Medical Device Code of Ethical Marketing and Business Practice

"The Code"
Version 5

Disclaimer:

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

Tel: +27 11 704 2440 | Fax: +27 086 407 4765 | email: info@samed.org.za
PO Box 651761, Benmore, 2010, South Africa | Hammets Crossing Office Park, No. 2 Selbourne Avenue , Randburg

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Contents

List of abbreviations

CPD	Continued professional development
EO	Executive Officer
FMV	Fair market value
HCO	Healthcare organisation
HCP	Healthcare professional
HPCSA	Health Professions Council of South Africa
IVD	In vitro diagnostic
KOL	Key opinion leader
PCO	Professional conference organiser
SAMED	South African Medical Technology Industry Association
SANC	South African Nursing Council
VAT	Value Added Tax

Introduction

Promoting an ethical industry

The healthcare industry is one of the most carefully scrutinised industries in the world. This Code contains valuable information about the many laws, codes and procedures that govern the way we do business in South Africa, and in particular, how we conduct interactions with healthcare professionals (HCPs) and healthcare organisations (HCOs). It helps to further define our commitment as an industry and as individuals to abide by government laws, industry standards and procedures that apply to these day-to-day interactions. This Code underpins SAMED's vision which is: *to develop a sustainable medical device industry by responsibly improving patient access to innovative medical devices.*

Purpose and principles of the Code

The fundamental purpose of the Code is to promote and encourage among SAMED members, ethical principles and practices. As such it is envisaged that the Code will become an essential guide and support for SAMED members in their business and marketing interactions with their customers. The Code is founded on the following ethical values:

- An industry that is socially responsible towards not only its customers, but to society at large and patients in particular.
- The desire to promote a spirit of co-operation and shared responsibility among both public and private HCPs and providers within the context of effective, efficient and transparent healthcare delivery.

In support of these values, the underpinning principle of the Code is that SAMED members will not offer any inappropriate inducement to any HCP or other customer in order to sell, lease, recommend or arrange for the sale or lease of their products.

The Code is binding on all SAMED members and is a condition for new and ongoing membership. The Code will be continuously reviewed borrowing from best practice both locally and globally. The Code also includes a set of questions and answers to assist SAMED members in the interpretation and practical implementation of the Code.

SAMED is committed to the following principles:

- To ensure that all activities of SAMED shall be in the best interests of its members, provided that such shall not detract from the needs and rights of patients.
- To promote and encourage among its members ethical principles and practices, voluntarily agreed upon, and to this end, to ensure that a Medical Device Code of Ethical Marketing and Business Practice which shall be binding on all members, is published.
- To the establishment of a healthcare system that is people centred, equitable, coherent and efficient and in particular to the contribution that high quality, cost-effective healthcare technology can make toward achieving good health outcomes.
- To promote fair competition between members based on the value of products and associated marketing skills, and not based on any unacceptable business practice.
- SAMED encourages ethical business practices in interactions between its members and HCPs, in particular that members will not offer any inappropriate inducement to any HCP or other customer in order to sell, lease, recommend or arrange for the sale or lease of their products.

- Thus, in pursuing this mission, SAMED members ("members") recognise, respect and encourage adherence to ethical standards and compliance with both the spirit and letter of applicable laws and guidelines in all business endeavours.
- Members recognise that all South Africans have the right of access to healthcare, and that right should be progressively realised through cooperation and shared responsibility between the private and public healthcare sectors.
- Members furthermore support an industry that is socially responsible towards not only its customers, but to society at large and patients in particular.

Interactions between medical device industry and HCPs

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

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

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

Application of the Code

This Code binds members of SAMED, whether such members are manufacturers, importers, distributors or agents and includes their employees, agents and contractors working for or in conjunction with such member, 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 SAMED member. Members should ensure that reference is made to this Code in agreements with third parties mentioned in this context.

All members are urged to adopt policies and procedures to ensure compliance with the principles of this Code, which includes, *inter alia*, mechanisms to ensure that all events, sponsorships, marketing and advertising campaigns are signed off by a responsible senior staff member / compliance officer.

Members are under an obligation to workshop and communicate the principles of this Code to their employees, agents, dealers and distributors as it is a requirement that they adhere to this Code. This Code is intended to facilitate ethical behaviour and is not intended to be, nor should it be construed as, legal advice.

Interpretation and definitions

This Code does not substitute any obligation or provision found in any other code or legislation 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 the aforementioned 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, as well as the Code.

In drafting the Code, regard has also been given to various international and local codes currently binding the medical device industry, and interpretations awarded to such codes may guide the interpretation of this Code. 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 following principles:

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

The Principle of Separation (patient best interest)
Interaction between industry and HCPs must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of members' products. Members may therefore not hold positions on any executive committee or board of any medical association, society or other healthcare organisation where a conflict of interest may occur.

The Principle of Transparency
Interaction between industry and HCPs must be 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 remuneration paid by the member must be commensurate with, and represent a fair market value for, the services performed by the HCP.

The Principle of Documentation
For interactions between a member and an HCP, such as where services are performed by an HCP for or on behalf of a member, there must be a written agreement setting out, *inter alia*, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the member. The activities envisaged by the 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 remuneration paid.

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

"Company Code compliance officer" means anyone duly authorised by the company, or appointed by the 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 member company, including but not limited to a legitimate business need to interact with customers including HCPs and/or HCOs.

"Entertainment" includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (eg skiing, golf, rugby or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute entertainment.

"Faculty" means a podium speaker, moderator and/or chair, who presents during a third-party organised Educational Event. Poster- and abstract-presenters are not considered to be faculty.

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

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

Note: unless otherwise stipulated the term, HCP includes and is applicable to HCOs.

"Medical Device" refers to medical devices as defined in the Medicines and Related Substances Act as amended and includes in-vitro diagnostics.

"Members" means companies that are members of the South African Medical Device 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.

"Product and Procedure Training and Education Event" means a type of Company Event that is primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on:

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

In all cases the information and/or training directly concern a Member Company's medical technologies, therapies and/or related services.

"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, and includes meetings where pertinent clinical, healthcare or treatment issues are discussed which may relate to a particular issue (such as a treatment protocol for a particular disease), or which may be called by a member in order to advise the HCP on the impact or use of its specific technology, the clinical merits or place of the technology in treatment within a certain disease area, etc.

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

"Third-party organised educational conferences" means a type of third-party organised educational event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote

scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings.
These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, professional conference organisers (PCOs), patient organisations or accredited continuing medical education providers.

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

- Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies).
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

For the avoidance of doubt, proctorship and preceptorship are not considered to constitute third-party organised procedure training.

"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 a medical device 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 behavior.

Any reference to a feminine gender shall always include the masculine and vice versa.

Enforcement of the Code

The Code is based on the principle of self-regulation of the industry through a procedure for handling complaints. The process of enforcement is set out in Part 2 of this Code. As a member of SAMED, you are bound by this Code. You must read this Code and should you become aware of a violation of this Code, you must report it in line with the provisions of Part 2 of this Code. Failure to report a violation is itself a violation.

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

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.

PART 1: Interactions with HCPs

Chapter 1: General criteria for events

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

1. Event programme

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

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

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

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

Type of event	Applicable rule
Third-party organised educational events (main programme)	Companies will not be able to directly support a healthcare professional, neither as a delegate nor as a speaker
Company-organised events in the framework of third-party organised events (eg satellite symposia)	Companies may directly support speakers (ie their consultants) at the company-organised event but not delegates
Third-party organised procedure/hands-on trainings	Companies may support delegates but not speakers, the latter being independent
Company-organised product/procedure trainings	Companies may directly support a healthcare professional either as a delegate and/or as a speaker

The criteria for selection of attendees/invitees must be transparent and available on request for scrutiny.
Payment of registration fees, travel and accommodation must be made to the professional associations/organisers and not directly to the HCP or their administrative staff. No payment may be made to the HCP for time spent at the event.

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

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

2. Event location and venue

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

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

Further considerations to be taken into account:

- Central location - taking into account the place of origin of the majority HCP invitees, the venues selected must be centrally located.
- Capitals and major cities are recommended.
- The ease of access – The geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure.
- Venues situated on the beachfront can be considered under the following circumstances:
    - There are no suitable alternative venues in the geographic location
    - The venue is not considered as luxurious in nature. In general a 5 star rated venue would not be considered appropriate.
    - The venue is well known as a business or commercial centre conducive to the exchange of scientific or medical information.

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

3. Guests

Member companies are not permitted to pay for meals, travel, accommodation or other expenses for guests or spouses of HCPs.

4. CPD meetings

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

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

5. Reasonable hospitality

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

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

The term "hospitality" includes meals and accommodation and it is important that member companies differentiate between "hospitality" which is permitted and entertainment which is not.

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.

6. Travel

General principles

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

International travel

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

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

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

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

First class is never appropriate.

