SAMED

advancing patient care through MedTech

MEDICAL TECHNOLOGY

CODE OF ETHICAL MARKETING AND BUSINESS PRACTICE

[THE CODE]

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1. DISCLAIMER

Although SAMED is committed to ensuring that its members adhere to the principals of the Code, SAMED cannot be held responsible for the conduct of any of its members who may be alleged to be in contravention of the Code. SAMED does however bear responsibility to deal with transgressions on receipt of a complaint as laid out in the Code.

2. LIST OF ABBREVIATIONS

CPD	Continued Professional Development
DENOSA	The Democratic Nursing Organisation of South Africa
FMV	Fair Market Value
HCO	Healthcare Organisation
HCP	Healthcare Professional
HOD	Head of Department
HPCSA	Health Professions Council of South Africa
IVD	In Vitro Diagnostic
KOL	Key Opinion Leader
NPA	National Prosecuting Authority
PCO	Professional Conference Organiser
SAHPRA	South African Health Products Regulatory Authority
SAMED	South African Medical Technology Industry Association
SANC	South African Nursing Council
SAPS	South African Police Service
SOP	Standard Operating Procedure
TPOE	Third-Party Organised Educational Event
TPPT	Third-Party Organised Procedure Training
VAT	Value Added Tax

NOTES

- All references to a feminine/singular shall always include the masculine/plural respectively and vice versa.
- In the document, terms that can be found in the glossary are always capitalised.
- More than 90 questions/answers are provided in the document. The questions address topics that SAMED receives the most enquiries about and/or points of uncertainty as suggested by requests for SAMED Code advisory opinions and tip-offs through the whistleblowing hotline.

3. GLOSSARY AND DEFINITIONS

In relation to this Code, and, unless the particular context indicates otherwise, the following words and phrases carry the following meaning:

Advertisement	in relation to any Medtech, means any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the sale, use or supply of Medtech, such as: advertising to HCPs; advertorials; branded materials relating to Medtech sponsorship; aerial promotions such as blimps; booklets; cinema commercials; consumer leaflets; direct mailers; website and other internet materials including press releases intended for internet publication, LinkedIn, Facebook, Twitter, TikTok and other such mediums; out-of-home, digital and touch-screen applications; point-of sale-materials; posters; print Advertisements; promotional and direct selling aids; promotional scripts for call centres and helplines; promotional text messages; consumer promoters in retail outlets; television and radio/ audio commercials; sports, art and other sponsorships; airport, washroom, shopping centre Advertising and/or promotion; aisle, ceiling, floor Advertising and other signs; countertop Advertising; window displays; gondola-end Advertising; bunting; Advertising on electronic ordering systems; bus, taxi and other vehicle Advertising; light box Advertising as well as any other form of marketing or promotion that is brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of that Medtech and "Advertise" has a corresponding meaning.
Charitable Donations	means provision of cash, equipment, Member 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 charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.
Compliance Officer	means anyone duly authorised or appointed by the Member Company in writing, to sign documents or give instructions on behalf of the company in relation to provisions in the Code.
Company Events	means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of Member Companies to fulfil a legitimate, documented business need of the company, including but not limited to a legitimate business need to interact with Customers including HCPs and/or HCOs.
Consulting Arrangement	means any provision of service by an HCO or HCP for or on behalf of a Member Company. Consulting Arrangements include, but are not limited to marketing and clinical research activities, providing technical expertise for the development, testing etc of Medtech, providing feedback in post-market evaluations and market research, providing speaking services at Events, providing teaching and training on how to use the Member Company's Medtech, participating in research-related meetings etc.
Customer(s)	means any HCO or HCP that may enter or is already in a business relationship with Member Companies.
Customer-facing Personnel	means personnel such as Medtech representatives, marketing and sales representatives, customer service employees, Event management staff and any other relevant personnel who interact with HCOs or HCPs.
Day	means calendar day. Where a period consisting of a number of days is prescribed, it will be determined by excluding the first and including the last day.

3. Glossary and definitions (continued)

Delegate	means HCPs who passively attend an Event neither as Faculty nor as HCPs who are providing services to Member Companies for the specific Event. For avoidance of doubt, presenters of posters and abstracts are considered as Delegates.
Demonstration Products (Demos)	means either single-use or multiple-use products provided free of charge by or on behalf of a Member Company to Customers 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 exclude 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, eg as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.
Educational Grants	means provision of funding, Member Company's or third-party's products or other In-kind support to an HCO by or on behalf of a Member Company solely for the support and advancement of genuine medical education of HCPs, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved and where such support is provided solely for a specified intended purpose within this category.
Employer Notification	means the prior written notification provided to an HCO, an HCP's superior or other locally designated competent authority of any interaction, collaboration or other matter concerning any Member Company and any HCP, the purpose and/or scope of which requires notification under this Code.
Entertainment	includes, but is not limited to, arrangements where (live) music is the main attraction, sight-seeing trips, theatre excursions, yearend functions, sporting Events (eg golf, rugby or football match) and other leisure activities. For the avoidance of doubt, incidental background music shall not constitute entertainment.
Evaluation Products	means either single-use or multiple-use products and/or equipment provided free of charge to an HCO or HCP 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 exclude 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, eg as part of an agreed discount arrangement or as substitute products provided pursuant to a warranty agreement.

Event	means either a Company Event or Third-Party Organised Educational Event and includes: (i) "In-person Events" means delegates are physically in attendance and interact with one another face-to-face at a specific physical location (or locations). (ii) "Virtual Events" are virtual exhibitions, presentations, panel discussions or live clinical procedures broadcast to an audience not physically in attendance and whose delegates attend exclusively remotely in a virtual environment enabled by digital technology rather than at a physical location. (iii) "Hybrid Events" which consist of exhibitions, presentations, panel discussions or live clinical procedures where the attendance is a mix of speakers and HCPs attending either in-person and/or virtually. The filming of presentations, discussions etc taking place during a physical TPOE and their broadcasting to audiences not present at the in-person event – whether at the time or after the Event – qualifies as a hybrid event.
Faculty	means a podium speaker, facilitator, moderator and/or chair who presents during an Event and therefore needs to prepare ahead of the presentation/ moderation. Poster and abstract presenters are not considered as Faculty.
Fair Market Value (FMV)	means the value of the specified consultancy services (or products, if applicable) which would be paid by the Member Company to the consultant (eg HCP or HCO), each dealing at an arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell and both parties have reasonable knowledge of the relevant facts.
Financial Hardship	refers to extreme and unavoidable financial distress within an HCO resulting from matters outside the HCO's control where the HCO is unable to operate and where patient care is jeopardised. Financial distress resulting in whole or in part from mismanagement of the HCO's funds or other matters within its control is not considered to be Financial Hardship. Financial Hardship must be documented and objectively substantiated.
Healthcare Organisation (HCO)	means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of Medtech or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, university or other teaching institution or learned or professional society (except for patient organisations), or through which one or more HCPs provide services.
Healthcare Professional (HCP)	means any individual (with a clinical or non-clinical role; whether a government official or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research coordinators 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 Medtech or related services. HCPs include but are not limited to individuals, entities, their employees, employers, agents or other delegates and persons registered with the Health Professions Council, Allied Health Professions Council, the Nursing Council, the Pharmacy Council, medical schemes or funders, managed care and group purchasing organisations, Council for Medical Schemes, tender boards, other purchasing entities, hospital or other institution registered with the Department of Health or other regulatory or organisational body, such as a health facility.

	This definition does not include purchasing professionals employed in the retail sector unless these individual purchasers arrange for the purchase of Member Companies' Medtech or related services for or on behalf of medical or clinical personnel. For example, if a Member Company's Medtech or related services are sold as part of the common merchandise of a retail outlet, interactions between the Member Company and the purchasing professional do not fall within the Code. However, where the Member Company's Medtech or related services are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Member Company and the responsible purchasing professional will fall within the Code. Note: unless otherwise stipulated the term, HCP includes and is applicable to HCOs.
Independent Chairperson	is a legally qualified expert appointed by the SAMED Board for a period as determined by the Board and who is responsible that all complaints and hearings related to the Code are dealt with speedily and fairly and who is the custodian of the Code complaint adjudication process, ensuring that both the principles of administrative justice and the substance of this Code are preserved and promoted.
In-kind	means the provision of Grants, Charitable Donations and other types of support in the form of goods or services other than money, including the provision of labour, lent or donated goods, or lent or donated services (eg catering services for Events, provision of venue space, company products and other services).
Items of Medical Utility	are those provided by or on behalf of a Member Company to another person or organisation, which has a genuine educational function that is intended to aid in the medical care of patients. Such items enhance the provision of medical services and patient care and have no personal benefit to the HCP.
List Price	means that price which is a Member Company's maximum price at which such item may be sold to a Customer.
Medical Technology (Medtech)	indicates medical devices as defined in the Medicines and Related Substances Act 101 of 1965, as amended and includes in vitro diagnostics.
Member Company (Member)	means companies that are Members of the South African Medical Technology Industry Association (SAMED) as defined in the SAMED Constitution, and includes their employees, distributors, agents and contractors working for or in conjunction with such Member. Member/Member Company also means companies that are not members of SAMED but have signed up to be signatories to the Code.
National Pharmaceutical Product Interface Code (NAPPI Code)	means a unique code which is allocated by MediKredit to a "medical device" as defined in the Medicines and Related Substances Act 101 of 1965, as amended. NAPPI Codes are allocated to all reimbursable medical devices in accordance with MediKredit's NAPPI Code Allocation Policy to identify such products using the product description and catalogue number linked to the supplier and associated price thereof. This allows identification of exactly which stent, catheter, cochlear implant etc is being supplied. Only one such code shall apply per product as identified per catalogue number per supplier.
Occasional	means an interaction or activity that occurs infrequently and not on a routine basis.
Other Inducements	means inducements of any nature or form eg payment for information or shelf space, supply of bonus or free goods and the like, where such payments are deemed to be perverse.

Product and Procedure Training and Education Event	means a type of Company Event that is primarily intended to provide HCPs with genuine education, including information and/or training on the safe and effective use of Medtech, therapies and/or related services; safe and effective performance of clinical procedures; and/or related disease areas. In all cases the information and/or training directly concern a Member Company's Medtech, therapies and/or related services.
Perception	means the process by which one screens, selects, organises and interprets stimuli to give them meaning. It is a process of making sense out of the environment in order to make an appropriate behavioural response. Perception refers to the way we interpret and understand the world around us, based on our individual experiences, biases and beliefs.
Preceptorship	means a type of clinician-to-clinician training funded by a Member Company where the supervising clinician oversees the procedural training of the trainee clinician, and the trainee does not have primary responsibility for the patient undergoing the procedure.
Proctorship	means a type of clinician-to-clinician training funded by a Member Company where a trainee clinician performs a procedure under the supervision of another clinician and where the trainee clinician has primary responsibility for the patient undergoing the procedure.
Professional Conference Organiser (PCO)	means a for-profit company or organisation which specialises in the management of congresses, conferences, seminars and similar Events.
Promotional Items	are items provided by or on behalf of a Member Company to another person/organisation and that are intended as a promotional reminder/campaign relating to the Member Company and its products. Records of all promotional campaigns must be kept for a period of five years.
Registry	means an organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure, and that serves one or more predetermined scientific, clinical or policy purposes.
Rebate	is a practice which facilitates a payment to a customer in relation to the purchase of a medical device or IVD, usually after the sale has occurred, either directly to the customer or to a related entity, which has the effect of reducing the cost of the medical device or IVD.
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 exclude 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, eg as part of an agreed discount arrangement or as substitute products provided pursuant to a warranty agreement.

Satellite Symposium	is a company-organised and company-funded programme that is appended to a third-party programme agenda but that the third-party organiser does not control. Member Companies may purchase Satellite Symposia packages at Third-party Organised Educational Conferences and provide presentations on subjects that are consistent with the content of such Events. Member companies may determine the content of these Satellite Symposia and be responsible for speaker selection.
Scientific Meetings, Advisory Boards and Clinical Committees	refers to meetings that are not necessarily conducted under the auspices of an independent scientific committee and which are not generally open to the whole scientific community affected, includes meetings where pertinent clinical, healthcare or treatment issues are discussed, which may relate to a particular issue (eg treatment protocol for a disease), or which may be held by a Member Company in order to advise the HCP on the impact or use of specific technology, the clinical merits or place of the technology in treatment within a certain disease area etc.
Scholarships and Fellowships	means Educational Grants provided to an HCO by or on behalf of a Member Company to support Scholarships or Fellowships offered by the HCO. Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a Fellowship is a period of intensive training for post-graduate physicians in a clinical sub-specialty (eg medical training after a residency). “Scholars” and “Fellows” shall be understood accordingly.
Settlement Discount	means that discount which is granted for timeous settlement of an account, and which reflects the normal ‘cost of money’.
Third-party	in the context of educational Events and grants, means national, regional or specialty medical associations or societies, hospitals, PCOs, training institutions (eg medical schools and teaching hospitals), patient organisations or accredited medical education providers. Legal entities established by HCPs in private practice are not considered compliant under the definition of a third-party. Such entities serve the self-interest of the HCPs, do not allow for unbiased selection criteria and fail to safeguard the anonymity of potential beneficiaries due to the generally small size of the pool of potential beneficiaries.

Third-Party Organised Educational Conferences	means a type of third-party organised educational Event that is a genuine, independent, educational, scientific or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional or specialty medical associations/societies, hospitals, PCOs, patient organisations or accredited medical education providers.
Third-party Organised Educational Events (TPOE)	means activities of any type that are planned, budgeted, managed and executed in whole or partly by or on behalf of a person or entity other than a Member Company to fulfil HCPs' medical education needs.
Third-party Organised Procedure Training (TPPT)	means a type of TPOE that is primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern: • Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of Medtech). • Practical demonstrations and/or training for HCPs, where most of the training programme is delivered in a clinical environment. For the avoidance of doubt, Proctorship and Preceptorship are not considered as TPPTs.
Transparent Invoicing Model	means a SAMED-developed best-practice framework set to ensure that Members provide accurate, transparent and responsible billing information to HCPs, reimbursement authorities and other payors. Such documentation should be in writing and kept on record. The application of this model has been compulsory for SAMED Members since 2007.
Unacceptable Fees	refer to the payment of data, marketing, formulary, managed care or similar types of fees which are used to encourage or increase the purchase, loan or use of Medtech and which data, marketing or managed care is of no or limited value to the buyer or which services or information is not legitimately and actually provided by the seller, or which is not in existence; and which is bought solely or mostly in order to reward or secure a particular purchase or utilisation behaviour, whether under implicit or explicit conditions relating to such behavioural change or sustained behaviour.
Volume Discount	means that discount which may be applied to the Maximum List Price in order to compensate the customer for volume purchasing.

4. INTRODUCTION

4.1 Promoting an ethical Medtech industry

The South African Medical Technology Industry Association (SAMED) is a not-for-gain voluntary trade association. SAMED's Members include multinationals, distributors, wholesalers and local manufacturers of medical devices and in vitro diagnostics (ie Medtech).

SAMED is committed to the principles of evidence-based medicine. Stakeholders, including patients, caregivers, providers, payers, regulators and manufacturers share the commitment to improve the quality and increase the efficiency of healthcare. SAMED's Members, as Medtech manufacturers and suppliers, recognise the need to ensure that there is adequate and accurate information to guide healthcare decision-making concerning the safety, effectiveness and value of Medtech.

SAMED's constitution determines that one of its purposes is to encourage the adoption and implementation by the Members of ethical principles and practices in the conduct of their businesses and affairs. In pursuing this purpose, SAMED formulates and enforces applicable codes of good practice. To this end, SAMED has formulated this Code which is binding on all SAMED members and is a condition for new and ongoing membership.

The Code is based on the principle of self-regulation of the industry through a procedure for handling complaints. The Code underpins SAMED's mission, which is to enable a sustainable, ethical and transformed industry that ensures patient access to Medtech. Member Companies recognise, respect and encourage adherence to ethical standards and compliance with both the spirit and letter of applicable laws and guidelines in all business and marketing endeavours.

The Code is continuously reviewed against local and global best practices, and it includes scenarios represented as questions and answers to assist SAMED members and stakeholders to interpret and implement the Code.

The Code also references international and local codes currently binding the industry, and interpretations awarded to such codes may guide the interpretation of this Code.

4.2 The value of Medtech company interactions with Healthcare Professionals

HCPs' first and highest duty is to act in the best interests of patients. Medtech companies help HCPs meet this duty through necessary and collaborative interactions. These include:

- Medtech companies and HCPs advance medical care and clinical science through research, product development and product testing that results in new or improved innovative Medtech.
- Medtech companies instruct, educate and train HCPs on the safe and effective use of Medtech.
- Medtech companies provide product service and technical support for HCPs to help ensure safe and effective use of Medtech.
- Medtech companies support HCPs' scientific and medical research as well as the enhancement of clinical skills and educational opportunities to improve patient care.
- Medtech companies promote public awareness of medical and health conditions through support of patient education and provision of care to communities.

"To this end, SAMED has formulated this Code which is binding on all SAMED members and is a condition for new and ongoing membership."

The healthcare industry and by inference, the Medtech sector, is one of the most carefully scrutinised industries in the world. This Code contains valuable information about the many laws, activities and procedures that govern the way Medtech Companies do business in South Africa, and how they conduct interactions with HCPs and HCOs. It helps to further define SAMED's and Members' commitment as an industry, as companies and as individuals who abide by government laws and industry standards and procedures that apply to these day-to-day interactions.

Question & answer

QUESTION: Why is the SAMED Code different from codes that govern pharmaceutical or biologics companies?

ANSWER: Drugs and biologics act on the body by chemical means and can often be administered by the patient alone without the direct supervision of an HCP or the involvement of a company representative to instruct on their safe and effective use. Medtech often consists of complex tools, devices and technology requiring highly dependent "hands-on" interactions with HCPs. HCPs require training on and an understanding of how to use these products in a safe and effective way. We have developed the Medical Technology Code to address interactions with HCPs and HCOs that are specific to the Medtech industry.

These interactions are a distinguishing feature of our industry. 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.

4.3 Purpose of the Code

The Code exists in order to promote and encourage among Members and the broader Medtech industry, ethical principles and practices and to ensure that Members do not offer any inappropriate inducements to Customers in order to sell, lease, recommend or arrange for the sale or lease of their products.

The Code provides guidance to Members on ethical business and marketing interactions with Customers based on underpinning principles and values elaborated below. Companies are obliged to examine all interactions with Customers in light of these principles and values and are obliged to always avoid practices designed to circumvent the Code.

4.4 Underpinning principles

The 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.

The Principle of Separation | Patient Best Interest

Interaction between Members and HCPs must not be tainted by improper or undue advantages that seek to influence purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Members' products. Members may not hold positions on any executive committee or board of any HCO where a conflict of interest may occur.

The Principle of Transparency

Interaction between industry and HCPs must be fair, open and transparent and comply with national and local laws, regulations and professional codes of conduct.

The Principle of Equivalence

Where HCPs are engaged by a Member to perform a service for or on behalf of a Member, the compensation paid by the Member must be commensurate with and represent a FMV for the services performed by the HCP.

The Principle of Documentation

There must be a written agreement for interactions between a Member and an HCP for services performed by the HCP for or on behalf of the Member, setting out, inter alia, the purpose of the interaction, services to be performed, method for reimbursement of expenses and the compensation to be paid by the Member. The activities envisaged by the Consulting Agreement must be substantiated and evidenced by activity reports, financial records and the like. Adequate documentation such as the agreement, related reports, invoices etc must be retained by the Member to support the need for, and materiality of, the services as well as the reasonableness of the compensation paid.

4.5 Underpinning values

Members are obliged to ensure that they consider and reflect the following SAMED values.

Education

Deliver high-quality training and education to help ensure that HCPs use Medtech safely and effectively.

Integrity

Conduct business with integrity at all times and avoid real or perceived conflicts of interest with HCPs. Do what is right, not what is easy!

Respect

Respect the independent clinical judgment of HCPs to decide the best manner and method for treating patients.

Co-operation and responsibility

Promote socially and ethically responsible marketing and business practices that protect patients, their rights and their safety.

Promote a spirit of co-operation and shared responsibility among role-players in the public and private healthcare sectors to achieve ethical and transparent healthcare delivery.

Promote the right of all South Africans to access healthcare and contribute to progressively realising this right through cooperation and shared responsibility between the public and private healthcare sectors.

4.6 Interpretation of the provisions of the Code

The Code may be silent on a specific interaction or may not address all aspects of an interaction with an HCP. Any interpretation of the provisions of this Code, as well as Members' interactions with HCPs not specifically addressed in this Code should be made in light of the afore mentioned principles and values.

The Code is intended to help Member Companies make reasonable and appropriate decisions that align with the Code's principles and values.

5. SCOPE

5.1 Legal principles

The Code does not provide legal advice or create legal rights or obligations. This Code does not substitute any obligation or provision found in any other code or legislation, local or international dealing with the same or similar practices, and is intended to align with, among others the provisions of the Prevention and Combating of Corrupt Activities Act, the National Health Act, the Health Professions Act and related ethical guidelines, the Medicines and Related Substances Act and all regulations and guidelines issued in terms of this legislation, the Competition Act, the POPI Act, the Consumer Protection Act, King IV and all other relevant laws applicable to businesses and activities in the health sector.

Members may be simultaneously bound by these laws and the Code. Member Companies have a legal duty to ensure that they are aware of and comply with such and the strictest rule applies.

Question & answer

QUESTION: Does the Code offer legal advice??

ANSWER: No. The Code is intended to facilitate ethical behaviour, and is not intended to be, nor should it be, construed as legal advice. All Members have an obligation to ascertain that their interactions with HCPs comply with all current laws and regulations. On request, the SAMED Code Committee via the SAMED Office will provide a free-of-charge non-binding code advisory opinion service to Members and stakeholders.

5.2 Geographic reach

The Code applies to all Member Company interactions with South African HCPs and HCOs, whether occurring inside or outside South Africa (such as at a conference or other Event), even if an employee or agent pays for the interaction himself/herself.

It is noted that there may be laws and other codes applicable to relationships with HCPs, including relationships with government employees such as the Foreign Corrupt Practices Act.

Medtech companies based in South Africa may have principals, partners or employees who are based internationally. These employees fall outside the jurisdiction of this Code. However, should these principals, partners or employees visit the South African offices or conduct business or engagements on behalf of the local company, they shall do so under the auspices of the local company and its compliance requirements. If the local company's Compliance Officer is based internationally, the individual will be required to fulfil all the criteria and duties of a locally based Compliance Officer.

Question & answer

QUESTION: Is the Code applicable to engagements between Members and HCPs of other countries?

ANSWER: No. However, the Code will apply should the Member sell or engage with a South African HCP outside of South Africa. Although SAMED does not have jurisdiction in other countries it is expected that Members abide by any South African legislation that is applicable abroad. Again, the stricter code or rule within a code applies.

QUESTION: Who are HCPs? Does the term include non-clinical people who make product-purchasing decisions? Does it include decision-makers within group purchasing organisations?

ANSWER: Yes. As per the Glossary, the term HCP applies a broad definition, intended to encompass anyone with material influence over purchasing, utilisation and similar decisions.

QUESTION: Does the definition of HCP include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a supermarket chain?

ANSWER: No. The definition of HCP does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Member's products for or on behalf of medical or clinical personnel. For example, if a Member Company's products are sold as part of the common merchandise of the retail outlet, interactions between the Member Company and the purchasing professional do not fall under the Code. However, where the Member Company's products are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Member Company and the responsible purchasing professional will fall under the Code.

5.3 Applicability of the Code

This Code binds Members, whether such Members are multinational or local entities, manufacturers, distributors or wholesalers and includes their employees, agents and contractors working for, or in conjunction with, such Members, as well as marketing agencies, advertising agencies, Event management entities, commission agents or independent sales representatives, procurement or software entities, working for or on behalf of a Member. Members should ensure that reference is made to this Code in agreements with third parties mentioned in this context.

Member Companies are required to communicate the Code's provisions to its employees, agents, dealers and distributors, with the expectation that they will adhere to the Code.

Non-members of SAMED may become signatories to the Code without having to join SAMED. However, on becoming a signatory to the Code, they agree to be bound by all aspects of the Code, including compliance requirements and enforcement processes.

The SAMED office can be contacted in this regard and will keep a signed record of non-member signatories.

Question & answer

QUESTION: Does the Code govern the actions of Members' agents and distributors?

ANSWER: Yes. Members will communicate the Code's principles and revisions to their employees, agents, dealers and distributors with the expectation that they will adhere to the Code. Note, the Code is only applicable to interactions pertaining to HCOs and HCPs registered in South Africa and to agents and distributors based in South Africa.

5.4 Multiple business lines

Member Companies with different business lines (eg Medtech, pharmaceuticals, biologics, consumer items and/or research-only products) may have other industry codes that apply to their businesses. This Code applies to Member Companies' interactions linked to Medtech, including combination products classified as a medical device. In the event that a Member Company has different lines that involve the same HCP or HCO, and the activity or interaction is in relation to both the medical device and other lines, then the stricter industry code will apply.

Question & answer

QUESTION: To which Member Company employees, agents, dealers, or distributors does the Code apply?

ANSWER: The Code is intended to apply to all bona fide employees and agents of a Member Company when acting on the Member Company's behalf, regardless of the individual's job function or position. The Code also applies to all dealers, distributor and resellers – including sub-dealers and sub-distributors – that provide sales and marketing support for the Member Company and that interact with South African HCPs or HCOs on the company's behalf.

QUESTION: Delegates invited to a TPOE include HCPs to which a Member Company markets both pharmaceuticals and Medtech. The Member adheres to both the Marketing Code and this Code. However, the Marketing Code does not prohibit direct sponsorship of HCPs to attend TPOEs. Which Code applies in this instance?

ANSWER: The stricter code will apply, namely the Medical Technology Code which prohibits direct support of HCPs to TPOEs.

6. COMPLYING WITH THE CODE

6.1 Mandatory Code certification

It is mandatory for all Members to comply with the Code and appoint a Compliance Officer who is responsible for ensuring company Code compliance and that all relevant personnel are trained on the Code. It is also mandatory for all Member Company Compliance Officers and Customer-facing Personnel to pass the Code certification test as and when communicated by SAMED and at the required intervals.

