

The Medical Technology Code of Ethical Marketing and Business Practice

Non-binding Code Advisory Opinions Process and Library

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Purpose of this document

To facilitate greater understanding of the Medical Device Code of Ethical Marketing and Business Practice (the Code) and enable members and stakeholders to learn from similar situations, this document provides a summary of advisory opinions sought and their outcomes.

This will enable companies to refer to and learn from the advisory opinions to assist in avoiding potential Code transgressions in the future.

Process for obtaining opinions/guidance and interpretations of the Medical Technology Code of Ethical Marketing and Business Practice.

The Medical Device Code of Ethical Marketing and Business Practice (the Code) governs interactions between SAMED members (Signatories to the Code) and their customers, namely healthcare providers, and healthcare professionals. It fosters trust in the medtech industry by creating a framework for ethical activity that protects the reputation of industry stakeholders.

The Code is an instrument for self-regulation of the medical technology industry and SAMED is the custodian of the Code. Its key principle is that signatories to the Code will not offer inappropriate inducements to healthcare providers and healthcare professionals in order to sell or lease their products.

It may be that you require guidance relating to marketing and business practices in relation to the Code to ensure that you or your organization do not inadvertently transgress the Code. In this regard you can request a non-binding, free of charge code advisory opinion from SAMED by following the below process.

All queries must be lodged in writing by email with the SAMED office i.e., info@samed.org.za. Written queries should not contain any competitively sensitive information. We will use our very best endeavours to ensure that adequate measures are put in place to ensure that queries are kept confidential. The anonymised query will be forwarded to the SAMED Code Advisory Sub-Committee via email for review. If we have had similar queries where an advisory opinion was given, that advisory will be forwarded along with your request. The Code Advisory Sub-Committee will provide a response within 2 weeks from receipt of the query.

If the case is urgent, please indicate as such in your request, as the Code Advisory Sub-Committee will then be given 72 hours to respond. SAMED will not be able to process queries requiring less than the 72 hours for response.

In cases where the Code Advisory Sub-Committee are unable to arrive at a majority consensus, the SAMED Board will be asked to provide an opinion. SAMED will ensure that any committee member who may be a competitor to your company, will not participate in the consideration of the query and the committee are obliged to disclose any conflicts of interest. Once the committee and/or Board have come to a decision, the SAMED Secretariat will draft the Code advisory opinion, which once approved by the Code Advisory Sub-Committee will be provided to you in writing.

Note: The advisory opinion does not constitute legal advice. All members have an independent obligation to ascertain that their interactions with their customers comply with all current laws and regulations and the principles as set out in the Code. Advisory opinions will be accompanied with the relevant SAMED disclaimer.

Disclaimer, non-binding SAMED Code Committee advisory opinions and limitation of liability.

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Code advisory opinions provided pre-2024

1.1 Conversion of a company masterclass training into a pre-conference workshop

Query: A company was requested by a society to incorporate the masterclass that they had arranged adjacent to the societies conference

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 1: General criteria for events

Member companies may invite HCPs to company events and third-party organised educational events, conferences and procedure training. The principles and criteria set out in this chapter shall apply to all such events supported in any way by member companies, irrespective of who organises the event.

PART 1, Chapter 1, Clause 1: Event programme

The event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs. For third-party organised educational events, the agenda should be under the sole control and responsibility of the third-party organiser.

The meeting and event should be appropriate to all delegates' scope of practice.

Taking the above into account the Code Committee arrived at the following opinion:

- A "trade show" is an exhibition and promotion of medical technologies by various suppliers and is not a training or educational event. It would, therefore not be appropriate for the company to sponsor the HCP.

1.2 Sponsorship of an HCP to an international trade show

Query: A company wanted to know if it would be appropriate to sponsor an HCP to attend an international trade show, such as Medica or Arab Health.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 1: General criteria for events

Member companies may invite HCPs to company events and third-party organised educational events, conferences and procedure training. The principles and criteria set out in this chapter shall apply to all such events supported in any way by member companies, irrespective of who organises the event.

PART 1, Chapter 1, Clause 1: Event programme

The event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs. For third-party organised educational events, the agenda should be under the sole control and responsibility of the third-party organiser.

The meeting and event should be appropriate to all delegates' scope of practice.

Taking the above into account the Code Committee arrived at the following opinion:

- A "trade show" is an exhibition and promotion of medical technologies by various suppliers and is not a training or educational event. It would therefore not be appropriate for the company to sponsor the HCP.

1.3 Business Class flights for HCP with medical condition

Query: A company sought allowance to provide business class flights to a healthcare professional (HCP) owing to a medical condition which would make travelling by economy for an extended period uncomfortable/unfeasible. The HCP was travelling to a company international training event.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 1, Clause 6: Travel

Member companies may sponsor business class travel for HCPs **only** for:

- Faculty members irrespective of day of arrival.
- HCPs attending advisory boards and clinical investigations irrespective of day of arrival.

Premium economy flights may be considered in the class of international economy travel; however, perception and cost are important factors when deciding whether premium economy flights may be acceptable.

Taking the above into account the Code Committee arrived at the following opinion:

- The HCP should provide the member with a medical certificate not older than 3 months from his own physician confirming his condition.
- The company may offer a premium upgradeable economy class ticket. Should the surgeon not wish to fly premium economy then he should contribute the difference in costs from premium economy to business.

1.4 Co-pay for HCP Business Class flights

Query: A company hosting an international product training event intended to provide flights for local HCPs to attend. One of the HCPs elected to pay his own costs (flights and accommodation), while the costs of two others were being sponsored by the company. The HCP not being sponsored had opted to fly business class while the two sponsored HCPs were due to fly economy in line with the Code.

The company was concerned that the perception of the two sponsored HCPs would be that the company provided the business class fare for the other HCP. The company wanted to provide the value of the economy class tickets to the sponsored HCPs as a co-pay should they want to upgrade to a business class flight.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 1, Clause 6: Travel

Member companies may sponsor business class travel for HCPs **only** for:

- Faculty members irrespective of day of arrival.
- HCPs attending advisory boards and clinical investigations irrespective of day of arrival.

Premium economy flights may be considered in the class of international economy travel; however, perception and cost are important factors when deciding whether premium economy flights may be acceptable.

Taking the above into account the Code Committee arrived at the following opinion:

- The company could offer an upgradeable economy class ticket and mention to the surgeons that they may fund the difference to upgrade to business class themselves.
- The company was encouraged to develop a consistent Travel Policy to deal with matters related to HCPs wanting flight upgrades (i.e., economy except for genuine exceptions or everyone can upgrade if they pay for it themselves).

1.5 Participation in HCP arranged golf day

Query: The company received a request from a group of HCPs to provide sponsorship for a hosted golf day in which various other HCPs would be participating. Sponsorship options included providing prizes, displaying marketing material (banners, logo on prizes) and/or ‘manning’ a tee. The company wanted to source prizes on the HCP’s behalf and participate in other ‘marketing’ activities.

Opinion provided: The Code Committee cited the following sections in the code:

Introduction

- The Principle of Image and Perception
- The definition of “Entertainment” includes but is not limited to... sporting events (e.g., skiing, golf, rugby or football match) and other leisure arrangements.

PART 1, Chapter 1: General criteria for events

The principles and criteria set out in this chapter shall apply to all such events supported in any way by member companies, irrespective of who organises the event.

A member company shall not organise events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements which form part of third-party organised educational events...Entertainment should not dominate or interfere with the overall scientific content of the programme and should not be the main attraction of the event.

PART 1, Chapter 1, Clause 2: Event location and venue

The event location and venue should not become the main attraction of the event...The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an entertainment venue.

PART 1, Chapter 3, Clause 2: Promotional items

Definition: An item that is provided by or on behalf of a Member to another person or organization and is intended as a promotional reminder / campaign relating to the Company and its products (records of all promotional campaigns must be kept for a period of five years).

Promotional items to HCPs, appropriate administrative staff, sales and other staff are acceptable provided that they are:

- Within the cost limit set from time to time by SAMED.
- Not for personal use e.g., no entertainment CDs/DVDs, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.
- Educational and/or of scientific value, benefit the patient and/or be relevant to the practice.
- No cash or cash equivalents (e.g., vouchers) are allowed. Promotional items must be branded with Company name and/or Product and/or Logo.

PART 1, Chapter 3, Clause 6: Competitions

Competitions should fulfil the following criteria:

- The competition is based on medical/product knowledge or the acquisition of scientific knowledge.
- Individual prizes or educational items offered should benefit the patient and / or be relevant to the practice; and within the cost limit set from time to time by SAMED.
- The prize cannot comprise of cash or a cash equivalent (e.g. vouchers).
- Entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.
- No cash or cash equivalents (e.g. vouchers) are allowed for completion of a survey or as a prize for a competition.

Taking the above into account the Code Committee arrived at the following opinion:

- In respect of the code's prohibition of support of social, sporting and/or leisure activities or other forms of entertainment of HCPs and that the prizes are for personal use by the HCPs, include vouchers and are not of benefit to the patient/or relevant to the practice, this activity would constitute a transgression of the code. This is irrespective of the fact that prizes were elicited at no cost to the company.

1.6 Support of virtual training event

Query: A company was approached to provide sponsorship/support to third party virtual surgical workshop. The company would provide sponsorship in exchange for their company logo on slides/invitations and a slot to play a short demonstration video.

The company wanted to know if they can provide the funding to the institution hosting the training in exchange for promotion and if the video may include products or must be a generic company video.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 1: General criteria for events

The principles and criteria set out in this chapter shall apply to all such events supported in any way by member companies, irrespective of who organises the event.

PART 1, Chapter 1, Clause 1: Event programme

The event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs. For third-party organised educational events, the agenda should be under the sole control and responsibility of the third-party organiser.

The direct sponsorship of HCPs to attend third-party organised educational events is prohibited.

- Third-party organised educational events (main programme) Companies will not be able to directly support a healthcare professional, neither as a delegate nor as a speaker
- Third-party organised procedure/hands-on trainings: Companies may support delegates but not speakers, the latter being independent

Advertisement and promotion at events are subject to relevant domestic legislation and / or regulations.

PART 1, Chapter 1, Clause 4: CPD meetings

No product promotion is allowed in the CPD meeting room. Company-branded items/promotions are permissible.

It was noted that due to the Covid-19 pandemic many trainings and congresses had to be conducted virtually. Many organisers proposed virtual sponsorship options over the traditional exhibition space they would ordinarily sell to offset the costs of the event.

Taking the above into account the Code Committee arrived at the following opinion:

- Whether a virtual or face to face meeting, restrictions contained in the code still apply.
- In respect of a CME meeting (CPD point meetings), no commercial promotion of the product may be allowed during the presentation as this would be the same as no product promotion in the 'room' where the academic discussions are taking place. If not a CME meeting, it would be acceptable for the video to contain product promotion.
- Company names may be displayed as logos on slides and programme/invitation as this is applicable to face-to-face meetings as well.
- In respect of payment, it is acceptable to pay the third-party event organisers for sponsorship options as the company may have done as much for exhibition space which would have been used for company promotion.

1.7 Taking an HCP/HCPs out for a meal

Query: A company wanted to know if it was permissible to invite an HCP/HCPs (without spouses) for a meal (lunch/dinner)?

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 1, Clause 1: Event programme

A member company shall not organise events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements where part of third-party organised educational events.

PART 1, Chapter 1, Clause 2: Event location and venue

The event location and venue should not become the main attraction of the event. For the location and the venue, member companies must take into account at all times the following considerations:

- Potential adverse public perceptions of the location and venue for the event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an entertainment venue.
- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.

PART 1, Chapter 2, Clause 3: Sales, promotional, product launch and other business meetings

Where it is appropriate, member companies may organise sales, promotional and other business meetings where the objective is to discuss product and related services, features and benefits, conduct contract negotiations or discuss sales terms.

Taking the above into account the Code Committee arrived at the following opinion:

- It would be appropriate to invite an HCP to a meal (without their spouse) if there is a legitimate business purpose to holding the meal with them and as long as the company can justify that the venue is conducive to the exchange of scientific and medical information and the transmission of knowledge.
- Taking an HCP out for meal simply for the sake of it, even without their spouse, would not be in accordance with the requirements of the Code and may well be deemed to be 'entertainment or leisure'.

1.8 Donations toward a hospital awards evening

Query: A hospital hosting an awards ceremony for their staff at the hospital invited the company to make a financial contribution (donations) towards the event. The company wanted to know if participation was acceptable.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 1, Clause 1: Event programme

The event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs. For third-party organised educational events, the agenda should be under the sole control and responsibility of the third-party organiser.