For any other travel, economy class travel is the standard class of travel that companies may offer HCPs to

attend both international and local events, including congress attendance and site visits.

7. Satellite symposia

Member companies may purchase satellite symposia packages at third-party organised educational conferences and provide presentations on subjects that are consistent with the overall content of the third-party organised educational conference. Member companies may determine the content of these satellite symposia and be responsible for speaker selection.

8. Transparency

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

9. Third-party Organised Procedure Training

Member Companies may support Third-party Organised Procedure Training either via Educational Grants or by providing financial support directly to individual Healthcare Professionals to cover the cost of attendance at Third-party Organised Procedure Training sessions i.e. member Companies may pay for travel, hospitality and the registration fee.

Chapter 2: Company events

1. General principles

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

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

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

2. Product and procedure training and education events

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

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

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

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

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

Chapter 3: Promotional items, items of medical utility, gifts and competitions

1. General principles

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

2. Promotional items

Definition:

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

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

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

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

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

3. Items of medical utility

Definition:

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

Items of medical utility, including, informational and educational materials, scientific medical reference books, journals, periodicals and anatomical models intended for teaching or patient benefit (value as determined from time to time by SAMED), are allowed to be provided to HCPs within the cost limit set from time to time by SAMED. For values, please see Part 3: Questions and answers.

4. Gifts

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

5. Other interactions with HCPs

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

6. Competitions

Competitions should fulfil the following criteria:

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

Note: In accordance with the prohibition of direct sponsorship to HCPs to third-party arranged events, a prize in the form of congress sponsorship is prohibited as of 1 January 2018.

Chapter 4: Charitable donations

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

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

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

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

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

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

Chapter 5: Arrangements with consultants

1. General principles

Member companies 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 remuneration of fair market value 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 member companies 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, member companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with 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.

2. Criteria for genuine consulting arrangements

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 achieve 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 1 for an example template of a consultancy agreement.
- The hiring of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the member company's products or services.
- The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided.
- Member companies must maintain records of the services, and associated work products provided by the consultant HCPs and of the use made of those services by the member company.
- The venue and other arrangements (e.g. hospitality, travel etc) for member company meetings with consultants shall follow the rules for such arrangements as set out in **Chapter 1: General Criteria for Events.**

3. Remuneration and fair market value

The remuneration paid to HCPs engaged as consultants by member companies shall reflect fair market value for the services provided. It shall not be in any way 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.

Fair market value (FMV) definition

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.

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 were no potential for additional business. For example, a company may be paying an HCP fair market value for a study, but is that study really necessary?

Valuation elements

Business needs: Assess the need relative to the resource deployed. For example, 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.

A higher risk of potential non-compliance exists where:

- No formal valuation processes are established.
- Payment rates are based upon anecdotal information about what other companies are paying.
- Demands placed on a company by the HCP to over-compensate.
- Lack of documentation.

Risk of non-compliance can be reduced where:

- Independent accredited appraisers are used.
- Formal documentation processes are in place.
- Accepted valuation approaches are used.
- Logic and consistency are applied.

Assessing FMV for HCPs and Key Opinion Leaders (KOLs)

Compensation earned by a 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 company, product group or department engaging with the HCP.

- The specific services required.
- The HCP's experience and expertise.
- The time requirements for the engagement.
- The HCP's clinical specialty.

HCPs versus KOLs

HCPs – Healthcare Provider / Professional	KOLs – Key Opinion Leaders
• Can include physicians, nurses, technicians, pharmacists, academic researchers, administrators etc. • Range in expertise and experience from local-level provider to international-level expert. • Valuation is based on specialty / job class and determined level of expertise and experience (ie tier). • Valuation can be applied to all HCPs within the specialty / job class (eg all nephrologists, all oncologists, etc).	• Generally, does *not* include nurses or technicians. • Requires a level of experience, expertise and/or credentials that are (i) greater than a typical international level HCP or a (ii) skills set that is rare or unique. • 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.

4. Payments

All payments made for services must comply with all applicable tax and other legal requirements. member companies may pay for expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement including reasonable travel, meals and accommodation expenses incurred by consultants if attending meetings with or on behalf of member companies.

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 company.

5. Disclosure and transparency

Member companies 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 superior (or designated competent authority), as applicable.

Member companies 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 6: Demonstration products and samples

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

1. Definitions

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

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

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

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

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

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

2. General principles

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

service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

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

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

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

3. Demonstration products (demos)

Member companies may provide examples of their products to HCPs and/or HCOs in the form of mock-ups (such as unsterilised single use products) that are used for HCPs and patient awareness, education and training. For example, an HCP may use a demonstration product to show a patient the type of technology which will be implanted in the patient or may use the demo to train other HCPs in the use of the product.

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

4. Samples

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

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

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

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

Chapter 7: Loan or placed equipment

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

- HCPSA's Guidelines for Good Practice in the Healthcare Professions – Booklet 11, item 3.6 Technological Equipment:
  - HCPs shall only own and use technological equipment if it forms an integral part of their scope of the profession and practice and on condition that the HCP concerned has received appropriate training in using and managing such equipment.
  - HCPs shall not over-use equipment for procedures, tests and other applications that are not indicated, scientific or based on evidence. This constitutes over-servicing and is prohibited.
  - HCPs shall not use technological equipment, healthcare products or devices for profiteering and must refrain from charging patient's fees for the use of such products or devices that are not market related.
- The consumables are used to cross-merchandise the capital equipment in a manner which is defensible and fair.
- The consumables relate to the specific piece of capital equipment being financed by means of the purchase of the consumables and is defensible in terms of the provisions of the National Credit Act.
- The placement of equipment agreement should be in writing and, in cases of valid complaints, made available as per the complaints handling process in Part 2: Dealing with infringements of the Code.
- In the case of equipment licensed with the Radiation Board, such equipment may only be loaned or placed as stipulated in the product license as issued by the Radiation Board.

Chapter 8: Bonusing, rebates and incentive schemes

Members must provide accurate, transparent and responsible billing information to HCPs, reimbursement authorities and other payors. Such documentation should be in writing and in cases of valid complaints should be available as per the complaints handling process in Part 2.

Members are expected to follow the principles of acceptable invoicing procedures as detailed in the SAMED Policy on Transparent Invoicing. See addendum 2.

No member may offer a bonus, free goods or other incentive scheme deemed to be perverse, to an HCP in relation to the acquisition of goods and services in contravention of regulations issued in terms of the Medicines and Related Substances Act.

Chapter 9: Royalty arrangements

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

A member 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 SAMED Ethics Committee 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: (1) 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; or (2) 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.

Chapter 10: Patient registries

A patient registry is defined as "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."[1]

A patient 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 randomised controlled clinical trials or other clinical study designs.
- 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 controlled clinical trials.
- Aid in the development or assessment of care guidelines.

With regard to HCPs providing information to registries, remuneration provided must be reasonable, of fair market value and in relation to 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 defensive project to obtain data/information. Proof of such *bona fide* registry data and documentation, including protocols, ethics committee approval and agreements, may be called for in the event of a complaint as per Part 2.

Registries should comply with all applicable laws, including but not limited to privacy protections, the consent of the person whose information it is, the Promotion of Access to Information Act, the National Health Act, the Health Professions Act and related guidelines, the Protection of Personal Information Act and the Consumer Protection Act.

When deciding on whether to conduct or participate in a registry, members are encouraged to consult and follow the SAMED Medical Device Registry Principles and Position Paper. See Addendum 3.

[1] Gliklich RE, Dreyer NA, eds. Registries for Evaluating Patient Outcomes: A User's Guide. 2nd ed. (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc. d/b/a Outcome] under Contract No. HHSA29020050035I TO3.) AHRQ Publication No.10-EHC049. Rockville, MD: Agency for Healthcare Research and Quality. September 2010

Chapter 11: Reimbursement for information and other economic data – marketing data, formulary, managed care and similar fees

Members may pay for marketing data, formulary listings, managed care or any 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 medical device.

Chapter 12: False claims regarding reimbursement

Since many healthcare programmes (medical schemes, etc) reimburse and pay for member products, each member must comply with the applicable laws and regulations.[2]

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 or 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.

[2] ie Criminal law and Criminal Procedure Act, as well as Medical Schemes Act and regulations.

Chapter 13: Healthcare representatives

1. General

Companies should ensure that healthcare representatives have adequate training to ensure sufficient scientific knowledge of the medical devices which they promote to enable the provision of precise and complete information about such products. Product training must be consistent with the instructions for use of a medical device.

Healthcare representatives are to conduct the promotion of a medical device in a professional manner, and are not permitted to disparage any opposition products.