6.2 Compliance Officer annual declaration

It is mandatory for all Member Company Compliance Officers to sign an annual declaration that all their Customer-Facing Personnel have undergone company training and passed the Code certification test.

6.3 New Members joining SAMED

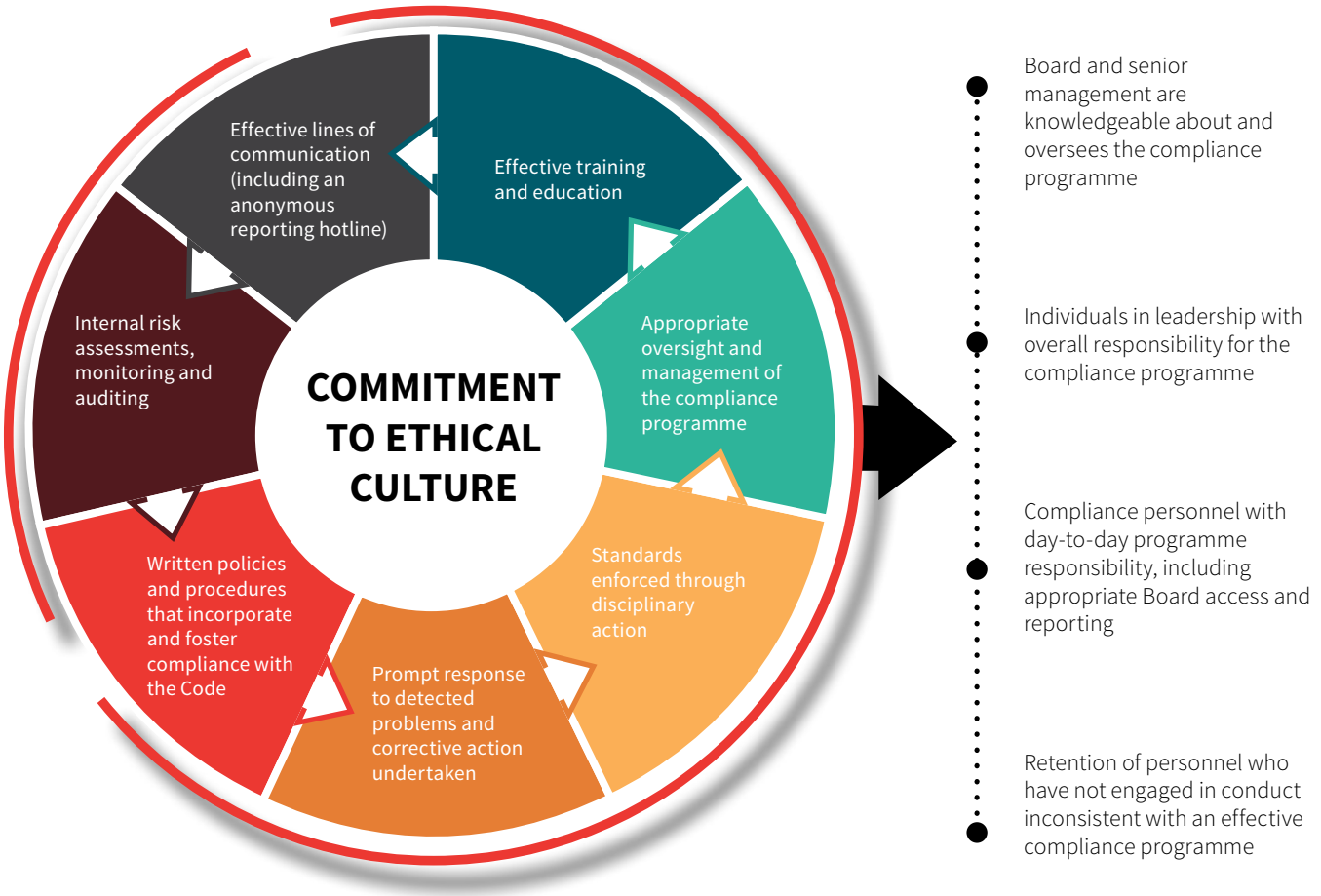
When new Members join SAMED and/or where an existing Member acquires or merges with a non-member, and they are not already compliant, the new entity is given six months to comply with the Code certification test and Compliance Officer declaration.

6.4 Company compliance programmes

Member Companies are strongly encouraged to adopt an effective ethics and compliance programme that:

- Promotes an organisational culture that encourages ethical business and marketing practices and a commitment to the law.
- Prevents and detects inappropriate conduct.

Graph 1: Elements of an effective compliance programme



Such elements include:

- The Member Company board and/or senior management have overall responsibility for the compliance programme, are knowledgeable about and oversee the programme.
- Compliance personnel have day-to-day programme responsibility, including appropriate board and/or senior management access and reporting.
- The Member ensures a prompt response to detected problems and that corrective action is undertaken and enforced through disciplinary action.
- The Member implements a company anonymous hotline to facilitate reporting of possible violations of the Code and publishes this on the company website. The Member also promotes SAMED's anonymous hotline to all personnel.
- The company adopts policies and procedures to ensure compliance with the Code, which includes, inter alia, mechanisms to ensure that all Events, sponsorships and marketing and advertising campaigns are signed off by a responsible senior staff member/Compliance Officer.
- Workshop and communicate the Code to employees, agents, Advertising service providers, dealers and distributors as it is a requirement that they adhere to the Code.

Member Companies are strongly encouraged to publish their commitment to the Code on their website and in marketing material. A SAMED Code logo is available from the SAMED office.

6.5 SAMED Code Committee

The SAMED Code Committee will promote the Code, review and adopt where relevant international codes or aspects thereof, and share best practice and Code advisory opinions with members.

The SAMED Code Committee will be composed of:

- At least one SAMED board member, who should if possible and available be the chair or vice-chair of the committee.
- The SAMED Board will elect the chair from among the members of the committee for renewable periods of two years or until the chair ceases to be a member of the Code Committee. The chairs of other SAMED committees are not eligible to simultaneously chair the Code Committee.
- A minimum of three member representatives (inclusive of the committee chair and vice-chair) who have experience in the area of compliance where the committee chair, vice-chair and the SAMED executive officer are satisfied that such representatives will positively enhance the representativeness, operation and objectives of the Code Committee.
- Only one representative from a Member may be a member of the Code Committee at any given time.
- The Code Committee may, as needed, invite external lawyers, subject to the relevant SAMED standard operating procedure, for a period they deem fit as non-voting members.

6.6 Code advisory opinions

Any entity requiring guidance in relation to the Code may request a non-binding, free of charge Code advisory opinion from SAMED by following this process:

- All queries must be lodged in writing with the SAMED office by email to secretariat@samed.org.za.
- The query should not contain any competitively sensitive information. The SAMED office will ensure that adequate measures are in place to safeguard the confidentiality of queries and if required suggest to the entity that they remain anonymous.
- Simple queries on which the Code is clear and that do not require interpretation will be responded to by the SAMED Executive Officer within seven days.
- Others that require interpretation will be forwarded to the SAMED Code Committee via email for review which will follow a board-approved standard operating procedure that may be amended from time to time.
- The SAMED office will provide to the querying entity, if relevant, the Code Committee members' names and companies they represent, and request that they confirm whether any of the individuals may in their view pose a potential conflict of interest and/or that they are a competitor to the querying entity. This would exclude such individuals from considering the query. Committee members are obliged to disclose in writing any conflicts of interest.
- The Code Committee will provide a response within 14 days from receipt of the query.
- If the case is urgent, this must be indicated by the querying entity. The Executive Officer or Code Committee whichever is relevant, will then be given 72 hours to respond. Any queries requiring less than 72 hours for response will not qualify to be processed.

- In cases where the Code Committee is unable to arrive at a majority consensus, the SAMED Board will be asked to provide an opinion.
- Once the committee and/or board have come to a decision, the SAMED Executive Officer will draft the Code advisory opinion, which once approved by the Code Committee will be provided to the querying entity.

Code advisory opinions do not constitute legal advice. All Members have an independent obligation to ascertain that their interactions with HCPs and HCOs comply with all current laws and regulations and the Code. The following SAMED disclaimer accompanies advisory opinions.

Disclaimer that accompanies Code advisory opinions

The South African Medical Technology Industry Association (SAMED) is providing this advice/opinion as guidance in the context of current legislation, relevant Codes and policies, as well as industry practice, where available. The advice is provided on the basis of the information submitted by the requester. The advice is not a substitute for appropriate legal advice and is not binding on SAMED. SAMED, its board members, committees, employees and members, will not be responsible for any inaccuracies or omissions or liable for any damages or loss of whatsoever nature suffered by any person as a result of relying on or using the advice provided. Although SAMED is committed to ensuring that its members adhere to the principals of the Code, SAMED cannot be held responsible for the conduct of any of its members who may be alleged to be in contravention of the Code. SAMED does however bear responsibility to deal with transgressions on receipt of a complaint as laid out in the Code.

6.7 Enforcement of the Code

The process of enforcement is set out in Part 2 of the Code. Members are bound by this Code, must read this Code and if they become aware of a violation of this Code, they must report it in line with its provisions. Failure to report a violation is itself a violation.

SAMED has the power to refer complaints not within the scope and ambit of this Code to appropriate authorities, councils or bodies with the authority to deal with such matters.

SAMED has the power to outsource any of its enforcement functions in terms of the provisions set out in Part 2 of this Code and/or to align its administration with that of other codes in force in the healthcare sector at any point in time.

INTERACTIONS WITH HEALTHCARE PROFESSIONALS

PART 1

SUMMARY OF ALLOWED/PROHIBITED TYPES OF SUPPORT FOR HCPs' PARTICIPATION IN EVENTS

			Direct support for HCP attendance	
Event	**Setting**		**Faculty/speaker**	**Delegate**
Third-party Organised Educational Conference	Main event/independent scientific programme		Not allowed	Not allowed
	Satellite Symposium		Allowed with Consulting Agreement	Not allowed
	Booth		Allowed with Consulting Agreement	Not allowed
Third-party Organised Procedure Training meeting			Allowed	Allowed
Company Events	Product and Procedure Training and Education Event	Not taking place at/about the same time as a TPOE	Allowed	Allowed
		Taking place at/about the same time as a TPOE	Allowed	Not allowed
	Sales, promotional and other business meeting	Not taking place at/about the same time as a TPOE	Allowed with Consulting Agreement	Not allowed except for demonstration of non-portable equipment
		Taking place at/about the same time as a TPOE	Allowed	Not allowed

CHAPTER 1 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.

Question & answer

QUESTION: Can companies continue to provide sponsorships to Event organisers (eg as a main Event sponsor)?

ANSWER: Yes, however, all Events supported by a company must comply with the Code.

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 (eg 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.

Question & answer

QUESTION: Can a celebration dinner or other type of social Event be supported?

ANSWER: No. Social Events, such as anniversaries, religious festivities or other similar Events may not be supported by Member Companies, neither as stand-alone Events nor as part of TPOEs. For the avoidance of doubt, Member Companies may also not invite HCPs to attend such Events at the Member Company's expense.

QUESTION: Can a Member sponsor a meal with entertainment during a TPOE (eg live music)?

ANSWER: No. The Code prohibits providing or paying for any entertainment or recreational activities during Events. Further, the Code requires all company-sponsored meals to be subordinate in time and focus to a bona fide discussion of scientific, educational or business information and "should not be part of an entertainment or recreational Event." Accordingly, a company cannot sponsor a meal with entertainment, even if held in connection with a TPOE.

3. TEMPLATE LETTER FOR MEMBERS TO USE IN RESPONSE TO REQUESTS FOR ENTERTAINMENT/RECREATION SUPPORT

Date (to be completed by Member Company)

To: (to be completed by Member Company)

Address (to be completed by Member Company)

Dear Sir/Madam,

RE: REQUEST FOR FUNDING/SPONSORSHIP

Thank you for your request, dated (to be completed by Member Company) appealing for (to be completed by Member Company). Due to (add Member Company name) compliance with the Medical Technology Code of Ethical Marketing and Business Practice (the Code), we hereby advise that we are not able to assist with this request for funding/sponsorship. The Code governs interactions with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), and in accordance with the provisions of the Code, member companies may not support Events that are not bona fide medical educational Events.

In terms of the Code, SAMED Member Company support of social, sporting and/or leisure activities or other forms of entertainment in relation to Healthcare Professionals is not permitted. If offered at an educational Event, such activities must be outside of the educational programme schedule; paid for separately by the Healthcare Professional; and should not dominate or interfere with the overall scientific content of the programme. Thus, yearend functions, religious celebrations and any standalone entertainment Events cannot be sponsored by our company.

In this regard, we refer you to the following excerpts from the Code:

Part 1: Interactions with HCPs, Chapter 1 General criteria for events Clause 2: Prohibition on Entertainment and Recreation

Member companies may not provide entertainment or recreation to Healthcare Professionals in any form. 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 third-party organised educational Events.

Social Events, such as anniversaries, religious occasions or other similar Events may not be supported by SAMED member companies, neither as stand-alone Events nor as part of third-party organised Events. For the avoidance of doubt, member companies are not permitted to not invite Healthcare Professionals to attend such an Event at the Member Company's expense.

The Code may be accessed on the SAMED **Medical Technology Code** website page.

We do hope that you understand and accept our position on this issue and would like to take the opportunity of wishing you a successful function. Please be assured of our continued commitment to providing the highest possible levels of customer service and care.

Yours sincerely,
(Company designated person to complete/sign)

4. 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.

Question & answer

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.

QUESTION: Under the Code, what is meant by "ease of access" in relation to Event location and venue?

ANSWER: When the originating location of the majority of attendees is considered, Event location and venue need to be in close proximity to appropriate local/international transport/logistics connections and infrastructure.

5. 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 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.

6. GUESTS

Members are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for guests of HCPs or for any other person who does not have a bona fide professional interest in the information being shared at the TPOE. Guests may include spouses, partners, family members or friends.

Question & answer

QUESTION: What does the term "facilitate" mean when used in connection with guest expenses?

ANSWER: The term "facilitate" refers to the prior arrangement, organisation or booking of meals, travel or accommodation by or on behalf of a Member Company on behalf of an HCP participant's guest. Such organisation or booking is not permitted unless the individual qualifies as a participant in their own right, irrespective of who pays. Such actions are open to misinterpretation. If HCPs attending the Event wish to be accompanied by a guest who does not have a professional interest in the information being shared, the HCP must take sole responsibility for the payment and organisation of the guest's expenses.

Question & answer

QUESTION: In case that an HCP is accompanied by a guest at the Event, may this guest be admitted to any Company Event or TPOE?

ANSWER: It is not appropriate for a guest of an HCP to attend either Company Events (including Satellite Symposia) or TPOEs unless the individual qualifies as a participant in their own right, nor is it appropriate, in the interest of maintaining scientific exchange, for a guest to participate in related hospitality during such Events even when the HCP pays for the guest's expenses. Member Companies, however, may financially support TPOEs which offer extra-curricular programmes/activities beyond the scientific, educational or training sessions for guests of HCPs (such as tourist activities and hospitality), always provided that such extra-curricular programme/activity (including attendance of the conference dinner or a cocktail reception) is subject to a separate charge which must not be paid for, facilitated or reimbursed by a Member Company.

7. CPD MEETINGS

No product promotion is allowed in the CPD meeting room. Company-branded items 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 proprietary product names, in order to promote a particular product, is not permitted.

8. REASONABLE HOSPITALITY

The term "hospitality" includes meals and accommodation. Member Companies should differentiate between permitted hospitality and prohibited entertainment.

The Code strikes for a balance between the courteous and professional treatment of HCPs by Members 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, Members 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.

Members may provide reasonable hospitality to HCPs in the context of Company Events and TPOEs, but any hospitality offered must be subordinate in time and focus to the Event purpose and presentation of scientific, educational or business information. Such hospitality must comply with the requirements under Part 1: Interactions with HCPs, Chapter 5: Educational grants and support to HCP participation in Events.

Members may not pay for or reimburse HCPs' lodging expenses at top category or luxury hotels. For the avoidance of doubt, if the Event venue is a hotel which complies with the requirements of the Code, it would be acceptable for Member Companies to offer participants meals and accommodation at the same hotel.

Accommodation and/or other services provided to HCPs should not cover a period of stay beyond the day before and the day after the official duration of the Event, unless when required by travel arrangements in relation to Company Events taking place in the context of TPOEs (see Part 1: Interactions with HCPs, Chapter 3 Company Events, Clause 4: Company Events taking place in the context of TPOEs).

Member Companies may not provide meals or refreshments for an entire office staff where everyone does not attend the meeting nor for guests of HCPs, nor for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

Establishing meal policies: Companies are strongly encouraged to develop policies on providing modest and occasional meals to HCPs. This may include establishing a per meal spending limit for meals and refreshments with an HCP and whether the amount should vary to account for geographic areas (eg New York City or London etc).

Question & answer

QUESTION: Can a Member sponsor a luncheon during a TPOE through a third-party organiser?

ANSWER: The Code permits a company to provide an Educational Grant to a third-party organiser which can in turn provide a meal to HCPs attending a TPOE. However the meal must be modest; subordinate in time and focus to a bona fide discussion of scientific, educational or business information; and offered in a setting that is conducive to such discussion.

A Member Company may occasionally provide HCPs with modest meals and refreshments, subject to the following principles:

Purpose. The meal or refreshments should be subordinate in time and in focus to the bona fide discussion and presentation of scientific, educational or business information. Companies should provide meals and refreshments in a manner conducive to the presentation or discussion of such information. The meal or refreshments should not be part of an entertainment or recreational Event.

Setting and location. Meals and refreshments should be provided in a setting that is conducive to bona fide scientific, educational or business discussions eg the HCP's place of business or an off-site space such as a restaurant.

Participants. A company may provide a meal or refreshments only to HCPs who actually attend and have a bona fide purpose for attending the meeting.

9. TRAVEL

9.1 General principles

Members may only pay for or reimburse HCPs' reasonable and actual travel. 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. In all instances, there must be objective and legitimate reasons that warrant the need for HCPs' travel.

9.2 Support in relation to travel pertaining to Events arranged by Member Companies

The general principles under Part 1: Interactions with HCPs, Chapter 1: General criteria for events, Travel pertaining to travel are applicable. Travel may be arranged and paid for by the Member Company (or a designated travel agent).

9.3 Support in relation to travel pertaining to indirect Educational Grants provided by Members

Member Company's indirect Educational Grants may be used to defray the cost of travel. However travel must be arranged and paid for by the third-party/entity that the educational grant was provided to and must comply with the general principles under Part 1: Interactions with HCPs, Chapter 1 General criteria for events, Clause 9: Travel.

Ticket class for air travel

- Member Companies may pay for or reimburse business class travel for HCPs only for:
  - Faculty members traveling internationally 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/partner 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, international or local, economy class travel is the standard class of travel.

Question & answer

QUESTION: An HCP attending a Third-party organised educational conference as Faculty has asked a company to support his expenses (travel, accommodation and registration). The Event organisers selected him as a Faculty member but will not cover these costs. Is it acceptable for the company to provide this support?

ANSWER: No. The ban on direct support of HCPs to Third-party organised educational conferences applies to all HCPs attending, whether as a delegate or as Faculty. Companies cannot directly pay for, organise or otherwise reimburse the expenses for any individual HCP to attend this type of Event.

QUESTION: An Event organiser has requested funding from a Member Company for travel and accommodation at a conference for a named Faculty member. Can the Member Company organise and pay for the travel and accommodation if the Event organiser sends them a written request?

ANSWER: No. The ban prohibits companies from directly covering the costs for any individual HCP to attend an Event. Even though this request has come via the Event organiser it relates to a specific named HCP and if the company arranges travel and accommodation, there is a direct link between it and the HCP.

QUESTION: A hospital has submitted a grant request to support one of their employees to attend a Third-party organised educational conference. The hospital does not have the facilities to arrange travel. Can a company arrange the travel on behalf of the hospital?

ANSWER: No. Companies are not permitted to make logistical arrangements for individual HCPs to participate in Third-party organised educational conferences. They can provide financial support to the hospital, but the hospital must make all arrangements themselves.

9.4 Transparency and employer notification

Members must disclose sponsorships in papers related to the meetings and in published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it. Members must comply with national laws or regulations related to the disclosure or approval requirements associated with support. Where no such requirements exist, the Member shall maintain appropriate transparency, as a minimum by requiring that Employer Notification be done prior to the Event whenever a Member Company engages an HCP or whenever a Member makes a financial contribution to the HCP's medical education. Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest promotional items related to the HCP's practice or for the benefit of patients do not require Employer Notification. The CPD and product-specific training of registrars, consultants, specialists and other HCPs greatly benefit the health sector and patients. Training provided by institutions, societies, experts and Medtech companies impart essential skills, techniques and product understanding required for operating and innovating within the medical field. Medtech companies also hold Events related to product promotion.

Member Companies should not be approaching registrars directly with training and CPD opportunities (ie local/international workshops, skills labs, congresses, conferences etc) or requesting permission from the academic/department heads/management (whichever is relevant for that facility) after the registrars have already been approached (retrospectively). Doing so is problematic for several reasons:

- Registrars have a commitment to public service and unapproved opportunities take them away from their patients and employment duties.
- The specialist training programmes for registrars are academically demanding and unsanctioned activities compromise their training and quality of service.
- Academic and department heads are uninformed of what training, skills and/or product exposure registrars have received.
- There is often a lack of equity, diversity and inclusion applied to beneficiaries of opportunities with the most promising and dedicated registrars often overlooked.
- When scrutinised, the relationships between Members and registrars may appear unethical or to be exerting undue influence due to a lack of separation in decision making.
- Failing to follow the correct processes shows a lack of respect for the academic/department head.

Instead, Members should contact the academic/department head or management for approval of training and CPD opportunities for registrars. Such Employer Notification and approval should be provided in writing. Where possible, the Member should provide an annual or advanced schedule of opportunities to the academic/department head or management for consideration.

Question & answer

QUESTION: When is Employer Notification applicable?

ANSWER: Employer Notification is applicable in all instances where the HCP is employed by another entity (that is, not self-employed). For example, Employer Notification must be obtained prior to approaching HCPs, registrars, consultants and specialists in public health institutions regarding Company Events and Educational Grants to attend TPOEs. Employer Notification must also be obtained prior to approaching nurses, technicians, electrical engineers etc employed at either public or private healthcare institutions.

QUESTION: Does a Member Company require Employer Notification to be given whenever company personnel meet HCPs at an HCO?

ANSWER: No. Unless the Member Company's interaction with an HCP entails a transfer of value or raises a potential conflict of interest there is no requirement for Employer Notification. However, Members must comply with any access requirements imposed by HCOs to visiting Member Company personnel.

QUESTION: When submitting Employer Notification, are Member Companies required to provide details of the proposed financial contribution Member Companies will make to the HCP in exchange for the services rendered?

ANSWER: The written notification must comply with national laws, regulations and professional codes. In countries where specific provision is not made, there is no requirement to notify employers of the amounts involved. Under the Code, Member Companies must ensure that the level of remuneration is commensurate with the services provided and not greater than FMV, as defined in the Glossary. However, the purpose of the Employer Notification is to provide transparency on the nature of the interaction between the Member Company and the HCP and to enable the employer to raise objections if there is a perceived potential conflict or there are other issues concerning the interaction.

Opportunities provided while registrars are on leave should also be approved with academic/department head/management. This will enable the academic/department head/management to:

- Manage and track the required approvals.
- Adequately plan for registrars to meet both their academic and employment requirements.
- Ensure that no one registrar can be unduly influenced through multiple or repeated opportunities from the same supplier.
- Track all knowledge, techniques, skills and products that registrars are exposed to in order to better gauge needs and gaps and avoid unnecessary duplication.

Question & answer

QUESTION: Can companies contact hospitals to offer grants to support the attendance of their HCP/allied professional employees to a Third-party organised educational conference?

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

Members should also consider the following Code principles:

The Principle of Image and Perception: What is the impression given when targeting only certain registrars for opportunities?

The Principle of Separation: Are repeated or non-inclusive opportunities creating undue or improper advantages? Is there sufficient separation in decision making to ensure registrars' commitment to their employment duties and patient needs comes first?

The Principle of Transparency: Is there sufficient transparency ensuring that the academic/department head knows what is being offered to their registrars?

The Principle of Documentation: Are current processes ensuring that the necessary permissions and approvals have been documented?

Note:

Members are prohibited from directly approaching or providing support (financial or other) to registrars or other HCPs to attend third-party organised educational conferences.

Rather the Member may provide an indirect educational grant to the relevant party eg the health facility department/hospital, HCO or PCO. However, the Member may not influence grant recipients or stipulate grant recipient criteria that favours a particular individual. SAMED has developed guidance in this regard and both HCPs and Members are urged to review this (see Addendum 1: Guidance on the management of indirect sponsorship and associated Educational Grants).

Question & answer

QUESTION: Why is it important to obtain Employer Notification particularly in the case of registrars, consultants, specialists and HCPs employed in public health institutions?

ANSWER: Training and other Member Company Events should not interfere with or disrupt HCP obligations to their patients, their academic training and/or their employment duties. Such Events should promote equity (impartial, fair and just treatment without favouritism or discrimination), diversity (including or involving people from a range of different social and ethnic backgrounds and of different genders, ages etc) and inclusion (providing equal access to opportunities and resources for people who might otherwise be excluded or marginalised). This is especially true for HCPs in training, such as registrars.

CHAPTER 2 THIRD-PARTY ORGANISED EDUCATIONAL EVENTS

Member Companies may provide financial and/or In-kind support (eg Member Company products) to Third-party Organised Educational Events in accordance with the rules of this Code. Such Events include:

- Third-party Organised Educational Conferences.
- Third-party Organised Procedure Training meetings.

1. THIRD-PARTY ORGANISED EDUCATIONAL CONFERENCES

Members may support Third-party Organised Educational Conferences with cash and/or In-kind provided these comply with Part 1: Interactions with HCPs, Chapter 1 General criteria for events.

Question & answer

QUESTION: What is meant by "In-kind support" in connection with Third-party Organised Educational Conferences?

