

Message from the Board of Directors at SAMED

The healthcare industry is one of the most carefully scrutinized industries in the world. This Code of Marketing and Business Practice 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 Health Care Professionals (HCPs). 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 our day-to-day interactions.

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 through the appropriate channel. Note, failure to report a violation is itself a violation.

From the outset, it is important to emphasize that the updated Code underpins SAMED's vision i.e.:

'The responsible and ethical advancement of the interests of the medical devices industry within the SA healthcare environment while promoting better patient outcomes'.

Purpose 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 interactions with their customers. The Code is not a rule book, but gives guidance, and this guidance springs from chosen ethical values. Such ethical values include:

- ❑ an industry that is socially responsible towards not only its customers, but to society at large and patients in particular and
- ❑ the desire to promote a spirit of co-operation and shared responsibility among public and private HCPs and providers, which shall include the State, as well as other relevant sectors, within the context of effective, efficient and transparent health care delivery.

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

SAMED will endeavour to ensure that the Code is circulated to all key Stakeholders i.e. HCPs, hospitals, Government, Tender Authorities, Funders etc and that it be accepted as the basis for engagement with these parties.

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The SAMED Code will be binding on all SAMED Members and be a condition for new and ongoing Membership. The Code will be continuously reviewed (at least once per annum), borrowing from best practice both locally and globally. In fact much of what appears in SAMED's Code has been adopted from the Eucomed and Advamed Codes of Business Practice.

The Code also includes a question and answer section to assist SAMED Members in the interpretation and practical implementation of the Code.

Infringements of the Code will be dealt with through the efforts of a formally constituted 'SAMED Ethics Committee' governed by documented and legally complaint processes. Being a voluntary code, SAMED urges its Members to adhere to the Code and report any infringements to the SAMED Ethics Committee.

Notwithstanding the above, Members should note that the latest amendments to the Medicines and Related Substances Act through the adoption of Act 72 of 2008 will elevate the status of the Code to that of regulations, when published by the Minister of Health in terms of section 18C of the Act.

Disclaimer:

SAMED bears no responsibility for the conduct of any of its Members who may be alleged to be in contravention of this Code. SAMED also bears no responsibility for the non-enforcement of this Code.

SAMED CODE OF MARKETING AND BUSINESS PRACTICE

**Updated and approved by the SAMED Board on
21 February 2010**

Note:

This Code supersedes and replaces all previous SAMED Codes of Business Practice.

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1. INTRODUCTION: GOAL AND SCOPE OF SAMED CODE OF MARKETING AND BUSINESS PRACTICE

1.1 SAMED is committed to the following principles:

1.1.1 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;

1.1.2 To promote and encourage among its Members **ethical principles and practices**, voluntarily agreed upon, and to this end, to ensure that a Code of Marketing and Business Practice which shall be binding on all Members, is published in terms of section 18C of the Medicines and Related Substances Act, 1965 as amended;

1.1.3 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.

1.1.4 To ensure **fair competition** between Members based on the value of products and associated marketing skills, and not based on any unacceptable business practice.

1.1.5 SAMED encourages ethical business practices in interactions between its Members and HCPs, in particular that Members will not offer any inappropriate inducement to an HCP or other customer in order to sell, lease, recommend, or arrange for the sale or lease of their products.

1.1.6 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.

1.1.7 Members recognise that all South Africans have the right of access to healthcare, and that right should be progressively realised through co-operation and shared responsibility between the private and public healthcare sectors.

1.1.8 Members furthermore support an industry that is socially responsible towards not only its customers, but to society at large and patients in particular.

1.2 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:

1.2.1 **Advancement of Medical Technology:** The development of innovative medical devices and the improvement of existing products requires collaboration between Industry and HCPs. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the facilities of medical device companies.

1.2.2 Safe and Effective use of Medical Technology: The safe and effective use of medical technology requires that Industry offer HCPs appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.

1.2.3 Research and Education: Industry's support of bona fide medical research, education, and enhancement of professional skills contributes to patient safety and increased access to new technology.

2. APPLICATION OF THE CODE

2.1 This Code binds Members of SAMED, whether such Members are manufacturers, importers, distributors or agents and include 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.

2.2 All Members are urged to adopt policies and procedures relating to the Code, which includes mechanisms to ensure that all events, sponsorships, marketing and advertising campaigns are signed off by a responsible senior staff member, which member has to take responsibility for all regulatory compliance, which includes compliance with this Code.

2.3 Members are under an obligation to workshop and communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code.

2.4 This Code is intended to facilitate ethical behaviour and is not intended to be, nor should it be construed as, legal advice. The intention is however for this Code to be promulgated in terms of the relevant peremptory provisions of the Medicines Act, elevating its status and widening its scope of application to also include non-SAMED Members.

3. INTERPRETATION AND DEFINITIONS

3.1 This Code does not substitute any obligation or provision found in any other Code dealing with the same or similar practices, including but not limited to the Code of Practice for the Marketing of Medicine, and is intended to align with, amongst others the provisions of the Prevention and Combating of Corrupt Activities Act No 12 of 2004, the National Health Act No 61 of 2003, the Health Professions Act No 56 of 1974 as amended, the Medicines and Related Substances Amendment Act No. 72 of 2008 and its principal Act and all policies and guidelines issued in terms of the aforementioned legislation, the Competition Act No 89 of 1998 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.

3.2 In drafting the Code, regard has also been made 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.

3.3 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:

3.3.1 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.

3.3.2 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.

3.3.3 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.

3.3.4 The Principle of Documentation: For interactions between a Member and a 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.

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

3.4.1 "Branded promotional items" refer to small items of utility to a healthcare practice or facility which are branded and include pens, mugs, magnets, note pads, etc.

3.4.2 "Conferences", "Congresses" includes events of a scientific nature, whether international or local in nature and which aim to create and share new understandings of developments in healthcare, healthcare policy, treatments and protocols, and which take place under the auspices of a body responsible for organizing the event, and which include a scientific committee or review panel which is responsible for the scientific contents and merit of the programme and all presentations or workshops.

3.4.3 “Entertainment” includes, but is not limited to events, performances, sporting matches, shows, movies, theatrical performance, recreation and tours, aimed to provide, for example distraction, diversion or amusement.

3.4.4 “Gifts” include, but are not limited to pens, stationery, books, models, pointers, flashcards, branded merchandise, or other items provided to HCPs and include scientific medical reference books and medical periodicals.

3.4.5 “HCP” includes Healthcare Professionals and Healthcare Facilities, and therefore includes individuals, entities, their employees or employers, their agents or other delegates, and includes, but is not limited to persons registered with the Health Professions Council of South Africa (HPCSA), Allied Health Professions Council, the Nursing Council, the Pharmacy Council, the Engineering Council for Clinical Engineers and includes institutions registered at the Department of Health or other regulatory or organisational body, such as a health facility (which includes hospitals, step-down facilities, etc), managed care companies, etc; which entities purchase, lease, recommend, use, maintain or arrange for the purchase or lease of, Members’ medical technology products in South Africa.