2. In the operating room / clinical environment

Healthcare representatives in the operating room / clinical environment:

- Must be trained on operating room / clinical environment protocol.
- May only enter an operating room / clinical environment upon permission from appropriate members of the medical staff of the facility and with written consent from the patient concerned.
- Must wear appropriate attire as provided or permitted by the facility.
- May only advise on technical aspects of 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 healthcare representative is attending the operating room / clinical environment in his/her capacity as a company representative and on company time he/she may not use and/or apply company product, deliver patient or medical care directly to a patient even if they hold appropriate certification/licences.

In the event that the healthcare 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 and should be in a position to produce the contract, within a reasonable time, upon request.

Also see addendum 4: SAMED protocol on member company employees' attendance in operating room / clinical environment.

Chapter 14: Advertising of and promoting medical devices

1. General Principles

- 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 the technology in line with the approved uses and attributes of the 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 Healthcare Professionals and patients.
- Minimum requirements must conform to the Medicines Act including the Regulations and MCC/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, and
  - an advertisement which contains two or more pages must not be false or misleading when each page is read in isolation
- 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.
- 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 the medical device.
- Promotional material must not be misleading as to the nature of the product, its ingredients or indications and must encourage the rational use of a medical device 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, and where such advertisement or promotion relates to help-seeking behaviour amongst the public.
- Must not use risk or safety information in a distorted way to scare members of 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 supplier 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; or
- 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 healthcare professionals

- When Company Representatives introduce a medical device to a healthcare professional for the first time, they should provide a 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 nurses or other non-healthcare professional sales person at retail level, to recommend or supply medical devices.

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 the medical devices regulatory authority.
- 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.
- 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 the complaints handling process. 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. 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).

6. Market and scientific research

- Market research activities, and the like 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 medical devices and their uses, whether promotional in nature or not, which is sponsored by a company 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 the like must not be disguised promotions. All clinical trials must comply with SA legal requirements, South African Good Clinical Practice Guidelines (GCP) and research ethics approvals as required.

7. 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 a medical device is only permitted if:
  - it is not misleading or disparaging,
  - medical devices for the same needs or intended for the same purpose are compared,
  - 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 the body of scientific evidence. Comparisons should not imply that the medical devices with which comparison is made, are harmful or ineffectual,
  - no confusion is created between the medical device advertised and that of a competitor or between the advertisers' trademarks, proprietary names, other distinguishing marks and those of a competitor,
  - the trademarks, proprietary names, other distinguishing marks, medical devices, 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,
  - medical devices are not presented as imitations or replicas of goods bearing another company trademark or trade name, and
  - hanging (open ended) comparisons are not allowed.

8. Endorsements and testimonials by healthcare professionals

- Advertising and/or promotion shall not contain recommendation of a medical device by scientists or healthcare professionals unless substantiated.
- The Health Professions Council South Africa does not allow endorsement for financial gain.
- The name or photograph or film / video, television advertisement, radio advertisement or any other reproduction of a member of a healthcare professional must not be used in any way that is contrary to the applicable professional code(s) for that profession and all endorsements, where permitted by professional codes, must be done within the scope of such codes.
- The use of healthcare professionals for marketing, promotion, endorsements or testimonial must take place within the scope set by the professional codes applicable to such professionals.
- Testimonials should be less than three years old and be the genuine views of the user.
- Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.

9. The use of non-promotional material

Material issued by companies that relates to medical devices but which is not intended as promotional material for those medical devices per se, for example corporate advertising, press releases, market research material, financial information to inform shareholders, the stock exchange, should be examined to ensure that it does not contravene the 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 healthcare professional 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 a healthcare professional, 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.

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 medical devices, 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 use by healthcare professionals

Advertising and/or promotion shall not refer to a 'college', 'hospital', 'institute', 'laboratory' or similar establishment, unless the establishment genuinely exists.

10. 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 medical device 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 medical devices 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, envelopes or wrappers, texts, etc. must not carry matter which may be regarded as advertising and/or promotion to the general public and which is contrary to relevant legislation.

11. Journal advertising

- An advertisement which contains two or more pages must not be 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 a size 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.

12. Electronic/digital media

Promotion of Medical Devices and IVDs via digital or electronic media must comply with all aspects of the Code.

Use of electronic/digital communications

The telephone, mobile phone, SMS, e-mail, 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, when first contact is made, details of the identity of the sender or the person on whose behalf the communication has been sent are provided ("identifying information") 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.

Audio visual material

Audio-visual or audio 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, and
- 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.

PART 2: Dealing with infringements of the Code

The overall goal of this procedure 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. This process applies to dealing with infringements of this Code.

Constitution of the ethics committee

Chairperson

The SAMED Board will appoint an independent chairperson of the ethics committee for a period as determined by the Board. The Chairperson will be a legally qualified expert.

The Chairperson will be responsible to ensure that all complaints and hearings are dealt with speedily and fairly and will be the custodian of the process, ensuring that both the principles of administrative justice, as well as the substance of this Code, are preserved and promoted.

Ethics committee

The SAMED Board will identify a panel of suitably qualified and experienced persons within the device industry, who together with the chairperson shall be eligible to serve on the ethics committee.

The ethics committee will consist of five members, one of which will be the chairperson.

The ethics committee will be appointed by the SAMED Board for a period as determined by the SAMED Board and may include individuals who are suitably experienced in regulatory affairs, marketing practices, sales practices, law or any other field of relevance to the subject-matter of this Code.

All members of the ethics committee must sign a private and confidential / non-disclosure document, as well as a disclosure of conflict of interest at every meeting. Members of the ethics committee must keep all details relating to the complaint at hand in the strictest confidence, unless the parties agree to specified disclosures.

The composition of the ethics committee may differ from case to case depending on the matter at hand and the potential for conflicts of interest which will be determined by the Chairperson of the committee.

The ethics committee shall have the powers to order that the matter be reported to any other body with an interest and jurisdiction in the matter, including but not limited to the Regulatory Authority responsible for device and IVD regulation and device or IVD establishment registration, the Health Professions Council of SA, the Nursing Council, Pharmacy Council or other professional body, the Hospital Association of SA, the Council for Medical Schemes, the Consumer Commissioner or the Department of Health.

Role of the secretariat and SAMED Executive Officer (EO)

The EO will fulfil a secretariat function in relation to handling infringements of the Code. Should the EO not be available, the SAMED Office Manager will fulfil this function.

Lodging a complaint

Any signatory to the Code, a member of the public, HCP or regulatory body ("the complainant") may lodge a complaint through the following channels:

- a formal written complaint in writing to the EO; or
- via the independent whistle-blowing mechanism.

Formal written complaints

A formal written complaint may be lodged on completion of the prescribed forms. Note there is no lodging fee required.

The prescribed complaint form, available on the code page of the SAMED website i.e. www.samed.org.za, has to reveal the following and has to be lodged with the EO:

- 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 putting a formal written complaint to SAMED.
- Company employing the complainant, and, if applicable, the representative body of the complainant.
- Field of business of the complainant (manufacturer, distributor, doctor, private hospital, etc).
- Name of alleged infringing company ("the respondent").
- Field in which infringement has occurred (e.g. insulin pumps, orthopedic implants, wound care, etc).
- Circumstances of the infringement (what, when, where, how).
- Clause(s) within the Code that has allegedly been infringed.
- Indication of the proof substantiating such complaint.

On receipt of the complaint, the EO will follow the process below:

- The EO shall within seven working days of receipt of the complaint send a copy of the complaint to the respondent and request a formal response within seven working days from the date upon which the respondent receives the complaint.

- The EO shall within seven working days from receipt of the response, if any, send a copy of the response to the complainant and invite a reply within five working days from the date upon which the complainant receives the response. The reply, if any, will on receipt be sent to the respondent. No further exchange of replies will occur.

- After receipt of the complainants reply, if any, the EO will forward the complaint, the response, the reply (if any) ("the documents") to the Chairperson of the Ethics Committee for consideration. The Chairperson will decide on further steps to be taken such as, but not limited to, further investigation by an independent investigator, conciliation or referral to the Ethics Committee.

- Note the complainant can file two documents, namely the original complaint and a reply (if the complainant so wishes) to the respondent's response. The respondent files only one document, namely "the response".

The complainant may at any time withdraw the complaint except after it has been referred to the Chairperson of the Ethics Committee.

Conciliation

In the case of formal written complaints, at the point where the complainant receives the respondent's response, the EO can, upon the request of one of the parties facilitate a process aimed at securing an informal resolution of the complaint, through a conciliation process, to be chaired by a suitable individual agreed to by the parties, or failing agreement, nominated by the EO.

Any resolution to the matter should be recorded in writing and forwarded to the EO in order to close the complaint.

Should the parties fail to reach an agreement within 14 working days of requesting conciliation, the complaint will proceed to the Chairperson of the Ethics committee for further consideration.

All information relating to the complaint and the resolution thereof will be confidential, unless the parties agree to the disclosure of specific details, e.g. an agreement that a particular practice will be stopped.

