HCP
- Expertise or experience level

Selection criteria should never direct the grant to a specific HCP.

31. QUESTION: Is it appropriate for a company that has provided an educational grant to support HCP attendance at a third party organised educational event to receive the names of the HCPs benefiting from the educational grant?

ANSWER: Yes, in South Africa due to B-BBEE reporting requirements, companies may request / be provided a list of those recipients who have specifically benefited from a particular company's educational grant. However, such HCP names should only be received by the company once the educational grant agreement has been signed and the independent selection process of the HCPs has been completed, and after the event has taken place.

Educational Grant Agreement Template

This template may be used by a third party and a company when entering into an educational grant agreement (Greyed text: either fill with the relevant information or choose from the available options).

This Educational Grant Agreement (the “Agreement”) is entered into and effective as of day month year **OR** the date of last signature herein (the “Effective Date”).

BY AND BETWEEN

Name, a company incorporated under the laws of South Africa with a registered address as ... (the “**Company**”)

AND

Name, an organization incorporated under the laws of South Africa with a registered address as ... (the “**Grant Recipient**”).

Together hereinafter referred as “Parties”, or each individually as a “Party”.

WHEREAS, Company and its affiliated companies are engaged in research, development, manufacturing, marketing, and sale of medical technologies;

WHEREAS, Company is committed to support independent medical education and intends to provide educational grants via funding or in kind support to independent third parties for the support and the advancement of genuine medical education.

WHEREAS, Grant Recipient is an independent third party, for example but not limited to: hospital/group purchasing organization / clinic / laboratory / pharmacy / research institution / foundation / university / teaching institution / learned/professional society / professional conference organiser which submitted the Grant Request Application (Annex I) to the company;

WHEREAS, Company has reviewed the Grant Request Application and wishes to provide support to grant recipient on the following terms and conditions:

Article 1 – Purpose of the Grant

- 1.1. The company offers to the grant recipient an educational grant for support for HCPs participation at third party organised educational events OR support for third party organised educational events OR indicate other type specified in article 2 (“the Grant”). The grant shall be provided to support independent medical education in accordance with the Medical Device Code of Ethical Marketing and Business Practice and all applicable laws, regulations and other codes of conduct.

The company has agreed the grant should be used in respect of the following (the “Programme”):

- a. Description and duration of programme, e.g. funding of a PhD position in the field of..., scholarship for participation in x of medical education programme, x number of HCPs to attend x conference etc.
- 1.2. The parties agree that each of the various components of the programme is for scientific and/or educational purposes only and will not promote any company's products or services, directly or indirectly.
- 1.3. The grant will not be used for:

- a. Direct or indirect promotion of company's medical products or services
- b. Support of off-label use of any product
- c. Payment by the grant recipient of exhibit or display fees for its promotion and services
- d. Support of charitable programmes
- e. Payment for organisational overhead such as purchase of capital equipment, software and non-medical staff training.

1.4. The grant recipient may use the grant only for the programme described above and the grant recipient shall be liable for any and/or misuse of said contribution. Any change in the intended use of the grant must be approved in advance by the company in writing.

Article 2 – The Grant

2.1. Subject to the provisions of this Agreement, the company shall pay to the order of the grant recipient, the sum of amount in words **and or other** (amount in numbers) (the “Grant”), to support grant recipient as set forth in article 1. It is understood that the grant shall be all inclusive and final and the company shall not be liable to pay any additional compensation or fee under this Agreement.

2.2. Payment will be made to the grant recipient within **thirty (30) days OR other** as agreed by signature of this Agreement by both parties to the following account of the grant recipient:

Account owner:

Bank:

Account No.:

Bank code:

IBAN:

BIC:

Article 3 – Ethics and Compliance

3.1. The grant recipient shall ensure that all use of grant funds:

- a. comply with the Medical Device Code of Ethical Marketing and Business Practice (which can be found at www.samed.org.za and all relevant local laws, regulations and other codes of conduct; and
- b. comply with applicable disclosure requirements of the grant as well as any other obligation relating to any beneficiaries of grant funds to any professional body, institution, or government agency that requires such disclosure.

3.2. The parties specifically agree that the provision of the grant is not implicitly or explicitly linked to an agreement for the grant recipient to purchase, lease, recommend, prescribe, use, supply or procure the company's products or services or used to reward past purchases, uses, orders recommendations, or referrals.

Article 4 – Independent Selection and Programme

4.1. The company shall not have any involvement in any way in the selection of the HCPs who will benefit from the grant. For example, where the grant is provided for the purpose of supporting HCPs' attendance at third party organised educational events, the grant recipient shall be solely responsible for selection of participants.