The meeting and event should be appropriate to all delegates' scope of practice.

A member company shall not organise events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements where part of third-party organised educational events. For third-party organised educational events, entertainment must be outside of the educational programme schedule and paid for separately by the HCPs. Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The entertainment should not be the main attraction of the event.

Part 1, Chapter 4: Charitable donations

Charitable donations mean provision of cash, equipment, company product or relevant third-party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable donations may only be made to bona fide registered charities whose main objects are genuine charitable or philanthropic purposes...

Charitable donations may be made if properly recorded and approved by the responsible person(s) in each company or organisation. Charitable donations are only allowed provided:

- They are documented and kept on record by the donor.
- Donations must not be paid directly to HCPs or to healthcare administration staff.

Companies are encouraged to make available publicly, information about charitable donations made by them as covered in this section.

Taking the above into account the Code Committee arrived at the following opinion:

- Such a donation would in all likely hood not be deemed appropriate as an annual award ceremony is not an educational event (which may be deemed to be of a mainly entertainment, social and/or leisure nature).
- In addition, the entity asking for the donation does not appear to be a bone fide charitable organisation and such donation may well be used to fund the entertainment / social aspect of the event and not for the purposes of supporting healthcare and research.
- Below are a few points to consider:
 - If it is a Government Hospital, then the Public Finance Management Acts applies, and it is very easy to violate this Act with a “Charitable Contribution”.
 - Additionally, a Charitable Contribution request should be approved by the Accounting Officer of that Institution.
 - It is only Charitable if a Tax Certificate 18A can be provided.

1.9 Charitable donation towards patient gowns

Query: A company received a request for a donation to a hospital to purchase patient gowns. They wanted an opinion on if the company would be permitted to provide a donation.

Opinion provided: The Code Committee cited the following sections in the code:

Part 1, Chapter 4: Charitable donations

Charitable donations mean provision of cash, equipment, company product or relevant third-party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable donations may only be made to bona fide registered charities whose main objects are genuine charitable or philanthropic purposes...

Charitable donations may be made if properly recorded and approved by the responsible person(s) in each company or organisation. Charitable donations are only allowed provided:

- They are documented and kept on record by the donor.
- Donations must not be paid directly to HCPs or to healthcare administration staff.

Companies are encouraged to make available publicly, information about charitable donations made by them as covered in this section.

Taking the above into account the Code Committee arrived at the following opinion:

- If such a donation were made, it may contravene the Code as it is not seen as a charitable donation in the context of the Code and the company should decline the request.
- Below are a few points to consider:
 - If it is a Government Hospital, then the Public Finance Management Act applies, and it is very easy to violate this Act with a “Charitable Contribution”.

- Additionally, a Charitable Contribution request should be approved by the Accounting Officer of that Institution.
- It is only Charitable if a Tax Certificate 18A can be provided.

1.10 Donations to and participation in a charity providing after hour surgeries

Query: A company was introduced to a charity project which raises funds for patients to get female cancer surgery after hours to assists with clearing patient backlogs at government facilities. Similar backlogs existed for male cancer patients.

The company was approached to work with the charity project to expand the charity's scope into offering male cancer surgery after hours as well.

The company was keen to be involved and wanted to pilot the programme, where the company would provide the equipment, a trained company representative to ensure understanding of the use of the equipment and disposable items required for the procedure.

Further to this, the company wanted to provide donations toward the after-hour rates for staff. The donation would be offered twice, after which the programme would need to raise funds to continue support of the programme. The company would, through the charity, provide this at the first two facilities. Various HCPs would offer their time in support of the charitable initiative.

Opinion provided: The Code Committee cited the following sections in the code:

Part 1, Chapter 4: Charitable donations

Charitable donations mean provision of cash, equipment, company product or relevant third-party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable donations may only be made to bona fide registered charities whose main objects are genuine charitable or philanthropic purposes.

Charitable donations shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the member company's products or services. It is important that support of charitable and/or philanthropic programmes and activities by member companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure member companies' products or services.

Member companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a charitable donation to a specific prospective recipient. The process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient.

Charitable donations may be made if properly recorded and approved by the responsible person(s) in each company or organisation. Charitable donations are only allowed provided:

- They are documented and kept on record by the donor.
- Donations must not be paid directly to HCPs or to healthcare administration staff.

Companies are encouraged to make available publicly, information about charitable donations made by them as covered in this section.

Taking the above into account the Code Committee arrived at the following opinion:

- The charity was deemed a bone fide charity, with a genuine charitable or philanthropic purpose and it was deemed appropriate for the company to participate in and make contributions to the project.

1.11 End-user competition prize value

Query: A company wanted to offer one of their products with a value exceeding R 5000 as a prize for end-users participating in a competition focused on awareness around the disease specific area.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 3, Clause 6: Competitions

Competitions should fulfil the following criteria:

- The competition is based on medical/product knowledge or the acquisition of scientific knowledge.
- Individual prizes or educational items offered should benefit the patient and / or be relevant to the practice; and within the cost limit set from time to time by SAMED.

PART 3: Questions and Answers

Q21: What is the maximum value for competition prizes?

A21: For a consumer competition:

The total value of the prizes for a consumer competition must not exceed R100 000 incl VAT; and each individual prize may not exceed R5 000 incl VAT. A donation of any nature linked to the competition needs to be included in the total prize money.

Taking the above into account the Code Committee arrived at the following opinion:

- The value of the prize exceeds the stipulated value of R5000 and thus would not be compliant with the Code.

1.12 Demo, sample, evaluation and/or loan classification

Query: A company sought clarification on how to classify (per chapter 6 and 7 of the Code) a capital device placed in ICU for a period of two to three weeks for the HCPs to work with and evaluate.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 6, Clause 1: Definitions

Demonstration products (demos): means either single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:

- Samples.
- Evaluation products.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g., as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Evaluation products: means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a member company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose. Evaluation products do not include the following:

- Demos.
- Samples.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g., as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Samples: means single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:

- Demos.
- Evaluation products.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g., as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

PART 1, Chapter 7, Clause 1: Definitions

The sale, loan/rental or placement of equipment with an HCP, where the contract between the member and the HCP includes the purchase of consumables / disposables associated with the equipment.

Taking the above into account the Code Committee arrived at the following opinion:

- This is an evaluation process to determine a purchase which is acceptable – thus an evaluation product. The process should be transparent and have the relevant documentation/company agreements and asset management in place.

1.13 Branded scrubs in a clinical environment

Query: A company noted that as per the guidance on permitted gifts to HCP's, branded scrubs are one of the items that members were permitted to provide to HCP on the condition that the value did not exceed specified maximums.

The company wanted to know if company representatives are also allowed to make use of branded scrubs for use in a clinical environment/operating room.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 13, Clause 2: In the operating room / clinical environment

Healthcare representatives in the operating room / clinical environment:

- Must be trained on operating room/clinical environment protocol.
- May only enter an operating room/clinical environment upon permission
- Must wear appropriate attire as provided or permitted by the facility.

Taking the above into account the Code Committee arrived at the following opinion:

- The company should defer to the facilities requirements. Most healthcare organisations do not permit company representatives to wear their own scrubs, as they need to ensure sterility which they cannot do for scrubs that are not provided by them.

1.14 Paying for HCP endorsements

Query: A company wanted to know if an endorsement of a medical device was prohibited and if not, then could the HCP be provided financial remuneration by the company.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 14, Clause 8: Endorsements and testimonials by healthcare professionals

- Advertising and/or promotion shall not contain recommendation of a medical device by scientists or healthcare professionals unless substantiated.
- The Health Professions Council South Africa does not allow endorsement for financial gain.
- The name or photograph or film / video, television advertisement, radio advertisement or any other reproduction of a member of a healthcare professional must not be used in any way that is contrary to the applicable professional code(s) for that profession and all endorsements, where permitted by professional codes, must be done within the scope of such codes.

- The use of healthcare professionals for marketing, promotion, endorsements or testimonial must take place within the scope set by the professional codes applicable to such professionals.
- Testimonials should be less than three years old and be the genuine views of the user.
- Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.

They also cited GNR.68 of 2 February 2009: Ethical Rules of Conduct for Practitioners registered under the Health Professions Act, 1974

23. Medicine and medical devices

- (1) A practitioner shall not participate in the manufacture for commercial purposes or in the sale, advertising or promotion of any medicine or medical device or in any other activity that amounts to selling medicine or medical devices to the public or keeping an open shop or pharmacy.
- (2) A practitioner shall not engage in or advocate the preferential use or prescription of any medicine or medical device which, save for the valuable consideration he or she may derive from such preferential use or prescription, would not be clinically appropriate or the most cost-effective option.

Taking the above into account the Code Committee arrived at the following opinion:

- The HPCSA prohibits the endorsement or advertisement of a particular medicine or medical device by an HCP and hence also any remuneration in respect thereof.

1.15 Catering for “Tearoom” events

Query: A company wanted to know if it was permissible under the Code to provide snacks/platters for tearoom visits where the purpose is part training and part product promotion.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 1, Clause 5: Reasonable Hospitality

- Member companies may provide reasonable hospitality to HCPs in the context of company events and third-party organised educational events, but any hospitality offered must be subordinate in time and focus to the event purpose.
- The Code seeks to find a balance between the courteous and professional treatment of HCPs by member companies, with the desire to avoid even the appearance that hospitality may be used by member companies as a means to induce HCPs to purchase, prescribe or recommend member companies’ products. Accordingly, member companies must assess what is “reasonable” in any given situation and regional variations will apply. As a general guideline, “reasonable” should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations, and professional codes of conduct.
- The term “hospitality” includes meals and accommodation, and it is important that member companies differentiate between “hospitality” which is permitted and entertainment which is not.

PART 1, Chapter 2: Company events

1. General principles

- Member companies may invite HCPs to company events. Such events include:
 - Product and procedure training and education events.
 - Sales, promotional, product launch and other business meetings.

- Company events should comply with the principles mentioned in Chapter 1: General Criteria for Events.
- Where there is a legitimate business purpose, company events may include or take place in member company's premises / manufacturing plant or HCOs used by the member company as reference centres.

2. Product and procedure training and education events

- Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, member companies should make product and procedure training and education available to relevant HCPs. Member companies shall ensure that personnel conducting the product and procedure training and education events have the appropriate expertise to conduct such training.

3. Sales, promotional, product launch and other business meetings

- Where it is appropriate, member companies may organise sales, promotional, product launches and other business meetings where the objective is to discuss product and related services, features and benefits, conduct contract negotiations or discuss sales terms.

Taking the above into account the Code Committee arrived at the following opinion:

- Reasonable hospitality is allowed for both company training and promotional events. Provision of light snacks at a tearoom appointment is not regarded as an undue inducement.

1.16 Travel provision for business workshop

Query: A company was hosting a business workshop (company event) for HCPs in main cities of business around the country. HCPs from outlying and regional areas were requesting sponsorship of their flights to attend the workshop. The company wanted to know if it would be suitable to pay for economy flights for these HCPs.

Opinion provided: The Code Committee cited the following sections in the code:

PART 1, Chapter 2: Company events

1. General principles

- Member companies may invite HCPs to company events. Such events include:
 - Product and procedure training and education events.
 - Sales, promotional, product launch and other business meetings.
- Company events should comply with the principles mentioned in Chapter 1: General Criteria for Events.
- Where there is a legitimate business purpose, company events may include or take place in member company's premises / manufacturing plant or HCOs used by the member company as reference centres.

2. Product and procedure training and education events

- Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, member companies should make product and procedure training and education available to relevant HCPs. Member companies shall ensure that personnel conducting the product and procedure training and education events have the appropriate expertise to conduct such training.

3. Sales, promotional, product launch and other business meetings

- Where it is appropriate, member companies may organise sales, promotional, product launches and other business meetings where the objective is to discuss product and

related services, features and benefits, conduct contract negotiations or discuss sales terms.

In addition, sales, promotional and other business meetings should also comply with the more stringent requirement that such meetings should, as a general rule, occur at or close to the HCPs place of business.

They also cited HPCSA Booklet 11, Clause 3.13.7

3.13.7. Distinction between education, training, and product promotion

A distinction should be made between education and training on the one hand and product promotion on the other. Healthcare practitioners cannot earn CEUs for attending product launches or other product promotion events. No travel, lodging or other expenses of healthcare practitioners should be paid for attendance at product promotion events or product launches. However, modest meals may be provided.