ANSWER: "In-kind support" can be provided to HCOs but Members should ensure such In-kind support does not, nor is perceived to, circumvent the prohibition against Member Companies providing direct financial support to identifiable HCPs to attend Third-party Organised Educational Conferences. For example, it would not be appropriate for Member Companies to directly handle the conference registration, travel or accommodation arrangements for individual (and identifiable) HCP delegates at a Third-party Organised Educational Conference. Examples of "In-kind support" which Members may provide could include modest secretarial and/or logistical support to assist with meeting arrangements.

QUESTION: Can a Member support a TPOE where the organisers are individual HCPs without the involvement of another legal entity, such as a PCO, an HCO or a travel agency?

ANSWER: For such an Event, no financial support may be transferred directly to the bank account of an individual HCP. In-kind support may be provided for this type of Event if it complies with all the requirements of the Code. Such In-kind support may include the (temporary) loaning of multiple use Medtech, the provision of single-use Demos and direct payment of catering, venue rental invoices and/or speakers through Consulting Agreements provided that these comply with all requirements of Chapter 9: Consulting arrangements of the Code. This type of support carries significant risks for all parties involved, which need to be managed even where such an Event complies with all other aspects of the Code, including the prohibition of support for attendance of identifiable HCPs at TPOEs.

Question & answer

QUESTION: What is meant by "genuine" as used in the definition of Third-party Organised Educational Conferences?

ANSWER: Any Event should be relevant to the HCP attendees; the detailed programme should be available sufficient time prior to the Event; and present a clear schedule with no gaps during the sessions (eg the minimum duration for a full-day Event should be six hours or three hours for a half-day Event including breaks). The Faculty must be identified for TPOEs. It is also important that all supporting materials (eg brochures, website) are consistent with the scientific or promotional nature of the programme content, as the case may be.

Members' support for Third-party Organised Educational Conferences may take the form of Educational Grants, promotional activities and Satellite Symposia.

1.1 Educational Grants

Refer to Part 1: Interactions with HCPs, Chapter 5: Educational Grants and support for HCP participation in Events.

1.2 Promotional activity

Member Companies may purchase packages that may include promotional and Advertising services, eg Advertising space and booth space for company displays. Members should ensure that the overall image projected by the promotional activity at Third-party Organised Educational Conferences is perceived as professional at all times. It should never bring discredit upon or reduce confidence in the Medtech industry.

Question & answer

QUESTION: What are examples of appropriate booth activities which will be perceived as professional?

ANSWER: Booth activities at Third-party Organised Educational Conferences should aim primarily at displaying Members' Medtech products and related services and literature. Other activities should be limited and reasonable and in principle only soft drinks and snacks should be served.

1.3 Satellite Symposia

Common elements of satellite symposia are:

- It takes place at a third-party organised Event and is part of the TPOE official programme ie addresses education and training aligned with the third-party's programme focus.
- Attendance is open to any delegate, not only to selected individuals.
- It has company branding and the company can promote the Event to Customers.
- Satellite Symposia programmes often take place during meal breaks at the third-party programme and may address education and training that coincide with the third-party's programme focus.

Question & answer

QUESTION: Can a Member Company pay for stand space, Advertising or Satellite Symposia at third-party organised educational Events?

ANSWER: Yes, provided the Event complies with Part 1: Interactions with HCPs, Chapter 1: General criteria for events.

Provisions

Members may purchase and organise Satellite Symposia within Third-party Organised Educational Conferences provided the following criteria are met:

- The Satellite Symposium is consistent with the overall content of the Event.
- The content of the Satellite Symposium should not be focused on the marketing of the Company's products.
- Satellite Symposia are held in a room that is separate from the main auditorium of the Event.
- Attendance at the Satellite Symposium should be open to all delegates attending the Third-party Organised Educational Conference.
- The Satellite Symposium timeslot should be reflected in the Third-party Organised Educational Conference brochure and sponsorship packages section, and not under Educational Grants.
- The Member Company may determine the content of the agenda, subject to a review by the organiser where required, of their Satellite Symposium and be responsible for speaker selection.

- A Satellite Symposium does not include a company-organised business meeting, advisory board, consultant meeting or product launch session that may be held in close physical and temporal proximity to a third-party programme and is not appended to or included in the official third-party programme agenda.

It is permissible for Member Companies to:

- Add Satellite Symposia speaker names to the company website/brochure of the Event.
- Directly engage with speakers (eg pay honorarium/ hospitality expenses) to their Satellite Symposium through a Contractual Agreement.
- Pay the speaker's registration fee related to the Satellite Symposium, where payment of such fee is required for speaker access to that Satellite Symposium.
- Invite HCPs already attending the Third-party Organised Educational Conference to the Satellite Symposium provided that Member Companies do not directly cover any cost related to registration, travel and accommodation of the participants at the Third-party Organised Educational Conference.
- Provide participants at Satellite Symposia with reasonable and modest hospitality.

It is not permissible for Members to cover additional expenses for speakers at their Satellite Symposia to attend the Third-party Organised Educational Conference (eg accommodation, registration, travel or meals for all the Event days).

The foregoing applies to physical, virtual and hybrid symposia.

2. THIRD-PARTY ORGANISED PROCEDURE TRAINING (TPPT)

Member Companies may support TPPTs either via Educational Grants, see Part 1: Interactions with HCPs, Chapter 5: Educational Grants and support for HCP participation in Events or by providing financial support directly to individual HCPs to cover the cost of attending TPPT sessions, subject to the following criteria:

- Financial support must comply with the criteria provided in Part 1: Interactions with HCPs, Chapter 1: General criteria for events.
- Member Companies may support HCP delegates but not speakers, the latter being independent.
- Member Companies may pay for HCP delegates' travel, hospitality and the registration fee.
- Should the participants' practical, hands-on portion of a TPPT be cancelled or made virtual, the Event itself would no longer qualify as a TPPT. As such, Members would only be able to support such an Event via an Educational Grant and registration fee/access to the Event recording. Under no circumstances may travel expenses be paid in such a situation.

Nonetheless, the following three criteria apply to TPPTs.

Programme: Unlike Third-party Organised Educational Conferences which are theoretical in nature, TPPTs consist of practical, hands-on training, generally involving more than one provider/Medtech company/sponsor. This must be evident from the programme and the practical, hands-on activities must comprise the majority of the programme. The programme, which is often referred to as a "course" rather than a conference or seminar, must be focused on acquiring or improving specific medical skills relevant to certain medical procedures (rather than products). Examples may include courses aimed at acquiring or improving the HCPs' skills in minimally invasive surgery; orthopaedic trauma surgery; or the implantation of cardiac rhythm devices etc.

The programme must also include practical demonstrations (and/or actual live surgeries, where allowed). Examples of practical demonstrations may include surgery simulations where Medtech is used on cadavers, skin models, synthetic bones, cath labs etc.

In order to be considered as a TPPT, the practical sessions must in all cases represent more than 50% of the full programme and hands-on sessions must represent at least one-third of the full programme. These requirements must be clearly indicated in the programme.

Venue: TPPTs are typically organised in a clinical environment as opposed to classroom or other academic settings. For the avoidance of doubt, the adjective "clinical" includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients. Examples of clinical environment include hospitals or clinics, where medical treatment on real patients may be given as well as conference rooms which are set up to simulate medical procedures eg with the availability of Medtech to be used on cadavers, skin models, synthetic bones etc.

Stand-alone Event: TPPTs must stand alone. Where the majority of the training is not given in a clinical environment, eg where the training is organised in connection with, adjacent to, or at the same time as a larger Third-party Organised Educational Conference, that training will not qualify as a TPPT, as defined in the Code.

Question & answer

QUESTION: Can a Member Company pay consulting fees and expenses for an HCP to participate as faculty at a company-arranged Satellite Symposia at a Third-party Organised Educational Conference?

ANSWER: Members must ensure all aspects of the arrangement comply with the Code, including entering into a Consulting Agreement with HCPs engaged as faculty at their Satellite Symposia. They can pay consulting fees (at FMV) to the HCP for providing services at a satellite symposium.

If the HCP only attends the satellite symposium, the Consulting Agreement may provide for payments to be made in respect of travel, accommodation and meal costs associated with providing Faculty services at the Satellite Symposia only. Where payment of a registration fee is required in order for Faculty to access Satellite Symposia, Members may also pay for the registration fee. If the HCP also attends the Third-party Organised Educational Conference associated with the Satellite Symposium, then the Member Company cannot pay any travel, accommodation and meal expenses directly associated with the third-party conference. They may pay for local transportation between the conference and the Satellite Symposium, if required.

QUESTION: Can a company offer meals and refreshments at a Satellite Symposium?

ANSWER: Yes, a company may offer meals and refreshments at a Satellite Symposium, provided that they comply with (a) the third-party programme organiser's or the relevant accrediting body's standards; and (b) Part 1: Interactions with HCPs, Chapter 1: General criteria for events Clause 8: Reasonable hospitality.

QUESTION: Can a Member Company organising a Satellite Symposium at a local/international Third-party Organised Conference select Faculty for their symposium?

ANSWER: Yes.

QUESTION: Is a journal club considered a TPOE?

ANSWER: Yes. A journal club is a group of HCPs who meet regularly to review and evaluate academic literature on a core medical or clinical topic. Companies should evaluate requests for journal club support based on all the facts and circumstances of the proposed arrangements. The Code permits companies to support journal clubs as a TPOE. A company can provide an Educational Grant to the journal club organiser. The journal club organiser can use the funding to defray the costs of putting on the programme (eg audio-visual, space rental) and to provide Code-permissible items to participants (eg modest meals). Secondly, a company could provide commercial sponsorship to the journal club organiser in exchange for marketing and promotional benefits, such as Advertising, signage or display space.

QUESTION: What are the main differences between TPOE and TPPT?

ANSWER: Both Third-party Organised Educational Conferences and TPPTs are types of TPOEs. Therefore, they must comply with Part 1: Interactions with HCPs, Chapter 1: General criteria for events. However, unlike Third-party Organised Educational Conferences, TPPTs are not subject to the prohibition of direct support for the attendance of HCPs.

Question & answer

QUESTION: May a Member pay for travel and lodging for an HCP to attend a TPPT as a delegate?

ANSWER: Third-party Organised Educational Conferences and TPPTs are types of TPOEs. They must comply with Part 1: Interactions with HCPs, Chapter 1: General criteria for events. However, unlike Third-party Organised Educational Conferences, TPPTs are not subject to the prohibition of direct support for the attendance of HCPs. Member companies may therefore pay for travel, hospitality and the registration fee.

QUESTION: What are examples of practical sessions in relation to a TPPT?

ANSWER: The following are examples of practical sessions:

- Hands-on sessions in which all attendees to the TPPT participate actively. In these sessions, attendees perform specific procedures in settings and environments appropriate for a practice or procedure. Examples of hands-on sessions may include surgery simulations where the technologies relevant to the specialty are practiced on cadavers, skin models, synthetic bones, cath labs etc. To ensure that attendants are able to fully benefit from the active aspects of hands-on sessions, no "station" (model, cadaver, table etc) can in principle have more than four participants. For ethical considerations, when human cadavers are used, up to eight participants may share a "station".
- Streaming eg video, 3D-rendering software, augmented reality or demonstrations of live surgeries.
- Case study sessions when trainees learn about procedure preparations and best practices from experts. These sessions must be interactive, using pictures, videos, animations, 3D-rendering software etc.

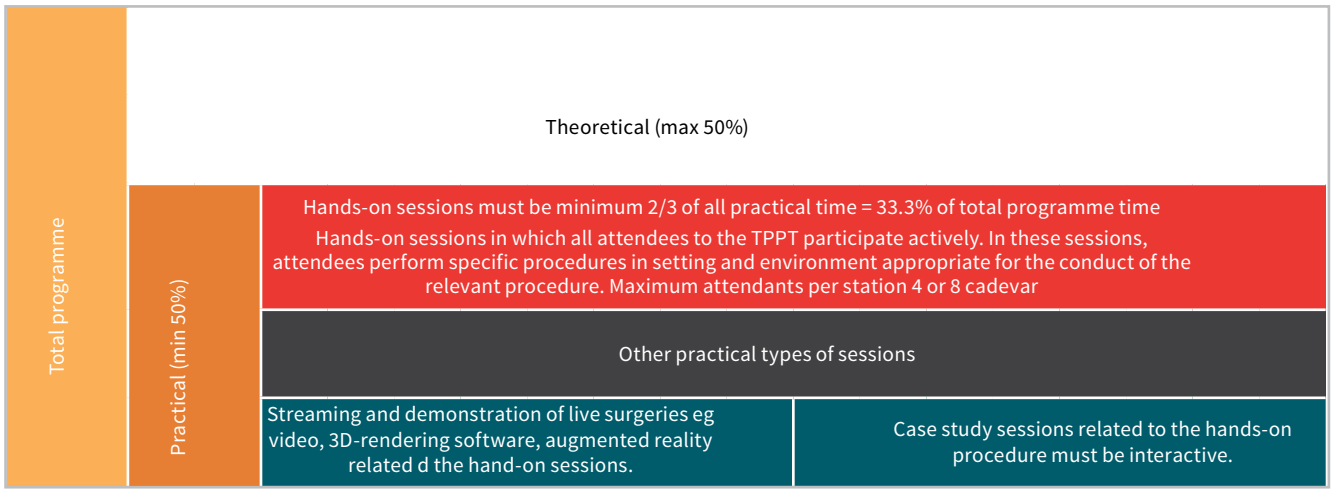
QUESTION: In the definition of TPPT, what is meant by "Proctorship" and "Preceptorship"?

ANSWER: For the purposes of the Code both Proctorship and Preceptorship are types of clinician-to-clinician training funded by Members. Proctorship is where the trainee clinician performs a procedure under the supervision of another clinician and where the trainee clinician has primary responsibility for the patient undergoing the procedure. Preceptorship is where a supervising clinician oversees the procedural training of a trainee clinician, and the trainee does not have primary responsibility for the patient undergoing the procedure. Such Proctorships and Preceptorships normally take place on HCO premises and are not considered as either a TPOE or a TPPT.

QUESTION: A Third-party Organised Educational Conference has practical workshops as part of the agenda. Does this mean Member Companies can provide direct sponsorships to individual HCPs to attend this conference?

ANSWER: No. Third-party organised hands-on training must be a stand-alone educational Event and not a component of a larger meeting. The Event must not be a pre-/post-meeting or symposium of a larger Event.

Table 1: TPPT programme governance



CHAPTER 3 COMPANY EVENTS

1. GENERAL PRINCIPLES

Members may invite HCPs to Company Events including:

- Company-organised educational Events
- Product and procedure training
- Sales, promotional, product launch and other business meetings
- Satellite Symposia.

Company Events should comply with the principles mentioned in Part 1: Interactions with HCPs, Chapter 1: General criteria for events.

Where there is a legitimate business purpose, Company Events may include or take place at Member Company's premises/manufacturing plant or HCOs used by the Member Company as reference centres.

Question & answer

QUESTION: What is meant by "legitimate" as used in the definition of a Company Event?

ANSWER: The Event should fulfil a legitimate, documented business need of the company, including but not limited to a legitimate business need to interact with Customers. The Event should be relevant to the HCP attendees; a detailed programme should be available sufficiently prior to the Event and present a clear schedule with no gaps during the sessions. The minimum duration for a full-day Event should be six hours or three hours for a half-day Event including breaks.

2. COMPANY-ORGANISED EDUCATIONAL EVENTS

The objective of these Company Events must be genuine and bona fide medical education and the enhancement of professional skills.

The aim of Company-organised educational Events is to directly communicate information concerning the use of Members' Medtech eg information about disease states and the benefits of Medtech to certain patient populations.

In all cases the information and/or training must directly concern a Member's Medtech, therapies and/or related services. This means that a Member must meet the following requirements when organising such an Event:

- The entire Event must comply with the criteria in Part 1: Interactions with HCPs, Chapter 1: General criteria for events.
- The programme must be rigorous from a scientific and/or educational perspective. Its content must include current scientific information of a nature and quality which is appropriate to the HCPs attending the Event.
- The programme must be genuine and bona fide educational, and therefore cannot have a primary sales and marketing objective. This means that the educational part must fill most of the programme.
- Information on the programme, clearly indicating the name of the company organising the Event, should be made available sufficiently in advance in order for invited HCPs to be able to make a reasoned judgment as to the rigor and quality of the programme, provided that subsequent changes, deletions and additions to the programme are acceptable to the extent that such changes, deletions and additions are reasonable and do not significantly affect the quality or nature of the programme.
- The programme should in principle involve full days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half-day Event, commences or ends at midday or lasts less than half a day. Such half-day or shorter sessions are permissible, but there should not be any non-scientific or non-educational Events or activities organised for the other part of the day. Furthermore, there should be no significant gaps in the programme to permit HCPs to engage in non-scientific or non-educational activities. For example, early morning sessions should not be followed by late afternoon or evening sessions with large blocks of free time in-between.
- For Faculty at Company Events, payment of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel, is permissible provided it is in terms of a written contract.

Question & answer

QUESTION: Is it acceptable to offer a cash advance by way of a bank transfer payable to an HCP for a specific amount to cover all or part of the HCP's travel or accommodation expenses for attendance at a Company Event?

ANSWER: It is not acceptable to make an advance payment to an HCP to cover prospective expenses. Payments should generally be made to the supplier/vendor or an intermediary agency. Alternatively, member companies may reimburse individual HCP expenses retrospectively against original invoices or receipts.

Question & answer

QUESTION: Are cruise ships or golf clubs appropriate venues for product/procedure training and educational Events?

ANSWER: No. Cruise ships, golf clubs, health spas and similar venues renowned for their entertainment/recreation are not appropriate venues and should not be used. Appropriate examples include hospital, clinic, surgical centre, laboratory and educational, conference or other appropriate settings including Member Companies' own premises or commercially available meeting facilities that are conducive to effective transmission of knowledge and required hands-on training.

3. PRODUCT AND PROCEDURE TRAINING

Where appropriate, in order to facilitate safe and effective use of Medtech, therapies and/or services, Members should make product and procedure training available to relevant HCPs. Members shall ensure that personnel conducting the training have the appropriate expertise to conduct such training. SAHPRA and other international regulatory authorities mandate this training and education.

4. COMPANY EVENTS TAKING PLACE IN THE CONTEXT OF TPOES

Member Companies cannot directly support travel, accommodation or other expenses of individual HCPs participating in Company Events which take place at same approximate time and location as a TPOE.

However, Company Events – including fee-for-service arrangements like advisory boards and clinical investigator meetings – may be organised at or around a TPOE for reasons of convenience and efficiency, given the attendance of HCPs at that TPOE.

If such an Event overlap occurs, the Member may only pay the contractual compensation and expenses agreed for the provision of the services by the HCP at the specific Company Event. Under no circumstances may a Member pay for incremental costs relating to the HCP's attendance at the TPOE, such as registration costs, hospitality, additional travel or accommodation.

The HCPs must have an active role at such Company Events rather than being mere passive attendees. For example, no support shall be provided by Member Companies to HCPs attending Company Events as a Delegate or trainee where this is organised at or around an TPOE.

4.1 Rules for certain Company Events, Satellite or speaking events organised in the context of TPOEs

The HCPs' registration fee for the TPOEs may be covered only if the HCPs' access to the Satellite Symposium or booth at the TPOE is conditional upon the payment of the registration fee. Where this applies, the registration fee must, where possible, be prorated to the actual attendance required in order to deliver the required services eg if the Satellite Symposium is held on a single day of the three-day Event, and it is possible to choose a one-day registration, that option should be selected.

The flight and accommodation costs can only be covered if the HCPs are not already benefiting from an Educational Grant covering their attendance to the Event.

4.2 Hospitality at Company Events organised in the context of TPOEs

If a Member Company wishes to organise a legitimate business or scientific meeting which includes lunch or dinner with selected HCPs in the context of a TPOE, the following conditions must be met before the Member may cover the hospitality costs:

- The meeting should have a legitimate business or scientific purpose and the lunch or dinner must not be the primary purpose of the invitation but must instead be clearly subordinate to the purpose of the meeting.

The invitation to the lunch or dinner should only be made to a small number of participants, in order to ensure effective contribution by way of transfer of knowledge, discussion and exchange among the participants in line with the meeting's legitimate business or scientific purpose. Any such invitation should comply with Part 1: Interactions with HCPs, Chapter 5: Educational grants and support to HCP participation in Events, Clause 1: Support for HCP participation at TPOEs. Under no circumstances may a Member Company issue a blanket invitation to all the participants at the TPOE.

The Member Company must ensure that the hospitality provided complies with all local laws and regulations, and with Part 1: Interactions with HCPs, Chapter 1: General criteria for Events, Clause 8: Reasonable hospitality.

- In all cases, Members should take special care of instances where HCPs may already be benefiting from an Educational Grant which covers all forms of hospitality and be mindful of the impact that their interactions with HCPs may have on the image and perception of the Medtech industry.

Question & answer

QUESTION: Can companies directly support travel and/or accommodation or other expenses of an individual HCP as a delegate at company-organised educational Events/Satellite Symposia, happening during or around a TPOE?

ANSWER: No. Since 1 January 2018, Member Companies cannot directly support travel, accommodation or other expenses for HCPs who are passively participating as delegates at Company Events which happen at the same approximate time and location as a TPOE.

Company events eg advisory boards and clinical investigator meetings but not sales, promotional and other business meetings, may be organised at or around a TPOE for reasons of convenience, given the attendance of HCPs at that Event. In such circumstances, the Member may only pay for the contractual remuneration and expenses agreed for the provision of services by the HCP at the company-organised education Event. Under no circumstances may a Member pay for a registration fee, travel, accommodation or other costs associated with the TPOE.

The following should be considered when determining whether an Event is a TPOE or a Member Company Event:

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

5. SALES, PROMOTIONAL, PRODUCT LAUNCH AND OTHER BUSINESS MEETINGS

Members may organise product launches, sales, promotional and other business meetings where the objective is to discuss products and related services, features and benefits, conduct contract negotiations or discuss sales terms.

In addition to the principles laid down in Part 1: Interactions with HCPs, Chapter 3: Company Events, Clause 1: General principles, sales, promotional and other business meetings should comply with the following more stringent requirements:

- Such meetings should, as a general rule, occur at or close to the HCP's place of business.
- The objective of a sales, promotional or other business meeting is to affect the sale and/or promotion of a Member Company's products and related services. These meetings may cover product features, benefits and use and/or commercial terms of supply.
- Companies should generally not pay for travel and accommodation. Exceptions might be a national launch or where demonstrations of non-portable equipment are necessary.

Question & answer

QUESTION: Is it appropriate for Members to invite HCPs to a company plant or factory tours where the HCPs reside outside the country of location of the plant or factory?

ANSWER: Yes, it is appropriate for Member Companies to invite HCPs to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose and the tour complies with the Code in all respects.

CHAPTER 4 VIRTUAL AND HYBRID EVENTS

1. GENERAL PRINCIPLES

The principles and activities that apply to face-to-face meetings as detailed in Part 1: Interactions with HCPs, Chapter 1: General criteria for events and Part 1: Interactions with HCPs, Chapter 3: Company Events, shall apply to all virtual and hybrid company Events and TPOEs.

Meals to HCPs during virtual Events are prohibited unless the Event is held at a hub and more than three HCPs are in attendance. In such instances:

- Only meal delivery is permitted. Providing cash or cash equivalents (eg restaurant or meal delivery service vouchers or gift cards) are prohibited.
- Invited HCPs must confirm their attendance before the Event and Members must track attendance to ensure that only appropriate recipients are receiving meals.

In respect of continuing medical education, no commercial promotion of the product may be allowed during the CME-accredited presentation sections of the Event. Commercial promotion is allowed during non-CME slots and meal breaks earmarked for Advertising purposes.

Question & answer

QUESTION: Do the minimum duration requirements of Part 1: Interactions with HCPs, Chapter 1: General criteria for events apply to virtual Events?

ANSWER: No. Virtual Events are not affected by the duration requirements of Part 1: Interactions with HCPs, Chapter 1: General criteria for events of the Code.

CHAPTER 5 EDUCATIONAL GRANTS AND SUPPORT TO HCP PARTICIPATION IN EVENTS

Members may provide Educational Grants for the advancement of medical education. Members shall specify the intended purpose of the Educational Grant in a Consulting Arrangement. 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.

1. SUPPORT FOR HCP PARTICIPATION AT THIRD-PARTY ORGANISED EDUCATIONAL EVENTS

Effective 1 January 2018, Member Companies are prohibited from directly supporting ie paying for the costs for HCPs to attend Third-party organised educational conferences. Instead, Member Companies may support such Events by providing Educational Grants to an appropriate third-party recipient organisation eg PCO, HCO, HCP professional society.

On request for an Educational Grant by a third-party grant recipient, the company may respond by sending this template to the recipient for completion and submission.

Application Form: Educational Grant for a Third-party Organised Educational Event

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

Instructions – please read before completing the form

- Grant applications must be submitted at least x days prior to the first Event/activity taking place with all supporting documentation attached. Any application not complying with this timeline will be rejected.
- Please note there is no guarantee that all of the amount requested will be granted. The company may reject, approve in full or approve a lower amount at its absolute discretion.

The completed and signed form including all other required documents must be submitted by email to email address.