Reporting through the whistleblowing mechanism

Any person ("the complainant") may lodge a 'complaint against a SAMED member or signatory to the Code via the whistleblowing mechanism as indicated on the code page of the SAMED website i.e. www.samed.org.za. Complaints lodged through this mechanism may be made anonymously. On receipt of the complaint from the whistle-blowing service provider, SAMED will follow the process below:

- The EO shall within seven working days of receipt of the whistleblowing report send a copy of the report to the respondent and request a formal response within seven working days from the date upon which the respondent receives the complaint.

- The EO shall within seven working days from receipt of the response, if any, send a copy of the response to the service provider managing the whistleblowing mechanism (and invite a reply within five working days from the date upon which they receive the response. The reply, if any, will on receipt be sent to the respondent. It may happen that this will result in a resolution of the complaint.

- In the event the complainant is anonymous, tt will be incumbent on the anonymous complainant to contact the whistle-blowing service provider within 21 days of lodging the complaint to obtain feedback from the respondent. The anonymous complainant should reply within five working days from the date of which they received the response via the whistle-blowing service provider. The anonymous complainant's response should be sent to the whistle-blowing service provider who will, within 24 hours, send the response to the EO.

- Should the anonymous whistle blower choose not to respond and/ or the complaint not be resolved at this point, the EO will forward the complaint, the reply and the response, (if any) ("the documents") to the Chairperson of the Ethics Committee for consideration. The Chairperson will decide on further steps to be taken such as, but not limited to, further investigation by an independent investigator, conciliation or referral to the Ethics Committee.

Conciliation

In the case of the complainant being anonymous, and should the Chairperson recommend conciliation, the EO will inform the whistle-blowing service provider of the Chairperson of the Ethics committee's recommendation of conciliation. It is incumbent on the anonymous complainant to contact the whistle-blowing service provider for feedback on the process and decide whether they want to reveal their identity in order to take part in a conciliation process.

Any resolution to the matter should be recorded in writing and forwarded to the EO in order to close the complaint.

All information relating to the complaint and the resolution thereof will be confidential, unless the parties agree to the disclosure of specific details, e.g. an agreement that a particular practice will be stopped.

If the anonymous complainant wishes to remain anonymous the matter will be referred back to the Chairperson of the Ethics committee for further consideration. Any and all decisions made by the Chairperson and/ or Ethics committee in relation to the resolution of anonymous complaints will be communicated to the whistle-blowing service provider. It is incumbent on anonymous complainants to contact the whistle-blowing service provider for feedback.

The independent investigator

In the event that the Chairperson of the Ethics committee decides that an independent investigation is required, the Chairperson will appoint the independent investigator from a panel of independent investigators.

The independent investigator will upon receipt of the documents launch an investigation into the complaint and will prepare a report of his/her factual findings within 15 working days of receipt of the documents.

The independent investigator can determine his/her own process for the investigation, but he/she will be allowed to interview the complainant directly or via the whistleblowing service provider in the event of an anonymous complaint and the respondent and/or representatives of the complainant and the respondent.

Within 7 working days after receipt of the independent investigator's report the Chairperson of the Ethics committee will consider the independent investigator's report and relevant documents and decide on further action as set out below. Should it transpire that a complaint had no merit (for example was frivolous, vexatious or malicious), the complaint will be dismissed. Should the complaint be found to have merit (i.e. be valid), the ethics committee will adjudicate on the complaint. The members of the ethics committee shall not have any direct or indirect interest in the matter adjudicated upon.

Pre-hearing procedure

The Chairperson will advise the EO within 7 working days of receiving the documentation if a hearing is required and the date of the hearing and shall request the EO to advise the complainant and the respondent in writing of the date and venue for the hearing. The EO will forward the documentation to the ethics committee and inform them of the date and venue for the hearing.

In the case of the complainant being anonymous, the EO will inform the whistle-blowing service provider of the Chairperson's recommendation of a hearing. It is incumbent on the anonymous complainant to contact the whistle-blowing service provider for feedback on the process and decide whether they want to reveal their identity in order to take part in a hearing. If the anonymous complainant wishes to remain anonymous the matter will be referred back to the ethics committee for further consideration. Any and all decisions made by the ethics committee in relation to the resolution of anonymous complaints will be communicated to the whistle-blowing service provider. It is incumbent on anonymous complainants to contact the whistle-blowing service provider for feedback.

All correspondence will be held in confidence and no appointed member of the ethics committee may enter into discussion or correspondence with either the complainant or the respondent.

At the hearing

Both the complainant and respondent may be present at the hearing. In the event of the parties being juristic persons, they will be represented by an official of the juristic person.

The parties shall not be entitled to have legal representation unless the ethics committee, having regard to, *inter alia*, the complexity of the matter, the legal issues involved, the seriousness of the matter and the sanction which may be imposed, in its sole discretion determines otherwise. In such case, the respondent shall be entitled to legal representation by a practicing attorney and/or practicing advocate. Should the respondent be allowed legal representation, the complainant shall also be entitled to be represented by a practicing attorney and/or practicing advocate.

Should any party so request and provide substantiation for such a request, the hearing may, in the absolute discretion of the ethics committee, be conducted in camera.

The complainant has the right to present the complaint and their reply to the respondents response, if any, to the ethics committee.

The respondent has the right to present its response to the complaint to the ethics committee.

The parties have the right to present evidence through oral statements or witness testimony, or to hand other evidence to the ethics committee, and the opposing party has the opportunity to respond to such evidence being presented.

The ethics committee may ask questions during the presentation of either party's case and/or question witnesses or request additional information or that any information or evidence be substantiated.

The ethics committee may in its discretion call any person as an expert to present evidence in person or in writing.

The ethics committee will attempt to conclude the hearing within one working day, but the ethics committee may adjourn a hearing on the substantiated request of either party, or in its sole discretion, whether to obtain more information or to ensure a fair hearing.

The ethics committee may determine its own procedure and the timeframes stipulated in this Code may be deviated from if the circumstances so dictate.

After the hearing

The ethics committee must make a substantiated finding within 7 working days after the hearing, and the chairperson must provide such finding and the reasons for the finding in writing to the EO, who will provide a copy of the finding to both parties and/or the whistleblowing service provider.

The ethics committee will attempt to reach its finding by consensus, failing which the committee will vote on the matter, and, in the case of a tie, the chairperson will have the casting vote.

The confidentiality referred to in this Part 2 of the Code does not extend to the EO / secretariat making a brief summary of the facts of the case and the finding, as such findings then become examples of violations or conduct acceptable under the Code.

In cases of extreme and/or repeat violations of the Code, the confidentiality rights of the respondent will give way to the public interest, in ensuring that such violations do not occur again, or that patients or clients are protected.

Costs

Each party will bear its own costs.

Member companies whose employees are nominated will bear the costs of such employees participating in the ethics committee (e.g. time off at work and travel to the hearing).

SAMED will cover all costs relating to the venue and refreshments required to conduct a proper hearing.

A reasonable honorarium may be paid to any expert asked by the ethics committee to provide additional information to the committee, in consultation with the SAMED EO, the SAMED Chairperson and the SAMED Treasurer.

The chairperson of the ethics committee and the Independent Investigator (where used) will be remunerated at a fee negotiated between the Board and the person to be appointed by the Board.

Members who terminate their membership of SAMED prior to, during, or after the initiation of an investigation or the hearing before the ethics committee shall still be liable for payment of any costs incurred during the process.

The ethics committee may award costs as it sees fit.

Sanctions

Principles for determining sanctions

The reasoning behind the imposition of a sanction should be transparent to both the complainant and respondent company.

It must be acknowledged that sanctions are not static. The upper limits of monetary sanctions will be reviewed as part of the periodic review of the Code. However, within the limits identified in the Code, the ethics committee has the discretion to apply a range of monetary fines and other sanctions based on consideration of these principles.

Note, resignation or cancellation of membership does not release a member company of its obligation to implement or pay sanctions imposed.

The following includes some of the principles which will be taken into consideration by the ethics committee in determining an appropriate sanction following a finding of breach/es of the Code.

Principal factors in determining a sanction

Decisions regarding sanctions should consider the following factors:

- 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 clearly evident to the company.

- The length of time that the breach has been in place
- The number and type of alleged breach/es.
- Previous similar breaches, including but not limited to:
  - History of previous breaches of the Code
  - Sanctions previously imposed on the company under the Code in relation to the same or similar types of breach/es or in comparable circumstances.
  - Repeated or multiple breaches.
  - Any evidence that previous breaches or sanctions have not been successful in encouraging improved compliance within the company (not necessarily within the same therapeutic area).
  - Any evidence that the breach related to an activity that was not sanctioned by the company's operating procedures or training of personnel.
  - Cooperation / acknowledgement of offence and evidence of internal procedures implemented to avoid similar breaches in future.
- Impact on patients, providers and/or healthcare service provision.
- Harm to competitors, patients, providers and/or healthcare service provision.
- The non-implementation of previously imposed sanctions and/or corrective action and/or failure to implement undertakings previously made.
- Circumstances e.g. the environment in which the activity took place.
- The potential costs to be incurred by a company for corrective action – the ethics committee will consider the overall monetary cost of the package of sanctions, for example the cost of issuing a corrective letter in combination with a fine.