Taking the above into account the Code Committee arrived at the following opinion:
Based on the information provided, the business workshop constituted a ‘other business’ type meeting and not a company arranged educational, product or procedure training event and hence sponsorship of travel costs for HCP’s would not be appropriate.

1.17 Sponsorship of HCP fellowship

Query: A public healthcare facility approached a company requesting funding (sponsorship) of an HCP’s fellowship. The company would not be able to select the fellow as this would be done by the healthcare facility. The company wanted to know if this would be permissible in terms of the Code.

Opinion provided:

The Medical Device Code does not state that you cannot provide a grant for a fellowship. As such the committee stated it was permissible to give an educational, as long as there is formal documentation and a written contract between the company and the institution in which fair market value was applied. It is essential that the company is not involved in the selection of the fellowship and is not informed of who the recipient of the grant is, i.e. keep an arm’s length as best possible.

The committee also referred the company to SAMED’s [Guidance pertaining to the Management of Indirect Sponsorship and Associated Educational Grant](#)

1.18 Donation of medtech to a patient who cannot afford it

Query: A customer of the company requested the donation of a medical device for a patient who could not afford the device as they did not have private medical cover. The company received several such requests annually.

Opinion provided: The Code Committee cited the following sections in the code:

Chapter 5: Charitable donations

Charitable donations mean provision of cash, equipment, company product or relevant third-party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable donations may only be made to bona fide registered charities whose main objects are genuine charitable or philanthropic purposes.

Charitable donations shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the member company's products or services. It is important that support of charitable and/or philanthropic programmes and activities by member companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure member companies' products or services.

Member companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a charitable donation to a specific prospective recipient. The process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient. Charitable donations may be made if properly recorded and approved by the responsible person(s) in each company or organisation.

Charitable donations are only allowed provided:

- They are documented and kept on record by the donor.
- Donations must not be paid directly to HCPs or to healthcare administration staff.

Companies are encouraged to make available publicly, information about charitable donations made by them as covered in this section.

Taking the above into account the Code Committee arrived at the following opinion:
If the patient approaches the company directly to request the donation, with no HCP or hospital involvement, it would be considered a purely CSR/philanthropic action guided by the company's internal policies and procedures. Charitable donations can only be made to a registered charity/NPO and not to customers.

1.19 Hire of a hospital venue

Query: The company understood that the code prohibits payments to doctors or groups of HCP's either directly or indirectly, for rental for rooms or other services, but had been requested by a healthcare institution to pay venue hire for CPD events. Shorter business and sales meetings could proceed with a charge. The company wanted to confirm if such payment was prohibited in terms of the Code.

Opinion provided: The Code Committee cited the following sections in the code:

Chapter 4, Clause 5: Other interactions with HCPs

Payments may not be made to doctors or groups of HCPs, either directly or indirectly, for rental for rooms or other services.

They also cited HPCSA Booklet 11, Clause 3.10

3.10 CHARGING OR RECEIVING FEES RULE 7

3.10.2 For seeing representatives Health care practitioners shall not charge a fee or receive any financial gain or other valuable consideration for seeing medical representatives.

Taking the above into account the Code Committee arrived at the following opinion: Signatories to the Code may not pay HCPs or HCOs directly or indirectly for this type of 'other' services and HCPs should not be charging medtech suppliers a fee in return for the medtech companies' representatives to hold a meeting with them, whether this is for a CME event, company product launch or other. This is in alignment with The HPCSA Booklet 11, clause 3.10.2.

1.20 Skills development at congress

Query: The company wanted to conduct demonstration and skills development at their company stand at a medical congress. The surgeons would be provided an opportunity to experience the device at the stand.

Opinion provided: The Code Committee cited the following sections in the code:

Page 7: Interactions between medical device industry and HCPs

There are many forms of interactions between the medical device industry and HCPs. Such interactions act to advance medical science and improve patient care. This is a distinguishing feature of the medical device and IVD industries and such interactions act as a backdrop to the following:

- Advancement of medical devices: The development of innovative medical devices and the improvement of existing products requires collaboration between industry and HCPs, often occurring outside the facilities of medical device companies.
- Safe and effective use of medical devices: The safe and effective use of medical devices requires that industry offers HCPs appropriate instruction, education, training, service, and technical support. Regulators may also require this type of training as a condition of product approval.
- Research and Education: Industry's support of bona fide medical research, education, and enhancement of professional skills contributes to patient safety, improved patient outcomes and increased access to new technology.

In such interactions member companies must continue to respect the obligation of HCPs to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry.

Chapter 2: Company events

1. General principles

Member companies may invite HCPs to company events. Such events include:

- Product and procedure training and education events.
- Sales, promotional, product launch and other business meetings.

Company events should comply with the principles mentioned in Chapter 1: General Criteria for Events.

Where there is a legitimate business purpose, company events may include or take place in member company's premises / manufacturing plant or HCOs used by the member company as reference centres.

2. Product and procedure training and education events

Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, member companies should make product and procedure training and education available to relevant HCPs. Member companies shall ensure that personnel conducting the product and procedure training and education events have the appropriate expertise to conduct such training.

3. Sales, promotional, product launch and other business meetings

Where it is appropriate, member companies may organise sales, promotional, product launches and other business meetings where the objective is to discuss product and related services, features and benefits, conduct contract negotiations or discuss sales terms.

In addition to the principles laid down in Chapter 2, Section 1: General Principles, sales, promotional and other business meetings should also comply with the following more stringent requirement:

- Such meetings should, as a general rule, occur at or close to the HCPs place of business.

Taking the above into account the Code Committee arrived at the following opinion:
This is viewed as a skills training/promotional offering which happens to be at the same time as a congress and there are no concerns with respect to the proposed interaction, provided it occurs outside the CPD meeting room and is part of the promotional side of the congress.

1.21 Donation of a television

Query: A company received a request from a public healthcare institution for the donation of a television for the nuclear medicine division. The HPC who sent the request motivated that the television was to provide a diversion to patients who had to wait for several long hours for scans. Majority of the patients were illiterate and as such reading materials were not suitable. The company wanted to know if it would be acceptable to contribute to making patients' experience more pleasant when visiting the public hospital.

Opinion provided: The Code Committee cited the following sections in the code:

Chapter 4: Promotional items, items of medical utility, gifts and competitions

1. General principles

There should be no personal enrichment of HCPs or other healthcare providers. No gift, benefit in kind, rebate, discount, kickback, or any other pecuniary advantage shall be offered or given to members of the health professions, administrative staff, government officials or the general public as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any medical device.

2. Promotional items

Definition: An item that is provided by or on behalf of a Member to another person or organization and is intended as a promotional reminder / campaign relating to the Company and its products. (Records of all promotional campaigns must be kept for a period of five years).

Promotional items to HCPs, appropriate administrative staff, sales and other staff are acceptable provided that they are:

- Within the cost limit set from time to time by SAMED.
- Not for personal use e.g. no entertainment CDs/DVDs, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.
- Educational and/or of scientific value, benefit the patient and/or be relevant to the practice.
- No cash or cash equivalents (e.g. vouchers) are allowed.

Promotional items must be branded with Company name and/or Product and/or Logo.

For values, please see Part 3: Questions and answers.

3. Items of medical utility

Definition: An item that is provided by or on behalf of a member to another person or organization, which has a genuine educational function that is intended to aid in the medical care of patients. Items of medical utility generally include items that are beneficial to enhancing the provision of medical services and patient care and have no personal benefit to the HCP.

Items of medical utility, including, informational and educational materials, scientific medical reference books, journals, periodicals and anatomical models intended for teaching or patient benefit (value as determined from time to time by SAMED), are allowed to be provided to HCPs within the cost limit set from time to time by SAMED.

For values, please see Part 3: Questions and answers.

4. Gifts:

Member companies may not give gifts of any nature, including but not limited to those pertaining to cultural, religious or national events.

Part 3: Questions and answers

Q14: What are examples of promotional items that are “relevant to the HCP’s practice and/or for the benefit of patients”.

A14: Stationery items, calendars, diaries, computer accessories for business use and clinical items such as wipes, nail brushes, surgical gloves and tourniquets are examples of modest value items that could be appropriately provided to HCPs provided their value falls within the maximum value prescribed under national laws, regulations and industry and professional codes of conduct. Promotional items should not be for personal use e.g. no entertainment CDs/DVDs, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.

Entertainment should not dominate or interfere with the overall scientific content of the programme and should not be the main attraction of the event. Advertising support (brochures, website and other materials) should highlight the scientific nature of the programme content. The materials should not emphasize the geographic location and should not make excessive or inappropriate references to or contain images of entertainment, sporting events or other non- scientific activities, which could be seen as promoting the location/venue instead of the event content.

Taking the above into account the Code Committee arrived at the following opinion:
A television used to provide entertainment to patients whilst they wait to be treated would not be considered an appropriate donation as a television does not align with the definitions in the code of a promotional item or an item of medical utility.

The Code committee understood the aim is to give patients a more pleasant waiting room experience, however, determined the hospital should incur this expense as an overhead/running

cost of providing a service to their patients. It would be impossible to monitor whether staff share the use of the television during their breaks and so indirectly this would provide entertainment, which companies are prohibited from providing to HCPs.

1.22 Placement of a medical device in exchange for product scripts

Query: A company had encountered a new practice within their segment in which a competitor was placing a medical device at an HCP practice free of charge for use by the practice. In return, the HCP was scripting for only their medical device for patient home use. The querying company was no longer receiving scripts as a result and had been requested to provide a free device to the practice in the same type of exchange. It is also not known whether a written placement agreement existed. The HCP is also allegedly gaining an advantage by not having to pay for a consumable equivalent required by patients in the HCP's rooms. The company was concerned that this was a transgression of the Code and was uncertain if this could be reported as such.

Opinion provided: The Code Committee cited the following sections in the code:

The Principle of Equivalence

Where HCPs are engaged by a member to perform a service for or on behalf of a member, the remuneration paid by the member must be commensurate with, and represent a fair market value for, the services performed by the HCP.

Chapter 8: Loan or placed equipment

While it is acceptable for products to be placed pursuant to a placement agreement, certain criteria would need to be met i.e.

The sale, loan/rental or placement of equipment with an HCP, where the contract between the member and the HCP includes the purchase of consumables / disposables associated with the equipment, are subject to the following provisions:

HCPSA's Guidelines for Good Practice in the Healthcare Professions – Booklet 11, item 3.6 Technological Equipment:

- HCPs shall only own and use technological equipment if it forms an integral part of their scope of the profession and practice and on condition that the HCP concerned has received appropriate training in using and managing such equipment.
- HCPs shall not over-use equipment for procedures, tests and other applications that are not indicated, scientific or based on evidence. This constitutes over-servicing and is prohibited.
- HCPs shall not use technological equipment, healthcare products or devices for profiteering and must refrain from charging patient's fees for the use of such products or devices that are not market related.
- The consumables are used to cross-merchandise the capital equipment in a manner which is defensible and fair.
- The consumables relate to the specific piece of capital equipment being financed by means of the purchase of the consumables and is defensible in terms of the provisions of the National Credit Act.
- The placement of equipment agreement should be in writing and, in cases of valid complaints, made available as per the complaints handling process in Part 2: Dealing with infringements of the Code.
- In the case of equipment licensed with the Radiation Board, such equipment may only be loaned or placed as stipulated in the product license as issued by the Radiation Board.

Chapter 7: Demonstration products and samples

Definitions

Demonstration products (demos): means either single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use.

Evaluation products: means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a member company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose.

Samples: means single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use.

General principles

Member companies may provide their own products as demonstration products and/or samples (see the definitions above) at no charge in order to enable HCPs and/or HCOs (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

Demonstration products and/or samples may be either single- or multiple-use products. Member companies may also provide products from another company in conjunction with the member company's own demonstration products and/or samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the member company's products, e.g. computer hardware and software produced by a company other than the member company.

Provision of demonstration products and/or samples must not improperly reward, induce and/or encourage HCPs and/or HCOs to purchase, lease, recommend, prescribe, use, supply or procure member companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Member companies shall in all cases maintain appropriate records in relation to the provision of demonstration products and/or samples to HCPs and/or HCOs, for example recording proof of delivery for any demonstration products and/or samples provided and receipt of return for multiple-use demonstration products and/or samples. Member companies shall clearly record in the member company's records as well as clearly disclose to HCPs and/or HCOs the no-charge basis and other conditions applicable for the supply of such demonstration products and/or samples no later than the time of the supply. The disclosure to HCPs and HCOs shall be in writing.