3.4.6 “HCPs in training” refers to persons undergoing training towards a first, or further Healthcare Professional qualification, and does not include occasional training provided to professionals in the form of continued professional development or other similar shorter courses.

3.4.7 “Medical technology”, “Medical devices”, “Health Technology” refers to medical devices as defined in the Medicines and Related Substances Amendment Act, 2008, and include in-vitro diagnostics.

3.4.8 “Members” means organisations that are Members of the South African Medical Device Industry Association (“SAMED”) as defined in the SAMED Articles of Association, and includes their employees, agents and contractors working for or in conjunction with such Member.

3.4.9 “Scientific meetings”, “Advisory Boards”, “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 Member 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.

3.4.10 “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.

4. COMPANY SPONSORED PRODUCT TRAINING AND EDUCATION

4.1 Members have a responsibility to make product education and training available to HCPs in the interest of ensuring the appropriate, safe and effective utilisation of a particular type of medical technology.¹ “Training” means training on the safe and effective use of Medical Technologies. “Education” means communicating information directly concerning or associated with the use of Companies’ Medical Technologies, e.g. information about disease states and the benefits of Medical Technologies to certain patient populations. Training and Education programs include, but are not limited to, “hands on” training sessions, cadaver workshops, lectures and presentations, plant tours and demonstrations.

Such programs often occur at centralised locations (necessitating out-of-town travel for some participants), and may extend to more than one day.

4.2 The following rules apply in this context:

4.2.1 Programs and events should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge.

4.2.2 Programs requiring “hands on” training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. All training staff should have the proper qualifications and expertise to conduct such training.

4.2.3 Members may provide HCP attendees with modest meals and refreshments. These should be subordinate in time and focus to the educational or training purpose of the meeting.

4.2.4 Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Members may pay for reasonable travel, economy class airfares and modest lodging costs of the attending HCPs who reside outside of the main centre or centres where such training takes place. It is not appropriate for Members to pay for the meals, refreshments, travel, or other expenses for guests or spouses/partners of HCPs or for any other person who does not form part of the trainees or invited attendees at such a meeting.

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¹ This fact differentiates devices from the pharmaceutical industry, as user skill and training are an integral part of the successful utilisation of a device, and a factor in evaluating the purposefulness of a device.

5. CONGRESSES AND EDUCATIONAL CONFERENCES

Any independent educational, scientific, or policymaking conference which promotes scientific knowledge, medical advancement or the delivery of effective healthcare is considered to be *bona fide*. These typically include conferences organized under the auspices of (sponsored by) international, national,² regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Members may support these conferences in various ways:

5.1 Educational Grants for International Conferences:

Members may sponsor HCPs, both qualified and in training, to attend International events like congresses, conferences and scientific meetings, subject to the following:

5.1.1 Members may pay registration fees and may only offer economy travel, modest accommodation and meals. The level of accommodation offered must be appropriate, modest in nature, and the costs involved must not exceed that level that the recipients would normally adopt when paying for themselves.

5.1.2 No monies may be paid directly to a HCP upfront. Members may reimburse HCP's for legitimate expenditure incurred outside of congress related expenses but only on production of original invoices e.g. taxi fees, meals and refreshments. Conference fees and other expenses related to the conference should be paid directly to the Conference organizers.

5.1.3 Spouses and other accompanying persons, unless qualified as HCPs, may not attend the actual meeting and may not receive any associated meals and refreshment at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany;

5.1.4 Members may pay for the attendance of a HCP at congress organized events such as an opening address or gala dinner, but not for any add-on events, such as sporting events (ski, golf, etc), sight-seeing tours, etc.

5.1.5 Members may pay for business class flights only for both incoming and outgoing faculty members. Faculty members are defined as those HCP's that are presenting scientific papers at the congress or educational event overseas. This would also apply to international visiting professors that are invited to attend local CPD accredited meetings and events.

5.1.6 Members may not provide financial support to HCP's to attend trade shows.

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5.2 Educational Grants for Local Conferences:

5.2.1 Members may only sponsor HCPs in the public sector, HCP's in training, registrars, nursing staff, technicians and other deserving persons to attend local CPD accredited events like congresses, conferences and scientific meetings. In this regard, Members may pay registration fees and only offer economy travel and modest accommodation.

The level of accommodation offered must be appropriate, modest in nature, and the costs involved must not exceed that level that the recipients would normally adopt when paying for themselves.

5.2.2 Members may only provide a grant directly to the entity under whose auspices the conference is taking place to reduce or defray conference costs and may also choose to make such grant directly to a training institution, or to the attendee's employer to allow attendance of such conference or training by HCPs in training, registrars, nursing staff and technicians. Such grant is subject to the following:

5.2.2.1 the event is primarily dedicated to promoting objective scientific and educational activities and participating in scientific discourse;

5.2.2.2 grants should be paid only to organisations with a genuine educational purpose or function, and may be used only to reimburse the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with relevant guidelines established by professional societies or organisations. The entity under whose auspices the conference or training event is taking place, should be responsible for and control the selection of program content, faculty, educational methods, and materials; and/or

5.2.2.3 no monies may be paid directly to the sponsored individual.

5.3 Conference Meals and Refreshments

Members may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, Members themselves may provide meals and refreshments for HCP attendees if such meals and refreshments are provided: (1) to all HCP attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity.

Meals and refreshments may be provided to fewer than all HCP attendees if the Member providing such meals and refreshments satisfies all other principles related to meals set forth in Section 6. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference.

¹ In South Africa, these may include professional associations such as SAOA, SAGES, SASOG, SATS, etc

5.4 Faculty Expenses for HCPs visiting South Africa

5.4.1 Members may make grants to conference sponsors to cover the costs of reasonable honoraria, travel, lodging, and meals for HCPs visiting South Africa who are *bona fide* conference attendees and/or speakers.

5.4.2 While Members are encouraged not to reimburse HCPs directly for costs incurred directly related to the scientific components of the Conference, it is realised that there may be *bona fide* occasions where direct payments are justified. In these situations Members have to comply with national laws, their internal company code of conduct guidelines and good financial internal auditing practice. Reimbursement of expenses may only be made on production of original invoices.

5.5 Advertisements and Demonstrations

5.5.1 Members may purchase advertisements and lease booth space for company displays at conferences.

5.5.2 Competitions may be used as a mechanism to promote products, provided that:

5.5.2.1 the competition is open to all HCPs at an event or within a certain geographical area,;

5.5.2.2 the prize offered is modest in nature and does not exceed the limit established from time to time by the SAMED Board;

5.5.2.3 the competition question relates to a scientific issue, product knowledge or medical knowledge;

5.5.2.4 the prize is relevant to the discipline of healthcare;

5.5.2.5 entry into the competition is not dependent on the sale, use or recommendation of a particular product or products.

5.5.3 A competition, consisting of a *bona fide* and open draw, may also be used as a mechanism to sponsor a professional or student to attend an educational conference, provided that the prize consists of only *bona fide* conference fees, accommodation and travel for the winner only and does not include any add-ons or extra activities that do not relate to the scientific content of the conference.