The following table provides guidance on to the possible types of sanction that might be applied:

Breach Classification	Expanded definition	Possible Corrective Action/Public Disclosure	Fine	Timelines
Minor	No safety implications for patients' wellbeing. No effect on how healthcare professionals will use product.	Immediate suspension of activity. Company to issue a corrective statement, as determined by ethics committee, including target audience. Written reprimand to company by SAMED. Notify HCP of breach, if relevant.	R10000-R50000	30 working days
Moderate	No safety implications to patients' wellbeing. May have effect on how healthcare professionals will use product.	Immediate suspension of activity. Company to issue a corrective statement, as determined by ethics committee, including target audience. Written reprimand to company by SAMED. Notify HCP of breach, if relevant.	R100000-R200000	30 working days
Serious/severe	Will have safety implications to patients' wellbeing. Will have effect on how healthcare professionals 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 ethics committee.	R200000 – R300000	30 working Days
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 ethics committee		Further fine of R50000	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 ethics committee for consideration.	Further fine of R100000	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 newspaper with national circulation along with the name of the offending company. Publication of the infraction on SAMED website. Inform the MCC of infringement 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: R10000 + original fine Second: R15000 + original fine Third: R25000 + original fine R200000 max	60 working days
Frivolous, vexatious or malicious complaints	Does not comply with requirement of complaint as defined in Code.	SAMED informs complainant in writing.	Complaint lodging fee forfeited plus R10000	60 working days

Double jeopardy

The ethics committee will not rehear a complaint against a particular section or sections of the Code in relation to the same activity or same material irrespective of whether there was a finding of a breach of the Code, unless there is an allegation that the material has not been withdrawn or the activity has not ceased. If a complaint is received in relation to an activity or material already considered by the ethics committee, the complainant will be referred to the outcome of the previous complaint.

Guidelines in relation to specific sanctions

In the case of a corrective letter, the ethics committee 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 ethics committee prior to release.

Publication of Outcome of Complaints

An outcome of code complaints without names of companies will be published on the SAMED website and circulated to members.

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.

PART 3: Questions and Answers

Interactions between medical device industry and HCPs

Q1: Why did SAMED develop a Code? How does this Code relate to other Policy documents, such as the HPCSA's Perverse Incentives Policy or the SA Code of Marketing Practice?

A1: *This Code reflects the unique interactions between medical device companies and HCPs. Distinguishing features in the Code arise primarily from the fact that members interact with HCPs because of the complexity of medical devices and the importance of having HCPs understand how to use the technology safely and effectively.*

The Code aims to be in line as far as is practicable with other applicable Policy documents that bind health professionals, such as the 'Guidelines and Ethical Rules of Conduct for Practitioners Registered under the Health Professions Act' and the HPCSA Policy on Undesirable Business Practices. See www.hpcsa.co.za.

Application of the Code

Q2: Who are "HCPs"? Does the term include non-clinical people who make product-purchasing decisions? Does it include decision-makers within group purchasing organisations?

A2: *The term "HCP" includes: individuals, entities, their employees or employers, their agents or other delegates, and includes, but is not limited to persons registered with the Health Professionals Council, Allied Health Professions Council, the Nursing Council, the Pharmacy Council or, an institution registered with the Department of Health or other regulatory or organisational body, such as a health facility, and who purchase, lease, recommend, use, maintain, arrange for the purchase or lease of members' medical device products in South Africa.*

This includes both clinical and non-clinical people who make product-related decisions. It also includes decision-makers within group purchasing organisations (GPOs). This is a broad definition, intended to encompass anyone with material influence over purchasing, utilisation and similar decisions.

Other examples of entities that fall within the definition of "HCP" are: the Board of Healthcare Funders, private and public hospitals, medical schemes or funders, Council for Medical Schemes, laboratory and pathology technicians.

Note that there may be laws and other Codes applicable to relationships with HCPs, including relationships with government employees including the Foreign Corrupt Practices Act.

Q3: Is the Code binding on those members who sell products in other countries e.g. Angola?

A3: *No, however should the member sell or engage with a South African HCP outside of South Africa, the Code will be applicable. Although SAMED does not have jurisdiction in other countries it is expected that Members abide by any South African legislation that is applicable abroad.*

Q4: Does the Code govern the actions of members' agents and sub distributors?

A4: *Yes. As the Code states, members will communicate the Code's principles to their employees, agents, dealers and distributors with the expectation that they will adhere to the Code. It is important that members inform these entities of any revisions to the Code and that they are made aware of the ethical business practices reflected in the Code's provisions. Note, the Code is only applicable to HCPs registered in South Africa and to agents and sub distributors based in South Africa.*

Q5: Does the definition of HCP include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a supermarket chain?

A5: *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 members medical devices for or on behalf of medical or clinical personnel. For example, if a member company's medical devices 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 medical devices 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.*

Chapter 1: General criteria for events

Q6: What is meant by "legitimate" or "genuine" as used in the definitions of 'company event' and 'third-party organised educational conferences'?

A6: *Any event should be relevant to the HCP attendees; the detailed programme should be available sufficient time prior to the event; present a clear schedule with no gaps during the sessions, (e.g., the minimum duration for a full day event should be six hours or three hours for a half-day event including refreshment breaks). If it is a third-party organised educational event, the faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be.*

Q7: Under the Code, how does the "season" impact evaluation of Event location and venue?

A7: *For European and international events, ski resorts in the ski season, island resorts, beach resorts and other geographic locations renowned primarily as seasonal vacation or holiday destinations are not appropriate geographic locations during the season in question. member companies must not support or organise events at these locations during those seasons.*

Q8: In the event that an HCP is accompanied by a guest at the event, may this guest be admitted to any company event, or third-party organised educational events?

A8: *It is not appropriate for a guest of a HCP to attend either company events (including satellite symposia) or third-party organised educational events (unless the individual qualifies as a participant in their own right), nor is it appropriate, in the interest of maintaining the scientific exchange, for a guest to participate in related hospitality during such events (for example, lunches and coffee breaks) even when the HCP pays for the guest's expenses. Member companies, however, may financially support third-party organised educational events 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 an 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.

Q9: Is it acceptable to offer a cash advance by way of a cheque or bank transfer payable to a HCP for a specific amount to cover all or part of the HCPs' travel or accommodation expenses for attendance at the event?

A9: *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 intermediary agency. Alternatively, member companies may reimburse individual HCP expenses retrospectively against original invoices or receipts.*

Q10: What are the main differences between Third-party Organised Educational Conferences and Third-Party Organised Procedure Training?

A10*: Both Third-Party Organised Educational Conferences (see Interpretation and Definitions) and Procedure Trainings (see Interpretation and Definitions) are a type of Third-party Organised Educational Event. Therefore, they must comply with Chapter 1. General Criteria for Events. However, unlike Third-party Organised Educational Conferences, Third-party Organised Procedure Trainings are not subject to the prohibition of direct support for the attendance of HCPs. Nonetheless, for Third-party Organised Procedure Trainings the following three criteria shall apply:*

- *Programme: Unlike Third-party Organised Educational Conferences which are theoretical in nature, Third-party Organised Procedure Trainings consist of practical, hands-on trainings, generally involving more than one provider/manufacturer/sponsor. This must be evident by the programme of the Event. The programme, which is often referred to as a "course", rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or medical technologies). Examples may include courses aimed at acquiring or improving the Healthcare Professional's 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 technologies are used on cadavers; skin models; synthetic bones; cath labs; etc.*
- *Venue: Third-party Organised Procedure Trainings are typically organised in a clinical environment, as opposed to, e.g., a classroom setting. For the avoidance of doubts, 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 appropriately set up to simulate medical procedures, for example with the presence of medical technologies to be used on cadavers; skin models; synthetic bones; etc.*
- *Stand-alone event: Third-party Organised Procedure Trainings must stand-alone. Where the majority of the training is not given in a clinical environment, for example, where the Training is organised in connection, adjacent to or at the same time as a larger Third-party Organised Educational Conferences, that Training will not qualify as a Third Party Organised Procedure Training, as defined in the Code*

Q11: In the definition of Third-party Organised Procedure Training, what is meant by "Proctorship" and "Preceptorship"?

A11: *For the purpose of the Code both Proctorship and Preceptorship are types of clinician-to-clinician training funded by a Member Company. 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 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. Such Proctorships and Preceptorships normally take place on HCO premises and are not considered to be either a Third-party Organised Educational Event or a Third-party Organised Procedural Training.*

Chapter 2: Company events

Q12: Is it appropriate for member companies to invite HCPs on company plant or factory tours where the HCPs reside outside the country of location of the plant or factory?