Taking the above into account the Code Committee arrived at the following opinion:
The mentioned activity may well contravene the principle of equivalence, i.e. there is no justifiable commercially relevant reason or other for the HCP to be provided a product free of charge. The placement for free of the products is not commensurate with the services performed by the HCP regarding the writing of scripts.

From the facts provided, it appeared no consumables were linked to the placed medical device. It is also not apparent that the product placed at no additional charge forms part of the overall purchase price in a commercial supply arrangement.

It was also alleged that the medical device was placed free of charge in return for the HCP prescribing scripts for at home device for the placement company. This may well constitute an inducement by the placement company i.e. the activity may improperly reward, induce and/or encourage the HCPs to recommend and prescribe the companies' products or services.

The code committee viewed this practice as a possible transgression of the Code and deemed it inappropriate. The querying company was encouraged to report this via the whistleblowing hotline or formal complaint channels.

1.23 Catering request for a journal club meeting

Query: The Company's staff have been informed that in order to receive a training slot during a Journal club meeting, they must sponsor the meals/drinks for all the HCP's attending (25-30 individuals). The journal clubs are held in the auditoriums of the government hospitals, the content of the discussion will depend on which department head is presenting. Once the department heads have presented on certain diseases/techniques /articles, the related industry representatives are asked to detail their products used during the particular procedure. Food can vary from just teas coffees and some sandwiches or platters for bigger groups. Historically, the company had advised staff to not supply any eats/meals during any training session. What does the Code say on this matter? Would it be appropriate to sponsor meals?

Opinion provided: The Code Committee cited the following sections in the code:

5. Reasonable hospitality

Member companies may provide reasonable hospitality to HCPs in the context of company events and third-party organised educational events, but any hospitality offered must be subordinate in time and focus to the event purpose.

The Code seeks to find a balance between the courteous and professional treatment of HCPs by member companies, with the desire to avoid even the appearance that hospitality may be used by member companies as a means to induce HCPs to purchase, prescribe or recommend member companies' products. Accordingly, member companies must assess what is "reasonable" in any given situation and regional variations will apply. As a general guideline, "reasonable" should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations and professional codes of conduct.

8. Transparency

When meetings are sponsored by companies, other organisations or by individuals, the fact must be disclosed in the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

Part 1: Interactions with HCPs

1. Event programme

The event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs. For third-party organised educational events, the agenda should be under the sole control and responsibility of the third-party organiser. The meeting and event should be appropriate to all delegates' scope of practice.

A member company shall not organise events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements which form part of third-party organised educational events. For third- party organised educational events, entertainment must be outside of

the educational programme schedule and paid for separately by the HCPs. The registration fee should cover only the scientific programme and hospitality.

Entertainment should not dominate or interfere with the overall scientific content of the programme and should not be the main attraction of the event. Advertising support (brochures, website and other materials) should highlight the scientific nature of the programme content. The materials should not emphasize the geographic location and should not make excessive or inappropriate references to or contain images of entertainment, sporting events or other non-scientific activities, which could be seen as promoting the location/venue instead of the event content.

4. CPD meetings

No product promotion is allowed in the CPD meeting room. Company-branded items/promotions are permissible.

Speakers should, in so far as possible, use the non-proprietary names of products during CPD events. Companies must make it known to speakers that the use of trade names, in order to promote a particular product, is not permitted.

Taking the above into account the Code Committee arrived at the following opinion:
It is concerning that it appears that from the information provided, that HCPs are obliging industry representatives to entry criteria (in the form of sponsored meals/drink) in order to receive a training slot on their medical devices.

It appears that the provision of meals and drinks is a form of sponsorship i.e. the company is getting a benefit from this “sponsorship” by being provided a training slot. As such, it would be better to structure it in such a way that the company pay a fee for the training slot and be shown that the price they are paying is ‘Fair Market Value’ and what the fee will be used for (i.e. catering). Ultimately, it would also be better for the hospital to arrange and pay for the catering.

1.24 Overnight stay at a BnB as a competition prize

Query: One of the company’s patients owns a guesthouse and offered to gift a weekend away to any of our customers (and their partner). The value of the prize is R1 880.00 and the idea is to add the prize to an envelope and place this under a chair at the training – i.e. it would be like a lucky draw. Would it be appropriate to use this goodwill gesture as a prize at our next training event?

Opinion provided: The Code Committee cited the following sections in the code:

Definitions: “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.

Chapter 4: Promotional items, items of medical utility, gifts and competitions

1. General principles

There should be no personal enrichment of HCPs or other healthcare providers. No gift, benefit in kind, rebate, discount, kickback or any other pecuniary advantage shall be offered or given to members of the health professions, administrative staff, government officials or the general public as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any medical device.

6. Competitions

Competitions should fulfil the following criteria:

- The competition is based on medical/product knowledge or the acquisition of scientific knowledge.
- Individual prizes or educational items offered should benefit the patient and / or be relevant to the practice; and within the cost limit set from time to time by SAMED.
- The prize cannot comprise of cash or a cash equivalent (e.g. vouchers).
- Entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.
- No cash or cash equivalents (e.g. vouchers) are allowed for completion of a survey or as a prize for a competition.

Taking the above into account the Code Committee arrived at the following opinion:
The type of customer referred to would be a healthcare professional and clauses in the govern member interaction with HCPs should be duly considered. Competition prizes should not be for the personal enrichment of the HCP and should instead benefit the patient or practice. A guest house stay would be solely for the recreational (personal) benefit of the healthcare professional (and their partner) and would not benefit his/her patients, service offering or practice. A pure lucky draw does not lend itself to medical/product/scientific knowledge or the acquisition thereof.

As such, the Code Advisory Sub-committee, concluded that it would not be acceptable to offer an overnight stay for an HCP (and their partner) as part of a lucky draw at a training event. A better option would be for HCPs to answer a medical/product/scientific question as entry for a competition (which could include a random draw selection from the correct answers), the prize for which benefits their patients or their practice and conforms to the prescribed maximum values.

1.25 International event merit review

Query: Our company is a South African importer of medical devices and a member of SAMED. Our international principal, with whom we have a formal distributor agreement, is based in the USA and, to the best of my knowledge, is not a member of any industry association (e.g., Advamed, MedTech). This event was reviewed internally, as a company event (owned and organized by our international principal), for sponsorship by our company for RSA HCP's to attend the event.

Due to various non-compliant components highlighted below, it was concluded that sponsorship of HCP's to attend this event is not compliant. The RSA management team is familiar with the requirements of local and international Codes; they fully understood and accepted the outcome of the review. However, we received strong push-back from our international principal, therefore this request for an unbiased and independent Advisory Opinion

Opinion provided: The Code Committee cited the following sections in the code:

The Principle of Image and Perception

Members should, at all times, consider the image and perception of the medical device industry that will be projected to the public when interacting with HCPs.

1. Event programme

The event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs. For third-party organised educational events, the agenda should be under the sole control and responsibility of the third-party organiser. The meeting and event should be appropriate to all delegates' scope of practice.

A member company shall not organise events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements which form part of third-party organised educational events. For third-party organised educational events, entertainment must be outside of the educational programme schedule and paid for separately by the HCPs. The registration fee should cover only the scientific programme and hospitality.

Entertainment should not dominate or interfere with the overall scientific content of the programme and should not be the main attraction of the event. Advertising support (brochures, website and other materials) should highlight the scientific nature of the programme content. The materials should not emphasize the geographic location and should not make excessive or inappropriate references to or contain images of entertainment, sporting events or other non-scientific activities, which could be seen as promoting the location/venue instead of the event content.

The direct sponsorship of HCPs to attend third-party organised educational events is prohibited.

Type of event	Applicable rule
Third-party organised educational events (main programme)	Companies are prohibited from directly supporting a healthcare professional, neither as a delegate nor as a speaker. Companies may consider indirect sponsorship in the form of an educational grant, provided that the requesting entity fulfils the requirements as per the definition of a "third-party".
Company-organised events in the framework of third-party organized events (e.g. satellite symposia)	Companies may directly support speakers (i.e. their consultants) at the company-organised event but not Delegates
Third-party organised procedure/hands-on trainings	Companies may support delegates but not speakers, the latter being independent
Company-organised product/procedure trainings	Companies may directly support a healthcare professional either as a delegate and/or as a speaker

The criteria for selection of attendees/invitees must be transparent and available on request for scrutiny.

Payment of registration fees, travel and accommodation must be made to the professional associations/organisers and not directly to the HCP or their administrative staff. No payment may be made to the HCP for time spent at the event.

Advertisement and promotion at events are subject to relevant domestic legislation and / or regulations.

For speakers, payment of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel, are permissible provided it is in terms of a written contract.

2. Event location and venue

The event location and venue should not become the main attraction of the event. For the location and the venue, member companies must take into account at all times the following considerations:

- Potential adverse public perceptions of the location and venue for the event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an entertainment venue.
- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.
- No company may organise or sponsor an event that takes place outside its home country unless:
 - Most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country.

- Given the location of the company's training facility, relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an "international event").

Further considerations to be taken into account:

- Central location - taking into account the place of origin of the majority HCP invitees, the venues selected must be centrally located.
- Capitals and major cities are recommended.
- The ease of access – The geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure.
- Venues situated on the beachfront can be considered under the following circumstances:
 - There are no suitable alternative venues in the geographic location.
 - The venue is not considered as luxurious in nature. In general, a 5-star rated venue would not be considered appropriate.
 - The venue is well known as a business or commercial centre conducive to the exchange of scientific or medical information.
- In general, the following venues will not be considered compliant:
 - Resort venues (meaning a venue which is part of a complex offering significant recreational, amusement or sporting facilities).
 - Cruise ships, golf clubs (including those owned or operated by a hotel), spas (where the spa is the main attraction and well known for its spa facilities), wine estates or venues with on-site casinos.
- The image of the location among the public, media and authorities cannot be perceived as a purely luxury, touristic/holiday and/or entertainment venue.
- The financial advantage that a venue rental may present should not be considered a factor when deciding on the appropriateness of a venue.

Member companies may invite HCPs to company events. Such events include:

- Product and procedure training and education events.
- Sales, promotional, product launch and other business meetings.

Company events should comply with the principles mentioned in **Chapter 1: General Criteria for Events**.

Where there is a legitimate business purpose, company events may include or take place in member company's premises / manufacturing plant or HCOs used by the member company as reference centres.

1. Product and procedure training and education events

Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, member companies should make product and procedure training and education available to relevant HCPs. Member companies shall ensure that personnel conducting the product and procedure training and education events have the appropriate expertise to conduct such training.

2. Sales, promotional, product launch and other business meetings

Where it is appropriate, member companies may organise sales, promotional, product launches and other business meetings where the objective is to discuss product and related services, features and benefits, conduct contract negotiations or discuss sales terms.

In addition to the principles laid down in **Chapter 2, Section 1: General Principles**, sales, promotional and other business meetings should also comply with the following more stringent requirement:

- Such meetings should, as a general rule, occur at or close to the HCPs place of business.

Taking the above into account the Code Committee arrived at the following opinion:

The principle of the strictest rule applies when considering any aspect of local and international Codes, i.e. even though the Principal company does not belong to or adhere to any Codes, the local company is bound by the Code as SAMED members. The principle of image and perception must also be considered. The venue is a luxury venue and the event promotes entertainment/tourism

activities as central to the event. The image of the location cannot be perceived as a purely luxury, tourist/holiday and/or entertainment venue.

In terms of the venue, which is a 4-star luxury hotel located on the beach front of Monte Carlo, the venue does not meet the requirements within the Code. Venues situated on the beachfront should only be considered if there are no suitable alternative venues in the geographic location, the venue is not considered as luxurious and/or the venue is well known as a business or commercial centre conducive to the exchange of scientific or medical information. As such it would not be permissible/compliant for the local SAMED Member to participate by sending delegates to attend the event.

Code advisory opinions provided in 2024

1.26 Flight exception request - HCP medical condition

Query: The Company has symposium taking place internationally (Europe) in November and received a request from an HCP for their flight to be booked in Business class due to medical reasons. Considering that the Code does not allow us to book Business Class, except for 2 conditions (Faculty members irrespective of day of arrival/ HCPs attending advisory boards and clinical investigations irrespective of day of arrival) and this is not the case for this HCP, would it be possible to grant an exception in regards this case due to this medical condition?