1. Applicant (third-party grant recipient) Information	
Full name	
Operational structure/Legal status	
Tax ID	
Address	
Mission of organisation	
(a description of the organisation's educational/ scientific mission, field of activity, notable projects/co operations)	
Website	
Head of organisation Full name:	 Position/title:
Contact person submitting the request	
Full name:	Position/title:
Telephone:	Address:
2. Grant Request Details	
Type of grant (please tick the appropriate box) ☐ Support for HCPs participation at third-party organised educational event (the "educational event") ☐ Support for the educational event	
Therapeutic or diagnostic areas	
Country(s) for which the grant is intended	
Please provide a detailed description on how the grant will be used (eg number of HCPs to be supported, average amount proposed per HCP for flights (in Rand/other), average amount proposed per HCP for registration fees (in Rand/other) etc). *Note: The grant must only cover costs related to the organisation of the educational event (eg event venue, registration, travel and accommodation costs of participating HCPs). The grant will not be provided to cover costs linked to leisure/entertainment activities or for the invitation of spouses/partners of HCPs. No funding will be provided to cover ordinary operating and/or running costs of the organisation and other budget items not directly linked to education.*	
Amount of funding requested from the company (in Rand/other)	
Amount of funding requested from other external parties in total (in Rand/other)	

Percentage of overall budget sought from the company		
Details of personnel responsible for financial controls over grant funds (eg applicant's financial department, independent auditors etc)		
Bank account details		
(This must be an account in the name of the body making the application and not an individual)		
Bank name:		
Bank country:		
Account holder:		
IBAN number:		
BIC/SWIFT code:		
3. Educational event details		
Title		
Start date (dd/mm/yyyy):	End date (dd/mm/yyyy):	
Location	City:	
	State:	
	Country:	
Venue	Name:	
	Address:	
	Website:	
Objective of the educational event: please provide a detailed description of scope, purpose and anticipated outcome of the programme.		
Target audience for the event (please tick all boxes that apply)	☐ Local ☐ National ☐ International	
4. HCPs participation at educational events		
Describe the application procedure and criteria for selecting grant beneficiaries		
Name and/or position of the person responsible for selecting HCPs to attend the educational event		
5. Previous Grant Support		
Has your organisation already applied for or received funding from our company before?	☐ YES ☐ NO	
If "YES", please indicate the amount, date and purpose of the requested/awarded grant?		
6. Notes		
7. Supporting documents		
Supporting documents to be attached to this application form: • Copy of most up-to-date draft programme, agenda or communication material related to the educational event • Draft budget presenting how the funds will be spent		
I declare that: This form was completed on behalf of the requesting organisation. The information provided in this form and supporting documents is true and accurate. The grant request is not implicitly or explicitly linked in any way to past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the company's products or services.		
Date		
Name		
Position		
Signature		

Question & answer

QUESTION: Why is it prohibited for Member Companies to directly support HCPs to attend third-party organised educational Events? Will this approach not stifle vital continued medical education of HCPs?

ANSWER: SAMED has aligned with other countries/ Medtech associations which have implemented the same prohibition on direct support to HCPs in order to strengthen independent decision-making by HCPs. These changes promote transparency and continued training and education of HCPs in new Medtech and therapies.

QUESTION: Which other industry associations and regions have prohibited direct support of HCPs to Third-party organised Educational Conferences?

ANSWER: Medtech Europe – Europe; MECOMED – Middle East; APACMed – Asia Pacific; Advamed China – China; ABIMED – Brazil; AMID – Mexico. Direct sponsorship has been prohibited even earlier than SAMED's 2018 requirements in the USA – Advamed; Australia – MTAA; New Zealand – MTNZ and India – UCPMP.

QUESTION: How are HCPs being informed of the prohibition of direct support to attend third-party organised educational events? How should a Member respond to requests by HCPs to support their attendance of such events?

ANSWER: SAMED continually communicates and engages with relevant stakeholders about this and other Code matters. Companies can direct the HCP to HCOs/conference organisers from which they can request a grant to support their attendance. The company must make it clear that while they may make an educational grant to these third-party entities, the company has no role in deciding who receives a grant.

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.

For the avoidance of doubt, Educational Grants to support HCP participation at a TPOE may, subject to local laws and regulations, cover matters such as travel, accommodation and hospitality, including meals. Members should be mindful of any specific notification or disclosure requirement linked to support of hospitality.

When providing an Educational Grant to support HCPs' participation at TPOEs, Members should not proactively seek to receive the names of the HCPs benefiting from the Educational Grant. Generally, when a TPOE is supported by more than one company, all companies should receive the same attendance list from which it should not be possible to identify which HCPs have benefited from a particular Member's Educational Grant.

However, where required by law, a Member Company may, in accordance with the applicable legal requirements, request and obtain the names of the HCPs participating in the Event and who are benefiting from that Member's Educational Grant.

For purposes of auditing, compliance and monitoring by relevant company functions, after the Event has taken place, it may be necessary for a Member Company to request and receive the names of HCPs and respective HCO that benefited from the company's Educational Grant.

In the above cases, unless required by law, such HCP names should never be received by the Member until the Educational Grant agreement has been signed and the independent selection process of the HCPs has been completed.

Where the prospective beneficiary of an Educational Grant is the organiser of the TPOE and is also an HCO, the recipient HCO shall be solely responsible for:

- The programme content.
- The selection of Faculty.
- The payment of Faculty honoraria, if any.

Members shall not have any detailed involvement in determining the content of the educational programme for selection of Faculty and this shall be reflected in the written grant agreement. If expressly requested to do so, Member Companies may recommend speakers or comment on the programme.

Question & answer

QUESTION: Can a Member Company's educational grant include having the event organiser (grant recipient) invite specific HCPs to a third-party organised conference on behalf of the company?

ANSWER: While the Event agreement can include funds to support a defined number of HCPs to attend the Event, the event organiser (grant recipient) is responsible for selection of specific HCPs. The event organiser (grant recipient) cannot invite them on behalf of a company as this could potentially encourage HCPs to favour that particular company.

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

ANSWER: Member Companies should document grants and contracts in relation to grants. It is the responsibility of the HCOs to promote their grant offerings. A Member can advise inquiring HCOs and/or HCPs that the company has grants available but also explain that it has no role in the selection of grant recipients.

QUESTION: Is it acceptable for a company to agree to a funding request by an Event organiser for conference travel and accommodation for Faculty members?

ANSWER: Yes. It is allowed to agree to a request from an Event organiser for a grant to support travel and accommodation costs for unnamed Faculty members. The company should pay the money to the Event organiser.

QUESTION: An Event organiser asks a company to recommend Faculty for an Event. Is the company allowed to provide details to the organiser of a surgeon who would be a great speaker?

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

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

ANSWER: Yes. If there is a sufficient number of trainee surgeons so the company does not thereby influence the selection or gets to identify a particular individual.

QUESTION: A hospital has requested funding for one of their employees to attend a third-party organised educational conference. To ensure that a suitably qualified hospital employee attends the Event, can the company provide funding specifically for the hospital's Head of Department to attend?

ANSWER: No because Head of Department is too specific. Refer to Criteria for companies' support for Third-party Organised Educational Conferences.

QUESTION: Can a Member Company giving an Educational Grant to an international conference organiser to support South African HCPs to attend its annual conference specify the HCP selection criteria?

ANSWER: Yes. It is acceptable to provide criteria for grants to congress organisers or societies provided the ultimate decision on recipient suitability rests with the Event organiser and the criteria does not direct the grant to a specific HCP. Based on the Event's educational objectives, criteria can include inter alia speciality, country of the HCPs' residence and level of expertise/experience.

QUESTION: What are some examples of giveaways or other benefits that under the Code cannot be purchased by the TPOE organiser using funds from the Educational Grant?

ANSWER: The following are examples of prohibited items:

- Gifts
- Entertainment
- Recreational activities
- Non-branded promotional items
- Concerts or live shows
- Sport event tickets.

Refer to Part 1: Interactions with HCPs, Chapter 1: General criteria for events and Part 1: Interactions with HCPs, Chapter 7: Promotional items, items of medical utility, gifts and competitions.

Question & answer

QUESTION: What does the term HCO mean in relation to providing Educational Grants to Event organisers and HCOs for them to support HCPs' attendance of TPOEs?

ANSWER: In this context, Healthcare Organisations (HCO) include professional associations, medical associations and hospitals.

QUESTION: Can a small HCO receive Educational Grants to support HCPs' participation at TPOEs?

ANSWER: Yes, in principle. There are no size limits for HCOs to receive Educational Grants. However, Member Companies must ensure that the final beneficiaries of the Educational Grant cannot be identified beforehand. For example, HCOs composed of a single HCP will in practice not be allowed to receive Educational Grants to support the HCP's participation at a TPOE since the final beneficiary is known upfront.

QUESTION: Is it appropriate for a company to get the names of HCPs who attend a TPOE for which the company gave an Educational Grant?

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

QUESTION: What are the differences between an Educational Grant and a commercial sponsorship?

ANSWER: Commercial sponsorships in the context of TPOEs would involve objective consideration, such as access to the participants for marketing purposes, Advertising opportunities or booth space. On the other hand, an Educational Grant is exclusively provided for the advancement of medical education in situations where the Member neither requests, expects nor receives any consideration for the support. Public notes or mentions thanking the providers of Educational Grants do not amount to consideration for these purposes.

QUESTION: Can an Educational Grant be provided to a specific hospital or department or to specify a particular hospital or department as criteria for HCOs and/or PCOs?

ANSWER: One of the guiding principles in the Code is that Members should not receive or be able to determine the names of HCPs who will benefit from Members' support/funds. The inclusion of a criterion specifying an individual hospital or hospital department is not prohibited under the Code. However, Member Companies should bear in mind that the smaller the recipient hospital or department, the greater is the risk of Member Companies being able to identify individual beneficiaries. In addition, Members should be mindful of any proximate or ongoing tender proceedings with a specific hospital, as such tenders may raise additional red flags.

QUESTION: Can Members give criteria for HCOs and/or PCOs to allocate their Educational Grant?

ANSWER: Yes. Objective criteria for HCOs and/or PCOs to select HCPs to benefit from Educational Grants may be provided as long as such selection criteria are relevant to the HCPs' educational needs and are not so specific that it would effectively select individual HCPs. Examples of criteria for selecting Educational Grant recipients are HCPs' specialty, years of practice, city/region of practice and/or academic criteria such as number of publications, participation in clinical trials in a given pathology or specific hospital provided the HCP beneficiaries are not identifiable.

QUESTION: A Member Company is approached by an HCP requesting that the company directly support their or other HCPs in their department to attend a TPOE. The Member Company suggests that the HCP place the request on a letterhead of the department/hospital and make the request for an Educational Grant to the company that way. Is this acceptable?

ANSWER: No. This would not be acceptable, and the Member Company should not suggest as such. Even though the request now appears to be coming from the department/hospital, the company has already been made aware of who the specific individual HCP/HCPs are who will receive the Educational Grant and may be perceived as circumventing the prohibition on direct support to HCPs to attend a TPOE. In such cases, the Member should on receiving the initial request, reject the request and inform the HCP about the prohibition against direct support. Members may suggest that in future, the HCP channel such requests via a professional society or the department head/hospital CEO, but then such requests should ensure that the Member Company has no previous knowledge of who the individual recipient(s) of the grant are prior to the request being made.

2 SUPPORT FOR TPOES VIA COMMERCIAL ORGANISATIONS NOT INVOLVED IN EVENT ORGANISATION

Members must consider that certain compliance risks may arise from working with intermediary companies for the management of Educational Grants and must therefore take all necessary actions to mitigate these risks.

In particular, Member Companies must ensure that any company receiving funds for the management of Educational Grants does so in accordance with the Code. The Member must ensure that the managing company has sufficient experience and expertise to make an appropriate selection of HCPs to benefit from the Grant. Members must include appropriate and specific compliance-related criteria in all contractual arrangements relating to the management of Educational Grants, to ensure that the funds are used appropriately and in accordance with ethical standards and local rules and regulations.

The Contractual Arrangement should encompass effective measures that provide the Members the right to monitor and audit the activity of the company managing the Educational Grant.

Members may not provide an Educational Grant or funds for education directly to a third-party travel agency. For the avoidance of doubt, a Member may provide an Educational Grant to an HCO or funds earmarked for education to a PCO if the appointed HCO/PCO has arrangements for remitting payments for travel, accommodation and registration (where applicable) directly from the Member Company to a third-party travel agency.

In these circumstances the Member may choose to establish a tripartite contract with the HCO/PCO and the third-party travel agency. Such a third-party travel agency could be the same agency also used by the Member for its own internal travel arrangements, provided this is not an internal function at the Member Company or a Member Company-owned entity.

Where a Member decides to use any such arrangement involving funding for, or payments to, a third-party travel agency to arrange travel, accommodation and/or registration (when applicable), it is important that the Member Company carries out prior appropriate due diligence on a country-by-country and case-by-case basis in order to evaluate and mitigate possible compliance risks and practicalities. The Member must include in all Contractual Arrangements appropriate and specific compliance-related criteria and conditions for the HCO/PCO to outsource travel arrangements to a third-party travel agency, which should include appropriate provisions to allow effective monitoring and control of the activity of the third-party travel agency.

Question & answer

QUESTION: In the event that a commercial organisation, such as a PCO organises a TPOE independently of any HCO, is it appropriate for Members to sponsor such Events and what rules apply?

ANSWER: Members may enter into a commercial sponsorship arrangement with a PCO that is organising a TPOE and acting independently of any HCO. However, such arrangements do not fall within the definition of Educational Grant as PCOs are for-profit organisations. Sponsorship arrangements are therefore commercial in nature and Members should document these in a written commercial agreement in accordance with normal business practice. Where a Member provides funds earmarked for the advancement of genuine educational purposes to a PCO acting independently of any HCO, all the Code provisions governing Educational Grants shall apply.

3. SCHOLARSHIPS AND FELLOWSHIPS

Members may provide Educational Grants in the form of grants for Scholarships and Fellowships to support advancement of genuine medical education of HCPs. Only HCOs where HCPs are in training shall be eligible to request and/or receive such Educational Grants. A Member shall not provide Educational Grants to support Scholarships and Fellowships of individual HCOs. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant, and this shall be reflected in the written grant agreement between the Member Company and the recipient HCO.

A Member Company may not pay for or reimburse the additional travel or other participation costs incurred by a Scholar or Fellow attending a TPOE. Such costs shall be included in the Educational Grant supporting the Scholarship or Fellowship if it is intended that the grant should extend to such attendance.

Refer to Addendum 1 for a detailed guide on managing Educational Grants in relation to support for HCPs' participation in Events.

Transparent criteria, documenting grants and selection of attendees/ invitees

In order to mitigate the risks of potential bribery and corruption related to the provision of an Educational Grant to a specific prospective recipient, Member Companies shall implement an independent decision-making and review process with criteria that are not sales or commercially oriented. The Member Company's sales and/or commercial function shall not be involved in decisions regarding Educational Grants. This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organisation or entity.

Such an evaluation shall consider all the circumstances including the legal status and structure of the requesting (and/or prospective) recipient organisation as well as of the nature and scope of its activities and the terms and conditions to which the Educational Grant will be subject.

All Educational Grants must comply with the following rules:

- Be appropriately documented by the Member Company.
- Educational Grants shall only be provided in response to a written request from PCO/HCO.
- The requesting organisation must provide sufficient information to allow the Member Company to make an objective evaluation of the request. The Member's review must consider a detailed scope, purpose and content of the project being proposed for the Educational Grant. It shall also contain a description of the proposed recipient, its legal status and structure, and where relevant, a budget. No Educational Grant shall be provided until a written agreement documenting the terms is signed by both parties.

For Educational Grants provided in relation to Third-party Organised Educational Events, Member Companies should consider evaluating how the funds have been applied by the recipient in relation to previous equivalent Events and whether funds have been spent in accordance with the terms and conditions of previous grants.

A Company may provide Educational Grants to training institutions eg medical schools and teaching hospitals and to other third-party entities in support of legitimate educational and training activities.

This includes, but is not limited to, Educational Grants to support the education and training of HCPs (eg physicians, medical students, residents, fellows or other HCPs-in-training), patients and the public.

A company may not make an Educational Grant to individual HCPs or individual HCPs-in-training, and Members may not select or influence the selection of individual HCPs who might benefit from the company's support.

SAMED has prepared guidance to assist Member Companies and third-party grant recipients to manage indirect sponsorships and associated Educational Grants (see Addendum 1: Guidance pertaining to the management of indirect sponsorship and associated educational grants).

4. EDUCATIONAL GRANTS FOR GENERAL MEDICAL EDUCATION TOPICS

Member Companies may support genuine medical education for HCPs on general healthcare topics through Educational Grants in accordance with the Code. The topic must directly relate to the Member's area of business, Medtech, therapies or related services. The Event must be conducted in accordance with and meet other requirements of Part 1: Interactions with HCPs, Chapter 1: General criteria for events of the Code.

Members can also support genuine medical training on general healthcare topics through Member Company-organised product and procedure training and educational Events.

Question & answer

QUESTION: Is it appropriate for a Member Company to provide an Educational Grant to an HCO for the limited purpose of covering, in whole or in part, the cost of some form of peer-to-peer, general public or patient education or training? If so, under what circumstance can such grants be provided, and which criteria would need to be applied?

ANSWER: As a matter of principle, Member Companies should not cover an HCO's normal overhead or routine costs of operation ("overheads") that would fall under the normal HCO budgeting. Different types of HCOs have different routine costs, and each related request must be assessed on a case-by-case basis. Where a particular activity cannot be run due to funding constraints, it does not mean that such activity is not routine activity and cost for that HCO as defined by "overheads" above. It may be helpful to consider previous experiences with that or similar HCOs to understand if the activity is usually internally funded. If so, this is typically a routine activity.

As an exception to the above and provided that local laws do not prohibit such setups, Members may support peer-to-peer or public/patient training/education via Educational Grants under the following conditions:

- If part of a lawful tender, which includes internal educational set-ups as "value adds" to cover, in whole or in part, hospital overheads which are related to tender requirements.
- Fellowships and Scholarships in accordance with the provisions of the Code.
- Support of legitimate educational programmes which benefit the delivery of care and/or provide specific expertise to internal or external audiences. For such educational support, Members must consider the following to ensure appropriate safeguards against conflicts of interest between their aims and the aims of the HCO, particularly in relation to procurement and competition:
  - The purpose and scope of the support should be transparent and fully disclosed to the hospital administration as well as, where required, other locally-designated competent authority.
  - Such support should be limited in time and not renewed for indeterminate periods.
  - The supported programme/activity should genuinely aim to improve patient safety and/or clinical outcomes. As such, it must go above and beyond supporting normal hospital capacity and capability, considering the primary purpose of the hospital. It would not be appropriate to support routine or administrative capacity. This support should be brand-agnostic, meaning that it should not promote specific Member Company/Medtech. Additionally, while respecting the need for transparency, it should not promote the specific HCO.

5. GRANTS FOR PUBLIC AWARENESS CAMPAIGNS

Members may provide Educational Grants to HCOs for the legitimate purposes of providing information, promoting awareness and educating patients, carers or the general public about healthcare topics or medical conditions in therapeutic areas of interest to the Member Company.

Additionally, a Member Company may provide an Educational Grant to support the provision of high-quality information, promoting awareness and/or educating patients, carers and the public about health topics provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved.

Such disease-awareness campaigns must not, however, be designed or used to promote Member Company's therapies, products or to promote specific HCOs.

CHAPTER 6 SUPPORTING INDEPENDENT THIRD-PARTY RESEARCH

Members supporting third-party research programmes and partnering with HCPs to advance independent research can provide valuable scientific and clinical information, improve clinical care, lead to promising new treatments, promote improved delivery of care and otherwise benefit patients. To help meet these objectives, a Member Company may provide In-kind or monetary research grants in support of independent research with scientific merit.

Objectives and milestones: A Member may provide support for research that has defined goals, objectives and milestones. Requests for research grants should be accompanied by adequate clinical protocols. Requests for research grants should document the nature and scope of the research activity, the budget, the approximate duration of the research, and where applicable, the requirements for independent authorisations or approvals.

Limitations: Research grants may include In-kind or monetary support for legitimate, study-related, documented expenses or services and/or reasonable quantities of no-charge products for the limited duration of the research.

Member Company involvement: The recipient of a Member Company's monetary or In-kind research support should retain independent control over the research.

Member Company review processes: A Member Company should establish protocols for reviewing requests for research grants.

Sales involvement: Sales personnel should not control or unduly influence the decision of who will receive support or the amount of the support. A Member Company's sales personnel may provide input about the proposed research programme or recipient.

CHAPTER 7 PROMOTIONAL ITEMS, ITEMS OF MEDICAL UTILITY, GIFTS AND COMPETITIONS

1. GENERAL PRINCIPLES

There should be no personal enrichmen of HCPs. No gift, benefit In-kind, rebate, discount, kickback or any other material advantage shall be offered or given to HCPs, HCOs, administrative staff, government officials or the general publ as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any Medtech.

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.

2. PROMOTIONAL ITEMS

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

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

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

3. ITEMS OF MEDICAL UTILITY

Items of medical utility including informational and educational materials, scientific/medical reference books, journals, periodicals and anatomical models intended for teaching or patient benefit are allowed to be provided to HCPs within the values set by SAMED.

4. GIFTS

Members may not give gifts of any nature to HCPs including but not limited to those pertaining to cultural, religious or national Events. This means that a Member Company may not provide HCPs with the following:

- Items that the HCP or his or her family members, office staff or friends can use for non-educational or non-patient-related purposes (for example office supplies, scrubs, phones, tablets, laptops or other mobile devices suitable of personal use).
- Gifts such as wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents (eg gift cards).

Question & answer

QUESTION: May a Member Company or its representative provide a gift to recognise a life event for an HCP, such as a wedding, birth, anniversary or death of a family member?

ANSWER: The Code prohibits all types of gifts that may be given to an HCP so it would not be appropriate to give gifts to mark significant life events such as a marriage, birth or birthday. However, in the case of a bereavement, it is for each Member to determine the appropriateness of making an appropriate gift to the HCP or direct family members as a mark of respect only. In terms of the monetary value of the gift, members should consider the value limits applied to promotional items.

Question & answer

QUESTION: Does the Code include any restrictions on a company employee or representative accepting a gift from an HCP?

ANSWER: No. The Code does not address whether a company employee or representative can accept a gift from an HCP. Companies are encouraged to develop their own internal policies on this concept, recognising that the giving and acceptance of gifts could create a real or perceived conflict of interest.

QUESTION: Where HCPs engaged by Members as consultants or speakers decline a professional fee for their services, would it be appropriate for the Member to show appreciation by giving the HCP a small gift such as a bottle of wine or a bouquet of flowers?

ANSWER: No. It would not be acceptable for the Member to provide such a gift because to do so could be open to misinterpretation and would be likely to breach the Principle of Image and Perception and the prohibition of providing gifts.

5. 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 by SAMED.
- Entry into a competition must not be dependent upon prescribing, ordering or recommending a product and no such condition shall be made or implied.
- No cash or cash equivalents (eg vouchers) are allowed for completion of a survey or as a prize for a competition.

6. ACCEPTABLE VALUES OF PROMOTIONAL ITEMS, ITEMS OF MEDICAL UTILITY AND COMPETITIONS

The SAMED Code Committee will review the values of Promotional Items, items of medical utility, competitions and any other items as contained in the Code every three years.

The committee will propose reviewed values based on the average CPI index over the three-year period. This average increase will be applied to all items (excepting for anatomical models and scientific reference books) where the rate of exchange versus the US Dollar will be considered in addition to the average CPI increase.

Note: In accordance with the prohibition of direct support to HCPs to attend TPOEs, a prize in the form of direct support to attend such Events is prohibited.

For example: *in respect of Promotional Items, items of medical utility (excluding anatomical models and scientific journals), competitions and any other items:*

CPI – 2022 annualised	+2023 annualised	+2024 annualised	/3 years	= proposed % increase to be applied to values
5.9	+6.2	+4.9	/3 years	= 5.7% increase to be applied to values

For example: *in respect of anatomical models and scientific journals:*

USD RoE at last review	USD RoE at current review	= % increase	+ CPI proposed increase	= proposed % increase to be applied to values
R16.48 (2022)	R17.30 (2024)	= 4.9%	+ 5.7%	= 10.6% increase to be applied to values

The value reviews will be undertaken as of 31 March of the review year. The proposed values will then be sent to the SAMED Board for ratification.

The table below lists acceptable values ratified by the SAMED Board for the period 31 March 2022 to 31 March 2025 and serves as a benchmark for future review.

Table 2: Acceptable values of Promotional Items for period 2022-2025

Item	Prior 2022	New value	% increase
Promotional item: individual HCP	R300 per item	R400 per item	33
Promotional item: a unit/department within a hospital (ie not a practice)	R1 000 per item	R1 300 per item	30
Item of medical utility: to an individual HCP or patient excl. anatomical models and scientific medical reference books/journals and periodicals	R300 per item	R400 per item	33
Item of medical utility: for a unit/department within a hospital (ie not a practice) excl. anatomical models and scientific medical reference books/journals and periodicals	R1 000 per item	R1 300 per item	30
Anatomical model: per HCP/practice/department per annum	R5 000 per item	R6 500 per item	30
Scientific medical reference books/journals and periodicals: for individual practicing HCP or practices	R2 500 per annum	R3 250 per annum	30
Scientific medical reference books/journals and periodicals: training or academic institutions	R10 000 per annum	R12 500 per annum	25
Competition prizes: consumer competition A donation of any nature linked to the competition needs to be included in the total prize money.	R100 000 total prize value Each individual prize may not exceed R5 000	Unchanged	0
Competition prizes: HCPs and HCOs In accordance with the prohibition of direct support to HCPs to attend third-party organised Events, a congress attendance sponsorship prize is prohibited	R2 000 per Event or promotional activity	Unchanged	0

Question & answer

QUESTION: What are examples of educational items of greater value that can be provided to HCOs under the Code?

ANSWER: Examples of educational items of greater value that can be provided may include medical textbooks or anatomical models, but only if those relate to the therapeutic areas relevant to the Member Company.

QUESTION: What are examples of items of medical utility?

ANSWER: These items might include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject. Other items could be informational or educational materials that advance disease or treatment education, are designed for the education of patients or HCPs, and have no personal benefit to the HCP. Informational or educational materials might include educational brochures on diseases, patient self-assessment and tracking tools, and brochures that HCPs use when instructing patients about adherence to medicine regimens, healthy lifestyle choices or the availability of patient assistance programmes. Other items of medical utility might be anatomical models and scientific medical reference books/journals and periodicals ie items which have a genuine educational function that are intended to aid in the medical care of patients.

QUESTION: Are memory sticks containing informational or educational materials permissible?

ANSWER: As a general rule, memory sticks (and other electronic storage devices like DVDs etc) containing informational or educational materials can be provided to HCPs. Such items may only be provided to an HCP if they are within the limit of that set for items of medical utility and contain informational or educational content that is directly relevant to the practice of medicine or pharmacy and beneficial to the care of patients.

CHAPTER 8 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 eg 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.

Question & answer

QUESTION: What is an example of an "independent decision-making/review process"?