5.6 Interactions with HCPs

During conferences (local and international) the organizers will often make provision for interaction between Industry and delegates e.g. a free evening. The following principles will apply to such interactions:

5.6.1 Members interactions should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Member may provide and pay for a meal and refreshments only if such hospitality is subordinate in time and purpose to the exchange of medical or scientific information and meets the requirements of Section 6. Entertainment of any nature is prohibited. See section 7.

5.6.2 Events or interactions may not be organised at the same time as congress related events.

5.7 Sponsoring congress related events

Members may sponsor congress related events (excluding recreational and sporting events) e.g. opening address, gala dinner provided:

5.7.1 the event is organised by the congress organisers; and

5.7.2 attendance is open to all registered delegates.

5.8 Inappropriate Venues

It is inappropriate for Members to host HCPs at venues that would be considered holiday destinations and which are distant from their normal place of practice, unless it is a bona fide educational meeting, conference or congress, endorsed by a Professional Healthcare Association.

6. MODEST MEALS ASSOCIATED WITH HCP BUSINESS INTERACTIONS

A Member's business interactions with HCPs may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described in this Code. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

6.1 Purpose. The meal should be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.

6.2 Setting and Location. Meals should be in a setting that is conducive to bona fide scientific, educational, or business discussions. Meals may occur at the HCPs place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the HCPs place of business, for example, (1) where the Medical Technology cannot easily be transported to the HCPs location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site.

6.3 Participants. A Member may provide a meal only to HCPs who actually attend the meeting. A Member also may not provide a meal where its representative is not present. A Member may not pay for meals for guests of HCPs or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

7. PROHIBITION OF ENTERTAINMENT AND RECREATION

7.1 Member interactions with HCPs should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Member should not provide or pay for any entertainment or recreational event or activity for any HCP. Such activities include, for example, theatre, sporting events, golf, skiing, hunting, and leisure or vacation trips.

7.2 Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the Member engages the HCP as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

7.3 Receptions. It is inappropriate for Members to host or sponsor meals or receptions for large groups of HCPs that are entirely unconnected to any Congress, Business premises or educational event.

This includes year end functions.

8. CONSULTING AGREEMENTS

SAMED Members engage HCPs to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and / or transfer of intellectual property, participation on advisory boards, presentations at Member-sponsored training and other services.

Members may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful or unethical inducement. Members should comply with the following standards in connection with consulting arrangement with HCPs.

8.1 Consulting agreements should be written and describe all services to be provided. When a Member contracts with a consultant to conduct clinical research services, there must also be a written research protocol.

8.2 Consulting arrangements may only be entered into where a legitimate need for the services is identified in advance and documented.

8.3 Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.

8.4 Compensation paid to a consultant should be consistent with fair market value for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business.

8.5 A Member may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging.

8.6 The venue and circumstances for Member meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.

8.7 A Member's sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular HCP as a consultant. Members should consider implementing appropriate procedures to monitor compliance with this section.

9. SCIENTIFIC ADVISORY BOARD

9.1 If the scientific meeting or advisory board is called by the Member, such Member is bound by the requirements in relation to the *bona fide* consulting services provided by the attendees and such meetings must be defensible on scientific grounds.

9.2 Members may not pay HCPs for the attendance of CPD events under the guise that such events are scientific meetings or advisory board meetings.

9.3 The general rules relating to spouses/partners, meals and refreshments and entertainment also apply in this context.

10. PRODUCT LAUNCHES and CONTINUED PROFESSIONAL DEVELOPMENT (CPD) EVENTS

10.1 In general, CPD meetings have to take place within the framework created by the specific professional statutory body, such as the HPCSA, SAPC or SANC.

10.2 Meals and refreshments should be modest and secondary to the CPD event, i.e. in duration, content and value, and be conducive to the educational nature of the CPD meeting.

10.3 Invitations may not be extended to spouses or partners of HCPs.

10.4 No product branding may take place in the meeting room, and branding outside the CPD meeting room has to comply with regulatory requirements relating to advertising to the general public and the MCC regulations pertaining to section 21 products.

10.5 Stand alone product launches do not qualify as CPD events.

11. ROYALTY ARRANGEMENTS

11.1 Arrangements involving the payment of royalties to an HCP should meet the contractual standards as set in Section 8. 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, for example, 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.

11.2 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.

For example, 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 technology 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 technology upon commercialization. Members are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the HCP and / or member of the HCPs practice.

12. SALES AND MARKETING PROGRAMS

12.1. Advertisements and promotions

12.1.1 The objective of this section is to ensure that the marketing and advertising of medical devices to consumers and HCP's is conducted in a manner that promotes the quality use of medical devices, is socially responsible and does not mislead or deceive the consumer. In interpreting this section, emphasis will be placed on the principles mentioned and the total presentation and context of the advertisement.

12.1.2 Definitions

12.1.2.1 Advertisement includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

12.1.2.2 Broadcast media in relation to an advertisement or generic information, means any means by which the information is disseminated electronically in a visible or audible form or a combination of such forms.

12.1.2.3 Label means a display of printed information:

- (a) on or attached to the goods; or
- (b) on or attached to a container or primary pack in which the goods are supplied; or
- (c) supplied with such a container or pack.

12.1.2.4 Mainstream media means any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

12.1.2.5 Specified media in relation to an advertisement or generic information, means:

- (a) mainstream media, or
- (b) broadcast media, or
- (c) cinematograph films; or
- (d) displays about goods, including posters:
 - (i) in shopping malls (except inside individual shops);
 - (ii) in or on public transport; and
 - (iii) on billboards.

12.1.2.6 Typical means that which reflects the characteristic of a group ie. a result obtained from the use of a product which would be likely to be attained by most people using the product within the audience to which the advertisement is directed.

12.1.3 General Principles

12.1.3.1 All technology has to 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 and IVDs.

12.1.3.2 Advertisements and promotions have to portray the technology in line with the approved uses and attributes of the technology. Where products are not registered in South Africa or any other jurisdiction, advertisements and promotions have to be in line with the known uses and attributes of the technology, and the appropriateness of promoted or advertised uses or attributes may be investigated on receipt of a complaint in this regard.

12.1.3.3 The use of all artwork (logos, tables, graphics, illustrations, etc) should reflect the principles of fairness, balance and accuracy and should not distort, mislead, etc.

12.1.3.4 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 above principles, i.e. should be subject to substantiation, be accurate and balanced.

12.1.3.5 All promotions and advertisements should be of a high standard and respect HCP's and patients.

12.1.3.6 Promotions or advertisements to the public have to take place within the applicable regulatory frameworks, and where such advertisement or promotion relates to help-seeking behaviour amongst the public, conform to the following:

12.1.3.6.1 Should not make or allude to inappropriate healthcare claims associated with a particular product;

12.1.3.6.2 Should 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 of competitor products;

12.1.3.6.3 May let the public know of a particular disease or condition and that treatment exists for such disease or condition.