Initial

- 4.2. Where the grant recipient is the organiser of the third party organised educational event, the grant recipient shall be solely responsible for (i) the programme content; (ii) the selection of podium speakers, moderators and/or chair, who present during a third party organised educational event (the “Faculty”); and (iii) the payment of Faculty honoraria, if any. The company shall not have any detailed involvement in determining the content of the educational programme for selection of Faculty. If expressly requested to do so, the company may recommend speakers or comment on the programme.
- 4.3. The grant recipient has a fair and transparent selection process which is available on request by the company.
- 4.4. The company shall not have any influence on the list of attendees, speakers or subjects for the event.

Article 5 – Review and Verification Rights

- 5.1. Upon request of the company, the grant recipient shall provide to the company a follow up report on the use of the grant and/or adequate documentation (e.g. copies of booking documents, copies of original tickets) verifying that the grant was used in accordance with the terms and conditions of this Agreement.
- 5.2. Subject to applicable laws and/or internal regulatory, tax or auditing obligations the company may have to abide by, the grant recipient agrees that the company may itself or through an independent third party conduct ad hoc on-site reviews at any time in order to verify that the grant was used in accordance with the terms and conditions of this Agreement. Company’s representative(s) conducting such reviews shall be given full access by the grant recipient to all information, premises and employees as required by the company for this purpose. The grant recipient shall comply with all reasonable requests, directions and monitoring requirements of the company and shall generally cooperate with and assist the company in such reviews. The company shall provide at least fourteen (14) days notice to the grant recipient of any review under this Agreement that it plans to conduct.
- 5.3. If a grant recipient has received funds in excess of the costs incurred, the company may request that the grant recipient return its portion of excess funds.

Article 6 – Representations and Warranties

The grant recipient represents and warrants that:

- a. it is fully aware of all anti-bribery / anti-corruption laws in force in the jurisdiction of its place of establishment and adheres to them; and
- b. it is familiar with the United States Foreign Corrupt Practices Act and without limiting the generality of the other provisions of this Agreement, the grant recipient agrees that it will not, and will ensure that its employees, directors, officers, agents or other persons acting on its behalf (the “Related Parties”) do not make any payment or give anything of value, either directly or indirectly, to an official of any government or government agency for the purpose of influencing an act or decision of the official in his or her official capacity or inducing the official to use his or her influence to assist the grant recipient in obtaining or maintaining business or in obtaining or paying for favorable treatment or any other special concession; and
- c. that it has not, in the past (i) used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity, or (ii) made any unlawful payment to government officials or government employees or to political parties or campaigns; and

Initial

- d. it is familiar with the Medical Device Code of Ethical Marketing and Business Practice, see: www.samed.org.za, and that the grant will not be used to support or fund, directly or indirectly (i) entertainment of any kind, (ii) the costs of any spouses or guests

Article 7 – Termination

The company will have the right to terminate this Agreement effective immediately at any time by written notice when:

- a. a material breach by the grant recipient is not cured by the grant recipient within thirty (30) days after receipt of written notice of breach from the company. In that event, the grant recipient shall return immediately the balance of the grant remaining as of the effective date of termination along with a detailed account of the grant already spent; or
- b. if applicable, the event under the programme is not approved via the Ethical Medtech Conference Vetting System. In that event, any unpaid grant funds will no longer be due and the grant recipient shall refund the amounts that have already been paid by the company.
- c. the event under the programme has been cancelled and / or significantly changed. In that event, any unpaid grant funds will no longer be due. In case the company already paid parts or the totality of the funds, the grant recipient shall refund such amounts.
- d. the grant recipient failed to use the grant in accordance with this agreement. In that event, grant recipient will refund the entire grant to the company within seven days from receipt of notice from the company.

Article 8 – Miscellaneous

- 8.1. This Agreement and its annexes contain the entire agreement and understanding between the parties with respect to the subject matter hereof and supersedes and replaces all prior agreements or understandings, written or oral, with respect to the same subject matter still in force between the parties.

This Agreement may not be amended or modified except by a written agreement signed on behalf of each of the parties hereto.

- 8.2. The grant recipient will not assign, transfer, or otherwise dispose of any of its rights, duties, or obligations hereunder without the prior written consent of the company.
- 8.3. This Agreement shall be construed and interpreted in accordance with the laws of South Africa. Any dispute, if not amicably settled, shall be submitted to the courts of South Africa.