ANSWER: Such a process could be led by a company's legal, finance or compliance functions, operating within a robust governance framework and according to clear, consistent and transparent criteria for review and decision-making.

QUESTION: May a Member Company make a Charitable Donation to support the general running of a hospital or other HCO?

ANSWER: No. A Member cannot make available a Charitable Donation to support the general running of a hospital or other HCO. A donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main purposes. For the purpose of the Code and irrespective of their legal status, hospitals and HCOs are considered to generally have health functions as their main purposes and accordingly are not generally considered to have charitable and/or philanthropic functions as their main purposes. It is therefore not appropriate to provide charitable donations to support their general running.

QUESTION: Is it permissible for a Member Company to make a donation to an HCP's designated charity in instances where the HCP has requested the Member to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the Member?

ANSWER: No. Under the Code it is not appropriate for a Member Company to support the favourite charity of an HCP in response to a request by that HCP irrespective of the underlying reasons. No exception can be made for sport Events, such as payment of the registration charge to participate in a charity run.

QUESTION: Under the Code, may a Member Company make a donation such as the purchase of a table of dinner invitations at a fundraising dinner or entries to participate in or attend a fundraising sports or other Event?

ANSWER: Yes. 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 organisation. The Member 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 should not invite HCPs to attend such an Event at the Member Company's expense. Furthermore, the Member is not permitted to suggest to the sponsoring organisation the names of HCPs who could be invited to attend the Event, irrespective of whether or not the specified HCPs will be seated at the Member Company's table.

QUESTION: A Member Company is asked to sponsor a local hospital's Heart Walk to raise money for heart disease research. In exchange for a fee, the Member Company will receive exhibit space at a health expo the hospital is holding in connection with the walk. The Member Company will also receive prominent placement in relevant advertising. Is this acceptable?

ANSWER: Yes. A Member Company may provide a commercial sponsorship in support of a fundraising Event, separate from a Charitable Donation. As with commercial sponsorship of a TPOE:

- The level of commercial sponsorship should reflect a commercially reasonable fee in exchange for the marketing and promotional benefits received by the company, such as advertising, signage, display/ exhibit space or other promotional opportunities.
- The commercial sponsorship must comply with applicable laws governing the marketing and promotion of its products.

QUESTION: Is it permissible for a Member Company to specify restrictions in relation to the final use of a donation where a Member Company wishes its Charitable Donation to be applied as part of a specific aid programme or as part of the relief effort following a specific natural disaster, such as a major earthquake in a particular country?

ANSWER: Members may specify the broad, general purpose for which a donation shall be applied, such as the relief of a specific disaster in a particular country (eg for use to aid reconstruction and/or re-equipping of healthcare facilities following an earthquake). However, Members must take care that such specifications do not amount to control over the specific, final use of the Charitable Donation by the recipient which is not allowed under the Code.

CHAPTER 9 CONSULTING ARRANGEMENTS

1. GENERAL PRINCIPLES

Medtech companies rely on HCPs' expertise in a variety of important ways, such as training on safe and effective product use, conducting research and developing product advancements. Based on legitimate need, member companies engage HCPs through written contracts that document the HCP's services and any FMV compensation for those services.

Members may engage HCPs as consultants and advisors to provide bona fide consulting and other services, including but not limited to research, participation on advisory boards, presentations at Company Events and product development. Member companies may pay HCPs compensation of FMV for performing these services. In all cases, Consulting Arrangements must be permitted under the laws and regulations of the country where the HCP is licensed to practise and be consistent with applicable professional codes of conduct in that country. The principles in this chapter are applicable to all Consulting Arrangements between HCPs and Members including where a consultant HCP declines a fee for provision of their services.

Consulting Arrangements shall not be contingent in any way on the prospective consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services. When selecting consultants, Members shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with use of consultants. This process shall include a documented prior evaluation of any such associated risks and of the relevant background information concerning each prospective consultant.

For example, the decision to engage a specific HCP/HCO as a consultant for sales reasons does not constitute a legitimate business need. If it is necessary for a company's sales function to be involved in decisions to engage specific HCPs/HCOs, the independent decision-making/review process should ensure decision-making is exercised to fulfil legitimate business needs.

2. CRITERIA FOR GENUINE CONSULTING ARRANGEMENTS WITH HCPS/HCOS

In addition to the general principles above, the arrangements which cover genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria.

- Consulting arrangements must be entered into only where a legitimate business need for the services is identified in advance.
- The number of consultants retained must not be greater than the number reasonably necessary to fulfil the identified need.
- Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified need. The volume or value of business generated by a prospective consultant or the HCO where s/he performs her/his professional activity is not a relevant criterion.

Consulting arrangements with HCPs must be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must specify the nature of the services to be provided and the basis for payment for those services (see Addendum 2: Example template consulting framework agreement).

- When engaging HCPs/HCOs as a consultant, Members should be mindful of any potential conflict of interest that might arise from the specific project or from the engagement of that specific HCP/HCO.
- The engaging of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the Member's products or services.
- The compensation for the services rendered must be reasonable and reflect the FMV of the services provided.
- Members must maintain records of the services and associated work products provided by the consultant HCP and of the use made of those services by the Member Company. Examples of the documentation include presentations, invitation letters, agendas, attendance lists, minutes etc.

The venue and other arrangements (eg hospitality, travel) for Member Company's meetings with consultants shall follow the rules for such arrangements as set out in Part 1: Interactions with HCPs, Chapter 1: General criteria for events.

3. COMPENSATION AND FAIR MARKET VALUE

The compensation paid to HCPs engaged as consultants by Member Companies shall reflect FMV for the services provided. It shall not in any way be contingent upon the value of products or services which consultants may purchase, lease, recommend, prescribe, use, supply or procure in the course of their own professional practice or that may be purchased, leased, recommended, prescribed, used, supplied or procured by HCOs where they perform their professional activities.

Commercial reasonableness: In addition to the establishment of a value for services, such services should also be commercially reasonable where the agreement would make commercial sense if entered into by reasonable parties even if there is no potential for additional business. For example, a company may be paying an HCP FMV for a study, but is that study necessary or has a similar study already been undertaken?

Valuation elements: Assess the business need relative to the resource deployed eg the need for more than four HCPs on an advisory board.

Terms of agreement: Assess what services will be provided and the manner in which parties will be compensated.

The valuation risk assessment: It is essential that any risk related to any agreement be minimised.

Circumstances that elevate the risk of non-compliance	How to reduce the risk of non-compliance
• No formal valuation processes are established • Payment rates are based upon anecdotal information about what other companies are paying • Demands are placed on a company by the HCP to over-compensate • Lack of documentation	• Use independent accredited appraisers • Put in place formal documentation processes • Use accepted valuation approaches • Apply logic and consistency

Assessing FMV for HCPs and KOLs: Compensation earned by an HCP in his/her practice may not be directly comparable to the compensation associated with providing services to a Member Company.

Compensation should be based on an objective and consistent methodology including:

- Specific requirements of the Member Company, product group or department engaging with the HCP.
- The specific services required.
- The HCP's clinical specialty, experience, expertise.
- The time requirements for the engagement.

Distinguishing between HCPs and KOLs

Healthcare Provider/Professional (HCP)	Key Opinion Leader (KOL)
• Includes physicians, nurses, technicians, pharmacists, academic researchers, administrators etc • Range in expertise and experience from local-level service provider to international-level expert • Valuation is based on specialty/job class and determined level of expertise and experience (that is, tier) • Valuation can be applied to all HCPs within the specialty/job class (eg all nephrologists, all oncologists etc)	• Requires a level of experience, expertise and/or credentials that are (i) greater than a typical international level HCP or (ii) rare or unique skills • Valuation is based on (i) the KOL's specialty; (ii) the unique expertise/experience/credentials of the individual KOL; (iii) the specific responsibilities of the position the KOL will be engaged to perform; and (iv) the number of hours per year the KOL will be engaged • Valuation is specific to the individual

Question & answer

QUESTION: What is meant by FMV in the context of Consulting Arrangements?

ANSWER: Fair market value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.

QUESTION: How should member companies determine FMV for a service?

ANSWER: A Member must be able to demonstrate internal methodology to determine FMV. Among other matters this shall take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company.

QUESTION: How should a company respond to a request from a medical society for a grant of R100 000 to support the attendance of two of their unnamed members at a local conference? How does a company ascertain if this is a reasonable amount to pay?

ANSWER: Companies should formulate guidance on the fair market value (FMV) costs for supporting HCPs to different categories of Events in their market. This guidance should be available in the event of a complaint.

4. PAYMENTS

All payments made for services must comply with all applicable tax and other legal requirements. Members may pay for expenses reasonably incurred by consultants in providing the services as per the Consulting Agreement including reasonable travel, meals and accommodation expenses if attending meetings with or on behalf of Members. The written Consulting Agreement must detail which expenses can be claimed by the consultant in relation to the provision of the services and the basis for payment of these by the Member.

5. DISCLOSURE AND TRANSPARENCY

Members shall ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with their use of HCPs as consultants. All required consents and approvals shall be obtained, including from the hospital or other HCO administration or from the HCP's employer/superior (or designated competent authority), as applicable.

Members shall include appropriate obligations on the consultant to ensure that the individual's status as a consultant for the Member Company and his/her involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation.

CHAPTER 10 DEMONSTRATION, SAMPLES AND EVALUATION PRODUCTS

1 GENERAL PRINCIPLES

Members may provide their own Medtech as Demos, Evaluation Products or Sample at no charge in order to enable HCPs and/or HCOs 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.

Members may provide products from another company in conjunction with its own Demos and/or Samples on an exceptional basis if the other company's products are required in order to properly and effectively demonstrate, evaluate or use the Member Company's products eg computer hardware and software produced by a company other than the Member Company.

Provision of Demonstration and Evaluation 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 Members' 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.

Members shall in all cases maintain appropriate records in relation to the provision of Demonstration, Evaluation Products and/or Samples to HCPs and/or HCOs eg recording proof of delivery for any such products provided and receipt of return for multiple-use products. Members 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, Evaluation Products and/or Samples no later than the time of the supply. The disclosure to HCPs and HCOs shall be in writing.

2. DEMONSTRATION PRODUCTS (DEMOS)

Members may provide examples of their products to HCPs/HCOs in the form of mock-ups (such as unsterilised single-use products) that are used for HCPs and patient awareness, education and training. For example, an HCP may use a Demo 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. Demos are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer.

3. SAMPLES

Members 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.

Question & answer

QUESTION: What is a sample?

ANSWER: Samples are products provided free of charge by companies to equipped and qualified HCPs/HCOs to enable professionals to familiarise themselves with the products in clinical use.

QUESTION: What is a demonstration product?

ANSWER: Demonstration products are provided by companies to equipped and qualified HCPs/HCOs solely for the purpose of demonstrating their functionality and safe and effective use. They are not intended for clinical use.

QUESTION: What is an evaluation product?

ANSWER: Where a legitimate business need exists, Member Companies may initiate post-market third-party evaluation of their Medtech, therapies and/or related services and may provide Evaluation Products on a no-charge basis, under a written contract, in order to obtain defined user evaluation by HCPs or HCOs. The requested user feedback from HCPs at the HCO shall be formally described in a written protocol or questionnaire forming part of the contract.

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. Members shall 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.

4. EVALUATION PRODUCTS

Where there is a legitimate business need to do so, Member Companies may initiate post-market third-party evaluation of their Medtech, therapies and/or related services and may provide Evaluation Products under a written contract in order to obtain defined user evaluation by HCPs or HCOs. Evaluation Products may be provided on a no-charge basis in return for the requested user feedback from HCPs at the HCO, which shall be formally described in a written protocol or questionnaire forming part of the contract. Where the Evaluation Products are multiple-use products, the defined period of time necessary for the evaluation and feedback will depend on the frequency of anticipated use; the nature of the user evaluation feedback requested; and the duration of any required training and similar considerations that are reasonable in the context. Member Companies shall in all cases ensure that they retain title to multiple-use Evaluation Products and that they have a process in place for promptly removing such multiple-use Evaluation Products and/or any unused single-use Evaluation Products from the HCO's location at the conclusion of the evaluation period unless these are purchased or leased by the HCO. Provision of Evaluation Products and/or related services 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 related services. Any offer and/or supply of Evaluation Products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct and ethical requirements.

CHAPTER 11 LOAN OR PLACED EQUIPMENT

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

- Adherence with the Provisions of the *HPCSA'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 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 transgressions 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 12 BONUSING, REBATES AND INCENTIVE SCHEMES

All bonuses, rebates, free goods or other incentive schemes may only be provided as aligned with relevant legislation and regulations.

Any bonus, rebates, free goods or incentive scheme must be transparent, "defensible and fair" and should not encourage or incentivise over-servicing or profiteering by HCPs or HCOs.

No monetary or other benefits should flow to any HCP or HCO as a result of a Member Company provision of a bonus, rebate or incentive scheme. Any bonus, rebate and incentive scheme should be in accordance with both competition law requirements and also be for the benefit of patients and/or the health system.

In the event of the provision or sale of an item that falls within the category of special requests, charitable donations and pro bono supplies, an invoice must be submitted along with supportive documentation, explaining in detail the reason for such provision or sale.

Question & answer

QUESTION: Is it acceptable for a Member Company to pay for shelf space?

ANSWER: No, it is not acceptable to pay for shelf or storage space in an HCP practice, hospital or hospital group warehouse, excluding retail pharmacies.

CHAPTER 13 ROYALTY ARRANGEMENTS

HCPs, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve Medtech. They may develop intellectual property eg patents, trade secrets or know-how, under a product or technology development or intellectual property licensing agreement.

A Member Company should enter into a royalty arrangement with an HCP only where the HCP is expected to make or has made a novel, significant or innovative contribution to the development of a product, technology, process or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

Arrangements involving the payment of royalties to an HCP must be formalised in a written agreement, which may be subject to scrutiny by the Code Independent Chairperson and/or compliance panel if such interaction forms part of a complaint lodged in terms of this Code.

The calculation of royalties payable to an HCP in exchange for intellectual property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence.

Royalties paid in exchange for intellectual property should not be conditioned upon:

- A requirement that the HCP purchase, order or recommend any product or medical device of the Member or any product or technology produced as a result of the development project.
- A requirement to market the product or medical device upon commercialisation. Members are strongly encouraged to exclude from the calculation of royalties the number of units purchased, used or ordered by the HCP and/or member of the HCP's practice.

Local and international laws pertaining to royalties and intellectual property need to be adhered to.

Question & answer

QUESTION: Does the Code address arrangements between a Member and an HCP relating to the development of new Medtech for the Member?

ANSWER: Interactions relating to product development and intellectual property would be subject to the general principle that Members shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful or unethical inducement in order to sell, lease, recommend, use, maintain or arrange for the sale, lease or prescription of their products.

CHAPTER 14 MEDICAL TECHNOLOGY REGISTRIES

A Medical Technology Registry may be designed to achieve one or more of the following objectives:

- Improve patient care and outcomes by understanding the effects of products, facilities, patient populations and pathways over the full care cycle.
- Improve patient access to new therapies by efficiently collecting data to support regulatory applications for expanded use and indications.
- Obtain data to support coverage, reimbursement and value analysis.
- Evaluate the "real-world" safety and/or effectiveness of products outside of clinical studies.
- Meet regulatory requirements for post-market data collection.
- Reduce pre- and post-market burdens for data collection by providing regulators with alternative methods to monitor the performance of technologies.
- Aid in the assessment of effectiveness across multiple products or therapies.
- Develop hypotheses for further evaluation in clinical trials.
- Aid in the development or assessment of care guidelines.

Registries are typically prospectively defined. A medical technology registry may be sponsored by a Member Company, professional society, patient advocacy group, government agency, provider group or a combination thereof.

- With regard to HCPs providing information to registries, compensation provided must be reasonable, of FMV and in perspective with the work performed. Registries may not be disguised as promotion, should be of scientific and/or healthcare policy merit and relate to a legitimate and justifiable project to obtain data/information. Proof of such bona fide Registry data and documentation, including protocols, compliance panel approval and agreements, may be called for in the event of a complaint as per Part 2: Dealing with transgressions of the Code.
- Registries should comply with all applicable laws, including but not limited to privacy protections, the consent of the person whose information it is, the Helsinki Declaration, The Promotion of Access to Information Act, the National Health Act, the Health Professions Act and related guidelines and ethical rules, the Protection of Personal Information Act, the Consumer Protection Act, the Medical Device Regulations etc. When deciding on whether to conduct or participate in a Registry, members are encouraged to consult and follow the SAMED Medical Technology Registry Principles and Position Paper (see Addendum 3: SAMED Medical Technology Registry Principles and Position Paper).

CHAPTER 15 REIMBURSEMENT FOR INFORMATION AND OTHER ECONOMIC DATA

Members may pay for marketing data, formulary listings, managed care or other similar information to persons or institutions offering such services or information, provided that such fees:

- Are based on a written agreement detailing the exact nature and extent of the service or information for which the fees are paid, which agreement should be available on request or for evaluation in the case of a valid complaint.
- The service or information is of legitimate and lawful use to the buyer and such service or information is known to form part of the legitimate business of the seller thereof.
- The purchase of the service or information is not a condition for the support of the Member or the Member's product and is in no way linked to sales value and/or sales volume, targets and/or preferential usage or recommendation of any Medtech.

Question & answer

QUESTION: Is it appropriate to demonstrate that a product can be used in an economically efficient manner?

ANSWER: It is appropriate for Members to provide accurate information relating to the costs, savings and revenues associated with the use of a particular product. Without this information, it may be difficult for an HCP to properly evaluate whether it is economically feasible or desirable to purchase any particular product.

CHAPTER 16 FALSE CLAIMS REGARDING REIMBURSEMENT

Since many healthcare programmes (eg medical schemes) reimburse and pay for Member products, each Member must comply with applicable laws and regulations. These laws may impose liability on anyone who knowingly submits a false claim or record in order to obtain payment or to retain money to which they may not be entitled. A Member employee or Member Company that helps, encourages or causes someone else to make a false claim for reimbursement can also be liable for the false claim. No Member may suggest mechanisms for billing for services that are not medically necessary, or for engaging in any fraudulent practice to achieve inappropriate reimbursement.

CHAPTER 17 MEMBER COMPANY REPRESENTATIVES PROVIDING SUPPORT IN CLINICAL SETTINGS

1. GENERAL

Access to truthful and non-misleading information relating to Medtech is critical to an HCP's ability to exercise his or her medical judgment, to provide high-quality care and to safely use Medtech.

- Member Companies are encouraged to apply the principles outlined in this section and develop related controls.
- Member Companies should ensure that their company representatives have adequate training to ensure sufficient scientific knowledge of products which they promote to enable the provision of precise and complete information about such products. Product training must be consistent with the Medtech instructions for use.
- Member Company representatives are to promote Medtech in a professional manner and are not permitted to disparage any opposition products.
- Member Company representatives play an important role in the clinical setting by providing technical support on the safe and effective use of Medtech. Some examples include:
  - Company representatives may need to explain how a product's unique settings and technical controls function and may make recommendations.
  - Company representatives may assist the clinical/operating room team to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with Medtech that involves multiple devices and/or accessories.

Member Companies should apply the following principles:

- Company representatives should enter and be present in the clinical setting only at the request of and under the supervision of an HCP.
- Company representatives should be transparent that they are acting on behalf of the Member Company in a technical support capacity.
- Company representatives should not interfere with an HCP's independent clinical decision-making.
- Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements.
- A Member Company's technical support should not eliminate an overhead or other expense that the HCP should otherwise incur while providing patient care.

2. IN THE OPERATING ROOM/ CLINICAL ENVIRONMENT

Company 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 from appropriate members of the medical staff of the facility.
- Must wear appropriate attire as provided or permitted by the facility.
- May only advise on technical aspects of Member Company products consistent with the approved package insert/instructions for use.
- May not give clinical diagnostic advice, surgical advice or recommend treatment, even as the result of a direct request from the surgeon, operating room staff or any other healthcare professional.

In the event that the Member Company representative is attending the operating room/ clinical environment in his/her capacity as a company representative and on Member Company time he/she may not use and/or apply company product and deliver medical care directly to a patient even if they hold appropriate certification/ licences.

In the event that the Member Company representative is attending the operating room/ clinical environment in his/her capacity as a trained HCP, he/she must have a written contract with the hospital/facility and should be in a position to produce the contract, within a reasonable time, upon request.

Members are also required to adhere to the SAMED protocol on Member Company employees' attendance in the operating room/clinical environment and must make this a condition of employment for any personnel who might be present in an operating room/clinical environment.

SAMED protocol on Member Company employees' attendance in the operating room/clinical environment
Addressed to SAMED Member Company employees who enter an operating room/clinical environment

Prior to entering an operating room/clinical environment, you must complete relevant training on operating room/clinical environment protocol.

You are expected to know and follow the relevant policies and procedures of the facilities you visit. In some instances, this may require documentation that you meet certain requirements related to:

- Your current personal medical status.
- Your training with respect to safety protocols around blood borne pathogens.
- Operating room/clinical environment procedures and requirements.

Requests for documents verifying such information related to training should be made to your company management. Any documentation regarding personal medical status must be provided directly to the facility by you, in line with any legal requirements or restrictions.

It is incumbent upon you to ensure that personal liability cover is in place.

It is incumbent upon you to ensure that a discussion has taken place with the surgeon confirming that he/she has received patient consent for you to be present.

It is incumbent upon you to ensure that you have signed a confidentiality agreement with the hospital concerned.

You may only enter an operating room/clinical environment in accordance with permission from appropriate members of the medical staff of the facility. You are expected to wear appropriate attire, as provided by/or approved by the facility. It remains the responsibility of the facility to provide appropriate clothing.

However, if this is not possible then the facility must provide authorisation for you to provide your own appropriate attire.

You should be prepared to advise on technical questions related to the assembly and operational performance of company products consistent with the labelling and instructions for use.

You may not provide clinical diagnostic advice, surgical advice or recommend treatment, even as the result of a direct request from the surgeon, operating room staff or any other healthcare professional.

When acting on behalf of your company, company products may not be used and/or applied directly to a patient by you even if you hold appropriate certification/licenses. You may not deliver patient care or perform medical services of any type, even if you possess an appropriate medical license/certification. Your purpose in the operating room/clinical environment is to provide expertise relating to the preparation, assembly and use of instrumentation/devices which must be facilitated by communicating with the appropriate healthcare professional performing the procedure.

You may not have any hands-on contact with the patient or any part of the patient during surgery or a clinical event.

If there is any doubt about compliance with this protocol and involvement in the operating room/clinical environment then you should seek guidance from your company management before the procedure, and not enter the room.

Indemnification of liability

Notwithstanding the fact that you have followed all these procedures, it is important that you are aware that this will in no way indemnify you from any liability in the event that any action is taken by either the hospital, patient or healthcare professional.

Question & answer

QUESTION: May a Member Company representative who is a registered theatre sister work in a hospital after hours?

ANSWER: Company representatives may not work as HCPs in their spare time unless this is known and agreed to by the Member Company. Guidance should be sought from DENOSA or SANC and the hospital policy will prevail.

QUESTION: May company representatives take/wear their own/company branded overshoes and/or theatre clothes into theatre?

ANSWER: Company representatives may only wear such items if they are appropriate and have been approved by the facility.

QUESTION: What should a company representative do should a hospital group/HCP ask the representative to obtain patient consent?

ANSWER: Under no circumstances may a company representative obtain consent from patients. This is the HCP's responsibility.

QUESTION: May a company representative touch a patient?

ANSWER: No, regardless of whether they are a registered HCP or not, a company representative may not touch a patient under any circumstances even if demonstrating/training on a product.

CHAPTER 18 MEDTECH ADVERTISING AND PROMOTION

1. GENERAL PRINCIPLES

Access to truthful and non-misleading information relating to Medtech is critical to the HCPs' ability to exercise medical judgment, provide high-quality care and safely use Medtech.

Companies are encouraged to apply the principles outlined in this section and develop related policies and controls.

The conformity of an advertisement with this section should be assessed in terms of its probable impact upon the reasonable person to whom the advertisement is directed.

All medical devices must be Advertised and promoted according to any applicable laws and regulations which exist or may be set for the promotion and advertisements of medical devices in South Africa. Advertisements and promotions must portray Medtech in line with the approved uses and attributes of such technology.

Advertising and/or promotion shall not suggest that a medical consultation or surgical operation is unnecessary, nor shall it discourage consumers from seeking medical advice. Consideration should be given to the inclusion of information concerning the availability of professional advice.

All promotions and advertisements should be of a high standard and respect HCPs and patients.

Minimum requirements must conform to the Medicines Act including the Regulations and SAHPRA Guidelines. In other words, they must:

- Be provided in a clear and legible manner.
- Be consistent with the most recently approved instructions for use.
- An advertisement which contains two or more pages must not be false or misleading when each page is read in isolation.

No company shall be involved in promotional schemes which are hazardous to the public or which bring the industry into disrepute.

Information, claims, and comparisons used in promotional materials and activities must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and must reflect that evidence.

Such information or the manner in which it is portrayed must not mislead either directly or by implication or by distortion or undue emphasis. Material must be sufficiently complete to enable the recipients to form their own opinion of the therapeutic value of Medtech.

Promotional material must not be misleading as to the nature of the product, its ingredients or indications and must encourage the rational use of Medtech by presenting it objectively and without exaggerating its properties.

2. PUBLIC RISK

The use of words such as safe, new and other claims should be within the relevant legal frameworks and should not be used in contravention of the principles of the Code.

Promotions or advertisements to the public must take place within the applicable regulatory frameworks. Where such advertisement or promotion relates to help-seeking behaviour among the public, it:

- Must not use risk or safety information in a distorted way to scare the public or to induce a sale based on fear, exaggerated, distorted or misleading information or in a manner that leads consumers to make deductions on the comparative safety or risk.
- Must not abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress.
- Must contain correct and balanced statements only and claims which the Member Company has already verified.
- Must not be likely to arouse unwarranted and unrealistic expectations of product effectiveness.
- Must not be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases.
- Must not mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions:
  - That they are suffering from a serious ailment.
  - That harmful consequences may result from the technology not being used.
  - That encourages, or be likely to encourage, inappropriate or excessive use.
  - That contain any claims, statement or implication that it is infallible, unfailing, magical, miraculous or that it is a certain, guaranteed or sure cure.
  - That contains any claim, statement or implication that it is effective in all cases of a condition.
  - That contains any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects.