The Code Committee cited the following sections in the code:

PART 1: Interactions with HCPs, Chapter 1: General criteria for events, clause 6. Travel

6. Travel

General principles

Member companies may only pay or reimburse for reasonable and actual travel. Travel may be arranged by the sponsoring company (or their designated travel agent). Travel provided to HCPs should not cover a period of stay beyond the day before and the day after the official duration of the event.

International travel

Member companies may sponsor business class travel for HCPs **only** for:

- Faculty members irrespective of day of arrival.
- HCPs attending advisory boards and clinical investigations irrespective of day of arrival.

Business class airfares may not be exchanged for two economy tickets so that a companion/spouse may accompany the HCP.

Premium economy flights may be considered in the class of international economy travel however perception and cost are important factors when deciding whether premium economy flights may be acceptable.

First class is never appropriate.

For any other travel, economy class travel is the standard class of travel that companies may offer HCPs to attend both international and local events, including congress attendance and site visits.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

Considering the surgeon's medical letters and condition, the company may offer a premium upgradeable economy class ticket. Should the HCP not wish to fly premium economy then they should contribute towards the difference from premium economy to business.

1.27 Sun City as an event venue

Query: Is Sun City an appropriate venue to host an event? Sun City is large enough to meet our needs in respect of accommodating a large number of attendees and all the planned workshops, parallel sessions, etc.

The Code Committee cited the following sections in the code:

The Principle of Image and Perception

Members should, at all times, consider the image and perception of the medical device industry that will be projected to the public when interacting with HCPs.

1. Event programme

The event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs. For third-party organised educational events, the agenda should be under the sole control and responsibility of the third-party organiser. The meeting and event should be appropriate to all delegates' scope of practice.

A member company shall not organise events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements which form part of third-party organised educational events. For third-party organised educational events, entertainment must be outside of the educational programme schedule and paid for separately by the HCPs. The registration fee should cover only the scientific programme and hospitality.

Entertainment should not dominate or interfere with the overall scientific content of the programme and should not be the main attraction of the event. Advertising support (brochures, website, and other materials) should highlight the scientific nature of the programme content. The materials should not emphasize the geographic location and should not make excessive or inappropriate references to or contain images of entertainment, sporting events or other non-scientific activities, which could be seen as promoting the location/venue instead of the event content.

2. Event location and venue

The event location and venue should not become the main attraction of the event. For the location and the venue, member companies must take into account at all times the following considerations:

- Potential adverse public perceptions of the location and venue for the event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an entertainment venue.
- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.
- No company may organise or sponsor an event that takes place outside its home country unless:
 - Most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country.
 - Given the location of the company's training facility, relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an "international event").

Further considerations to be taken into account:

- Central location - taking into account the place of origin of the majority HCP invitees, the venues selected must be centrally located.
- Capitals and major cities are recommended.
- The ease of access – The geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure.
- Venues situated on the beachfront can be considered under the following circumstances:
 - There are no suitable alternative venues in the geographic location.
 - The venue is not considered as luxurious in nature. In general, a 5-star rated venue would not be considered appropriate.
 - The venue is well known as a business or commercial centre conducive to the exchange of scientific or medical information.
 - In general, the following venues will not be considered compliant:
- Resort venues (meaning a venue which is part of a complex offering significant recreational, amusement or sporting facilities).
- Cruise ships, golf clubs (including those owned or operated by a hotel), spas (where the spa is the main attraction and well known for its spa facilities), wine estates or venues with on-site casinos.
- The image of the location among the public, media and authorities cannot be perceived as a purely luxury, touristic/holiday, and/or entertainment venue.
- The financial advantage that a venue rental may present should not be considered a factor when deciding on the appropriateness of a venue.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

This location for this event does not align with the principle of image and perception and the venue is considered primarily a resort venue. The location of the venue (and its surrounds) promotes entertainment/tourism activities. The venue is also not centrally located nor has ease of access.

As such supporting such an event would potentially be in contravention of the Code.

1.28 Providing consumables free of charge for a pilot project

Query: May a SAMED member provide product free of charge for a pilot project?

The Code Committee cited the following sections in the code:

It is our understanding that the products are to be used in a pilot project which is typically for evaluation purposes. If so, then the section in the code on evaluations would apply.

Demonstration products and samples

This chapter is limited to the provision of demonstration products and/or samples and related services at no charge.

1. Definitions

Demonstration products (demos): means either single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and

effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:

- Samples.
- Evaluation products.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Evaluation products: means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a member company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose. Evaluation products do not include the following:

- Demos.
- Samples.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Samples: means single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:

- Demos.
- Evaluation products.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

2. General principles

Member companies may provide their own products as demonstration products and/or samples (see the definitions above) at no charge in order to enable HCPs and/or HCOs (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

Demonstration products and/or samples may be either single- or multiple-use products. Member companies may also provide products from another company in conjunction with the member company's own demonstration products and/or samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the member company's products, e.g. computer hardware and software produced by a company other than the member company.

Provision of demonstration products and/or samples must not improperly reward, induce and/or encourage HCPs and/or HCOs to purchase, lease, recommend, prescribe, use, supply or procure member companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Member companies shall in all cases maintain appropriate records in relation to the provision of demonstration products and/or samples to HCPs and/or HCOs, for example recording proof of delivery for any demonstration products and/or samples provided and receipt of return for multiple-use demonstration products and/or samples. Member companies shall clearly record in the member company's records as well as clearly disclose to HCPs and/or HCOs the no-charge basis and other conditions applicable for the supply of such demonstration products and/or samples no later than the time of the supply. The disclosure to HCPs and HCOs shall be in writing.

3. Demonstration products (demos)

Member companies may provide examples of their products to HCPs and/or HCOs in the form of mock-ups (such as unsterilized single use products) that are used for HCPs and patient awareness, education and training.

For example, an HCP may use a demonstration product to show a patient the type of technology which will be implanted in the patient or may use the demo to train other HCPs in the use of the product.

Demonstration products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member companies shall clearly record in the member company's records as well as clearly disclose to HCPs and/or HCOs the no-charge basis and other conditions applicable for the supply of such demonstration products no later than the time of the supply. It is recommended that the disclosure to HCPs and HCOs shall be in writing.

4. Samples

Member companies may provide a reasonable number of samples at no charge to allow HCPs and/or HCOs to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

For single-use product samples, the quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the HCPs/HCOs to acquire adequate experience in dealing with the products.

For multiple-use product samples, the specific length of time necessary for an HCP to familiarise him/herself with the product will depend on the frequency of anticipated use; the duration of required training; the number of HCPs who will need to acquire experience in dealing with the product; and similar considerations.

Member companies shall in all cases ensure that they retain title to multiple-use samples and that they have a process in place for promptly removing such multiple-use samples from the HCP's location at the conclusion of the familiarisation period.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

There should be an agreement in place outlining the terms and conditions of this project (including ensuring that the general principles referred to above are included/adhered to) as well as the responsibilities of the HCP and that:

- a) the medical devices / items are being provided free of charge
- b) and therefore, that they are not to be billed either to the patient or the medical scheme

The committee also recommends that the member or the HCP involved should ensure that the medical schemes are informed accordingly.

1.29 Port Elizabeth Boardwalk as an event venue

Query: A society is hosting their annual Congress; the hosting region is the Free State. A PCO is managing the event for the society. The programme is robust and medically focused. CPD points will be applied for once all the speakers and topics have been identified.

Approximately 250-300 attendees are expected, including trade who will have exhibition opportunities. The vast majority of delegates (if not all of them) would be local HCP's, with the exception of a few international invited speakers, for whom the Congress would be covering travel costs directly from our budget.

A venue is required that can accommodate 250 pax in the conference room, but also have enough accommodation onsite or in close proximity for each delegate. Exhibition space is also required. The venue should be easily accessible by road and air, so that HCP's can leave easily in the event of any life-threatening emergencies or callouts (i.e.: we need to be near an airport).

Due to a lack of suitable venues in Bloemfontein that meet the above capacity requirements, as well as the remote location of Bloemfontein, the PCO expanded the venue search to the surrounding areas (also looking at Nelspruit and the Drakensberg - neither suitable in various permutations of our requirements).

The society would prefer not to locate this year's Congress in one of the typical "major centres" (Cape Town, Johannesburg, or Durban) as it has been hosted in all these locations previously. They want to reach locations where they can support the growth of neurosurgery and "spread" knowledge and expertise to other typically under-supported regions of the country (but remaining accessible to members attending from other regions)

The society also wants to work closely with the newly launched Medical School at the University of PE to grow neurosurgery training and expertise in the region.

Given all the considerations above, the city of Gqeberha (formerly known as Port Elizabeth) was identified as a suitable location, being easily accessible to members across all regions of SA and taking the event to a typically under-served area in terms of neurosurgical training.

The only venue that can accommodate all the requirements as stated above is the Southern Sun Boardwalk Hotel. This venue is located on the beachfront and has an adjoining casino. We are aware that this would automatically disqualify it in terms of the MedTech Conference Vetting System. We are also certain that our event is "out of scope" of the MedTech CVS requirements based on the above circumstances we outlined, but we hope to still be within the SAMED guidelines and requirements, and as such, we seek your opinion please.

None of the Congress activities will be hosted in or near the casino or the beachfront. They will all only take place within the Hotel's conference facilities. No tours or activities are being paid for or are included in the delegates' or speakers' registration fees or costs.

The Code Committee cited the following sections in the code:

The Principle of Image and Perception

Members should, at all times, consider the image and perception of the medical device industry that will be projected to the public when interacting with HCPs.

1. Event programme

The event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the event or be sufficiently relevant to justify the attendance of the HCPs. For third-party organised educational events, the agenda should be under the sole control and responsibility of the third-party organiser. The meeting and event should be appropriate to all delegates' scope of practice.

A member company shall not organise events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements which form part of third-party organised educational events. For third-party organised educational events, entertainment must be outside of the educational programme schedule and paid for separately by the HCPs. The registration fee should cover only the scientific programme and hospitality.

Entertainment should not dominate or interfere with the overall scientific content of the programme and should not be the main attraction of the event. Advertising support (brochures, website, and other materials) should highlight the scientific nature of the programme content. The materials should not emphasize the geographic location and should not make excessive or inappropriate references to or contain images of entertainment, sporting events or other non-scientific activities, which could be seen as promoting the location/venue instead of the event content.

2. Event location and venue

The event location and venue should not become the main attraction of the event. For the location and the venue, member companies must take into account at all times the following considerations:

- Potential adverse public perceptions of the location and venue for the event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an entertainment venue.
- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.
- No company may organise or sponsor an event that takes place outside its home country unless:
 - Most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country.
 - Given the location of the company's training facility, relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an "international event").

Further considerations to be taken into account:

- Central location - taking into account the place of origin of the majority HCP invitees, the venues selected must be centrally located.
- Capitals and major cities are recommended.
- The ease of access – The geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure.
- Venues situated on the beachfront can be considered under the following circumstances:
 - There are no suitable alternative venues in the geographic location.

- The venue is not considered as luxurious in nature. In general, a 5-star rated venue would not be considered appropriate.
- The venue is well known as a business or commercial centre conducive to the exchange of scientific or medical information.
- In general, the following venues will not be considered compliant:
 - Resort venues (meaning a venue which is part of a complex offering significant recreational, amusement or sporting facilities).
 - Cruise ships, golf clubs (including those owned or operated by a hotel), spas (where the spa is the main attraction and well known for its spa facilities), wine estates or venues with on-site casinos.
 - The image of the location among the public, media and authorities cannot be perceived as a purely luxury, touristic/holiday, and/or entertainment venue.
- The financial advantage that a venue rental may present should not be considered a factor when deciding on the appropriateness of a venue.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

This would not be an appropriate event venue due to the close proximity of a casino. The Code Committee recommends that other venue options be investigated and considered.

1.30 Golf tournament as a charitable fundraiser

Query: Can SAMED members provide sponsorship towards a golf tournament as a charitable fundraiser?

The Code Committee cited the following sections in the code:

Charitable Donations

Member Companies may make Charitable Donations for charitable or other philanthropic purposes. They can support these programmes for many valid reasons, such as advancing medical education and training for HCPs, raising patient and public awareness on important health topics, helping underserved or under-resourced populations through bona fide charitable programmes, or funding independent scientific or clinical research. Members may support charitable programmes through monetary, in-kind, and other contributions such as equipment, company or relevant third-party product, for exclusive use for charitable or philanthropic purposes and/ or to benefit a charitable or philanthropic cause.