12.1.3.7 An advertisement must:

12.1.3.7.1 contain correct and balanced statements only and claims which the supplier has already verified;

12.1.3.7.2 include the phrase: "For more information, refer to your HCP".

12.1.3.8 An advertisement must not:

12.1.3.8.1 be likely to arouse unwarranted and unrealistic expectations of product effectiveness;

12.1.3.8.2 be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases;

12.1.3.8.3 mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions;

12.1.3.8.4 abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress;

12.1.3.8.5 contain any matter which is likely to lead persons to believe:

12.1.3.8.5.1 that they are suffering from a serious ailment; or

12.1.3.8.5.2 that harmful consequences may result from the technology not being used.

12.1.3.8.6 encourage, or be likely to encourage, inappropriate or excessive use;

12.1.3.8.7 contain any claim, statement or implication that it is infallible, unailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;

12.1.3.8.8 contain any claim, statement or implication that it is effective in all cases of a condition;

12.1.3.8.9 contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects.

12.1.4 Incentives to pharmacy assistants and other non-healthcare professional sales

An advertisement must not offer any personal incentive to a pharmacy assistant, or other non-healthcare professional sales person at retail level, to recommend or supply medical devices.

12.1.5 Scientific Information

12.1.5.1 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.

12.1.5.2 Publication of research results must identify the researcher and financial sponsor of the research.

12.1.5.3 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).

12.1.6 Comparative Advertising

12.1.6.1 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.

12.1.6.2 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.

12.1.7 Professional Recommendation

12.1.7.1 Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and is not presented as an endorsement of a medical device.

12.1.7.2 Advertisements must not contain or imply endorsement by:

12.1.7.2.1 any government agency;

12.1.7.2.2 hospitals and other facilities providing healthcare services;

12.1.7.2.3 individual or groups of healthcare professionals, other than where the emphasis is on the availability, which may include the price of the technology through his/her retail business; or

12.1.7.2.4 by individuals, who are healthcare professionals by way of their representation in advertisements or academic qualifications, and / or who are likely to be known as healthcare professionals by the reasonable person.

12.1.7.2.5 Advertisements must not contain or imply endorsement of the goods by bodies or peak healthcare professional associations that:

12.1.7.2.5.1 represent the interests of health consumers;

12.1.7.2.5.2 conduct or fund research into a disease, condition disorder or syndrome; or

12.1.7.2.5.3 represent healthcare professionals;

unless:

12.1.7.2.5.4 the advertisement names the body or association;

12.1.7.2.5.5 the endorsement is authenticated;

12.1.7.2.5.6 the nature of the endorsement is clearly disclosed; and

12.1.7.2.5.7 the endorsement is based upon an objective assessment of available scientific data supporting the use of that product. Where this is not the case and where the body or association has received valuable consideration for the endorsement, the advertisement must acknowledge that consideration.

12.1.8 Testimonials

Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.

12.1.9 Samples

An advertisement for technology must not contain an offer of a sample.

12.1.10 Conformity

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

13. GIFTS

13.1 Members may provide modest gifts to HCPs and staff, to a **maximum value per annum** as set from time to time. Scientific medical reference books and medical periodicals are not subject to the value restriction providing these would be relevant to the practice, facility or clinical department.

13.2 Gifts may not be personal in nature, and should be of relevance to the healthcare practice or healthcare facility.

13.4 Members may occasionally give HCPs branded promotional items of minimal value related to the HCPs work or for the benefit of patients.

13.5 Gifts may not be given in the form of cash or cash equivalents (e.g. gift vouchers), as these are by their very nature personal and without any guarantee as to their use.

13.6 The provision of samples, product evaluations etc is governed separately under sections 18 and 19 and in terms of the Medicines and Related Substances Act and is not covered by this provision.

14. GRANTS AND OTHER CHARITABLE DONATIONS

14.1 Members may make donations for a charitable purpose, such as supporting *bona fide* independent medical research for the advancement of medical science or education, indigent care, patient education, public education, or the sponsorship of non-HCP organized events where the proceeds are intended for charitable purposes.

14.2 Donations should be made only to charitable organizations or, in rare instances, to individuals engaged in genuine charitable missions for the support of that mission.

14.3 Charitable donations must not be tied in any way to past, present or potential future use of the Member's products or services.

14.4 All donations should be appropriately documented and open for scrutiny on receipt of a complaint. For example, a written request should be submitted by the charitable organisation, detailing the purpose of the charity and the nature of its activities.

14.5 Charitable donations to a bona fide organization should not be made in response to requests made by HCP's unless the HCP is an employee or officer of the charitable organization and / or submits the request on behalf of the organization. It would not be appropriate for a Member to support the favorite charity of a HCP in response to a request by that HCP.

14.6 Members should have no control over the final use of funds provided as charitable donations to charitable and other non-profit organisations.

14.7 Examples of appropriate charitable grants and related considerations are:

14.7.1 Advancement of Medical Education. Members may make grants to support the genuine medical education of medical students and residents participating in fellowship programs, which are charitable or have an academic affiliation, or to set up or support an educational or scientific unit or programme. (For additional considerations regarding educational grants, see Section 5.1 and 5.2 Educational Grants)

14.7.2 Support of Research with Scientific Merit. Members may make research grants to support *bona fide* medical research. The purpose of the grant must be clearly documented and all subsequent publications of research results etc should acknowledge such support.

14.7.3 Public Education. Members may make grants for the purpose of supporting education of patients or the public about important healthcare topics.

14.7.4 Grants for structural and institutional advancement or establishment, such as setting up of research and/or academic centers, units, chairs, etc. and all costs incidental thereto, including but not limited to the required infrastructure, equipment (including health technology) required, etc, provided that all donations to the state and private institutions are made in accordance with relevant legislative and ethical provisions.

14.8 Donations of technology have to take place within those relevant legal frameworks that may exist and which may stipulate conditions to donations or place limitations on the recipients of donations.

15. CLINICAL TRIALS

15.1 All clinical research (Phase 1, 2, 3 and 4) needs to be approved by a properly constituted ethics committee. In terms of the South African Guidelines for Good Clinical Practice, it is the responsibility of an ethics committee to safeguard the dignity, rights, safety, and well being of all trial participants.

15.2 Each trial must pursue a scientific and therapeutically relevant aim. The aim of the trial must always be the improvement of therapy, diagnostic methods and/or medical knowledge in the best interest of patients.

15.3 The aim of the trial must be stated beforehand. Research protocols must be drafted in such a way as to ensure that this aim is achieved and that the conclusions of the study are valid and reliable.

15.4 The sponsor has to be disclosed to the patients recruited to the study. A Patient Information and Consent form must be completed for each trial/research participant and sufficient protections have to be in place in line with legal provisions on privacy and confidentiality.

15.5 A formal financial agreement between the sponsor and investigator/institution needs to be documented, and submitted as part of the ethics approval process.

15.6 This financial agreement should be transparent, and clearly show the method and quantum of payment from the sponsor to the investigator.