3. ADVERTISING AND PROMOTIONAL MATERIALS TO HCPS

When company representatives first introduce Medtech to an HCP, they should provide a copy (electronic or hard copy) of the latest instructions for use. On subsequent occasions, such information should be available on request. An advertisement or promotional material must not offer any personal incentive to a pharmacy assistant, clinic nurse or non-healthcare professional salesperson at retail level to recommend or supply Medtech.

4. CLAIM SUBSTANTIATION

All claims must be substantiated. Any information, claim or comparison must be capable of substantiation. No substantiation is required for claims in the instructions for use which have been approved by SAHPRA.

Upon any request, a company must, without delay, provide promotional material with accurate and relevant information relating to claims and comparisons about the products which the company markets. Substantiation for any information, claim or comparison must be provided without delay. Where a party fails to submit the requested information and/or legal opinion, the Code Independent Chairperson may assume that such party is not in a position to support its point of view.

When promotional material refers to (unpublished) data on file, the relevant part of this data must be provided without delay on request.

- If confidential data on file such as information relating to trade secrets, sensitive commercial information or information of a competitive nature is involved, the material may be given to the independent investigator as referred to in Part 2: Dealing with transgressions of the Code.

- Alternatively, the information may be requested to be shared on conditions acceptable to both parties. The independent investigator or person appointed will make an assessment as to whether the unpublished data in fact supports the statement(s) made in the promotional material.

5. LEGALITY

Where the alleged contravention of a law forms the only, or one of, the bases for a complaint, and the Independent Chairperson is unable to decide the complaint without resolving the question of whether or not a law has been contravened, the Independent Chairperson shall refer the complaint to the compliance panel, from which an appeal to the Final Appeal Committee will lie.

The compliance panel may call on the party or parties to such dispute to submit legal representations on the question of the alleged contravention to the compliance panel before deciding whether or not the law in question has been contravened. Nothing in this clause must be read as implying that the compliance panel may seek to enforce regulations or laws. This task falls on the relevant regulator. The compliance panel may only enforce the Code.

6. SCIENTIFIC INFORMATION

Any scientific information in an advertisement should be presented in a manner that is accurate, balanced and not misleading. Scientific terminology must be appropriate, clearly communicated, and able to be readily understood by the audience to whom it is directed. Publication of research results must identify the researcher and financial sponsor of the research. All references must be listed. Any statement made may be subject to scrutiny for its scientific validity, and independent experts may be called upon in the case of a complaint to verify such statement(s).

7. MARKET AND SCIENTIFIC RESEARCH

Market research and similar activities must not be disguised promotions, nor contain or lead to disparaging comments about competitors or their products. Such market research must be conducted with a primarily market research, scientific or educational purpose. Material relating to Medtech and its uses, whether or not it is promotional, and which is sponsored by a Member should clearly indicate by whom it has been sponsored.

All clinical trials must have a legitimate scientific purpose. Post-marketing surveillance studies, post authorisation studies, observational/non-interventional studies and similar activities must not be disguised promotions. All clinical trials must comply with South African legal requirements, South African Good Clinical Practice Guidelines (GCP) and research ethics approvals as required.

8. COMPARATIVE ADVERTISING

Comparative advertisements must be in alignment with South African law, be balanced and must not be misleading or likely to be misleading, either about the technology or classes of technology, with which it is compared. Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the technology, or classes of technology, with which comparison is made, are harmful or ineffectual.

A comparison in promotion of Medtech is only permitted if:

- It is not misleading or disparaging.
- It compares Medtech for the same needs or intended for the same purpose.
- One or more material, relevant and representative feature(s) which is/are capable of substantiation is/are compared. Points of comparison should be factual and reflect scientific evidence.
- No confusion is created between the Medtech advertised and that of a competitor or between the advertiser's trademarks, proprietary names, other distinguishing marks and those of a competitor.
- The trademarks, proprietary names, other distinguishing marks, Medtech, services, activities or circumstances of a competitor are not discredited or denigrated. No unfair advantage must be taken of the reputation of a brand, trademark, proprietary name or other distinguishing marks of another company.
- Trademarks/trade names or company names of another company may only be mentioned with written permission from the other company, unless doing so is permitted by intellectual property law and/or common law, as amended and developed from time to time.
- Medtech is not presented as imitations or replicas of goods bearing another company trademark or trade name.
- Hanging (open ended) comparisons are not allowed.

9. ENDORSEMENTS AND TESTIMONIALS BY HEALTHCARE PROFESSIONALS

Advertising and/or promotion shall not contain recommendation of a medical device by scientists or HCPs unless substantiated.

The use of HCPs for marketing, promotion, endorsements or testimonial must take place within the scope set by the professional codes applicable to such professionals.

The Health Professions Council of South Africa Advertising Rule 3.3 does not allow HPCs to Advertise, endorse or encourage the use of any medical device in a manner that unfairly promotes the practice of a particular HCP/HCO for the purpose of financial gain or other valuable consideration. In this instance "endorse" means any action whereby a person or body attaches approval to or sanctions any medical device with a view to encouraging or promoting the preferential use or preferential sale thereof for the purpose of financial gain or other material consideration.

The name or photograph or film, video, television/ radio Advertisement or any other reproduction of an HCP 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. 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.

10. THE USE OF NON-PROMOTIONAL MATERIAL

Material issued by companies that relates to Medtech, but which is not intended as promotional material for those technologies per se, for example, corporate advertising, press releases, market research material, financial information to inform shareholders or the stock exchange should be examined to ensure that it does not contravene relevant statutory requirements.

Provision of reprints and the use of quotations

Utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

Reprints of journal articles

Reprints of articles in journals must not be provided unsolicited to any HCP unless the articles are on-label and have been published in a peer-reviewed publication in line with good principles of scientific review and publication. If a non-peer-reviewed article is requested by an HCP, a copy may be provided on written request or as per requirements for scientific or medical information.

Scientific quotations

Quotations from medical and scientific literature must accurately reflect the intention and meaning of the author(s). If unpublished, personal communications shall not be used unless the company, organisation or individual is able to supply written substantiation based on scientific data upon request.

Question & answer

QUESTION: What about payment of patients (influencers) for testimonials/awareness around proper use of Medtech?

ANSWER: It would be considered inappropriate for paying patients (influencers) using a Member Companies' products to provide awareness of the proper use of Medtech, recommend or otherwise 'influence' others with regard to the product. Please consider relevant medical device regulations pertaining to use of the device. If it is a consumer awareness event at which individuals using the products were speaking about/sharing their experiences with the attendees, the company may consider reimbursing their travel and giving them a modest 'thank you' in line with the Code's requirements relating to Promotional items and items of medical utility. One should be mindful of the Code clauses regarding 'no gifts' and sampling.

Public quotations

Quotations taken from public broadcasts, for example radio, television or the Internet, and from private occasions, such as medical conferences or symposia relating to Medtech, must not be used without the formal permission of the speaker unless there is a published record of the proceedings, and this is accurately given as a reference.

Reference to healthcare establishments

Advertising and/or promotion shall not refer to a 'college', 'hospital', 'institute', 'laboratory' or similar establishment, unless the establishment genuinely exists and has approved the endorsement or use of the name in the promotional material or Advertisement.

11. ARTWORK AND VISUAL REPRESENTATIONS

All artwork, including illustrations, graphs, tables, logos and trade dress must conform to the principles of the Code.

Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal and must not be included unless they are relevant to the claims or comparisons being made.

Advertising shall not use misleading, alarming, or improper visuals to represent changes in the human body.

Visuals may not imply that a Medtech can be used to treat more serious forms of disease than the registration of the product would allow.

Advertisements should not be flippant or use inappropriate imagery or imagery out of context. Advertisers are encouraged to convey the message that Medtech should be treated with respect and may not be suitable for some people.

Promotional material must include either the date or a code number identifying the version on which the promotional material was drawn up or last revised.

Postcards, other exposed mailings or material, envelopes or wrappers shall not carry matter which may be regarded as Advertising or promotion material to the general public, and which is contrary to relevant legislation.

12. JOURNAL ADVERTISING

All pages of a journal advertisement must ensure content is not false or misleading when each page is read in isolation.

An advertisement taking the form of a loose insert in a journal may not be of larger than the page size of the journal itself, printed on one or both sides.

Advertisements in journals must not resemble editorial matter unless clearly identified as advertorial or as a sponsored feature.

13. ELECTRONIC/DIGITAL MEDIA

Promotion of Medtech via digital or electronic media must comply with all aspects of the Code.

Use of electronic/digital communications

The telephone, mobile phone, SMS, email, mobile messaging, social media, facsimile machines or any form of electronic communications as defined in the Electronic Communications and Transactions Act, No 25 of 2002, as amended from time to time, must not be used for promotional purposes, except where upon making the first contact, identifying information of the sender or the person on whose behalf the communication has been sent is provided and the option to opt out is given and the decision is subsequently respected. The identifying information option to opt out should also be provided on all subsequent communications, even if the addressee has not opted out after the first contact. This provision shall be subject to all national legislation in force from time to time, to the extent applicable.

Internet links

In the case of an advertisement included as part of independently produced information on the internet, the statement should be in the form of a direct link between the first page of the advertisement and the minimum information as required by the Medicines and Related Substance Act: Regulations relating to medical devices and in vitro diagnostic medical devices.

Audio-visual material

Audio-visual material such as films, video recordings, sound bites, interactive data systems and such like:

- The minimum information required by the South African legislative frameworks must be provided either by way of a document that is made available to all persons to whom the material is shown or sent or by inclusion on the audio-visual recording or in the interactive data system itself.
- When the minimum information is included in an interactive data system, instructions for accessing it must be clearly displayed.
- If the material consists of sound only, the minimum information may be provided by the way of a document that is made available to all persons to whom the material is played or sent.

DEALING WITH TRANSGRESSIONS OF THE CODE

PART 2

DEALING WITH TRANSGRESSIONS OF THE CODE

This process applies to dealing with transgressions of this Code and complaints received in relation thereto.

1. GENERAL PRINCIPLES

Disputes in relation to Code transgressions are best resolved amicably and efficiently by conciliation, mediation, or mutual settlement. The overall goal of dealing with Code transgressions is to ensure a complaint-handling process that withstands robust scrutiny, enjoys public confidence and Member support, and which is effective, lawful and efficient and not a cost burden for SAMED. In the event of a conflict between the provisions of this Code with any other code that the Member subscribes to, the provisions of the more stringent code should be applied.

A complaint handling procedure should not be initiated or should be suspended in case of a formal investigation by criminal law enforcement authorities or commencement of criminal proceedings or a proceeding at ordinary courts with respect to the same or a substantially similar subject matter. It is the responsibility of the parties to notify the Independent Chairperson and copy the SAMED Executive Officer of such proceedings.

2. WHO CAN COMPLAIN?

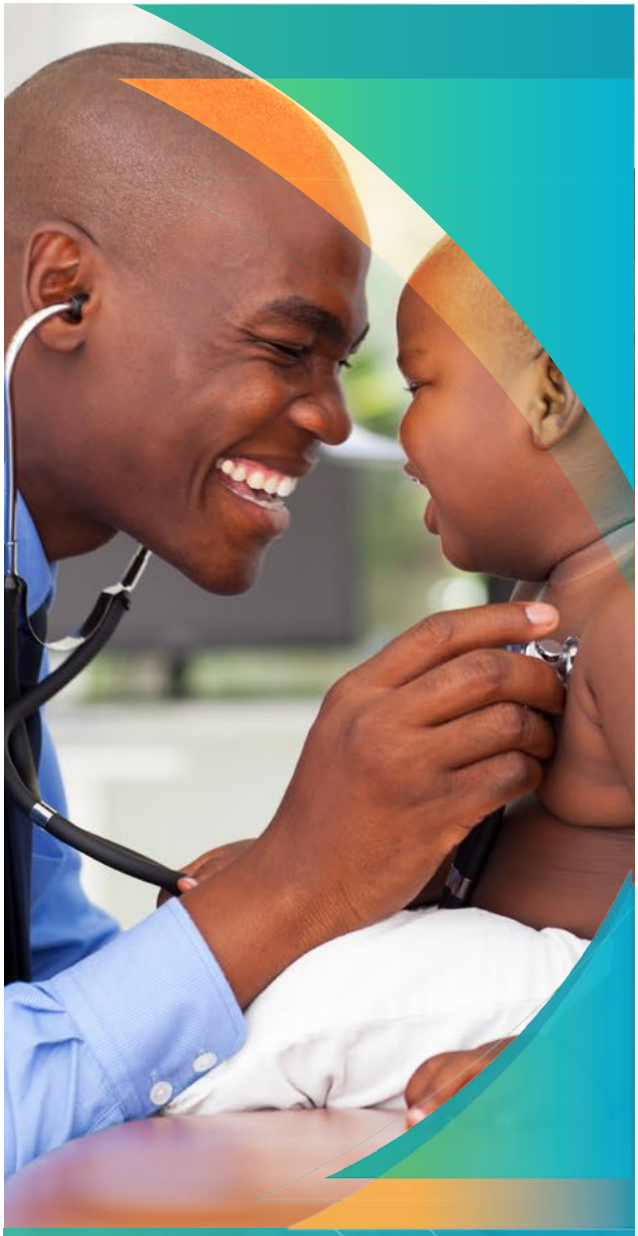
Any person, including but not limited to, a Member Company, Member Company employee, signatory to the Code, member of the public, HCP, HCO or regulatory body may report a transgression either via a formal written complaint or via a whistleblowing hotline. Such complaints may be lodged anonymously.

In the event that the SAMED Secretariat becomes aware of information or facts which could involve a breach of the Code by a Member Company, the SAMED Secretariat may itself file a complaint.

Prior to launching a formal or whistleblowing complaint against a Member Company, the complainant is encouraged to first attempt a genuine direct conciliation or mutual settlement in order to reach an amicable solution.

Nevertheless, if a complainant believes that such direct conciliation or mutual settlement is not suitable or if such is unsuccessful then s/he may lodge a complaint either via the formal written process or via the whistleblowing mechanism. Members must inform SAMED of the outcome of complaints resolved directly between Members.

SAMED
advancing patient care through MedTech



3. FORMAL WRITTEN COMPLAINTS

A formal complaint may be lodged using the prescribed forms sent directly to the Independent Chairperson at the following email address: michael@elawnet.co.za and copy michellet@elawnet.co.za; and secretariat@samed.org.za.

Medical Technology Code of Ethical Marketing and Business Practice Transgression Report Form
Any person, including but not limited to, a SAMED member, signatory to the Code, member of the public, healthcare professional, healthcare organisation or regulatory body may report a transgression.

Reports by a Member and/or signatory to the Code should, where possible, be initiated and administrated by the Compliance Officer and/or CEO of the Company.

- Send hotline reports to: samed@tip-offs.com
- Send formal complaints to: michael@elawnet.co.za; copy michellet@elawnet.co.za and secretariat@samed.org.za.

Date:			
1. Complainant (do not complete if you wish to remain anonymous):			
Name and surname:			
Job title:			
Email:			
Mobile number:		Work number:	
Name of company/organisation:			
Name of company CEO:			
Field of business of the complainant (manufacturer, distributor, doctor, private hospital, member of the public etc)			
2. Details of the individual/company that is the subject of the alleged transgression (the respondent):			
Name and surname:			
Job title:			
Name of company/organisation:			
Contact details of this person (if available):			
Email:			
Mobile number:		Work number:	
3. Field in which transgression has occurred (eg insulin pumps, orthopaedic implants, wound care etc):			
4. Clause(s) within the Medical Technology Code, details and circumstances relating to the alleged transgression. Succinctly describe the essence of the transgression in the table below. Use one line for each transgression. Where available, list and attach any proof/evidence substantiating the reported transgression:			
Indicate Code Clause (s)	Describe each alleged transgression (what, how, where)		Date/period of the alleged transgression	Indicate proof/evidence substantiating the reported transgression
	What How Where			
	What How Where			
	What How Where			
5. Statement of relief sought.				

Question & answer

QUESTION: What compulsory information must be provided when lodging a complaint in terms of a transgression of the Code?

ANSWER: The following information must be provided when lodging a complaint against the Code:

- Signature, name and contact details of complainant (including a named person who will represent the complainant and who could provide further information, if requested). No anonymous complaints will be entertained when submitting a formal complaint to SAMED.
- The company that employs the complainant and, if applicable, the representative body of the complainant.
- The complainant's field of business (manufacturer, distributor, doctor, private hospital etc).
- The name of the alleged infringing company (the respondent).
- The facts of the alleged transgression (what, when, where, how).
- The clauses of the Code that the respondent has allegedly infringed.
- Any supporting evidence in the possession of the complainant, which substantiates his or her allegations regarding the alleged transgression.
- A statement of relief sought.

QUESTION: Why is it important to add this information, when complaining either via a formal written complaint or via the whistleblowing hotline?

ANSWER: The Independent Chair is only able to review the provided information to make an initial determination on the alleged transgression. The more information that is provided, the more likely the Independent Chair will be able to investigate and potentially adjudicate against the reported company. Failure to provide sufficient information will hamper investigation efforts and may lead to the case being closed due to a lack of evidence.

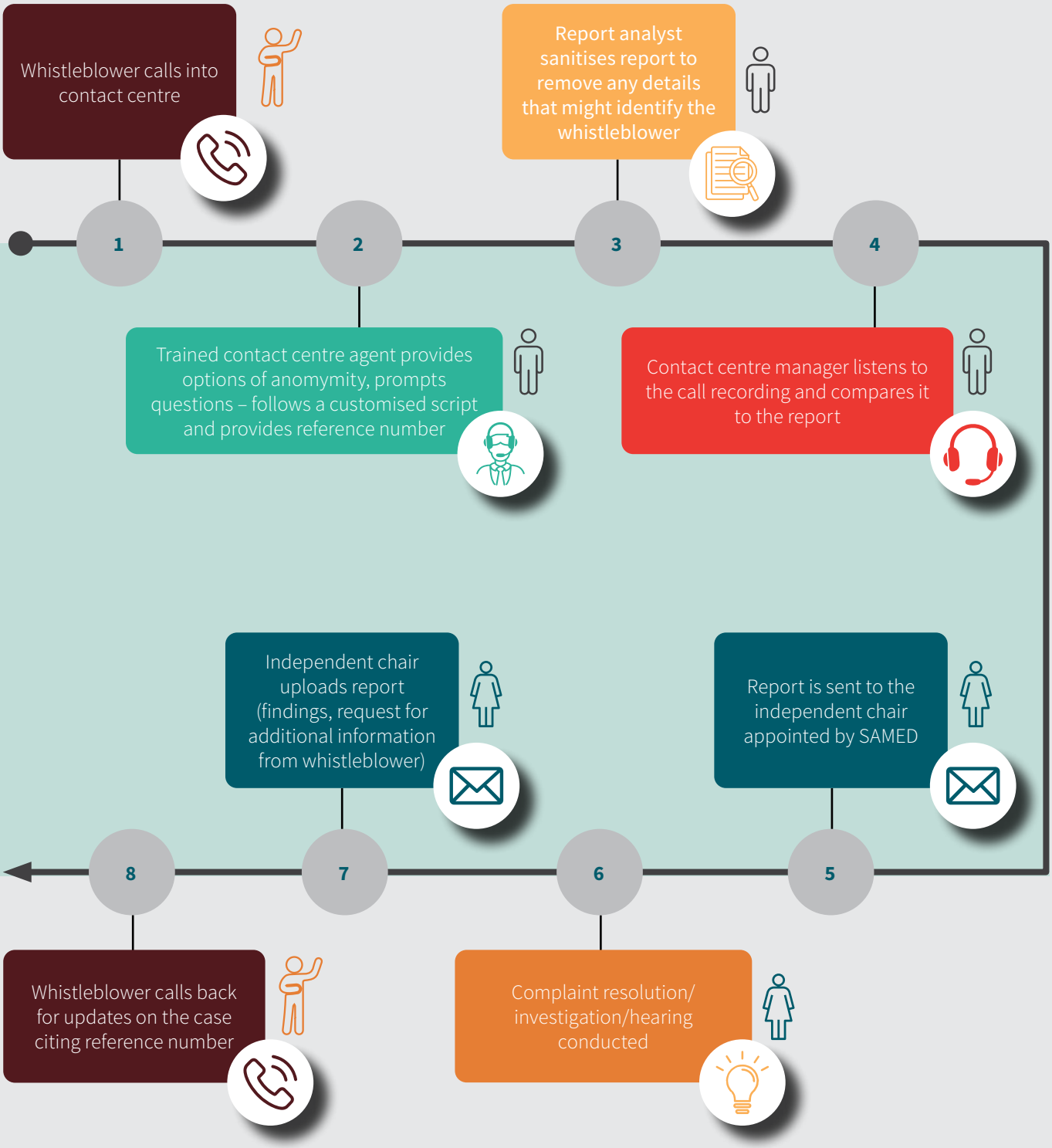
4. COMPLAINTS THAT ARE REPORTED THROUGH THE CODE WHISTLEBLOWING HOTLINE

Any person may lodge a complaint against a Member Company through the Medical Technology Code whistleblowing hotline. Such complaints may be lodged anonymously, as explained by the following instruction.

How to use the Medical Technology Code Whistleblowing Hotline

You have three options when you call the Medical Technology Code hotline:

1. **FULL ANONYMITY:** You don't need to disclose any personal information to the call centre agent. You will receive a reference number so you can follow up or provide additional information about the case.
2. **PARTIAL ANONYMITY:** You can choose to disclose your name and contact details to Deloitte only.
3. **FULL DISCLOSURE:** You can disclose any relevant details, and these will be included in the report.
   - Keep your reference number in a safe place as you would be required to quote this number to obtain feedback or when you call again to provide further information or for any other reason.
   - Complainants who choose to be fully anonymous are urged to call back within 10 days in case the Independent Chairperson reviewing the complaint requires more information to progress the complaint.
   - If further information is required to be furnished by the complainant, the complainant is required to furnish such information within five days. Should no further information be provided, as requested, the complaint will be dismissed without investigation.
   - The complainant should contact the hotline 21 days after lodging the complaint to obtain feedback.



DON'T SUPPORT IT. REPORT IT.

The Independent Chairperson has the powers to deal with such complaint as are set out under Part 2: Dealing with transgressions of the Code Clause 7: Independent Chairperson subject to the complainant remaining anonymous.

If at any stage of the proceedings it is no longer possible or fair to continue to conduct the proceedings while the complainant remains anonymous, the Independent Chairperson will communicate this to the whistle-blower and request him/her whether s/he consents to his identity being revealed so that the complaint may be dealt with to completion.

If the complainant elects not to disclose his/her identity, the Independent Chairperson will decide on further steps to be taken, including appointing an independent investigator from SAMED's panel of independent investigators and/or referring the complaint or the independent investigator's report to another authority, including but not limited to: SAHPRA, HPCSA, Pharmacy Council, the Hospital Association of South Africa, the Council for Medical Schemes, the Consumer Commissioner, the National Department of Health, the South African Police Service, the National Prosecuting Authority (NPA) etc.

Question & answer

QUESTION: How will a whistle-blower know the outcome of their complaint?

ANSWER: This is dependent on the type of anonymity that the whistleblower selected. Those who are not anonymous or have selected partial anonymity (ie the independent whistleblowing hotline team has their details, but not SAMED) will be contacted and updated by the Deloitte team as per the Independent Chair reports. A whistle-blower who chooses to be completely anonymous will need to call back with their reference within 10 days to receive an update.

QUESTION: What information will I get from the hotline in order to progress a complaint?

ANSWER: The call centre agent will provide you with a reference for your complaint. You will need to call the hotline and check on progress using this reference should you not have provided information to Deloitte to contact you.

Question & answer

QUESTION: If I complain via the whistleblowing hotline, am I truly anonymous?

ANSWER: Your level of anonymity is completely in your control. If you opt to be completely anonymous, you will not be asked to provide any personal details to the call centre agent. Furthermore, the call centre supervisor will ensure that all identifying information which may have been captured during the call is deidentified or removed in order to protect the anonymity of the whistleblower.

QUESTION: Do I have to submit a complaint form when I use the hotline?

ANSWER: If you are submitting a complaint (whether anonymous or not) via the hotline email address (samed@tip-offs.com), then yes, the form is a requirement as it provides the necessary details for SAMED to process a complaint. If you want to remain anonymous, please do not complete your personal details and you can create a specific email account via a free platform in order to send this in. The complaint form is also useful for those who are calling the hotline, as it outlines the information that you will need to provide to the call centre agent during the call. You will, however, not be required to submit the form.

5. COMPLAINTS IN RELATION TO WHICH SAMED DOES NOT HAVE JURISDICTION

If SAMED receives a complaint over which it does not have jurisdiction because the respondent is not a Member of SAMED, it may nonetheless appoint an independent investigator to investigate it further and/or refer the complaint or the report of the independent investigator to another authority, including SAHPRA, HPCSA, the Nursing Council, Pharmacy Council, the Hospital Association of South Africa, the Council for Medical Schemes, the Consumer Commissioner, the Department of Health, SAPS, the NPA etc.

6. CRIMINAL CONDUCT

If the Independent Chairperson is of the view that the complaint raises conduct that may constitute, involve or give rise to a crime, then in addition to dealing with the complaint in accordance with the provisions above, the Independent Chairperson will also refer the matter to SAPS and/or the NPA (as she/he deems appropriate).

Potentially criminal conduct is any conduct that involves harm to human lives or safety, which is intentional or negligent. Intentional conduct includes conduct where the potential harm to human life and safety is foreseen but the alleged wrongdoer nonetheless persists with the conduct.