Members shall have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Charitable Donations shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member's products or services. It is important that support of charitable and/or philanthropic programmes and activities is not viewed as a price concession, reward to favoured Customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure a company's products or services. If Charitable Donations are provided on more than one occasion to the same recipient, Members should be mindful that perception and contractual risks may arise. Companies should therefore establish internal controls and checks to mitigate these risks. Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship, provided that the Charitable Donation benefits patients, is limited to specific needs identified in advance or is explicitly permitted by applicable national laws. A company should exercise diligence to ensure the charitable organisation or charitable purpose is bona fide. Relevant factors to consider include but are not

limited to the entity's tax and corporate status and whether the organisation has a charitable mission or purpose.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

Charitable Donations made by members may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic organization. Members may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring charitable or non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the member shall not invite Healthcare Professionals to attend such an event at the Member Company's expense. Furthermore, members are not permitted to suggest to the sponsoring organisation, the names of Healthcare Professionals who could be invited to attend the event, irrespective of whether or not the specified Healthcare Professionals will be seated at the Member Company's table.

1.31 Sponsorship for nurses training

Query: Can we sponsor the training of a nurse in the public sector from a specified hospital, where we have identified the nurse who will receive the benefit of the training?

The Code Committee cited the following sections in the code:

Educational grants

Members may provide Educational Grants for the advancement of medical education. Members shall specify the intended purpose of the Educational Grant A Member Company shall also 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 intended purpose. Members shall document all Educational Grants

Member Companies may support such Events by providing Educational Grants to an appropriate third-party recipient organisation e.g., PCO, HCO, HCP professional society.

Where the Educational Grant is provided for the purpose of supporting HCPs attendance at TPOEs, the **HCO receiving the Grant shall be solely responsible for selection of participants** and this shall be stipulated in the written grant agreement.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

Based on the information provided by the company, this offer of grant support cannot be considered an unbiased sponsorship offered at arm's length.

- The Code is very clear on the of selection of beneficiaries.
- Maintaining the anonymity of potential beneficiaries is a critical aspect to ensure unbiased selection.
- A sponsoring company may not influence or be involved in any way in the selection of the beneficiary of the grant; such selection of the beneficiary is solely the responsibility of the grant recipient.

1.32 Handing out product samples at a conference

Query: As part of a product launch, can we hand out samples of the product (eye masks) at an upcoming conference?

The Code Committee cited the following sections in the code:

The following sections of the Code (see: the Code) apply to this query and you are urged to read through them.

Demonstration products and samples

This chapter is limited to the provision of demonstration products and/or samples and related services at no charge.

1. Definitions

Demonstration products (demos): means either single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:

- Samples.
- Evaluation products.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Evaluation products: means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a member company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose. Evaluation products do not include the following:

- Demos.
- Samples.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Samples: means single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:

- Demos.
- Evaluation products.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

2. General principles

Member companies may provide their own products as demonstration products and/or samples (see the definitions above) at no charge in order to enable HCPs and/or HCOs (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

Demonstration products and/or samples may be either single- or multiple-use products. Member companies may also provide products from another company in conjunction with the member company's own demonstration products and/or samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the member company's products, e.g. computer hardware and software produced by a company other than the member company.

Provision of demonstration products and/or samples must not improperly reward, induce and/or encourage HCPs and/or HCOs to purchase, lease, recommend, prescribe, use, supply or procure member companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Member companies shall in all cases maintain appropriate records in relation to the provision of demonstration products and/or samples to HCPs and/or HCOs, for example recording proof of delivery for any demonstration products and/or samples provided and receipt of return for multiple-use demonstration products and/or samples. Member companies shall clearly record in the member company's records as well as clearly disclose to HCPs and/or HCOs the no-charge basis and other conditions applicable for the supply of such demonstration products and/or samples no later than the time of the supply. The disclosure to HCPs and HCOs shall be in writing.

3. Demonstration products (demos)

Member companies may provide examples of their products to HCPs and/or HCOs in the form of mock-ups (such as unsterilized single use products) that are used for HCPs and patient awareness, education and training.

For example, an HCP may use a demonstration product to show a patient the type of technology which will be implanted in the patient or may use the demo to train other HCPs in the use of the product.

Demonstration products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member companies shall clearly record in the member company's records as well as clearly disclose to HCPs and/or HCOs the no-charge basis and other conditions applicable for the supply of such demonstration products no later than the time of the supply. It is recommended that the disclosure to HCPs and HCOs shall be in writing.

4. Samples

Member companies may provide a reasonable number of samples at no charge to allow HCPs and/or HCOs to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

For single-use product samples, the quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the HCPs/HCOs to acquire adequate experience in dealing with the products.

For multiple-use product samples, the specific length of time necessary for an HCP to familiarise him/herself with the product will depend on the frequency of anticipated use; the duration of required training; the number of HCPs who will need to acquire experience in dealing with the product; and similar considerations.

Member companies shall in all cases ensure that they retain title to multiple-use samples and that they have a process in place for promptly removing such multiple-use samples from the HCP's location at the conclusion of the familiarisation period.

And

Promotional items, items of medical utility, gifts, and competitions

1. General principles

There should be no personal enrichment of HCPs or other healthcare providers. No gift, benefit in kind, rebate, discount, kickback, or any other pecuniary advantage shall be offered or given to members of the health professions, administrative staff, government officials or the general public as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any medical device.

2. Promotional items Definition:

An item that is provided by or on behalf of a Member to another person or organization and is intended as a promotional reminder / campaign relating to the Company and its products. (Records of all promotional campaigns must be kept for a period of five years).

Promotional items to HCPs, appropriate administrative staff, sales, and other staff are acceptable provided that they are:

- Within the cost limit set from time to time by SAMED.
- Not for personal use e.g. no entertainment CDs/DVDs, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.
- Educational and/or of scientific value, benefit the patient and/or be relevant to the practice.
- No cash or cash equivalents (e.g. vouchers) are allowed.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

The items are not considered promotional items in terms of the Code as it is a new product / device (class A) and as such the sections on samples in the code should apply.

Samples should only be given to HCPs equipped and qualified to use them in clinical use. The event is not a clinical environment/ area of clinical use.

Samples should not be used as a promotional/marketing tool and indiscriminately handed out to the broad audience at a conference, even if you tried to regulate say 1 sample per healthcare professional. At the SAOA it will be exceedingly difficult to restrict distribution of the samples only to clinicians who would evaluate the product for use in their practice. It may therefore attract personal interest from various HCP's, not with the intention to evaluate for use in their practice but to use it for personal use.

“Samples: means single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarize themselves with the products in clinical use”.

As such giving these items out at the event may well be in contravention of the Code.

1.33 Donations of discontinued products

Query: We have received a request for one of our discontinued items to be donated to a University for training purposes on cadavers. By donating this equipment, there will be no support afterwards on this equipment to the University. According to the SAMED code, would this be compliant?

The Code Committee cited the following sections in the code:

Charitable Donations

Member Companies may make Charitable Donations for charitable or other philanthropic purposes. They can support these programmes for many valid reasons, such as advancing medical education and training for HCPs, raising patient and public awareness on important health topics, helping underserved or under-resourced populations through bona fide charitable programmes, or funding independent scientific or clinical research.

Members may support charitable programmes through monetary, In-kind, and other contributions such as equipment, company or relevant third-party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause.

Charitable Donations may only be made to charitable organisations or other non-profit entities which have charitable and/or philanthropic purposes as their main purposes, and which are objectively engaged in charitable or philanthropic activities.

Members shall have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes.

Charitable Donations shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member's products or services. It is important that support of charitable and/or philanthropic programmes and activities is not viewed as a price concession, reward to favoured Customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure a company's products or services. If Charitable Donations are provided on more than one occasion to the same recipient, Members should be mindful that perception and contractual risks may arise. Companies should therefore establish internal controls and checks to mitigate these risks.

Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship, provided that the Charitable Donation benefits patients, is limited to specific needs identified in advance or is explicitly permitted by applicable national laws.

A company should exercise diligence to ensure the charitable organisation or charitable purpose is bona fide. Relevant factors to consider include but are not limited to the entity's tax and corporate status and whether the organisation has a charitable mission or purpose.

Use of funds: a company must require that any donation is used solely for charitable or philanthropic purposes.

Donations to poverty-stricken patients: a company may make charitable donations of product for poverty-stricken patients, provided that these donations serve exclusively to benefit patients and are permitted under applicable laws. Companies should consider making product donations for

benefit of poverty-stricken patients contingent upon a hospital's agreement that no third parties will be billed for the donated product.

Charitable events. A company may not pay for or provide tickets to HCPs or their spouses or guests to attend charitable Events e.g. charitable galas and golf outings.

Members shall implement an independent decision-making/review process with criteria that are not sales and/or commercially oriented to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a Charitable Donation to a prospective recipient. The process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient.

Charitable Donations may be made if properly recorded and approved by the Member Company's responsible person(s). Charitable Donations are only allowed provided they are documented and kept on record by the donor and donations are not paid directly to HCPs or to healthcare administration staff.

Charitable Donations shall only be provided in response to a written request submitted by the requesting organisation or a documented initiative. The request should contain sufficient information to permit an objective evaluation of the request to be carried out by the Member. Minimum documentation required includes a detailed description of the scope and purpose of the programme, activity or other project proposed as the object of the Charitable Donation. It shall contain a description of the proposed recipient, its legal status and structure, and where relevant, a budget. No Charitable Donation shall be provided until a written agreement is signed by both parties.

A Member shall not provide Charitable Donations to individual HCPs. Charitable Donations must be provided directly to the qualifying organisation or entity, as the case may be. Charitable Donations shall not be provided in response to requests made by HCPs unless the HCP is an employee or officer of the qualifying organisation or entity and submits the request in writing on behalf of the qualifying organisation or entity.

Companies are encouraged to issue public notices about Charitable Donations as covered in this section.

Recipients of all Charitable Donations shall identify the Member Company as the provider of the Charitable Donation.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

This is a combination of Code compliance and Regulatory Affairs and could be handled as follows:

1. Code Compliance:

- A donation agreement would still apply, stipulating the details of the donation for educational purposes; the contract would include the standard donation agreement content (e.g. purpose, recipient institution, etc.) but in addition it would include the product details, item codes, quantities, and lot numbers as well as the fact that the product has been discontinued and is donated for educational purposes at the institution only.

2. Regulatory Affairs:

- Before the product is handed over to the institution, it should be opened and a label to the effect of "not for human use", "non-clinical training only" or similar should be added to the opened, unsterile product. I would also recommend taking photos of these opened, labelled products before delivering it to the recipient.

- Item codes and lot numbers are required for traceability purposes and a manifest/POD should accompany the products. This manifest should align with the items, quantities, lot details, etc. indicated in the Donation Agreement. +
- The institution to whom the product is being donated should sign the agreement.

1.34. Support of educational activity where the location and program are questionable

Query: We have been asked by an association to support a workshop during a congress / conference with equipment. No monetary contributions only the equipment to run these workshops, which we will oversee how these are used on the furry patients. The concern for us is related to the programme. Yes, no actual monetary transfer but still allowing them access to something of value namely the equipment for their workshops for this event. However, the event programme has things such as Sunrise and Sunset Safari (early and late game drive I assume), wining & dining to denote dinner. We will not be participating in these events and our focus is always around skills development and addressing much needed care. Hence our support of the workshop with equipment. The programmes are attached for your review. There are international guests at this event and perhaps the organisers are seeking participation through the interesting programme layout. Our dilemma is the support of the workshops with equipment when attached to this programme. We are not supporting speakers, contributing financial support, or even having a stand, but rather setup of equipment and use of the equipment on the animals during the workshop. The animals are our patients too. Please advise how we should approach this and if this should be a decline.

The Code Committee cited the following sections in the code:

General Criteria for Events

Member Company Events and Third-party organised educational events (TPOEs) such as conferences and procedure training allow companies to support HCP- and patient-related training and education; to participate in clinical research and scientific exchanges related to their Medtech; and to advertise and promote products and services. Such Events and their programmes may or may not be accredited to provide continuing education credits. The principles and criteria set out in this chapter shall apply to all such Events supported in any way by Members, irrespective of who organises the Event.

1. EVENT PROGRAMME

The Event programme should directly relate to the specialty and/or medical practice of the HCPs who will attend the Event or be sufficiently relevant to justify the attendance of HCPs. The detailed programme should be available in sufficient time prior to the Event and present a clear schedule of educational content which should comprise the majority time of the Event. The Faculty must be identified. All supporting materials (e.g. flyers, brochures, and website) need to be consistent with the scientific or promotional nature of the programme content. Agendas/programmes for TPOEs should be under the sole control and responsibility of the third-party organiser. The meetings and Events should be appropriate to all delegates' scopes of practice.