15.7 A healthcare provider must not receive payment or other benefit for referring patients to clinical trials.

15.8 An HCP may receive compensation for his/her work in the trial subject to the following:

15.8.1 The compensation of whatever kind must be related to the work done, and must be disclosed to the ethics committee reviewing the study protocol;

15.8.2 The compensation must not be linked to any expected result of the study.

15.9 In publications, lectures and other presentations the sponsor must be disclosed.

15.10 The HCP may receive compensation for lecturing about the trial and its results, and in accordance with the provisions above on consulting between Members and HCPs.

15.11 When giving presentations on trials the HCP must disclose his/her connection with all companies in the therapeutic field covered.

15.12 It is obligatory for the sponsor Company to arrange for or provide Health Insurance on behalf of the patients undergoing the treatment, including a specified post-operative period.

15.13 Where a trial is conducted and monies exchanged tangible written evaluation or trial results must be provided.

15.14 All clinical trials must have a finite time period or alternatively a finite number of procedures to be performed.

15.15 Clinical trials may not be used to disguise product promotion.

15.16 Member's representatives involved in clinical trials may only fulfill administrative duties and may not use the trial as an excuse to obtain entry into facility / practice and to market a product.

16. PATIENT REGISTRIES

16.1 With regard to healthcare providers providing information to registries, remuneration provided must be reasonable and of fair market value, in relation to the work performed.

16.2 Registries may not be disguised as promotion, and 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 from time to time by the SAMED Ethics Committee.

16.3 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 and the Consumer Protection Act.

17. BEHAVIOUR IN THE OPERATING ROOM OR CLINICAL ENVIRONMENT

In many specialties Member company employees play a crucial role in providing technical support to physicians in the operating room or clinical environment. The appropriate rules for behaviour in the various disciplines are set out in addendum 2.

It is strongly recommended that Members adopt the relevant protocols of behaviour in this regard and make such protocol a condition of employment for any personnel who might be present in an Operating Room or Clinical Environment.

PART B: BUSINESS AND FINANCIAL ARRANGEMENTS

18. PRODUCT EVALUATIONS

18.1 It is common practice for Medical Device companies to have local HCPs evaluate a new device, given the fact that devices are often closely related to the specific requirements of a healthcare practice or facility, and/or the skill, functionality or preference of a particular professional and/or the needs of particular patients or patient groups. Such evaluations may take place prior to a launch of the product nationally, or in combination with a launch, where supply companies are seeking to obtain the views of key decision makers regarding the suitability of their device for the South African market. The implementation of product evaluations should be conducted in accordance with the following general guidelines:

18.1.1 The provision of equipment for free has to take place within the applicable legislative provisions.

18.1.2. No payment may be made to the healthcare provider involved in the evaluation. If any payments are made, the evaluation must be done in full compliance with the rules of Clinical Trials/Product Registries, as stipulated in this Code.

18.1.3. Where an evaluation is conducted and monies exchanged due to the appraisal being part of a clinical trial or registered/approved research project, as per the relevant provisions under the Medicines Act and National Health Act and the regulations thereto, including but not limited to:

18.1.3.1 There must be a written contract;

18.1.3.2 Tangible written evaluation results must be provided; and

18.1.3.3 All evaluations must have a finite time period or alternatively a finite number of procedures to be performed.

18.1.4. Each evaluation must pursue a scientific and therapeutically relevant aim. Where the evaluation constitutes a research project, an Equipment Evaluation protocol must be drafted and approved by an accredited Ethics Committee before the evaluation commences.

18.1.5. It is recommended that appropriate indemnities are in place, even if the evaluation is not a clinical trial or research project.

18.1.6. All costs for the duration of the equipment evaluation will be borne by the equipment supplier. This is to be documented, and may be required to be provided as part of regulatory requirements or on receipt of a valid complaint in terms of the Code.

18.1.7. Should the appraisal lead to publications, lectures and other presentations the sponsor must be disclosed.

18.1.8. Technology may only be provided to hospitals, healthcare facilities or HCPs for appraisal, as such appraisals have to be undertaken by lawful and legitimate, trained users of the technology and subject to the patient providing informed consent for the specific procedure, which includes disclosure of the arrangement between the member and the HCP on the device to be used in line with the HPCSA Ethical Rules³.

18.2 The following specific guidelines apply in the specific situations outlined below:

18.2.1. Single Use/Consumables/Disposables: The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

18.2.2. Multiple Use/Capital Equipment: Multiple use products / Capital Equipment provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the HCPs location at the conclusion of the evaluation period unless the HCP purchases or leases the products.

19. SAMPLING AND EXHIBITION / DEMONSTRATION

19.1 Sampling may only take place within the ambit of the Medicines Act and applicable regulations, and includes the provision of devices for product evaluations / appraisals as outlined in this Code, and for purposes of exhibition.

19.2. Demonstration products which are not intended to be used in patient care should be accompanied by designations such as “Sample - Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompany the product.

20. LOAN OR PLACED EQUIPMENT

20.1 The sale or placement of equipment with a Healthcare Provider, where the contract between the Member and the Provider includes the purchase of consumables / disposables associated with the equipment are subject to the following provisions:

20.1.1 The consumables are used to cross-merchandise the capital equipment in a manner which is defensible and fair.

20.1.2 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, for example, the provisions of the National Credit Act.

□

³ Ethical Rules 23A, 27 and the HPCSA Booklet on Undesirable Business Practices. Part of informed consent processes as stipulated in the National Health Act, and the duty to say that the technology is used on the patient, and is used for appraisal purposes, and that the doctor should not bill if s/he gets the technology for free. If this appraisal is part of a clinical trial, should be stated as such, in line with SA Constitution's section 11 and the National Health Act.

20.1.3 It is inappropriate for a member to subject the Healthcare Provider to a quid pro quo situation where the Healthcare Provider is contracted to purchase any additional products that are not related to the specific Loan or Placed Contract/Agreement.

20.1.4 No targets may be set in relation to the purchase of disposables and consumables related to the equipment.

20.1.5 In cases of valid complaints, the placement of equipment agreement should be in writing and available as per the complaints handling process in Part C: Dealing with Infringements of the Code.

21. TRANSPARENT INVOICING

21.1 Members should provide accurate, transparent and responsible billing information to HCPs, reimbursement authorities and other payors.

21.2 No Member may offer a bonus, rebate (e.g. an off invoice discount) or other incentive scheme to an HCP in relation to the acquisition of goods and services in contravention of regulations to be issued in terms of section 18A and B of the Medicines and Related Substances Act, with particular reference to the Amendments as contained in Act 72 of 2008. Notwithstanding that this law has not yet been implemented

21.3 Members are expected to follow the principles of acceptable invoicing procedures as detailed in the SAMED Policy on Transparent Invoicing. See Addendum 1.

22. COMPETITION LAW

22.1 SAMED brings together suppliers and others involved in the South African Medical Device sector to discuss issues of industry-wide importance. Members may compete directly with each other and both individual Members and the Association have to comply fully with South African Competition law.