By their signatures below, the parties in this Agreement agree to all of the terms and conditions of this Agreement.

For and on behalf of the Grant Recipient

For and on behalf of the company

Insert the name

Insert the name

Date signed: _____

Date signed _____

Annex I: Grant Request Application Form

Educational Grant – Third Party Organised Educational Events

On request for a grant by a third party, the company may send this template to the third party for completion and return to the company

The company adheres to the Medical Device Code of Ethical Marketing and Business Practice which sets strict, clear and transparent rules for our industry's relationship with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), including support for independent medical education via grants.

Instructions – Please read before completing the form

- Grant applications must be submitted at least x days prior to the first event/activity taking place with all supporting documentation attached. Any application not complying with this timeline will be rejected.
- Please note there is no guarantee that all of the amount requested will be granted. The company may reject, approve in full or approve a lower amount at its absolute discretion.
- The completed and signed form including all required supporting documents must be submitted by e-mail to: email address.

1. Applicant Information		
Full name		
Operational structure/Legal status		
Tax ID		
Address		
Mission of organisation (please provide a description of the organisation's educational/scientific mission, field of activity, notable projects/co operations)		
Website		
Head of organisation	Full name:	
	Position within organisation:	
Contact person submitting the request	Full name:	
	Position within organisation:	
	Telephone number:	
	Address:	
2. Grant Request Details		
Type of grant (please tick the box)	<input type="checkbox"/> Support for HCPs Participation at third party organised educational event (the "Educational Event") <input type="checkbox"/> Support for the educational event	

Therapeutic or diagnostic areas		
Country(s) for which the grant is intended		
<p>Please provide a detailed description on how the grant will be used (e.g. number of HCPs to be supported, average amount proposed per HCP for flights (in Rand/other), average amount proposed per HCP for registration fees (in Rand/other) etc.)</p> <ul style="list-style-type: none"> Required supporting documentation: an overview of the budget <p><u>Note:</u> The grant must only cover the costs related to the organisation of the educational event (e.g. the rent of the premises where the event is taking place) or the costs of registration, travel and accommodation of participating HCPs. The grant will not be provided to cover the costs linked to the organisation of leisure/entertainment activities or for the invitation of spouses/partners of HCPs. In addition, no funding will be provided to cover ordinary operating and/or running costs of the organisation and other budget items not directly linked to the education.</p>		
Amount of funding requested from the company (in Rand/other)		
Amount of external funding requested in total (in Rand/other)		
Percentage of overall budget sought from the company		
Details of personnel responsible for financial controls over grant funds (e.g. applicant's financial department, independent auditors etc.)		
Bank account details (This must be an account in the name of the body making the application and not an individual)	Bank name:	
	Bank country:	
	Account holder:	
	IBAN number:	
	BIC or SWIFT Code:	
3. Educational Event Details		
Title		
Dates	Start date:	(dd/mm/yyyy)
	End date:	(dd/mm/yyyy)
Location	City:	
	State:	
	Country:	

Venue	Name:	
	Address:	
	Website:	
Objective of the educational event: please provide a detailed description of scope, purpose and anticipated outcome of the programme. <ul style="list-style-type: none"> Required supporting documentation: most up-to-date program 		
Targeted audience by the educational event (please tick the box)	<input type="checkbox"/> Local <input type="checkbox"/> National <input type="checkbox"/> International	
4. HCPs Participation at the educational events		
Please describe the application procedure and criteria based on which the beneficiaries of the grant will be selected		
Please provide the name and/or position of the person who is responsible to select the HCPs to attend the educational events		
5. Previous Grant Support		
Has your organisation already applied for or received funding from the company before?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
If "YES", please indicate the amount, date and purpose of the requested/awarded grant?		
6. Remarks		
7. Supporting Documents		
Please attach the following supporting documents to this form: <ul style="list-style-type: none"> A copy of most up-to-date draft programme, agenda or communication material related to the educational event A draft budget laying out how the funds will be spent 		
I declare that: This form was completed on behalf of the requesting organisation; The information provided in this form and supporting documents is true and accurate; The grant request is not implicitly or explicitly linked in any way to past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the company's products or services.		
Date		
Name		
Positions		
Signature		

Guide: Vetting Educational Conference Organisers

SAMED has developed the below 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.

Companies may vet conference organisers (and/or educational grant recipients, if different) to determine if supporting an organization's request for educational grant funding would pose legal, compliance, or reputational risks. Companies may request information similar to the criteria listed below. This list is not exhaustive, and companies may give greater weight to some criteria over others.

Examples include:

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.