Companies should adhere to all standards established by the PCO or the body accrediting the third-party programme, as applicable. Each third-party programme may vary in terms of the accreditation standards that apply and the third-party programme organiser's internal rules and requirements. Advertisement and promotion at Events are subject to relevant domestic legislation and regulations.

2. PROHIBITION ON RECREATION AND ENTERTAINMENT

Member Companies may not pay for or provide any form of entertainment or recreation to HCPs. A Member Company shall not provide or organise Events which include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements which form part of TPOEs. For TPOEs, entertainment must be outside of the educational programme and paid for separately by the HCPs. The registration fee should cover only the scientific programme and hospitality.

Entertainment should not dominate or interfere with the overall scientific content of the programme and should not be the main attraction of the Event. Advertising should highlight the scientific nature of the programme content. The materials should not emphasise the geographic location and should not make excessive or inappropriate references to or contain images of entertainment, sporting Events or other non-scientific activities, which could be seen as promoting the location/venue instead of the Event content.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

The Code is clear on touristic venues and programs that include entertainment and although no formal monetary event sponsorship would be provided by the SAMED member, the organizers and attending HCPs will benefit from the non-monetary contribution. Considering the location, venue, and entertainment indicated on the program, this would not be a permitted event for sponsorship by a SAMED member company, whether monetary or otherwise.

Whether the support is in-kind or monetary, does not detract from the fact that it is of value. It is also noted that the program includes “free time”, which is unnecessary as the event could end the day before the indicated time. The program should be the attraction, not the venue or entertainment.

1.35. Sponsorship of a workshop at a luxury hotel

Query: A doctor was approached by gynaecologists to present a workshop. This doctor requested our support for equipment and staff at this workshop, showcasing a range of our products. However, the venue is that of a 5-star luxury hotel – The Royal Marang Hotel. I have been advised that the venue was chosen as it is the only available venue with a conference facility large enough to accommodate all the practical hands-on stations and that this workshop is partnered with a company that supplies medical devices. Please advise whether there is leeway in this instance or not.

The Code Committee cited the following sections in the code:

[Medical Technology Code of Ethical Marketing and Business Practices](#), Part 1 Interactions with Healthcare Professionals - Event Location and Venue

EVENT LOCATION AND VENUE

The Event location and venue should not be the Event’s main attraction. For the location and the venue, Members must take into account the following considerations at all times:

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented or that of an entertainment venue.
- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.
- No company may organise or sponsor an Event that takes place outside its home country unless:

- Most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country.
- Given the location of the company's training facility, relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country (an "international Event").

Further considerations to be taken into account are:

- Central location: venues selected must be centrally located taking into account the place of origin of the majority of HCP invitees.
- Ease of access: the geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure. Capitals and major cities are recommended.
- Venues situated on the beachfront can be considered if:
 - There are no suitable alternative venues in the geographic location.
 - The venue is not considered as luxurious in nature. In general, a five-star rated venue would not be considered appropriate. Refer to the principle of image and perception. – The venue is well known as a business or commercial centre conducive to the exchange of scientific or medical information.
- In general, the following venues will not be considered compliant:
 - Resort venues (meaning a venue which is part of a complex offering significant recreational, amusement or sporting facilities).
 - Cruise ships, golf clubs (including those owned or operated by a hotel), spas (where the spa is the main attraction and well known for its spa facilities), wine estates or venues with on-site casinos.
- The image of the location among the public, media and authorities may be perceived as a purely luxury, tourist/holiday and/or entertainment venue.
- The financial advantage that a venue rental may present should not be considered a factor when deciding on the appropriateness of a venue.

And

UNDERPINNING PRINCIPLES

Principle of Image and Perception

Members, their employees, and agents should, at all times, be mindful of their interactions with HCPs and the image and perception of the Medtech industry that will be projected to the public when interacting with HCPs.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

The location for this event does not align with the principle of image and perception, and the luxury nature of the venue, and the location that is not centrally located nor has ease of access, does not align with the general requirements in respect of event venues. Thus, supporting such an event would potentially be in contravention of the Code.

1.36. Exception request to host an event at a wine estate

Query: I am writing to request an urgent review of the exception to the Medical Device Code of Ethical Marketing and Business Practice section 2, which typically applies in this situation i.e. to host an international event at Hazendal Estate in Cape Town. Due to scarcity of

venues that can accommodate a large number of delegates together with exhibition space, the standard requirements are unable to be met. We fully understand the importance of adhering to established guidelines however we hope that, given these circumstances, you might consider making an exception in this case.

Cited Source(s): The Code Committee cited the following sections of [the Code](#) -

General criteria for events

EVENT LOCATION AND VENUE

The Event location and venue should not be the Event's main attraction. For the location and the venue, Members must take into account the following considerations at all times:

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented or that of an entertainment venue.
- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.

Further considerations to be taken into account are:

- Central location: venues selected must be centrally located taking into account the place of origin of the majority of HCP invitees.
- Ease of access: the geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure. Capitals and major cities are recommended.
- In general, the following venues will not be considered compliant:
 - Resort venues (meaning a venue which is part of a complex offering significant recreational, amusement or sporting facilities).
 - Cruise ships, golf clubs (including those owned or operated by a hotel), spas (where the spa is the main attraction and well known for its spa facilities), **wine estates** or venues with on-site casinos.
- The image of the location among the public, media and authorities may be perceived as a purely luxury, tourist/holiday, and/or entertainment venue.
- The financial advantage that a venue rental may present should not be considered a factor when deciding on the appropriateness of a venue.

SAMED ADVICE REGARDING VENUES FOR TPOE

In line with international prohibitions on sponsoring Events or aspects thereof at venues that are considered resorts and/or have not been approved by the Medtech Europe CVS system, we advise stakeholders e.g. PCOs, HCOs etc to first consult with Member Companies, particularly multinational companies and to get a prior indication from them about an Event venue and whether they are able support the Event if it is held at that venue. Such stakeholders can then make informed decisions as to whether they will receive sufficient support from Medtech companies in order to make holding an Event at a particular venue viable or not.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

- The proposed event venue does not fulfil the criteria for compliance with the Code.
- The Code Committee does not act in the capacity of a Conference Vetting body and cannot provide exceptions; the Code Committee can provide guidance and clarification on the parts of the Code that relate to a specific query.

- SAMED member companies are advised to carefully review the relevant parts of the Code and to come to a conclusion considering the Code as well as the company's own internal policies and procedures and the codes and policies of any international affiliates of the company.
- It was noted that this is a locally hosted international event, but there is no record of CVS review. The Code Committee recommends that you review the [SAMED Ethical MedTech CVS Quick Guide](#) for guidance on when CVS review applies to locally hosted events.

1.37. Luxury five-star hotel as an event venue

Query: The TPOE will be at the Westin Hotel. Reasons as set out below. Please advise if this venue will be a breach/infringement of the SAMED code for members to support (sponsor/exhibit) by any means – bearing in mind the information below.

The reason why we went with the Westin Hotel as our venue for this year's congress is due to the following factors:

We needed a conference venue that could accommodate up to 220 people comfortably and we currently have 138 doctors attending and 64 trade.

1. The CTICC would have been far too big for this size congress, and we also looked at Century City Conferencing Venues and that was too big as well. Plus, their venue costs are extremely high.
2. We looked at other hotels such as the Lagoon Beach Hotel, but their trade area is in their underground parking, which would not be suitable for our trade. The Vineyard Hotel has different conference floors which meant that the trade would not be on the same floor as the delegates, and we did not want the trade to miss out on the opportunity to interact with all the delegates during the 2 tea breaks and luncheons.
3. We needed a venue that could accommodate more exhibition tables this year and we currently have 29 trade partners attending the congress.
4. We could not look at hotels such as the Arabella Hotel in Hermanus that we used in 2016 as it was too far out of Cape Town, and we could not use Spier as they no longer do big conferencing events.

As you will see the scientific programme is full every day and the Westin Hotel is not a resort hotel, so we chose it for the purpose in mind that it is a business hotel and our delegates will not be enticed to partake in golfing or spa activities, etc.

Another reason we chose this venue is in the lead up for the XXX International Congress that the same society is hosting in Cape Town next year for about 600 delegates.

Cited Source(s): The Code Committee cited the following sections of [the Code](#) -

Underpinning principles (specifically "Image and Perception")

Members, their employees, and agents should, at all times, be mindful of their interactions with HCPs and the image and perception of the Medtech industry that will be projected to the public when interacting with HCPs.

And

Chapter 1 General criteria for events

EVENT LOCATION AND VENUE

The Event location and venue should not be the Event's main attraction. For the location and the venue, Members must take into account the following considerations at all times:

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented or that of an entertainment venue.
- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.

Further considerations to be taken into account are:

- Central location: venues selected must be centrally located taking into account the place of origin of the majority of HCP invitees.
- Ease of access: the geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure. Capitals and major cities are recommended.
- In general, the following venues will not be considered compliant:
 - Resort venues (meaning a venue which is part of a complex offering significant recreational, amusement or sporting facilities).
 - Cruise ships, golf clubs (including those owned or operated by a hotel), spas (where the spa is the main attraction and well known for its spa facilities), wine estates or venues with on-site casinos.
- The image of the location among the public, media and authorities may be perceived as a purely luxury, tourist/holiday, and/or entertainment venue.

The financial advantage that a venue rental may present should not be considered a factor when deciding on the appropriateness of a venue.

SAMED ADVICE REGARDING VENUES FOR TPOE

In line with international prohibitions on sponsoring Events or aspects thereof at venues that are considered resorts and/or have not been approved by the Medtech Europe CVS system, we advise stakeholders e.g. PCOs, HCOs etc to first consult with Member Companies, particularly multinational companies and to get a prior indication from them about an Event venue and whether they are able support the Event if it is held at that venue. Such stakeholders can then make informed decisions as to whether they will receive sufficient support from Medtech companies in order to make holding an Event at a particular venue viable or not.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

- The proposed event venue does not fulfil the criteria for compliance with the Code.
- The Code Committee can provide guidance and clarification on the parts of the Code that relate to a specific query. SAMED member companies are advised to carefully review the relevant parts of the Code and to come to a conclusion considering the Code as well as the company's own internal policies and procedures and the codes and policies of any international affiliates of the company.
- It was noted that this is a locally hosted international event, but that there is no record of CVS review. The Code Committee recommends that the [SAMED Ethical MedTech CVS Quick Guide](#) be reviewed for guidance on when CVS review applies to locally hosted events.

1.38. Service satisfaction survey competition

Query: Please can you provide advice on the competition that we would like to run with our customers.

We have a service satisfaction survey that we would like to send out to our customers. In order to obtain many responses, we would like to link the survey to a competition. The competition is a lucky draw of the names of customers who have responded to the survey. Our CFO will draw a name, and we will send out a prize. The prize is a hamper of marketing items like pen, lip ice, model of the ear and confectionary.

Our survey questions are centred around rating our service delivery and giving customers an opportunity to comment on our service. Here is an example:

NPS Comment	Improve Comment			Value for money	Apps	Customer service
-	-	☒	☐	-	-	-
Excellent service Excellent product	Ordering and delivering process	☐	☒	3. Neither Satisfied nor Dissatisfied	3. Neither Satisfied nor Dissatisfied	3. Neither Satisfied nor Dissatisfied

The survey asks for a satisfaction rating as above on the following areas:

- Value for money
- Apps
- Customer Service
- Fitting software
- Hearing aids
- Marketing material
- Ordering and Delivering
- Your sales Representative
- Repairs
- Training/Seminars

Please can you advise if the above is compliant? Also, please advise if we need to publicly announce the winner, or can we just send the winner their hamper?

Cited Source(s): The Code Committee cited the following sections of [the Code](#) -

Chapter 7 Promotional Items, Items of Medical Utility, Gifts and Competitions

GENERAL PRINCIPLES

Any item given to a staff of an HCP or HCO should be treated as though it is given to the HCP or HCO and is subject to all applicable provisions of the Code. A Member Company may not raffle or give away items that could not otherwise be given to Customers under the Code.

PROMOTIONAL ITEMS

Promotional Items to HCPs, appropriate administrative, sales and other staff are acceptable provided that they are:

- a) Within the cost limit set by SAMED.
- b) Not for personal use e.g. no electronic entertainment items, tickets to sporting events or other forms of entertainment/recreation.
- c) Educational and/or of scientific value to benefit the patient and/or be relevant to the practice.
- d) No cash or cash equivalents (e.g. vouchers) are allowed.