22.2 It is the responsibility of SAMED and each of our Members individually, to ensure compliance with competition law. Part D contains guidelines which will help ensure compliance and which are applicable to all SAMED Members.

23. REIMBURSEMENT FOR INFORMATION AND OTHER ECONOMIC DATA - MARKETING DATA, FORMULARY, MANAGED CARE AND SIMILAR FEES

Members may provide economic efficiency and reimbursement information to HCPs and third party payors of their contractors, employees or administrators regarding Members' products.

23.2.1 Members may not pay unacceptable fees for marketing data, formulary listings, managed care, or any other similar information.

23.2.2 The payment of acceptable fees to persons or institutions offering services or information for such fees are permissible, provided that such fees:

23.2.2.1. 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 by the SAMED Ethics Committee in the case of a valid complaint.

23.2.2.2. 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.

23.2.2.3. 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.

24. FALSE CLAIMS

Since many healthcare programs (medical schemes, etc) reimburse and pay for Member products, each Member must comply with the applicable laws and regulations⁴.

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 payment.

⁴ i.e. Criminal law and Criminal Procedure Act, as well as Medical Schemes Act and regulations. In future, when devices are registered, the Act that governs the conditions of registration (Medicines Act or similar).

PART C: DEALING WITH INFRINGEMENTS OF THE CODE

The overall goal of this procedure is to ensure a complaint-handling process that enjoys public confidence and Member support, and which is effective, lawful and efficient and not a cost-burden for SAMED.

25. Constitution of the Ethics Committee

25.1 Chairperson

25.1.1 The SAMED Board will appoint an independent chairperson of the Ethics Committee for a period as determined by the Board.

25.1.2 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, is preserved and promoted.

25.2 Ethics Committee

25.2.1 The SAMED Board will appoint, from amongst a pool of suitably qualified and experienced persons within the device industry at least four who together with the chairperson, shall be eligible to serve on the Ethics Committee panel.

25.2.2 The pool of suitably qualified persons will be appointed for a period as determined by the SAMED Board and may include employees of companies 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.

25.2.3 All members of the Ethics committee panel must sign a private and confidential / non-disclosure document and must keep all details relating to the complaint at hand in the strictest confidence, unless the parties agree to specified disclosures.

25.2.4 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, in which analysis the Secretariat will play a key role throughout the complaint screening process.

25.3 Role of the Secretariat and COO

25.3.1 The COO will fulfil a secretariat function in relation to handling infringements of the Code, including the functions outlined below.

25.3.2 The COO must be present at all hearings, but will not be entitled to participate, or be present when the Ethics committee deliberate. Where the COO is the nominal complainant, she shall be entitled to participate to the same extent as a complainant would be entitled to. A reference to the feminine shall include a reference to the masculine.

26. Lodging a complaint

26.1 Any SAMED Member, customer or regulatory body (“the complainant”) may lodge a formal written complaint upon payment of the stipulated fee, set annually by the SAMED Board, and on completion of the prescribed forms.

26.2 The prescribed complaint form has to reveal the following and has to be lodged at SAMED’s official place of business:

26.2.1. 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;

26.2.2. Company employing the complainant, and, if applicable, representative body of complainant;

26.2.3. Field of business of complainant (manufacturer, distributor, doctor, private hospital, etc);

26.2.4. Name of alleged infringing company;

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

26.2.6. Circumstances of the infringement (what, when, where, how);

26.2.7. Clause(s) within the Code that has allegedly been infringed;

26.2.8. Indication of the proof substantiating such complaint.

26.3 The COO shall within 7 working days of receipt of the complaint, send a copy of the complaint to the respondent and request a formal response within 7 working days from the date upon which the respondent receives the complaint.

26.4 The COO shall within 7 working days from receipt of the response, send a copy of the response to the complainant and invite a reply within 5 working days from the date upon which the complainant receives the response. The reply, if any, will on receipt be sent to the respondent.

26.5 After receipt of the reply, if any, the COO will attempt to facilitate a conciliation of the dispute by following the process set out in clause 27. If the conciliation is not successful the COO will forward the complaint, the response, the reply (if any) (“the documents”) and a note advising that conciliation was not successful to the Chairperson of the Ethics Committee for further adjudication as provided for in this Code.

26.6 The complainant may at any time withdraw the complaint except after it has been referred to the Ethics Committee, where after the complaint will be adjudicated on.

26.7 THE COO AS COMPLAINANT

26.7.1 The COO shall monitor such conduct by SAMED members as she deems fit to ensure compliance with the Code.

26.7.2 Should the COO be of the opinion that there has been a breach of the Code, she shall immediately address a written notice, identifying the alleged breach of the Code, to the respondent with a request that it should take such remedial action and steps as may be prescribed and/or to furnish a written response to the COO within 10 working days of receipt of the complaint.

26.7.3 Should the COO be satisfied that the respondent has satisfactorily dealt or will deal with the complaint, she shall advise the respondent accordingly.

26.7.4 Should the COO not be satisfied with the response received from the respondent, the COO shall place the complaint before an Ethics Committee by following the procedure provided for in clause 26.5 of the Code. In this instance the COO will be the nominal complainant and no objection fees will be payable.

27. Conciliation

27.1 The COO will facilitate a process aimed at securing an informal resolution of the complaint, through the process outlined below.

27.2 The COO will after receipt of the documents request the parties to convene as soon as possible, offering to facilitate such a meeting in order to resolve the matter. In the event of the COO being the nominal complainant, she will request the respondent to meet with her in order to resolve the matter.

27.3 Any resolution to the matter should preferably be made in writing, and forwarded to the COO in order to close the file on the complaint. However, the COO shall be entitled, in the absence of a written resolution, to determine whether the circumstances relating to the matter evidences a resolution of the dispute and that the file should be closed. A resolution may, for example, entail an acknowledgement that the complaint is not substantiated, that the complaint is based on factual inaccuracies or a misunderstanding, an acknowledgement that the conduct does violate the Code, or parts thereof, or an agreement that the conduct will be modified or ceased.

27.4 Should the parties fail to reach an agreement within 14 days of being requested to meet the complaint will proceed to a hearing.

27.5 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.

28. Pre-hearing procedure

28.1 Within 7 days after receipt of the documents, the Chairperson of the Ethics committee will consider whether the complaint has merit or not. Should it be considered that a complaint has no merit (for example is frivolous, vexatious or malicious), the complaint will be dismissed and the stipulated fee will be forfeited. Should the complaint be found to have merit (i.e. be valid), the Chairperson will request the COO to constitute and appoint an Ethics Committee to adjudicate on the complaint. The Ethic Committee shall consist of the Chairperson and at least one other person. The COO shall ensure that no member appointed to the Ethics Committee shall have any direct or indirect interest in the matter adjudicated upon.

28.2 Where the COO is the nominal complainant, the Chairperson of the Ethics Committee shall constitute and appoint the Ethics Committee.