A12: *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.*

Q13: Are cruise ships or golf club's appropriate venues for product and procedure training and education events?

A13: *No. Cruise ships, golf clubs or health spas and venues renowned for their entertainment facilities are not appropriate venues and should not be used. Appropriate examples include hospital, clinic or surgical centre laboratory, 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 any required "hands on" training.*

Chapter 3: Promotional aids, items of medical utility, gifts and competitions

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

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

Q15: What is the maximum value of a promotional item?

A15: *The value as set by the SAMED Board for promotional items to an individual HCP is R300 incl VAT/per item and for a unit / department within a hospital (ie not a practice) is R1000 incl VAT/per item.*

Q16: What is the maximum value of an item of medical utility?

A16: *The value as set by the SAMED Board for items of medical utility (other than anatomical models and scientific medical reference books / journals and periodicals) to an individual HCP or patient is R300 incl VAT/per item and for a unit / department within a hospital (ie not a practice) is R1000 incl VAT/per item.*

Q17: What are examples of items of medical utility?

A17: *Items of medical utility 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.

Q18: Are memory sticks containing informational or educational materials permissible?

A18: 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 education content that is directly relevant to the practice of medicine or pharmacy and beneficial to the care of patients.

Q19: What is the maximum value of an anatomical model?

A19: *The value as set by the SAMED Board for an anatomical model is maximum R5000 incl Vat/per item per HCP / Practice / Department per annum.*

Q20: What is the maximum value of scientific medical reference books / journals and periodicals?

A20:

- *Individual practicing HCP or practices, the value should not exceed R2 500 incl VAT per annum.*
- *Training or academic institutions, the value should not exceed R10 000 incl VAT per annum.*

Q21: What is the maximum value for competition prizes?

A21*: For a consumer competition:*
The total value of the prizes for a consumer competition must not exceed R100 000 incl VAT; and each individual prize may not exceed R5 000 incl VAT. A donation of any nature linked to the competition needs to be included in the total prize money.

For a competition aimed at HCPs and HCOs:
The value of the prize must not exceed R2 000 incl VAT / event or promotional activity.

Note: In accordance with the prohibition of direct sponsorship to HCPs to third-party arranged event, a prize in the form of congress sponsorship is prohibited as of 1 January 2018.

Q22: May a member company provide a small gift to a Healthcare Professional to mark significant life events such as a marriage, birth, birthday or death?

A22: *The Code prohibits all types of gift that may be given to an HCP and 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 death, it is for each member company to determine the appropriateness of making a tasteful token to direct family members only, as a mark of respect.*

Q23: Where HCPs engaged by member companies as consultants or speakers decline a professional fee for their services, would it be appropriate for the member company to show its appreciation by giving the HCP a small gift such as a bottle of wine or a bouquet of flowers?

A23: *No, it would not be acceptable for the member company to make 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.*

Chapter 4: Charitable donations

Q24: Under the Code, can a member company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?

A24: *No, a member company cannot make available a charitable donation to support the general running of a hospital or other HCO. A charitable 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 not therefore appropriate to provide charitable donations to support their general running.*

Q25: Is it permissible for a member company to make a charitable donation to a HCP's designated charity in instances where the HCP has requested the member company to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the member company?

A25: *No. Under the Code it is not appropriate for a member company to support the favourite charity of a 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.*

Q26: Under the Code, may a member company make a charitable donation such as the purchase of a table of dinner invitations at a fundraising dinner or entries to participate in, or attend at, a fundraising sports or other event?

A26: *Yes, charitable donations made by member companies 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 company 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 company should not invite HCPs to attend such an event at the member company's expense. Furthermore, the member company 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.*

Chapter 5: Arrangements with consultants

Q27: What is meant by fair market value (FMV) in the context of consulting arrangements?

A27*: 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.*

Q28: How should member companies determine FMV for a service?

A28: *A member company must be able to demonstrate internal methodology to determine fair market value. Amongst 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.*

Chapter 8: Bonusing, rebates and incentive schemes

Q29: Is it acceptable to pay for shelf space?

A29*: It is not acceptable to pay for shelf or storage space in a HCPs practice, hospital or hospital group warehouse, excluding retail pharmacies.*

Chapter 9: Royalty arrangements

Q30: Does the Code address arrangements between a member and an HCP relating to the development of a new medical device for the member?

A30: *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 11: Reimbursement for information and other economic data – marketing data, formulary, managed care and similar fees

Q31: Is it appropriate to demonstrate that a product can be used in an economically efficient manner?

A31: It may be 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 13: Healthcare representatives

Q32: May a company representative who is a registered theatre sister work in a hospital after hours?

A32: *Company representatives may not work as HCPs in their spare time unless this is known and agreed to by the company. Guidance should be sought from DENOSA or SANC and the hospital policy will prevail.*

Q33: May company representatives take / wear their own / company branded overshoes and / or theatre clothes into theatre?

A33: *Company representatives may only wear such items if they are appropriate and have been approved by the facility.*

Q34: What should a company representative do should a hospital group / healthcare professional ask the representative to obtain patient consent?

A34: *Under no circumstances may a company representative obtain consent from patients. This is the HCP's responsibility.*

Q35: May a company representative touch a patient whilst doing product training?

A35: *No, regardless of whether they are a registered nurse or not, a company representative may not touch a patient under any circumstances even if demonstrating / training a product.*

Chapter 14: SAMED guidelines for the utilisation of nursing professionals by SAMED member companies as independent contractors or as employees

Q36: Is paying a nurse employed or contracted as a nurse by my company, a commission to use / sell my product considered perverse?

A36: *Yes.*

Q37: Can an HCP be reimbursed by a member for cleaning and packing a loan set at the place of their employ ie a theatre nursing sister?

A37: *No. This would be regarded as inappropriate to pay an HCP not in the employ of the member – member companies must train the hospital staff in the management of their loan sets. Movement of loan sets must be managed by the member themselves.*

PART 2: Dealing with infringements of the Code

Q38: What is the complaint lodging fee as set by the SAMED Board?

A38: *R2500 incl VAT.*

Other

Q39: Does the Code offer legal advice?

A39: No. The Code is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. All members have an independent obligation to ascertain that their interactions with HCPs comply with all current laws and regulations.

On request and without prejudice, the SAMED Code Committee via the SAMED Office will provide a free -of-charge non-binding advisory opinion service to members and other stakeholders. Such requests must be submitted in writing to: info@samed.org.za. The Code Committee will provide a response as is reasonably possible.

PART 4: Complaint Lodging Form

Complaint in terms of the Medical Device Code of Ethical Marketing and Business Practice

Any signatory to the Code, a member of the public, Healthcare Professional (HCP) or regulatory body ("the complainant") may lodge a formal written complaint. Note there is no lodging fee required to be paid by a member of the public, HCP or regulatory body. SAMED members and/or signatories to the Code must however pay a complaint lodging fee, see clause 5 below.

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

Kindly submit the complaint to info@samed.org.za

Date: _____ **Case Number issued by SAMED:** _____

1. Complainant:

a. Name and surname: _____

b. Job title: _____

c. E-mail address: _____

d. Mobile Number: _____ Work Number: _____

e. Name of Company / organisation: _____

f. Name of Company CEO: _____

g. Field of business of the complainant (manufacturer, distributor, doctor, private hospital, member of the public etc) _____

2. Details of the individual / Company who is the subject of the complaint ie 'the respondent'

a. Name and surname: _____

b. Job title: _____

c. Name of Company / organisation: _____

d. Contact details of this person (if you have them):

E-mail address: _____

Mobile Number: _____ Work Number: _____

3. Field in which infringement has occurred (e.g. insulin pumps, orthopedic implants, wound care, etc)

_____

4. Clause(s) within the Medical Device Code, detail and circumstances relating to the alleged infringement. Succinctly describe the essence of the complaint in the table below. Use one line for each infringement. Where available list and attach any proof/evidence substantiating the complaint.

Indicate Code Clause (s)	**Describe each alleged infringement ie what, how, where**	**Date / period of the alleged infringement**	**Indicate proof\/evidence substantiating the complaint**
	What: How: Where:		
	What: How: Where:		
	What: How: Where:		

5. Please provide proof of payment that you have paid the complaint lodging fee (R2500 incl vat) into the SAMED bank account. Note, there is no lodging fee required to be paid by a member of the public, HCP or regulatory body.

Account Holder Name: The South African Medical Technology Industry Association
ABSA Account No.: 40-8826-5446
Branch: Randburg
Branch code: 632005

Name: _____ Designation: _____

Company: _____ Signed: _____

PART 5: Addendums

Addendum 1

Template Consulting Framework Agreement

This Consulting Framework Agreement (for ongoing services, hereinafter the „Agreement") is made by and between
Company A, a division of Company Y , a company with offices at ------- (hereinafter Company Y);
and
Dr XYZ (hereinafter the "Consultant"; Company Y and Consultant collectively the "Parties").