Promotional Items must be branded with Company name and/or Product and/or Company logo.

And

COMPETITIONS

Competitions should fulfil the following criteria:

- a) The competition is based on medical/product knowledge or the acquisition of scientific knowledge.
- b) Individual prizes or educational items offered should benefit the patient and/or be relevant to the practice, and within the cost limit set by SAMED.
- c) Entry into a competition must not be dependent upon prescribing, ordering or recommending a product and no such condition shall be made or implied.
- d) No cash or cash equivalents (e.g. vouchers) are allowed for completion of a survey or as a prize for a competition.

Opinion provided: Taking the above into account the Code Committee arrived at the following opinion:

Whilst the Code is clear on competitions relating to medical/product knowledge, it does not address situations where organizations wish to obtain survey feedback that relates purely to their service delivery.

- ISO standards 9001 and ISO 13485 require that organizations obtain customer feedback, and a customer survey is an acceptable method of collecting such information.
- This proposed survey, or the prize to encourage participation, would be compliant provided that the principles of the Code are taken into account, with specific focus on -
 - The value of the prize should be within the cost limit set by SAMED (e.g. maximum value of the prize should not exceed R400 (inclusive of VAT) for the branded marketing items.
 - The value of the anatomical model should not exceed R6 500.
 - The prize should not include any items for personal use.
 - The prize should not include any food, sweets, flowers, confectionary, vouchers, etc.
- Transparent communication of the prize winner is best practice. It is however recommended that -
 - Consent be obtained from the prize winner prior to publishing the information.
 - If publishing the details of the winner via email, reasonable steps should be taken to protect the information of the recipients of the email (e.g. use of the Bcc function in the email application).

Code advisory opinions provided in 2025

1.39. Gqeberha Boardwalk as an event venue

Query submitted:

We have been using this venue to host society congresses since it was first built and have always received approval from CVS. The hotel and convention centre are not joined to the Casino; this is in a separate building.

The reason why CVS approval was given in the past was because this is the only convention centre in Gqeberha that can accommodate a medical conference with an exhibition, a plenary and a few breakaways. No other venue in Gqeberha offers this capacity.

In 2018 CVS approved the venue and various societies' conferences have taken place at this venue.

In 2023 a new compliance team was appointed and CVS indicated the venue as non-compliant. We explained why compliance had been granted in the past (e.g. because of the lack of an alternative venue that can accommodate the requirements around capacity in Gqeberha). Despite this information, the CVS decision was not reconsidered and they maintained that the venue was not compliant as it was a resort hotel. Anyone who has been to the Boardwalk will know that this is not the case.

Now that South African national congresses are not vetted by CVS it remains up to the individual companies whether to support an event at a venue such as the Boardwalk. Some of our trade members have asked us to approach SAMED to find out what their options are here. Please would you let us know how we can take this further with the trade as this situation will remain with the Boardwalk.

Cited Source(s): The Code Committee cited the following sections of [the Code](#) -

Underpinning principles

The Principle of Image and Perception (Page 11)

Members, their employees and agents should, at all times, be mindful of their interactions with HCPs and the image and perception of the Medtech industry that will be projected to the public when interacting with HCPs.

Chapter 1 General Criteria for Events

4. Event Location and Venue (Page 22)

The Event location and venue should not be the Event's main attraction. For the location and the venue, Members must take into account the following considerations at all times:

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented or that of an entertainment venue.
- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.
- No company may organise or sponsor an Event that takes place outside its home country unless:
 - Most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country.
 - Given the location of the company's training facility, relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country (an "international Event").

Further considerations to be taken into account are:

- Central location: venues selected must be centrally located taking into account the place of origin of the majority of HCP invitees.
- Ease of access: the geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure. Capitals and major cities are recommended.
- Venues situated on the beachfront can be considered if:
 - There are no suitable alternative venues in the geographic location.
 - The venue is not considered as luxurious in nature. In general, a five-star rated venue would not be considered appropriate. Refer to the principle of image and perception.
 - The venue is well known as a business or commercial centre conducive to the exchange of scientific or medical information.
- In general, the following venues will not be considered compliant:
 - Resort venues (meaning a venue which is part of a complex offering significant recreational, amusement or sporting facilities).
 - Cruise ships, golf clubs (including those owned or operated by a hotel), spas (where the spa is the main attraction and well known for its spa facilities), wine estates or venues with on-site casinos.
- The image of the location among the public, media and authorities may be perceived as a purely luxury, tourist/holiday and/or entertainment venue.
- The financial advantage that a venue rental may present should not be considered a factor when deciding on the appropriateness of a venue.

QUESTION: Can a Member Company organise or support an Event at a hotel or resort that offers significant leisure facilities such as golf, casino or water sports?

ANSWER: In principle no. It is not appropriate for a Member Company to organise or support Events at hotels or resorts renowned for their entertainment facilities or centred around recreational or sporting activities. Exceptions might be considered for venues well adapted to business meetings in an otherwise compliant geographic location where there is a compelling need to use the chosen venue eg a lack of alternative venues or genuine safety or security issues. In certain circumstances, hotel accommodation separate from the TPOE venue might be required for compliance.

Where an exception is considered, the Event's promotional material should not feature or promote the on-site leisure aspects of the venue and the Event's agenda should not provide time for attending HCPs to make use of leisure and sporting facilities during any significant part of a normal working day. Where hotels require additional payment to use the leisure or sporting facilities, Member Companies may not make such payments on behalf of the HCPs. **For reasons of perception, cruise ships or hotels with on-site casinos are under no circumstances compliant with the Code, either as an Event venue or for accommodation for HCPs.**

5. SAMED Advice Regarding Venues for TPOE (Page 23)

In line with international prohibitions on sponsoring Events or aspects thereof at venues that are considered resorts and/or have not been approved by the Medtech Europe CVS system, we advise stakeholders eg PCOs, HCOs etc to first consult with Member Companies, particularly multinational companies and to get a prior indication from them about an Event venue and whether they are able support the Event if it is held at that venue. Such stakeholders can then make informed decisions as to whether they will receive sufficient support from Medtech companies in order to make holding an Event at a particular venue viable or not.

Opinion provided: Taking the above into account the Code Advisory Panel arrived at the following opinion –

- This would not be an appropriate event venue due to the close proximity of a casino.

1.40. Emperors Palace Convention Centre as a third-party conference venue

Query Submitted: Please provide an opinion on the suitability of Emperors Palace Convention Centre as a third-party conference venue.
PathRed 2025 Pathology Research and Development Congress, Emperors Palace Convention Centre, 02-05 October 2025

Cited Source(s): The Code Advisory Panel cited the following sections of [the Code](#) -

Underpinning principles

The Principle of Image and Perception (Page 11)

Members, their employees and agents should, at all times, be mindful of their interactions with HCPs and the image and perception of the Medtech industry that will be projected to the public when interacting with HCPs.

Chapter 1 General Criteria for Events

4. Event Location and Venue (Page 22)

The Event location and venue should not be the Event's main attraction. For the location and the venue, Members must take into account the following considerations at all times:

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented or that of an entertainment venue.
- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.
- No company may organise or sponsor an Event that takes place outside its home country unless:
 - Most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country.
 - Given the location of the company's training facility, relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country (an "international Event").

Further considerations to be taken into account are:

- Central location: venues selected must be centrally located taking into account the place of origin of the majority of HCP invitees.
- Ease of access: the geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure. Capitals and major cities are recommended.
- Venues situated on the beachfront can be considered if:
 - There are no suitable alternative venues in the geographic location.
 - The venue is not considered as luxurious in nature. In general, a five-star rated venue would not be considered appropriate. Refer to the principle of image and perception.
 - The venue is well known as a business or commercial centre conducive to the exchange of scientific or medical information.
- In general, the following venues will not be considered compliant:
 - Resort venues (meaning a venue which is part of a complex offering significant recreational, amusement or sporting facilities).
 - Cruise ships, golf clubs (including those owned or operated by a hotel), spas (where the spa is the main attraction and well known for its spa facilities), wine estates or venues with on-site casinos.
- The image of the location among the public, media and authorities may be perceived as a purely luxury, tourist/holiday and/or entertainment venue.

- The financial advantage that a venue rental may present should not be considered a factor when deciding on the appropriateness of a venue.

QUESTION: Can a Member Company organise or support an Event at a hotel or resort that offers significant leisure facilities such as golf, casino or water sports?

ANSWER: In principle no. It is not appropriate for a Member Company to organise or support Events at hotels or resorts renowned for their entertainment facilities or centred around recreational or sporting activities. Exceptions might be considered for venues well adapted to business meetings in an otherwise compliant geographic location where there is a compelling need to use the chosen venue eg a lack of alternative venues or genuine safety or security issues. In certain circumstances, hotel accommodation separate from the TPOE venue might be required for compliance.

Where an exception is considered, the Event's promotional material should not feature or promote the on-site leisure aspects of the venue and the Event's agenda should not provide time for attending HCPs to make use of leisure and sporting facilities during any significant part of a normal working day. Where hotels require additional payment to use the leisure or sporting facilities, Member Companies may not make such payments on behalf of the HCPs. For reasons of perception, cruise ships or hotels with on-site casinos are under no circumstances compliant with the Code, either as an Event venue or for accommodation for HCPs.

Opinion provided: Taking the above into account the Code Advisory Panel arrived at the following non-legal, non-binding opinion –

- This would not be an appropriate event venue. SAMED members and signatories should apply appropriate internal review, considering the guidance of the Code, when determining the appropriateness of participation and/or sponsorship activities.

1.41. Request for exemption in respect of PathRed 2025 to be held at Emperors Palace

- Request Submitted:**
- Request for a limited exemption permitting SAMED members to sponsor PathReD 2025, given the strictly scientific use of the venue and overriding public health benefit.
 - Request for written confirmation that such sponsorship would not constitute a breach of SAMED's ethical or compliance standards.

Cited Source(s): The Code Advisory Panel cited the following sections of [the Code](#) -

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- The venue should be a business or commercial centre providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge.

- No company may organise or sponsor an Event that takes place outside its home country unless:
 - Most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country.
 - Given the location of the company's training facility, relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country (an "international Event").

Further considerations to be taken into account are:

- Central location: venues selected must be centrally located taking into account the place of origin of the majority of HCP invitees.
- Ease of access: the geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure. Capitals and major cities are recommended.
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Q&A Page 22

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Opinion provided: Taking the above into account, as well as the information provided (e.g., event program and the justification for selection of the event venue), the Code Advisory Panel arrived at the following non-legal, non-binding opinion –

- The Panel acknowledges the scientific merit and public health value of the proposed event but considers that the venue for this event is not compliant with the Code, in so far as the Code specifically prohibits events held at casinos.

- SAMED does not perform event or venue vetting, and nor does it have any power in terms of its Code to “exempt” any event from the application of the Code. SAMED can only issue a non-binding opinion on whether a proposed event will be in compliance with the Code or not.
- In due course, if any complaints regarding non-compliance are received, SAMED will deal with these in the ordinary course.
- In the event that delegates from the MedTech Europe or Mecomed geographic areas attend a locally hosted event, the requirements of EthicalMedTech for vetting on the Conference Vetting System, should be noted.
- SAMED members and signatories should apply appropriate internal review (with due consideration of the provisions of the Code) when determining the appropriateness of participation and/or sponsorship activities and should seek their own advice on compliance with the Code, to the extent that this may be required.

1.42. Exhibiting at PathReD 2025 to be held at Emperors Palace

Query We would like to confirm if it is compliant to exhibit at the upcoming PathReD Congress which will be held at Emperors Palace, given that the venue is an entertainment facility. Your guidance on this matter will be sincerely appreciated.

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Further considerations to be taken into account are:

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Opinion provided: Taking the above into account the Code Advisory Panel arrived at the following non-legal, non-binding opinion –

- The Panel acknowledges the scientific merit and public health value of the proposed event but considers that the venue for this event is not compliant with the Code, in so far as the Code specifically prohibits events held at casinos.
- SAMED's advisory opinions are not binding, and SAMED members and signatories to the code are accordingly advised to seek their own legal advice on compliance with the Code. They should also take into account any other applicable legal requirements on them. For example, in the event that delegates from the MedTech Europe or Mecomed geographic areas attend a locally hosted event, the requirements of EthicalMedTech for vetting on the Conference Vetting System, should be noted.