28.3 Copies of the documents shall be made available to the appointed members of the Ethics Committee by the COO.

28.4 The Chairman will advise the COO of the date of the hearing and shall request the COO to advise the complainant and the respondent in writing of the date and venue for the hearing.

28.5 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.

29. At the Hearing

29.1 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 serious nature of the matter and the penalty which may be imposed, in its sole discretion determines otherwise. In such case the respondent shall be entitled to legal representation by a practising attorney or advocate or both. Should the respondent be allowed legal representation, the complainant shall also be entitled to be represented by a practising attorney and/or practising advocate.

29.2 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.

29.3 The complainant has the right to present the complaint to the Ethics Committee.

29.4 The respondent has the right to present the case in response to the complaint.

29.5 Both parties have the right to present evidence through oral statements or witness testimony, or to hand other evidence to the Ethics Committee and the other party has the opportunity to respond to such evidence being presented.

29.6 The Ethics Committee may ask questions during the presentation of either party's case and/or question witnesses or request for additional information or the substantiation of information.

29.7 The Ethics Committee may in its discretion call any person as an expert, to present evidence in person or in writing.

29.8 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.

29.9 The Ethics Committee may determine its own procedure and the timeframes stipulated in this Code may be deviated from if the circumstance so dictate.

30. After the hearing

30.1 The Ethics Committee must make a substantiated finding within 7 days after the hearing, and must provide such finding and the reasons for the finding in writing to the COO, who will provide a copy of the finding to both parties.

30.2 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.

30.3 The confidentiality referred to in this Chapter of the Code does not extend to the COO / 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.

30.4 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.

31. Costs

31.1 Each party will bear its own costs, and no costs will be recoverable from the other party.

31.2 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).

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

31.4 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 COO and SAMED Chairperson.

31.5 The chairperson of the Ethics Committee will be remunerated at a fee negotiated between the Board and the person to be appointed by the Board.

31.6 All fines imposed in terms of this Code will be dedicated to activities relating to the Code, i.e. the costs associated with hearings, education campaigns, etc.

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

32. Sanctions

32.1 Should the Ethics Committee find that the respondent has breached the Code the Ethics Committee may impose the following sanction on the respondent, which sanctions may be imposed together or as a single sanction and parties may, during the hearing, make submissions as to whether a sanction should be imposed, and the appropriateness and proportionality of such a sanction:

32.1.1 Instructing the respondent to immediately cease the specific conduct;

32.1.2 A letter of censure and an order to comply with the Code;

32.1.3 A fine, the sum of which as may be considered appropriate by the Ethics Committee in the circumstances depending on *inter alia*, the gravity of the offence, its impact on patients, doctors and clients, whether the respondent has been a repeat-offender of the Code, the impact of the violation on the reputation of the device industry and SAMED, the deterrent value of the fine, the value of the deal or violating conduct;

32.1.4 That the respondent furnishes a written undertaking within a stipulated time period that the respondent will avoid similar breaches of the Code in the future;

32.1.5 That the respondent publicly apologises and/or publicly withdraws the materials or undertakes to cease the conduct;

32.1.6 That the respondent pays such costs and expenses relating to the hearing as the Ethics Committee considers just and equitable in the circumstances.

32.1.7 That, if the severity of the violation so warrants, that the name of the respondent is published to the SAMED Membership;

32.1.8 A recommendation to the SAMED Board to expel the respondent, following the procedure stipulated in the SAMED Articles of Association;

32.1.9 The Ethics Committee may, in the absence of an appeal, also refer the matter 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 or the Department of Health;

32.1.10 The Ethics Committee may make an order that the stipulated fee (provided for in clause 26.1), or any portion thereof, be forfeited or be refunded as determined by the Ethics Committee having regard to the outcome of the hearing;

32.1.11 Any other order as may be considered appropriate to the Ethics Committee in the circumstances.

33. Appeal Process

33.1 The SAMED board will appoint, from amongst a pool of suitably qualified and experienced persons within the device industry, at least four persons who shall be eligible to serve on the Appeal Panel. The SAMED board shall also appoint such senior advocates who have indicated that they will be willing to serve as members of the Appeal Panel.

33.2 All members of the Appeal Panel must sign a private and confidential / non-disclosure document and must keep all details relating to the complaint at hand in the strictest confidence, unless the parties agree to specified disclosures.

33.3 There shall be no appeal against:

33.3.1 a decision by the Chairman of the Ethics Committee to dismiss the complaint as provided for in clause 28.1;

33.3.2 any decision of the Ethics Committee where the party wishing to lodge an appeal was legally represented before the Ethics Committee.

33.4 An appeal against a decision by the Ethics Committee shall lie to an Appeal Board and to no other body. All decisions, penalties, rulings, determinations or findings of an Appeal Board shall be final and binding on the party or parties concerned.

33.4 Should either the complainant or the respondent wish to appeal the finding, decision or penalty imposed by Ethics Committee ("the appellant"), the appellant shall give notice in writing of his intention to appeal within 7 working days from the date on which the finding, decision penalty to be appealed against has been communicated to him. The notice of intention to appeal shall be addressed to the COO and shall be delivered within the prescribed time limit to the COO.

33.5 Every notice of intention to appeal shall be accompanied by the appeal fee prescribed by the SAMED board.

33.6 Once an appeal has been lodged, the COO shall:

33.6.1 as soon as possible thereafter make a copy of the record of the ethics hearing to which the appeal relates available to the appellant.

33.6.2 advise the other party (hereinafter referred to as the defendant) that an appeal has been lodged and also furnish the defendant with the copy of the record.

33.7 The appellant shall lodge, in writing, a notice of appeal within 10 working days, from the date on which he is notified that the transcript of the ethics hearing is available. The notice of appeal shall set out the penalty, decision or finding appealed against and the grounds of such appeal.

33.8 The notice of appeal shall be lodged with the COO. On good cause shown, the period for lodging a notice of appeal may be extended by the COO, on receipt of a written application from the appellant, which application shall be lodged within the time period allowed for the lodging of the notice of appeal.

33.9 Should a notice of intention to appeal or notice of appeal not be lodged within the prescribed time periods, the right of appeal or the appeal as the case may be shall lapse, provided that the COO may, on written application to her, in her sole discretion and on such terms and conditions as she may determine, condone the late lodging and reinstate any appeal which has lapsed.

33.10 Where an appeal has been lodged, the defendant may within 10 working days after being provided with a copy of the appellant's notice of appeal, lodge a written response with the COO. On good cause shown, the period for lodging a response may be extended by the COO, on receipt of a written application from the defendant, which application shall be lodged within the time period allowed for the lodging of the response. A copy of such response by the defendant, if any, shall be furnished to the appellant who shall be entitled to reply thereto within 5 working days.

33.11 An appeal may be withdrawn by the appellant at any time before the appeal is referred to the Appeal Board by the COO, in which case the appeal fee will be forfeited. Once the appeal has been referred to the Appeal Board the appeal cannot be withdrawn and will be adjudicated on.