7. INDEPENDENT CHAIRPERSON

Upon receipt of a complaint, the Independent Chairperson will, within 14 days, issue directions for the further resolution of the complaint. Her/his powers for resolving complaints are as follows:

i. To direct the respondent to file a written answer to the complaint and the complainant to reply thereto within a specified timeframe.

ii. To direct that the matter be submitted to conciliation or mediation by a recognised organisation.

iii. To direct the parties to attempt to settle the matter within a specified time period.

iv. To direct that a hearing is to be held before her/him in order to hear and determine the complaint. To give directions for the manner in which the hearing is to be conducted.

v. To direct that a hearing be held before a compliance panel constituted by her/him. To appoint two or more other persons from SAMED's list of suitably qualified experts to a compliance panel over which she/he will preside to hear and determine the complaint received and to give directions for the manner in which the hearing is to be conducted.

vi. In relation to a hearing conducted in terms of either clauses 7(iv) or 7(v) in this section, the Independent Chairperson or a member of a panel constituted under clause 7(v) who s/he delegates to do so:

- May, on good cause shown, by order, direct a specified person to appear before the panel at a time and place specified in order to give evidence, be questioned or to produce any document.
- The Independent Chairperson must administer an oath to or accept an affirmation from any person called to give evidence.

vii. In relation to a hearing conducted under clause 7(v) above, the opinion of the majority of the compliance panellists prevails, but if they are equally divided in opinion, the opinion of the panellist residing over the compliance panel shall prevail.

viii. If the complaint does not raise any material disputes of fact, the Independent Chairperson may direct that it is to be determined on the papers and to direct that the parties are to make oral submissions in relation to the complaint at a specified time and place.

ix. If in relation to a matter that is dealt with under clause 7(viii) above, material disputes of fact do arise, the Independent Chairperson may exercise the powers that are set out under clause 7(vi) above, or direct that the matter is to proceed to a hearing under either clause 7(iv) or 7(v) above.

x. In relation to a matter that is to be dealt with under clauses 7(iv) or 7(v) or 7(ix) above, to direct that a pre-hearing is to be held with the parties or between the parties to determine the manner in which the proceedings are to be conducted and/or to determine any interlocutory matters that have arisen between the parties.

xi. Prior to a pre-hearing that is to be held in terms of clause 7(x), the Independent Chairperson may send to the parties an agenda of issues that are to be covered at the pre-hearing meeting.

xii. The Independent Chairperson may, in the alternative to conducting a pre-hearing meeting in terms of clause 7(x) above, direct the parties to produce by agreement a written pre-hearing minute and to direct which issues are to be dealt with in such minute.

8. RULING

Within 30 days of the conclusions of proceedings in terms of clauses 7(iv) – 7(ix) above, the Independent Chairperson must issue a ruling (written findings) in relation to the complaint and reasons for such findings.

9. URGENT MATTERS

On application by the complainant or at the discretion of the Independent Chairperson, a matter may be dealt with as one of urgency, if the complainant alleges that the matter impacts on, or has the potential to impact on, human health or safety or if the Independent Chairperson is of the view that it is such a matter.

The Independent Chairperson will have the powers that are set out under Part 2: Dealing with transgressions of the Code, Clause 7: Independent Chairperson and to direct the timeframes within which the matter is to be heard and resolved, as warranted by the urgency of the situation.

10. COSTS

Each party will pay its own costs. However, such costs may be claimed from the other party subject to any costs order as directed by the Independent Chairperson/a compliance panel constituted to hear the complaint.

Member Companies whose employees are required to participate in complaint proceedings, for example as witnesses or as members of a compliance panel, will pay the costs of such, for example time off work and to travel to the hearing.

The Independent Chairperson and the members of a compliance panel constituted by her/him (provided they are not Member Company employees) will be paid by SAMED at a fee negotiated between SAMED and such persons.

If an independent investigator is tasked in relation to complaint proceedings, he or she will be paid by SAMED at a fee negotiated between SAMED and such person.

If a party has been found to have contravened the Code, such party may be liable for all legal costs and disbursements including but not limited to the costs of obtaining expert opinion.

Payment shall be made within 30 days of demand.

11. APPEAL

The SAMED Board will appoint an appeal chairperson who will be a legally qualified expert to hear the appeal.

Both parties have the right to appeal the Chairperson's ruling within 21 days of it being issued.

The appeal chairperson may, at their own discretion, direct that a hearing be held before an appeals panel constituted by her/him from SAMED's list of suitably qualified experts, over which s/he will preside to hear and determine the appeal with her/him.

Should either party wish to lodge an appeal they would need to lodge an appeal fee to be determined by the SAMED Board from time to time, a portion of which may be refundable in the event that the appeal is successful.

Note: Fee to lodge an appeal is R40 000.00 of which R10 000.00 is a non-refundable payment for administrative costs. In the event that they are successful in the appeal, SAMED may refund up to R30 000.00 to the appellant, at the discretion of SAMED, alternatively at the discretion of the appeal chairperson or appeal panel, as the case may be.

The notice of appeal, setting out the grounds of the appeal is to be submitted to the appeal chairperson at the following email address: secretariat@samed.org.za.

The appeal chairperson will give direction for the conduct of the appeal, including the parties' right to submit written and oral argument and the deadlines for such.

The appeal chairperson must send the findings to the parties, at the email address that they have provided to the Independent Chairperson for such purpose. The appeal chairperson will also provide a copy of the findings to SAMED's Executive Officer.

12. SANCTION

If the Independent Chairperson, or a compliance panel established in terms of clause 7(v) above, upholds the complaint, s/he has the power to issue a sanction that is appropriate in the circumstances and in accordance with the sanctioning guidelines in terms of Part 2: Dealing with transgressions of the Code, Clause 12.1: Sanctioning guidelines.

The following factors are relevant in determining an appropriate sanction:

- The nature and extent of the breach, including its impact on the market and the reputation of the industry.
- Whether the breach should have been evident to the company.

- The length of time over which the breach took place.
- The number and type of alleged breach/es.
- Previous and/or similar breaches of the Code.
- The impact of the breach on patients, providers and/or HCPs.
- The impact of the breach on competitors, patients, HCPs and/or the provision of healthcare services.
- The respondent's failure to implement previously imposed sanctions and/or undertakings.
- The circumstances in which the breach occurred.
- The potential costs to be incurred by a company in order to take corrective action. The Independent Chairperson or compliance panel will consider the overall cost of the sanctions, for example the cost of issuing a corrective letter in combination with a fine.

The Independent Chairperson/compliance panel will set out the reasons for imposing a sanction in the ruling. The Independent Chairperson/compliance panel must send the findings to the parties, at the email addresses that they have provided for such purpose. The Independent Chairperson/compliance panel will also provide a copy of the findings to SAMED's Executive Officer.

12.1 Sanctioning guidelines

The potential sanctions available to the Independent Chair and compliance panel must be proportionate to the transgression, act as a deterrent and be commensurate with the seriousness and/or persistence of the breach.

Such sanctions may range from:

- A written reprimand.
- The requirement that the offender takes steps to conform with the Code. Specific steps may be specified in whole or in part and may be subject to time limits.
- The inspection and audit by a third-party, at the offender's cost and expense, of the offender's relevant compliance systems.
- The requirement that the offender recovers items given in connection with the promotion of products and/or to issue a Customer communication regarding future corrective practice.
- The requirement that the offender publishes or otherwise disseminates corrective or clarificatory information or statements.
- The prohibition against offending company representative(s) standing for elected office within the institutions of SAMED.
- Suspension with specific time limit and conditions of reinstitution of SAMED membership.
- Expulsion from membership of SAMED.
- Publication of any decisions or sanctions imposed upon the offender.

Notwithstanding the foregoing, the Independent Chair shall ensure that any final decision taken in an individual case shall be rendered in writing, detailing the reasons for reaching this decision and signed by the members of the respective panel. At the minimum, copies of such decisions shall be made available to the parties of a proceeding.

The Independent Chair shall make available to the SAMED Board summaries in English of the main facts and conclusions of all decisions taken and if relevant, sanctions applied, pertaining to all complaints received (including cases resulting in the finding of a breach as well as those where no breach is found to have occurred). The SAMED Board, at its discretion, will publish summaries of cases on the SAMED website and make these known to SAMED members and other relevant stakeholders.

The following table provides guidance on the possible types of sanction that might be applied by the Independent Chairperson or the compliance panel or the appeal chairperson or the appeal panel, as the case may be, at their discretion.

	Expanded definition	Possible corrective action and/or public disclosure	Fine	Timelines
Breach classification				
Minor	No safety implications for patients' wellbeing. No effect on how HCPs will use the product.	Immediate suspension of activity. Company to issue a corrective statement, as determined by compliance panel, including target audience. Written reprimand to company by SAMED. Notify HCP of breach, if relevant. A monetary fine as determined by the chairperson or the compliance panel.	R10 000 to R50 000	30 working days
Moderate	No safety implications to patients' wellbeing. May have effect on how HCPs will use product.	Immediate suspension of activity. Company to issue a corrective statement, as determined by compliance panel, including target audience. Written reprimand to company by SAMED. Notify HCP of breach, if relevant.	R100 000 to R200 000	30 working days
Serious/ severe	Will have safety implications to patients' wellbeing. Will have effect on how HCPs will use product. Commercial impact on relevant market. Activities that bring disrepute to industry or reduce confidence in the industry.	Immediate suspension of activity. Written reprimand to company by SAMED. Company to issue a corrective letter to healthcare professionals/public, as determined by compliance panel.	R200 000 to R300 000	30 working Days

	Expanded definition	Possible corrective action and/or public disclosure	Fine	Timelines
Additional sanctions/fines				
Fines not paid	When a monetary fine is not paid within the required time period from receipt of the decisions and the reasons for the decisions of the compliance panel.		Further fine of R50 000	60 working days
Corrective action not implemented	Where corrective action has not been actioned within required timelines. Any other sanction including orders as to cost and fees.	The matter will be raised by SAMED with the subject company and may be taken to the compliance panel for consideration.	Further fine of R100 000	60 working days
Multiple breaches	Where SAMED, through monitoring, finds a number of breaches of the Code by a company, SAMED will usually consider the aggregate of the breaches to determine whether a sanction should be imposed.	SAMED may publish the decision in a national newspaper along with the name of the offending company. Publication of the infraction on SAMED website. Inform SAHPRA of transgression and recommend cancellation of registration of product/s involved. SAMED may impose a sanction in respect of each breach of the Code but may choose to impose an additional financial sanction.	First: R10 000 + original fine Second: R15 000 + original fine Third: R25 000 + original fine to a maximum of R200 000	60 working days
Frivolous, vexatious or malicious complaints	Does not comply with requirement of complaint as defined in Code.	SAMED informs complainant in writing.	R10 000	60 working days

12.2 Guidelines in relation to specific sanctions

In the case of a corrective letter, the Independent Chairperson will specify to whom the letter must be sent. This will reflect the audience that may have been involved/received the material found in breach of the Code. A copy of the distributed corrective letter (on company letterhead bearing the signature of the company Chief Executive Officer or Code Compliance Officer) should be provided to SAMED for the file records.

The number, format, size, wording, mode of publication, prominence, timing (including duration of publication) and method of distribution of corrective statements/letters must be approved by the Independent Chairperson.

13. REPOSITORY AND RECORD OF COMPLAINTS AND OUTCOME OF COMPLAINTS

The SAMED office will act as a repository of and keep records of Code complaints and outcomes to establish a database of historical cases.

14. POWERS OF SAMED

SAMED may cancel or refuse membership to any company that:

- Is unwilling to commit to the standards and values reflected in the Code.
- Fails to conduct its affairs in a manner consistent with the Code.

ADDENDA

ADDENDUM 1 GUIDANCE PERTAINING TO THE MANAGEMENT OF INDIRECT SUPPORT AND ASSOCIATED EDUCATIONAL GRANTS

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

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This document has been created by SAMED to assist both its Member Companies and third-party educational grant recipients in the implementation of indirect sponsorships and the management of associated Educational Grants.

a. Criteria for companies' support for third-party organised educational conferences

Effective 1 January 2018, Member Companies may no longer directly pay the costs for individual HCPs to attend third-party organised educational conferences. Instead, companies may support such Events through Educational Grants made to an appropriate third party that supports the training and education of HCPs and must heed the following criteria aligned with the Code, including but not limited to Part 1: Interactions with HCPs, Chapter 1: General criteria for Events:

- The Event must be primarily dedicated to objective scientific and educational activities.
- The conference organiser or grant recipient must be able to show the donor that the grant will only be used for a genuine educational purpose. For example, the grant may not be used to defray costs related to entertainment, social activities or partners accompanying HCPs.
- Industry should not have any control or responsibility for the selection of programme content, faculty, educational methods and materials of the TPOE.
- Only the conference organiser or grant recipient (if different) can select the individual HCPs who will receive support to attend the educational conference (see Guide: Third-party selection of grant recipients).
- The venue must be conducive to the educational programme.
- Member Companies cannot provide Educational Grants as a quid pro quo or with the intention to influence any decision to purchase, order, recommend or market a product.
- Requests for Educational Grants should reflect the actual FMV costs of the intended educational activities.
- All support for third-party educational conferences should be appropriately documented.

Member Companies may establish procedures to manage Educational Grant requests. This could include:

- A centralised portal or point of contact through which an appropriate third-party submits its request for Educational Grant funding.

- Require that the applicant for the Educational Grant includes detailed information on the Event, agenda, content, venue, faculty, budgets, details of the conference organiser or grant recipient (qualification, history of requests, organisational structure etc).
- A company should undertake a due diligence vetting or screening process before paying the Educational Grant.
- Member companies are urged to establish an internal, independent review committee to evaluate potential Educational Grant support against objective criteria.
- Company agreements with conference organisers or grant recipients, if different, should contain standard provisions prohibiting the use of funds to support entertainment and recreation, requiring compliance with applicable laws or codes and requiring organisers to provide companies with fund usage details.

b. Guide: Vetting third-party grant recipients

Companies may vet third-party grant recipients be they (i) a third-party conference organiser or (ii) another appropriate third party (such as a training institution, hospital, medical or other professional association, educational foundation or similar entity that supports the training and education of HCPs to determine if supporting the recipient's request for Educational Grant funding would pose legal, compliance or reputational risks. Companies may request information similar to the criteria listed below. This list is not exhaustive, and companies may give greater weight to some criteria over others.

Examples of criteria and questions to ask:

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

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

c. Guide: Third-party selection of grant recipients

SAMED urges third-party grant recipients to heed the following in relation to selecting grant recipients:

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

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

- Field and years of experience.
- HCP's participation in the management of the professional association and promotion of the discipline of ... (FIELD OF EXPERTISE).
- Senior HCP that has promoted the discipline of ... (eg orthopaedics) and has rendered a service to ... (eg orthopaedics) for some time.
- Active members of the HCOs that have assisted in the management, the organisation and attended meetings on a regular basis.
- HCPs that have been actively involved in their own original research and presentations to promote the discipline of ....
- HCPs that have published peer reviewed articles or that have presented peer reviewed presentations at meetings.
- HCPs that have been regular speakers at meetings and that have been actively involved in the continued professional development in ... by other HCPs.
- HCPs that have presented at industry/association meetings.
- HCPs who share knowledge with other HCPs and should after sponsored meetings organise and present the knowledge gained at the sponsored meeting with other HCPs at ... organised regional or national meetings.
- Previous sponsorship should always be considered as an exclusion criteria for HCPs, to ensure that others also be considered for sponsorship.
- Full curricula vitae could assist in the allocation of sponsorship by assisting to determine the merit of certain members as well as identify interests of certain members to attend certain important meetings that could relate to their interest and expertise.
- Other factors such as the individual's gender, historically disadvantaged status, geographical location in terms of rural and inaccessible locations and young and developing practitioners.

To facilitate continual professional development of HCPs who do not belong to a professional association, SAMED urges all societies to advertise opportunities on their websites and allow non-members to apply.

d. Template: Educational Grant Agreement

This template may be used by a third-party grant recipient and a Member Company when entering into an Educational Grant agreement. Highlighted text: either fill with relevant information or choose from the available options.

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

BY AND BETWEEN

Name, a company incorporated under the laws of South Africa with a registered address as … (the "**Company**")

AND

Name, an organisation incorporated under the laws of South Africa with a registered address as … (the "**Grant Recipient**").

Together hereinafter referred as "**Parties**", or each individually as a "**Party**".

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

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

WHEREAS, Grant Recipient is an independent third-party, for example but not limited to: hospital/group purchasing organisation/clinic/laboratory/pharmacy/research institution/foundation/university/teaching institution/learned/professional society/professional conference organiser which submitted the Grant Request Application (**Annex 1**) to the company;

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

ARTICLE 1 – PURPOSE OF THE GRANT

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

1.2 The company has agreed the grant should be used in respect of the following (the "**Programme**"):
   a. Description and duration of programme, eg funding of a PhD position in the field of…, scholarship for participation in x of medical education programme, x number of HCPs to attend x conference etc.

1.3 The parties agree that each of the various components of the programme is for scientific and/or educational purposes only and will not promote any company's products or services, directly or indirectly.

1.4 The grant will not be used for:
   a. Direct or indirect promotion of company's medical products or services
   b. Support of off-label use of any product
   c. Payment by the grant recipient of exhibit or display fees for its promotion and services
   d. Support of charitable programmes
   e. Payment for organisational overheads such as purchase of capital equipment, software and non-medical staff training.

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

Initial

ARTICLE 2 – THE GRANT

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

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

Bank:

Account No.:

Bank code:

IBAN:

BIC:

ARTICLE 3 – ETHICS AND COMPLIANCE

3.1 The grant recipient shall ensure that all uses of grant funds:

a. Comply with the Medical Technology Code of Ethical Marketing and Business Practice (access at https://samed.org.za/medical-device-code-whistleblowing-hotline/) and all relevant local laws, regulations and other codes of conduct.

b. Comply with applicable disclosure requirements of the grant as well as any other obligation relating to any beneficiaries of grant funds to any professional body, institution or government agency that requires such disclosure.

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

ARTICLE 4 – INDEPENDENT SELECTION AND PROGRAMME

4.1 The company shall not have any involvement in any way in the selection of the HCPs who will benefit from the grant. For example, where the grant is provided for the purpose of supporting HCPs' attendance at third-party organised educational events, the grant recipient shall be solely responsible for the selection of participants. Where the grant recipient is the organiser of the third-party organised educational event, the grant recipient shall be solely responsible for (i) the programme content; (ii) the selection of podium speakers, moderators and/or chair, who present during a third-party organised educational event (the "Faculty"); and (iii) the payment of Faculty honoraria, if any. The company shall not have any detailed involvement in determining the content of the educational programme for selection of Faculty. If expressly requested to do so, the company may recommend speakers or comment on the programme.

4.2 The grant recipient has a fair and transparent selection process which is available on request by the company.

4.3 The company shall not have any influence on the list of attendees, speakers or subjects for the Event.

Initial

ARTICLE 5 – REVIEW AND VERIFICATION RIGHTS

5.1 Upon request of the company, the grant recipient shall provide to the company a report on the use of the grant and/or adequate documentation (eg copies of booking documents, copies of original tickets) verifying that the grant was used in accordance with the terms and conditions of this Agreement.

5.2 Subject to applicable laws and/or internal regulatory, tax or auditing obligations the company may have to abide by, the grant recipient agrees that the company may itself or through an independent third-party conduct *ad hoc* on-site reviews at any time in order to verify that the grant was used in accordance with the terms and conditions of this Agreement. Company's representative(s) conducting such reviews shall be given full access by the grant recipient to all information, premises and employees as required by the company for this purpose. The grant recipient shall comply with all reasonable requests, directions and monitoring requirements of the company and shall generally cooperate with and assist the company in such reviews. The company shall provide at least fourteen (14) days' notice to the grant recipient of any review under this Agreement that it plans to conduct.

5.3 If a grant recipient has received funds in excess of the costs incurred, the company may request that the grant recipient return its portion of excess funds.

ARTICLE 6 – REPRESENTATIONS AND WARRANTIES

6.1 The grant recipient represents and warrants that:

a. it is fully aware of all anti-bribery/anti-corruption laws in force in the jurisdiction of its place of establishment and adheres to them; and

b. it is familiar with the United States Foreign Corrupt Practices Act, UK Bribery Act or other relevant Act and without limiting the generality of the other provisions of this Agreement, the grant recipient agrees that it will not, and will ensure that its employees, directors, officers, agents or other persons acting on its behalf (the "Related Parties") do not make any payment or give anything of value, either directly or indirectly, to an official of any government or government agency for the purpose of influencing an act or decision of the official in his or her official capacity or inducing the official to use his or her influence to assist the grant recipient in obtaining or maintaining business or in obtaining or paying for favourable treatment or any other special concession; and

c. that it has not, in the past (i) used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity, or (ii) made any unlawful payment to government officials or government employees or to political parties or campaigns; and

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

ARTICLE 7 – TERMINATION

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

a. a material breach by the grant recipient is not remedied by the grant recipient within thirty (30) days after receipt of written notice of breach from the company. In that event, the grant recipient shall return immediately the balance of the grant remaining as of the effective date of termination along with a detailed account of the grant already spent; or

b. if applicable, the event under the programme is not approved via the Ethical Medtech Conference Vetting System. In that event, any unpaid grant funds will no longer be due, and the grant recipient shall refund the amounts that have already been paid by the company.

c. the event under the programme has been cancelled and/or significantly changed. In that event, any unpaid grant funds will no longer be due. In case the company already paid parts or the totality of the funds, the grant recipient shall refund such amounts.

d. the grant recipient failed to use the grant in accordance with this agreement. In that event, grant recipient will refund the entire grant to the company within seven days from receipt of notice from the company.

Initial

ARTICLE 8 – MISCELLANEOUS

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

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

8.3 The grant recipient will not assign, transfer, or otherwise dispose of any of its rights, duties, or obligations hereunder without the prior written consent of the company.

8.4 This Agreement shall be construed and interpreted in accordance with the laws of South Africa. Any dispute, if not amicably settled, shall be submitted to the courts of South Africa.

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

For and on behalf of the grant recipient	For and on behalf of the company
Insert name	Insert name
Date signed	Date signed

Question & answer

QUESTION: What is meant by a third-party organised educational event?

ANSWER: A third-party organised educational event refers to all activities targeted at fulfilling HCP medical education needs and that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Medtech Company.

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

ANSWER: Medtech Industry associations in many countries have implemented a prohibition on direct sponsorship in order to preserve and enhance the independence of HCPs' decision-making. These changes promote the highest standards of transparency around industry interactions with HCPs while addressing the clear need for training and education of HCPs in Medtech and therapies.

QUESTION: If Member Companies can no longer provide direct sponsorships to individual HCPs, how may they support the training and education of HCPs in Medtech and therapies?

ANSWER: Member Companies can:

- Continue to support individual HCPs to attend company-arranged educational events.
- Provide sponsorship to a relevant third-party organisation.
- Provide direct support for individual HCPs to attend third-party organised procedure/hands-on training.

QUESTION: What is 'third-party organised procedure/hands-on training?

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

QUESTION: Does the prohibition on direct support of HCPs apply to company organised educational events?

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

QUESTION: What type of events are affected by the prohibition of direct support to HCPs?

ANSWER: The change applies to third-party organised educational events. That is a conference or meeting that is of a medical, scientific and/or educational nature, intended to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare, and is organised by a third-party eg professional association, healthcare institution or by a bona fide medical or other professional education provider.

QUESTION: Can Member Companies continue to provide sponsorships to event organisers (eg to be the Gold sponsors of an event)?

ANSWER: Yes. However, all events supported by a company must comply with the requirements of the Code.

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

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

QUESTION: Many HCPs are used to directly requesting from Member Companies to support their attendance at third-party arranged educational events. What should a Member Company do if an HCP asks for support to attend such events?

ANSWER: Member Companies can direct the HCP to the HCOs/PCOs from which they can request a grant to support their attendance. The company must make it clear that while they may provide Educational Grants to these third-party entities, they have no role in deciding who receives a grant.

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

ANSWER: No. Because an HOD is too specific (refer to Guide: Third-party selection of grant recipients).

Question & answer

QUESTION: An HCP-owned clinic has submitted a request for a grant to support an unnamed employee to attend a third-party organised orthopaedic conference. The HCP owner is the only orthopaedic surgeon. Can this request be approved?

ANSWER: No. This would constitute direct sponsorship as there is no separation between the provider of the grant (Member Company) and the ultimate beneficiary (the HCP).

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

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

QUESTION: Can a Member Company's third-party intermediaries (eg consultants, distributors, sales agents, brokers and suppliers) directly support HCPs to attend third-party organised educational conferences?

ANSWER: No. The prohibition on direct support applies to third-party intermediaries including consultants, distributors, sales agents, brokers and suppliers.

QUESTION: A Member Company would like to provide a grant to an international conference organiser to enable the attendance of HCPs from South Africa to their annual conference. They want to ensure the grant is used to support HCPs who will most benefit from the event. Is it acceptable to provide selection criteria?

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

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

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

ADDENDUM 2 EXAMPLE TEMPLATE OF CONSULTING AGREEMENT

DISCLAIMER: *This template is a suggested guide for Medtech companies and HCPs in terms of an example consulting agreement and should not be construed as legal advice. Use of this document or any parts thereof shall be at the sole discretion and risk of the user parties. SAMED shall not be held liable for any loss or damage that may result from use of this document or any parts thereof.*

This Consulting Agreement (for ongoing services, hereinafter the "Agreement") is made by and between Company, with offices at_____(hereinafter the Company); and Dr XYZ (hereinafter the "**Consultant**"); Company and Consultant (collectively the "**Parties**").

ARTICLE 1: SCOPE OF SERVICES

1.1 Consultant shall use best efforts to:

- Provide services to the Company as set out in this Agreement and in any agreed work order;
- Provide the Company with such reports, specifications, drawings, models, and the like, as are expressly agreed upon or appropriate to the nature of the services to be performed hereunder; and
- Keep detailed and reviewable records of work performed with a breakdown of time spent thereon, and of those expenses which are eligible for reimbursement by the Company -and to make all such records available to the Company upon request.

1.2 The Company shall be entitled to place specific work orders in the context of this Agreement. The details of the services to be rendered will then be further discussed between the Parties and subsequently set out in the applicable work order, all in accordance with the procedure set out under Article 1.3 below.