1. Article 1: Scope of services

1.1 *Consultant shall use best efforts to:*

a) provide services to Company Y as set out in this Agreement and in any agreed work order;

b) provide Company Y 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

c) keep detailed and reviewable records of work performed with a break down of time spent thereon, and of those expenses which are eligible for reimbursement by Company Y -and to make all such records available to Company Y upon request.

1.2 Company Y 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:

- *Company Y will provide Consultant with a description of the envisaged project, specifying amongst 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 Y project description.*
- *If Company Y 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.*
- *Company Y 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:

1. the work order;
2. the project description made by Company Y
3. the present Agreement;
4. the offer made by Consultant.

1.5 An affiliate of Company Y 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 Company Y shall be deemed to mean such affiliate and only such affiliate shall have the rights attributable to Company Y 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 Company Y 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.

2. Article 2: Remuneration

2.1 *In consideration of the Consultant performing the services as set forth in* ***Annex 1****,* Company Y AFFILIATE or its appointed agent *shall pay to the Consultant, within 7 days of the activity date. The Company Y 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, Company Y 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 Company Y 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 his country of residence.*

All travel arrangements for air, lodging and car rental will be directly organised by Company Y Affiliate in accordance with the applicable Company Y 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 Y 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.* Company Y will inform speaker in case the invoice needs to be addressed to its appointed agent instead of to Company Y 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 3 (Three) days per annum (inclusive of preparation time, as indicated above)				

Note that a deduction of 25% of the rate will apply in respect of PAYE, in cases where consultants are not VAT registered. If VAT registered, no PAYE deduction will apply.

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 remuneration and 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

Company Y and Consultant, and shall not obligate Consultant to purchase, use, recommend, or arrange for the use of any product of Company Y 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: _____

3. 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 fulfill 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.

4. Article 4: Confidentiality/Return of Documents

4.1 In view of Consultant rendering his services, Company Y may provide Consultant with information concerning Company Y including, without limitation, information regarding existing or contemplated Company Y products, processes, techniques, or know-how, that is confidential or proprietary and the disclosure of which would cause irreparable injury to Company Y (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 authorization from Company Y. Additionally, upon termination or expiration of this Agreement for any reason or upon the request of Company Y Receiving Party shall promptly return to Company Y 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 Company Y 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 Company Y upon expiry of this Agreement.

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

5. Article 5: Copyright/Publications/Inventions

5.1 Consultant hereby grants Company Y 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 in 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 remuneration 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. Company Y shall be entitled to assign or to sublicense in part of 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 company Y. Consultant shall hold Company Y harmless against third-party claims for infringement of copyrights related to the Right of Use granted to Company Y, and shall assist Company Y 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 Company Y be the property of Company Y. Consultant, without charge to Company Y other than reasonable payment for time involved in the event this Agreement shall have terminated, but at Company Y expense, shall execute, acknowledge, and deliver to Company Y all further papers, including applications for patents, as may be necessary to enable Company Y to publish or protect Service Inventions by patent or otherwise in all countries and to vest title to such Service Inventions in Company Y or its nominees, their successors or assigns. Consultant shall render assistance as Company Y 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 Company Y when requested or at the termination of the work. Where assignment by Consultant of rights of Service Inventions to Company Y is necessary in order for said Service Inventions to be the property of Company Y, Consultant undertakes to use his best efforts to obtain any and all necessary approvals, including, but without limitation, approvals of his employer.
The remuneration of Consultant pursuant to Article 2 above shall serve as sufficient consideration for granting respectively assigning the Service Inventions to Company Y.

6. Article 6: General Provisions

6.1 The relationship under this Agreement of Company Y 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 Company Y and Consultant and neither Company Y 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 authorized representatives of each of the Parties.

6.3 Furthermore, Consultant agrees that Company Y Affiliate may disclose the existence and content of this Agreement to the relevant professional organization 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 Company Y AFFILIATE if Consultant attains a position to influence purchasing decisions of a government entity or a health-care-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, Company Y AFFILIATE has the right to terminate this Agreement with immediate effect by written notice. Where such notification to Company Y 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 Company Y 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.*

6.8 *"In order to fulfil the purpose of this Agreement, Company Y might need to share your personal data with any third parties providing that support, such as travel agencies, hotels, event organisers, etc.*
This might involve transferring your data to third countries where those third parties might be located, as well as to other affiliates of ours located in those countries, where data protection standards might vary from those in your country.
Your personal data will be processed by Company Y, 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."

Signed:

For Company Y *Consultant:*

_____ _____

Title: _____ *Title:* _____

Date: _____ *Date:* _____

HCP: Dr XYZ

_____ *Date:* _____

ANNEX 1

Scope of Consulting Services/Fees for Consulting Services

In view of proper compliance with relevant Health Care Compliance Laws and Guidelines, it is imperative that you carefully prepare this Annex 1.

WORK ORDER N° XX

to the CONSULTING FRAMEWORK AGREEMENT between Company Y (hereinafter Company Y) 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 Dr XYZ will attend theatre cases in other surgeon's 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 HCP's in various settings.

Geographical location of the consulting services

Various major centres in South Africa.

Company Y's project assignment manager

Company Y 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 Company Y WORK ORDER number shall be sent to Company Y , for attention Ms relevant person (e –mail). Invoices must be submitted to Company Y within seven days of the activity date.

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

Company Y

Date :

_____

Dr D XYZ

Date :

_____

ANNEX 2

Compliance with Anti-Corruption Laws

Notwithstanding anything to the contrary in the Agreement Dr XYZ hereby agrees that:

(i) Dr XYZ 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) Dr XYZ 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 Company Y and/or its business in a manner that would violate Anti-Corruption Laws;

(iii) Dr XYZ shall not retain any government official or government employee in the performance of the Agreement unless it has been approved by Company Y and, if necessary, by the competent authority or authorities and such government official's or employee's employer. Furthermore, Dr XYZ shall immediately advise Company Y in writing in the event Dr XYZ 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 Dr XYZ that is a government owned entity;

(iv) Dr XYZ shall be available or when appropriate designate an individual within its organization to receive training from Company Y on Anti-Corruption Laws, as well as applicable rules on interactions with health care 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 CompanyY, on at least an annual basis to all persons employed by Dr XYZ who perform work for Company XYZ and interact with government officials or health care professionals] in the normal course of their responsibilities. Upon Company Y and Dr XYZ mutual agreement, such training may also be provided directly by Dr XYZ to such employees of Dr XYZ. Dr XYZ 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 Company Y does not relieve Dr XYZ of any obligations it has independent of the Agreement and Dr XYZ shall not rely on CompanyY training and materials for any such obligations;

(v) Dr XYZ shall certify on an annual basis in a format to be provided by Company Y that:

a. training and training materials on Anti-Corruption Laws, as well as applicable rules on interactions with health care professionals,] have been provided to all persons employed by Dr XYZ who perform work for Company Y and interact with government officials or health care professionals] in the normal course of their responsibilities and that it has provided the Company Y training and training materials to subcontractors used by Dr XYZ in the performance of the Agreement;
b. to the best of Dr XYZ's knowledge, there have been no violations of Anti-Corruption Laws by Dr XYZ or persons employed by or subcontractors used by Dr XYZ in the performance of the Agreement;
c. personnel of Dr XYZ who may be designated as "Key Personnel" by mutual agreement of Company Y and Dr XYZ have not changed, except as noted in a schedule attached to the certification provided by Dr XYZ
d. Dr XYZ has made no changes in its use of subcontractors to perform the services for Company Y under the Agreement, except as (1) permitted under the Agreement and (2) noted in a schedule attached to the certification provided by Dr XYZ ; and

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

(vi) *Dr XYZ shall maintain and provide Company Y 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 Company Y in order to document or verify compliance with the provisions of this agreement; and*

(vii) *if Dr XYZ 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, Company Y shall have the right to terminate the Agreement with immediate effect upon written notice to Dr XYZ without penalty or liability of any nature whatsoever.*

If the consultant is not **acting as intermediary with HCPs or government officials in the normal course of performing their services while acting on behalf of Company Y and/or its affiliates** (eg HCP agreements such as speaker agreements, advisory board agreements, etc) the above can be deleted and the following text should be used instead:

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 2

SAMED Policy and Procedure - Transparent Invoicing Model

SAMED POLICY AND PROCEDURE REGARDING A TRANSPARENT INVOICING MODEL

1 Preamble:

As a result of the changing regulatory environment in South Africa and its impact on the provision of affordable Health Care in the country, the need arose for the South African Medical Device Industry Association (SAMED) to develop a policy to transform business practices within the medical device industry.

In order to establish such a policy, it became necessary that SAMED constitute a committee – The Code of Ethical Business Practice portfolio committee, which was tasked with developing a policy to address transparency within the Healthcare industry. The **Transparent Invoicing Model**, to which this document refers, was workshopped with SAMED members on 31 August 2007. In addition, SAMED has consulted widely with key stakeholders including, but not limited to the various hospital groups and funders to ensure the successful implementation of this policy.

All members of SAMED are expected to adhere to this Model and the principle of presenting transparent invoices.

In addition, SAMED members must ensure their compliance with related legislation and/or regulation, and in particular must ensure that, in any discussion with any individual, institution; body and/or association, that their representations are complaint with Competition Law (see the Competition Act [Act No. 89 of 1998]).

2 Purpose:

To ensure that members provide accurate, transparent and responsible billing information to HCPs, reimbursement authorities and other payors members.

3 Definitions:

3.1 **Customers:** customers may include, but not be limited to: hospital groups, independent hospitals, health professionals etc

3.2 **Inception date:** that date by which all suppliers of medical devices shall commence with the transparent invoicing model and which is set as 1 October 2007.

3.3 **List Price:** that price which is the supplier's maximum price at which the item may be sold to a customer.

3.4 **NAPPI Code:** the National Pharmaceutical Product Interface Code, being that unique Code which is allocated by MediKredit to a "medical device" as defined in the Medicines and Related Substances Act 101 of 1965. NAPPI Codes are allocated to all reimbursable medical devices, in accordance with

3.5 MediKredit's NAPPI Code Allocation Policy, to uniquely 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.

3.6 **Other inducements:** inducements of any nature or form e.g. payment for information or shelf space, supply of bonus or free goods and the like, where such payments are deemed to be perverse.

3.7 **Settlement discount:** that discount which is granted for timeous settlement of an account and which reflects the normal 'cost of money'.

3.8 **Special requests, charitable donations and pro bono supplies:** those devices which are supplied to a customer at a reduced or nil price for special cases such as the indigent or non-medical scheme members.

3.9 **Volume discounts:** that discount which may be applied to the Maximum List Price in order to compensate the customer for volume purchasing.

4 The Transparent Invoicing Model:

The Transparent Invoicing Model in regard to the supply of medical devices shall commence by **1 October 2007** by adopting either of the following two transparent invoice models:

4.1 Model One: Nett Pricing Model

The nett pricing model allows for suppliers to invoice each line item at the contracted nett price as per the contract. This model is similar to the public bid system where no volume discount whatsoever is shown on invoice.

Suppliers are encouraged to display the NAPPI Code for each product and may also display the settlement discount percentage on the invoice for purposes of transparency.

4.2 Model Two: Discount Model

In some instances, where suppliers are required to indicate their discount from the Maximum List Price to the hospital/hospital group, this may be done provided that the Maximum List Price is clearly indicated and that the discount is shown as a deduction from the Maximum List Price. The result should be that the nett price is transparent on the invoice.

Suppliers are encouraged to display the NAPPI Code for each product and may also display the settlement discount percentage on the invoice for purposes of transparency.

To summarise:

The supplier shall ensure that the following appear on the invoice when charging their customer:

- List Price
- Volume discount
- Nett price
- Value added tax
- Total amount payable

4.3 In addition to the above two models, the following may also be reflected on the invoice in order to ensure further transparency:

- NAPPI Code
- Settlement discount terms e.g. 2,5% for 30-day settlement from date of invoice/statement

5. Maximum List Price / Nappi Codes:

In line with the affordability aspect of this policy document, SAMED implores its members to use this opportunity (ie the move to the Transparent Invoice Model) to review Maximum List Prices and revise these accordingly where possible to maximise cost benefits to the patient. As an association, we are committed to promoting action within our membership to address the spiralling cost of Health Care in the country. In accordance with this commitment:

5.1 All suppliers of medical devices are required to submit their revised pricing list, as applicable, to MediKredit. The revised Maximum List Price should be based on the maximum selling price per item as identified per catalogue number per supplier.

5.2 In reinforcing the policy governing NAPPI Codes, only ONE NAPPI Code should be applicable per item as identified per catalogue number per supplier. Where more than one NAPPI Code exists for the same item, the supplier shall inform MediKredit of this and request that the duplicate Nappi Code(s) be discontinued with immediate effect.

5.3 Where applicable, the process of submitting the Maximum List Prices to customers shall commence from **1 October 2007 and should be finalised and fully implemented by no later than 31 December 2007.**

5.4 Revised nett price and/or contracted nett prices below the Maximum List Prices can be negotiated between supplier and customer based on *inter alia* volume and other criteria determined by each supplier on a free market and competitive basis subject to compliance with the terms and conditions of section 4 of this policy.

6. Other inducements:

6.1 No inducements of any nature or form are to be paid or offered to customers e.g payment for information or shelf space, supply of bonus or free goods and the like, where such payments are deemed to be perverse.

7. Special Requests and pro bono supplies:

7.1 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.

8. Revisions:

This policy and procedure may be revised from time to time in consultation with all signatories/stakeholders and to ensure compliance with any statutory requirements.

9. Signatories:

Signatories; shall include, but not be limited to:

- Members of SAMED;

- Non-members of SAMED;
- Service provider groups;
- Schemes/Funders and;
- Other healthcare professionals.

10. Compliance:

This document is incorporated into this Code with its policy directives on ethical conduct and professional behaviour and the disciplinary measures which may be instituted against its members.

11. Enquiries:

All enquiries with regard to this policy document are to be submitted, preferably, in electronic format to: info@samed.org.za

Addendum 3

SAMED Medical Device Registry Principles and Position Paper

SAMED is committed to the principles of evidence-based medicine. Stakeholders, such as patients, their caregivers, providers, payers, regulators, and manufacturers share in the commitment to improve the quality and increase the efficiency of healthcare. As medical device manufacturers and suppliers, we recognise the need to ensure that there is adequate and accurate information to guide healthcare decision-making concerning the safety, effectiveness and value of medical interventions.

Registries are a mechanism to collect information about patient populations being treated, the provider's quality and processes of care, device performance, and the 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 SAMED 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 registry is defined as "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."[3] Registries are typically prospectively defined. A medical device registry may be sponsored by a manufacturer, professional society, patient advocacy group, government agency, provider group or a combination thereof.

A medical device 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, health care professionals, 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 randomized controlled clinical trials or other clinical study designs.
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.

[3] Gliklich RE, Dreyer NA, eds. Registries for Evaluating Patient Outcomes: A User's Guide. 2nd ed. (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc. d/b/a Outcome] under Contract No. HHSA29020050035I TO3.) AHRQ Publication No.10-EHC049. Rockville, MD: Agency for Healthcare Research and Quality. September 2010

To assure that the creation of a new registry is the appropriate mechanism to meet the above objectives, several threshold 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 medical device registry.

1) All medical device registries must be in accordance with applicable laws. Examples include but are not limited to: Helsinki Declaration, PAIA, POPI, Consumer Protection Act, National Health Act, Health Professions Act and related guidelines and ethical rules, Medical Device Regulations (once promulgated) 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.

    a) Sufficient safeguards should be established to ensure that valid data are entered into the registry.
    b) Data integrity and security must be maintained both during the active phase of the registry and after closure.
    c) 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.
    d) End points must be clearly defined.
    e) There should be a process for adverse event adjudication.
    f) 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:
        i) 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.
        ii) Controlled processes for data access and data release that take into account data privacy, maintaining data integrity and traceability as well as timing in relation to publication, market approvals and patent protection.
        iii) Guidelines for data transparency.
        iv) A process for device specific safety data reporting, including how information is shared with the manufacturer / supplier.

7. 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, poolability, 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 device characteristics (including unique device identifiers) should be collected to identify potential factors which affect patient outcomes.

h) The registry purpose and design should also recognize the unique characteristics of the device innovation life-cycle.

   i) Device innovation is an iterative process and a device life-cycle may conclude prior to a desired registry endpoint being achieved.

   ii) The design of a long-term registry must recognize and manage the potential for next generation devices entering the market during the data collection period.

4. 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.

5. 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 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 insure 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 analyzing 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 analyzing 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.

6. 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.

7. 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, health care professionals 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.

8) Policies should be established for the use and publication of registry data by stakeholders and outside registry data users. These policies should protect against unauthorized use of data and ensure appropriate 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 device 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 stakeholders as appropriate.**

d) Parties who purchase registry products (custom reports) may be charged a reasonable fee.

References: AdvaMed Board Approved Registry Principles 2013: http://advamed.org/res.download/397

Addendum 4

SAMED Protocol on Member Company Employees' attendance in an Operating Room / Clinical Environment

All SAMED member companies must make this protocol a condition of employment for any personnel who might be present in an 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 prior to entering any operating room/clinical environment.

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[4]
- 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.
In the operating room/clinical environment

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 authorization 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.

[4] This applies primarily to communicable diseases e.g. flu, hepatitis B etc, not those conditions you need not disclose by law

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.