1.3. Any and all work orders will be defined in accordance with the following procedure:

- The Company will provide the Consultant with a description of the envisaged project, specifying among other things and whenever applicable: the nature of the services to be provided, practical work arrangements, end-goals, status reporting methods, deliverables, completion dates.
- Consultant will submit an offer on the basis of the Company project description.
- If the Company accepts the offer submitted by Consultant, a work order will be entered into. An example of such a work order is attached hereto as Annex 1.
- The Company will issue a purchase order number for the work order.

Only after completion of all of the above steps will there be a full agreement between Parties with respect to the relevant work order.

1.4 All of the documents set forth in Article 1.3 above will form an integral part of this Agreement with respect to the relevant work order. In case of any inconsistencies or contradictions between these documents, the following order of descending precedence shall apply:

- the work order;
- the project description made by the Company;
- the present Agreement;
- the offer made by Consultant.

1.5 An affiliate of the Company can also execute one or more work orders for the Consultant's services relating to this Agreement and, for the purposes of such work order(s), references in this Agreement to the Company shall be deemed to mean such affiliate and only such affiliate shall have the rights attributable to the Company under such work order(s) or under this Agreement as it applies to such work order(s). In order to fall under the terms and conditions of this Agreement, such a work order needs to (i) clearly refer to this Agreement and (ii) be executed by an authorised representative of the affiliate of the Company and by the Consultant. Each such properly executed work order shall be deemed, upon its full execution, to be incorporated into this Agreement.

For the purpose hereof, "affiliate" means, with respect to a given company, any company which directly or indirectly owns or controls at least fifty per cent (50 %) of the voting stock of such given company, or any other company at least fifty per cent (50 %) of whose voting stock is directly or indirectly owned or controlled by such owning or controlling company or by the given company.

ARTICLE 2: COMPENSATION

2.1 In consideration of the Consultant performing the services as set forth in Annex 1, the Company AFFILIATE or its appointed agent shall pay to the Consultant, within X days of the activity date. The Company AFFILIATE or its appointed agent shall pay to the Consultant, upon receipt of the invoice, a service fee in the net amount as specified in Annex 1. Additionally, the Company AFFILIATE or its appointed agent shall reimburse the Consultant for any reasonable and documented out-of-pocket expenses incurred by Consultant in connection with the contracted consulting service, provided that such out of pocket expenses are consistent with the applicable reimbursement policy of the Company which will be made available to the Consultant. Payments shall be made by bank transfer and only to a bank account held in the name of Consultant in her/his country of residence.

All travel arrangements for air, lodging and car rental will be directly organised by the Company AFFILIATE in accordance with the applicable the Company travel policy. Invoices should, as a minimum requirement, contain the following items: (a) full name and address of party issuing the invoice; (b) where applicable, tax number of party issuing the invoice; (c) full name and address of the Company or its appointed agent; (d) place and date of invoice; (e) brief description of services invoiced with date of service rendered; and (f) where value added tax (VAT) is applicable, statement of net amounts invoiced, VAT amount and gross amounts. The Company will inform Consultant in case the invoice needs to be addressed to its appointed agent instead of to the Company AFFILIATE.

Service fees (in local currency)		
Per hour	**Per half day (4 hours)**	**Per full day (8 hours)**
R	Consulting Preparation Total per half day	Consulting Preparation Total per full day
For a maximum of X days per annum (inclusive of preparation time, as indicated above)		

The parties will ensure compliance with all tax legislature, eg PAYE, VAT, etc.

2.2 Where the service provided pursuant to Article 1 of this Agreement is subject to value added tax (VAT), the above net amount (Article 2.1 and Annex 1) shall be grossed up to include applicable VAT, provided however, that the invoice must properly state the VAT amount due. Consultant shall be responsible for proper treatment and declaration of direct taxes with regard to invoiced and paid amounts.

2.3 The Parties acknowledge and agree that the above compensation represents the fair market value for all services related to the contracted consulting service, has not been determined in a manner that takes into account the volume or value of any business otherwise generated between the Company and Consultant, and shall not obligate Consultant to purchase, use, recommend or arrange for the use of any product of the Company or its affiliates.

To facilitate all payments in respect of this Contract please provide the following bank details:

Account Name: _____

Account Number: _____

Bank Name: _____

Bank Address: _____

IBAN Number: _____

SWIFT Code: _____

ARTICLE 3: TERM AND TERMINATION

3.1 This Agreement shall commence on date and, unless sooner terminated as provided hereunder, shall continue in full force until date.

3.2 This Agreement can be renewed but shall require the express consent, and where applicable third-party approval, of the Parties as to conditions and duration of extension.

3.3 In the event that a Party materially fails to fulfil or breaches any material term or condition of this Agreement, and in case such failure or breach should not be remedied by the Party concerned within ninety (90) days of written notice of such breach given by another Party, said other Party may terminate this Agreement with a further ten (10) days' written notice.

ARTICLE 4: CONFIDENTIALITY/RETURN OF DOCUMENTS

4.1 In view of Consultant rendering her/his services, the Company may provide Consultant with information concerning the Company including, without limitation, information regarding existing or contemplated the Company products, processes, techniques or know-how, that is confidential or proprietary and the disclosure of which would cause irreparable injury to the Company (collectively, the "**Confidential Information**"). Consultant as receiving party (hereinafter a "**Receiving Party**") agrees not to disclose the Confidential Information to any person unless Receiving Party has received prior written authorisation from the Company. Additionally, upon termination or expiration of this Agreement for any reason or upon the request of the Company, Receiving Party shall promptly return to the Company all originals and copies of documents or other materials constituting or containing Confidential Information. Receiving Parties' obligations regarding the Confidential Information shall survive termination or expiration of this Agreement.

4.2 Where the Company has provided Consultant with documents related to or necessary for the performance under this Agreement, Consultant undertakes to properly store such documents and not to allow third parties to access such documents. Consultant shall return such documents to the Company upon expiry of this Agreement.

4.3 Consultant shall not disclose to the Company or induce the Company to use any confidential information belonging to others, including any other clients or former employers of Consultant.

ARTICLE 5: COPYRIGHT/PUBLICATIONS/INVENTIONS

5.1 Consultant hereby grants the Company a non-exclusive worldwide and, in time, unlimited right to use in all possible forms and media all copyrightable documents or products which are created by Consultant in the course of performance of this Agreement (hereinafter the "Work"), including, without limitation the right to use, adapt, edit, chose a title for the Work, translate, input and/or combine into (conventional, electronic, digital) database, reproduce (regardless of media of reproduction and of number of reproduced copies), publish, make available online (including in intranets and on the internet), sell, lease, give away for free, exhibit, record, film, and broadcast the Work, in its entirety or in part, in all forms of media, whether in printed or recorded form (analogous or digital), and regardless of whether in writing, as sound and/or as image, and regardless of whether for commercial or charitable purpose ("**Right of Use**"). The compensation of Consultant pursuant to Article 2 above shall serve as sufficient consideration for granting of the Right of Use.

5.2. The Right of Use shall survive the termination of this Agreement. The Company shall be entitled to assign or to sublicense in part or in full said Right of Use.

5.3 Consultant warrants that in granting the Right of Use, no rights of third parties, including data privacy rights have been infringed and that where necessary, Consultant has obtained approval by third parties in order to grant said Right of Use to the Company. Consultant shall hold the Company harmless against third-party claims for transgression of copyrights related to the Right of Use granted to the Company and shall assist the Company in defending against such third-party claims.

5.4 Any inventions, improvements or ideas made or conceived by Consultant in connection with or during the performance of this Agreement (hereinafter "**Service Inventions**") shall, either directly or by way of assignment by Consultant to the Company be the property of the Company.

Consultant, without charge to the Company other than reasonable payment for time involved in the Event this Agreement shall have terminated, but at the Company expense, shall execute, acknowledge and deliver to the Company all further papers, including applications for patents, as may be necessary to enable the Company to publish or protect Service Inventions by patent or otherwise in all countries and to vest title to such Service Inventions in the Company or its nominees, their successors or assigns. Consultant shall render assistance as the Company may require in any Patent Office proceeding or litigation involving Service Inventions. Consultant, as part of the services to be performed below, shall keep written notebook records of his/her work, properly witnessed for use as invention records, and shall submit such records to the Company when requested or at the termination of the work. Where assignment by Consultant of rights of Service Inventions to the Company is necessary in order for said Service Inventions to be the property of the Company, Consultant undertakes to use her/his best efforts to obtain any and all necessary approvals, including, but without limitation, approvals of her/his employer. The compensation of Consultant pursuant to Article 2 above shall serve as sufficient consideration for assigning the Service Inventions to the Company.

ARTICLE 6: GENERAL PROVISIONS

6.1 The relationship under this Agreement of the Company and Consultant shall be that of independent contractors. Neither this Agreement nor the services performed hereunder shall be construed to create the relation of principal and agent or joint venture between the Company and Consultant and neither the Company nor Consultant shall have the right to make any commitment for or create any obligation on behalf of the other party.

6.2 This Agreement and all of the documents referred to in Article 1.4 constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes any promise, agreement or consent on the subject matter hereof made between the Parties hereto by officers or employees of the Parties before the execution of this Agreement. No modification of this Agreement shall be binding upon either Party, unless approved in writing by authorised representatives of each of the Parties.

6.3 Furthermore, Consultant agrees that the Company AFFILIATE may disclose the existence and content of this Agreement to the relevant professional organisation and/or employer and/or relevant institution or government entities where the Consultant is active.

6.4 If permitted by local laws, regulations and Consultant's contractual obligations, Consultant shall notify the Company AFFILIATE if Consultant attains a position to influence purchasing decisions of a government entity or a healthcare-related institution owned or substantially controlled by a government or public body. Such purchasing decisions may relate, for instance, to tenders issued by health authorities or decisions of formulary committees of public hospitals. In case of such notification by Consultant, the Company AFFILIATE has the right to terminate this Agreement with immediate effect by written notice. Where such notification to the Company AFFILIATE is not permitted by local laws, regulations or Consultant's contractual obligations, Consultant shall notify the purchase decision-maker in said government entity, institution or hospital of Consultant's financial relationship with the Company AFFILIATE before any purchasing decision is made.

6.5 This Agreement shall be governed by South African law and the Parties hereto hereby submit to the jurisdiction of the competent courts of South Africa.

6.6 Consultant shall comply with all applicable laws and regulations (including applicable anti-corruption laws as stipulated in Annex 2) in providing its services under this Agreement.

6.7 If any provision of this Agreement is held to be invalid, illegal or unenforceable under applicable law the remaining provisions shall continue to be in full force and effect.

The Parties undertake to replace the invalid provision or parts thereof by a new provision, which will approximate as closely as possible the economic result intended by the Parties.

ARTICLE 7: COMPETITION LAW

7.1 It is the policy of Company [and its subsidiaries] to comply with all relevant competition law. The Consultant shall not engage in anti-competitive conduct in violation of any competition law. The Consultant shall not take unfair advantage of any customer, supplier, competitor or other person through manipulation, concealment, misrepresentation, or other unfair practice.

7.2 Strict compliance by the Consultant with the terms and conditions hereinabove as essential obligations of the Consultant under the agreement. The breach of which will constitute just cause for termination of this agreement by the Company.

ARTICLE 8: PRIVACY AND DATA PROTECTION

8.1 Consultant personal data will be processed by the Company, its affiliates and the third parties providing support for the services defined in this Agreement with the adequate privacy safeguards to protect the personal data you provide and only for the purposes of this Agreement." In order to fulfil the purpose of this Agreement, the Company may need to share Consultant's personal data with any third parties providing that support such as travel agencies, hotels, event organisers etc. This might involve transferring Consultant data to countries where the third party(ies) might be located, as well as to other affiliates located in those countries, where data protection standards might vary from those in Consultant country.

8.2 In accordance with applicable data privacy legislation, including but not limited to, the Protection of Personal Information Act No 4 of 2013 (POPIA) the Consultant shall secure the accessibility, integrity and confidentiality of personal information in their possession or under their control. The Act also requires that anyone processing any and all personal information (as defined in the Act) on behalf of the Company shall treat such personal information as confidential, not disclose it, establish and maintain reasonable technical and organisational measures to safeguard such personal information. The Consultant shall ensure compliance with all obligations as outlined in the applicable sections of the Act and shall demonstrate such compliance with the Act as may be requested by the Company from time to time.

8.3 Any confidential patient information that may be processed by the Consultant is legally protected. In performing the obligations in terms of the Agreement, the Consultant shall:

a) Comply with the provisions of the prevailing privacy and data protection legislation governing the collection, use and processing of Personal Information as defined in the relevant legislation.

b) Not process personal information for any purpose other than to perform the obligations under the Agreement in place between us and ensure that such processing will not place the Company in breach of any applicable privacy and data protection laws or stated requirements.

8.4 A breach of these conditions shall be regarded as a material breach of the Agreement between the Company and the Consultant.

Signed:

The Company	Consultant:
_____	_____
Title:	Title:
_____	_____
Date:	Date:
_____	_____

Annex 1: Scope of consulting services/fees for consulting services

In view of proper compliance with relevant healthcare compliance laws and guidelines, it is imperative that you carefully prepare this Annex 1.

WORK ORDER N° XX

to the CONSULTING AGREEMENT between Company (hereinafter the Company) and Dr XYZ (hereinafter the "Consultant"), signed on_____, hereinafter "the WORK ORDER" SERVICES

Task Description

Consulting Agreement (ongoing)

• Local on-site surgeon visitations. • Local off-site surgeon visitations where Consultant will attend theatre cases in other surgeons' theatres to give support in specific procedures. • Form part of a faculty and/or train surgeons in a workshop/cadaver lab environment.
Speaker: Educational speaker agreement for ongoing services • Present talks to invited HCPs in various settings.

Geographical location of the consulting services

Various major centres in South Africa

The Company's project assignment manager

The Company project assignment manager for the purposes of managing the relationship with Consultant and supervising the services described in this WORK ORDER pursuant to the Agreement shall be the Regional Sales Manager for the relevant territory.

Time schedule

The performance of the WORK ORDER shall commence on_____and shall be completed on_____

Invoicing

Invoices referenced with the Company WORK ORDER number shall be sent to the Company, for attention relevant person (e –mail). Invoices must be submitted to the Company within X days of the commencement/completion of the activity date.

Executed on_____ in duplicate, each Party acknowledging receipt of one copy.

Company	Dr D XYZ
Date:	Date:

Annex 2: Compliance with anti-corruption laws

Notwithstanding anything to the contrary in the Agreement, Consultant hereby agrees that:

(i) Consultant shall not perform any actions that are prohibited by local and other anti-corruption laws that may be applicable to one or both parties to the Agreement;

(ii) Consultant shall not, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other third-party related to the transaction with the purpose of influencing decisions related to the Company and/or its business in a manner that would violate anti-corruption laws;

(iii) Consultant shall not retain any government official or government employee in the performance of the Agreement unless it has been approved by the Company and, if necessary, by the competent authority or authorities and such government official's or employee's employer. Furthermore, Consultant shall immediately advise the Company in writing in the event Consultant becomes aware that any person engaged in the performance of the Agreement becomes a government official or employee, a political party official or a candidate for political office. The requirements of this subsection shall not apply with respect to employees of a Consultant that is a government owned entity;

(iv) Consultant shall be available or when appropriate designate an individual within its organisation to receive training from the Company on anti-corruption laws, as well as applicable rules on interactions with healthcare professionals, as mutually agreed to by the parties. Such designated individual shall then provide such training on anti-corruption laws, using applicable training materials to be provided by the Company, on at least an annual basis to all persons employed by Consultant who perform work for the Company and interact with government officials or healthcare professionals in the normal course of their responsibilities. Upon the Company and Consultant mutual agreement, such training may also be provided directly by Consultant to such employees of Consultant. Consultant shall also provide such training or training materials to any subcontractors it uses in the performance of the Agreement (to the extent the use of such subcontractors by intermediary is permitted under the Agreement). Any training and materials provided by the Company does not relieve Consultant of any obligations it has independent of the Agreement and Consultant shall not rely on the Company training and materials for any such obligations;

(v) Consultant shall certify on an annual basis in a format to be provided by the Company that:

a. training and training materials on anti-corruption laws, as well as applicable rules on interactions with healthcare professionals have been provided to all persons employed by Consultant who perform work for the Company and interact with government officials or healthcare professionals in the normal course of their responsibilities and that it has provided the Company training and training materials to subcontractors used by Consultant in the performance of the Agreement;

b. to the best of Consultant's knowledge, there have been no violations of anti-corruption laws by Consultant or persons employed by or subcontractors used by Consultant in the performance of the Agreement;

c. personnel of Consultant who may be designated as "Key Personnel" by mutual agreement of the Company and Consultant have not changed, except as noted in a schedule attached to the certification provided by Consultant;

d. Consultant has made no changes in its use of subcontractors to perform the services for the Company under the Agreement, except as (1) permitted under the Agreement and (2) noted in a schedule attached to the certification provided by Consultant; and

e. Consultant has maintained true and accurate records necessary to demonstrate compliance with the requirements of this agreement.

(vi) Consultant shall maintain and provide the Company and its auditors and other representatives with access to records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement as may be requested by the Company in order to document or verify compliance with the provisions of this agreement; and

(vii) if Consultant fails to comply with any of the provisions of this agreement, such failure shall be deemed to be a material breach of the Agreement and, upon any such failure, the Company shall have the right to terminate the Agreement with immediate effect upon written notice to Consultant without penalty or liability of any nature whatsoever.

Neither party shall perform any actions that are prohibited by local and other anti-corruption laws (collectively "anti-corruption laws") that may be applicable to one or both parties to the Agreement. Without limiting the foregoing, neither party shall make any payments or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other third-party related to the transaction in a manner that would violate anti-corruption laws.

ADDENDUM 3 SAMED MEDTECH REGISTRY PRINCIPLES AND POSITION PAPER

Registries are a mechanism to collect information about patient populations being treated, the provider's quality and processes of care, Medtech performance and clinical outcomes achieved. If designed and executed properly, a Registry can provide useful information about the safety and effectiveness of medical interventions as well as the value of the outcome of interventions. The purpose of these principles is to provide guidance to Member Companies as they consider Registry initiatives and to share industry's perspectives with potential Registry initiators in order to facilitate the process of Registry formation.

A Medtech Registry may be designed to achieve one or more of the following objectives:

1. Improve patient care and outcomes by understanding the effects of products, HCPs, facilities, patient populations and pathways over the full care cycle.
2. Improve patient access to new therapies by efficiently collecting data to support regulatory applications for expanded use and indications.
3. Obtain data to support coverage, reimbursement and value analysis.
4. Evaluate the real-world safety and/or effectiveness of products outside of clinical trials.
5. Meet regulatory requirements for post-market data collection.
6. Reduce pre- and post-market burdens for data collection by providing regulators with alternative methods to monitor the performance of technologies.
7. Aid in the assessment of effectiveness across multiple products or therapies.
8. Develop hypotheses for further evaluation in controlled clinical trials.
9. Aid in the development or assessment of care guidelines.

To assure that the creation of a new Registry is the appropriate mechanism to meet the above objectives, several priority questions need to be answered:

- Is using a Registry the least-burdensome means to collect the necessary data to achieve the scientific objectives?
- Do the objectives warrant the level of investment required to develop and maintain a Registry?
- Are there reliable data collection instruments available to collect the data needed to achieve the objectives?
- Will the Registry have a stable and diverse source of funding to promote long-term sustainability?

The following key principles should guide the development of any Medtech Registry.

1. All Medtech Registries must be in accordance with applicable laws. Examples include but are not limited to the Helsinki Declaration, PAIA, POPI Act, Consumer Protection Act, National Health Act, Health Professions Act and related guidelines and ethical rules, Medical Device Regulations etc.
2. Formation of a data governance committee and written procedures for data ownership, data access and data use must be established for each Registry before initiation. All stakeholders should be represented on the committee.
3. Sufficient safeguards should be established to ensure that valid data are entered into the Registry.
4. Data integrity and security must be maintained both during the active phase of the Registry and after closure.
5. Data should be reviewed and analysed in a systematic manner, as defined by the protocol and analytical plan. The protocol should define enrolment adequate to avoid population bias.
6. End points must be clearly defined.
7. There should be a process for adverse event adjudication.
8. Before the outset of the Registry, rules governing review and access to the data should be established, be well-defined, and be designed to manage unanticipated future requests. Governing rules should consider, if applicable:
    - Review and acceptance process for data requests and data analysis plans, taking into consideration informed consent restrictions, if any, and the objective of the initial Registry.
    - Controlled processes for data access and data release that take into account data privacy, maintaining data integrity and traceability and timing in relation to publication, market approvals and patent protection.
    - Guidelines for data transparency.
    - A process for Medtech- specific safety data reporting, including how information is shared with the manufacturer/supplier.

9. A well-balanced Registry design requires a clear purpose, objectives, analysis plan, and term before data collection begins.
    a. The purpose of the Registry will determine the design, cost and term of the Registry.
    b. Where needed to meet a research purpose, hypothesis-based designs and powered Sample size determinations may be appropriate. Consideration must be given to the difficulty of longitudinal follow up of Registry participants.
    c. For Registries that collect information and do not involve a research purpose, definitions of success (data collection, data quality, pool ability, quantity, funding) and failure should be prospectively defined in the protocol. Failure to meet criteria should result in Registry termination as defined in the governance documents.
    d. Key stakeholders must define a prospective process for considering changes in the Registry after initiation including items such as data collection, protocol revisions or funding.
    e. An appropriate quality plan needs to be established including monitoring, auditing and validation of participating sites for complete, accurate and timely data collection.
    f. Registries must collect sufficient data to identify, consider and allow risk adjustment for modifiable risk factors such as social, demographic and disease-related factors.
    g. Data on patient characteristics, patient medical conditions and comorbidities, facility characteristics, physician experience, interventional technique and associated parameters, and Medtech characteristics (including unique Medtech identifiers) should be collected to identify potential factors which affect patient outcomes.
    h. The Registry purpose and design should recognise the unique characteristics of the Medtech innovation life cycle.
        i. Device innovation is an iterative process, and a Medtech life-cycle may conclude prior to a desired Registry endpoint being achieved.
        ii. The design of a long-term Registry must recognise and manage the potential for next generation Medtech entering the market during the data collection period.

10. A robust evidence assessment should be performed prior to determining whether the additional data that may be collected by a Registry are needed.
    a. The evidence assessment should evaluate current literature and previous studies, as well as identify existing data collection efforts and ongoing studies and/or registries. These data sources should be evaluated and considered for their purpose, depth, rigor and timing of results compared to the proposed Registry.
    b. Duplication of purpose, data to be collected or analysis methods may indicate that the proposed Registry is redundant.
    c. The evidence assessment should be relied upon in developing the plan for the proposed Registry. The plan must identify the evidence gap to be addressed by the Registry and ensure that the data and analysis provide a true public health benefit and justify the additional costs associated with the Registry. The assessment should be shared with potential stakeholders, participants and funders before Registry design is developed and before data collection is initiated. The societal cost of the Registry must be justified by the knowledge to be gained from the defined analysis plan.

11. Registry data may be shared upon request from qualified scientific and medical researchers for purposes benefiting public health or patient care. A system should be implemented to receive and review data requests prior to approving the release of any data.
    a. The data governance committee will establish criteria for the review of requests and sharing of data. All requests for access to data will be reviewed according to these criteria. Recommended criteria include the validity of the hypothesis, whether the data to be requested and analysis plan will address the hypothesis and the qualifications of the requestor.
    b. The data governance committee will establish a process for submission of requests for sharing of data, including the information to be included in the request. Recommended information includes the hypothesis to be tested, a description of the data being requested, the benefit of the proposed work, the analysis plan, a publication and posting plan, qualifications and experience of the research team and any potential conflicts of interest, including how the data will be used and the source of any funding.
    c. The data governance committee will establish a process for protection of the shared data to ensure that researchers who are provided access to Registry data agree not to transfer the shared data or information to parties not identified in the research proposal.
    d. Data requesters may be charged reasonable costs associated with data sharing.

e. When there is a public health benefit to merging and analysing data from multiple independent Registries, the data governance committee(s) from each affected Registry will establish criteria for review and oversight of such projects. When extracting and analysing data from multiple Registries, the data governance committee(s) will ensure that:
   i. The original Registry purpose and objectives are considered to ensure the integrity and validity of any analyses or reports that are performed and to prevent inaccurate conclusions.
   ii. The plan for extraction, aggregation and analysis of the data is valid.
   iii. The plan includes the sharing of the analyses or reports with involved stakeholders.

12. Only the minimum data necessary for meeting the stated objectives of the Registry should be collected in order to reduce additional costs for the healthcare system and to maximize the likelihood of success.
   a. The data to be collected for the Registry should be well-defined and relevant to the Registry objectives.
   b. Consideration should be made for aligning data collection to be consistent with standard methodologies, where possible, to reduce the overall burden.
13. A Registry must comply with all applicable laws and regulatory requirements.
   a. Patient privacy should be protected.
   b. All confidential manufacturer/supplier, physician and hospital data must be identified as confidential and protected from release.
   c. Data provided to a Registry does not negate facility, physician or manufacturer obligations to make reports required under applicable laws or regulations.
   d. Unpublished Registry data should be non-discoverable and should not otherwise be used in legal proceedings.
   e. In choosing the best care for their patients, HCPs exercise their medical judgment and may use legally marketed products for off-label uses. The collection in a Registry of off-label use data may not represent either off-label promotion or approval by or even prior knowledge of the intended off-label usage by the product's manufacturer. A Registry may not be complete without inclusion of real world information, which may include off-label use.
14. Policies should be established for the use and publication of Registry data by stakeholders and outside Registry data users. These policies should protect against unauthorised use of data and ensure transparency.
   a. Registries, which are in part financially supported by industry, shall provide industry partners access to their complete data. Each participating industry partner shall have access to its own data as well as aggregated data (not including patient identifiers) from the entire Registry.
   b. Registries may help identify important safety signals. When such signals are Medtech-specific, the signals should be reported to the manufacturer's complaint department prior to public disclosure. The company, with input from the Registry, should conduct a further investigation and take action as appropriate.
   c. Regulatory bodies should seek input from and share relevant information with manufacturers prior to taking any regulatory action based upon Registry data including data aggregated from multiple Registries. There should be a plan for the sustainable funding of the Registry which includes all relevant stakeholders.
   d. Parties who purchase Registry products (custom reports) may be charged a reasonable fee.

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