33.12 In the event of the COO being the nominal complainant, appellant or defendant, the discretion to extend the time periods will be delegated to the Chairman of the Ethics Committee which made the ruling forming the subject matter of the appeal.

34. APPEAL HEARINGS

34.1 Once the process set out in clause 33 has been completed, the COO will forthwith appoint an Appeal Board consisting of at least three members from the persons listed on the Appeal Panel, one of which shall be a senior advocate. The COO shall document the substantiation for their selection. Pending the appeal hearing, the COO shall keep the identity of the appointed members confidential. Where the COO is the nominal appellant or defendant, the Chairman of the Ethics Committee shall appoint the Appeal Board.

34.2 The quorum for an Appeal Board shall be three. The Chairman shall not have a casting vote.

34.3 Should the number of members of an Appeal Board fall below the quorum stipulated in the Code then the proceedings before that board shall be a nullity and another Appeal Board may be constituted to hear the appeal de novo.

34.4 Save where otherwise provided in the Code, an Appeal Board, when hearing an appeal, shall adopt such procedures as it, in its sole discretion, may determine. The appeal will be decided on the record of the Ethics hearing and the representations filed by the parties. Only in exceptional circumstances should the Appeal Board call on the parties to appear before it to argue the appeal. In such a case the appellant shall be entitled to appear before the Appeal Board to argue his appeal but shall not be entitled to have legal representation unless the Appeal Board, having regard to, inter alia, the complexity of the matter, the legal issues involved, the serious nature of the matter and the penalty which had been imposed, in its sole discretion determines otherwise. In such case the appellant shall be entitled to legal representation by a practising attorney or advocate or both. Should the appellant be allowed legal representation, the defendant shall also be entitled to be represented by a practising attorney and/or practising advocate.

34.5 The appellant and the defendant t (and their respective legal representatives, if any) shall be bound by and confined to the record of the Ethics hearing and shall not be entitled to introduce new evidence save with the permission of the Appeal Board, which may determine such matter in its sole discretion and on such terms and conditions as it may deem fit.

34.6 The operation of the finding, penalty or decision of the Ethics Committee concerned shall be suspended:

34.6.1 during the 7 day period referred to in clause 33.4; and/or

34.8.2 when a notice of intention to appeal has been lodged, pending the final determination of such appeal by an Appeal Board, or the lapsing of the appeal or the withdrawal thereof.

35 POWERS OF AN APPEAL BOARD

35.1 An Appeal Board on hearing an appeal, shall have the powers:

35.1.1 to allow the appeal;

35.1.2 to dismiss the appeal;

35.1.3 to substitute any finding or decision as it deems fit or substitute such sanction as it deems fit, including any amended penalty;

35.1.4 to make such order as in its opinion the circumstances may require including an order to remit the matter for the hearing of further evidence or an order for the hearing de novo;

35.1.5 to hear further evidence or receive any documents on such terms and conditions as it in its discretion may decide;

35.1.6 at any time to order a Party to pay all or a portion of the actual costs and other expenses reasonably incurred by SAMED in connection with an appeal or any postponement thereof, in addition to any other sanction, if it is of the opinion that such order is warranted and to determine the amount of such costs and other expenses;

35.1.7 to order that the prescribed appeal fee, or any portion thereof, be forfeited or be refunded as it may determine having regard to the outcome of the appeal;

35.1.8 an 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 or the Department of Health;

35.1.9 to make such rulings as it in its sole discretion shall determine.

35.2 An Appeal Board, in addition to any of the powers set out above, shall be entitled to order that the outcome of the appeal hearing be published in such publications, including newspapers, as it may determine in its sole discretion.

36. Powers of SAMED

36.1 SAMED may cancel or refuse Membership to any company that:

36.1.1. is unwilling to commit to the standards and values reflected in the code and/or

36.1.2. fails to conduct its affairs in a manner consistent with the code.

36.2 Such cancellation or refusal of Membership shall be made only after review by the SAMED Board of Directors, and in line with the provisions of the Articles of Association.

(For further information, see SAMED Code of Business Practice - Frequently Asked Questions and Answers).

PART D: COMPETITION LAW COMPLIANCE GUIDELINES

The following guidelines apply to SAMED, any working group, individual Members, and any subgroup within the association.

36. The prohibition of anti-competitive agreements - general

36.1 The Competition Act 89 of 1998 prohibits competitors from concluding agreements which restricts competition. In particular, price fixing, dividing markets and collusive tendering are strictly prohibited.

36.2 Agreements between parties in a vertical relationship (i.e. at different levels of the supply chain) are prohibited if they restrict competition. In particular, the practice of minimum resale price maintenance is prohibited. This refers to an agreement between a supplier and a customer in terms of which that customer must sell the supplied product on to its customers at a price determined by the original supplier, rather than by market forces.

36.3 No SAMED Member should ever discuss or be involved in any of the following anti-competitive activities or agreements:

36.3.1 price-fixing, including the co-ordination of prices, discounts or any other element of pricing, and even discussing prices with competitors;

36.3.2 market division such as the allocation of customer groups or territories between competitors;

36.3.3 agreements on investment levels or production quotas;

36.3.4 the exchange of competitively sensitive information, for instance, on business plans, customer relations or ongoing or planned bids or tenders;

36.3.5 agreed restrictions on trade such as export bans, or prohibitions on sales to certain customers;

36.3.6 joint negotiations, selling or buying with competitors, except after obtaining legal advice;

36.3.7 any other agreement restricting competition such as, a collective boycott, any arrangement to avoid direct competition, or joint action to exclude competitors or new entrants;

36.3.8 resale price maintenance arrangements.

36.4 The Competition Act defines an agreement as including,

“a contract, arrangement or understanding, whether or not legally enforceable”

To be prohibited, an anti-competitive agreement need not be written down or binding. The same is true of the decision of an association of undertakings. A verbal information exchange or an informal agreement can be an infringement even if it is a mere understanding or "gentleman's agreement".

37. Information Exchange

37.1 Although there is not yet a precedent in our law prohibiting information exchange in itself, the Competition Commission views exchange of information between competitors as an area of extreme concern.

37.2 Members must not exchange information regarding price, volume, commercial strategy, business secrets or any other competitively sensitive information. Members should take particular care in discussions with fellow-Members who are or who may become competitors, whether the discussion are formal or informal.

37.3 Subjects to avoid are:

37.3.1 Prices and discounts, or price-related contractual terms (although you may discuss Government-imposed pricing principles and reimbursement policies as they impact on the industry as a whole);

37.3.2 Client relations, ongoing bids or plans to bid for business;

37.3.3 Business plans or commercial strategy;

37.3.4 Competitive strengths/weaknesses in particular areas;

37.3.5 Production planning or output levels;

37.3.6 Product development or investment in research programs which is not yet widely known;

37.3.7 Individualized market share data.

37.4 Benchmarking is allowed, provided the entity collecting and processing the data is bound by a confidentiality undertaking, and the data is not and cannot be linked to specific competitors. Market surveys are allowed provided results are presented in statistical form, individual price information is excluded and competitively sensitive information such as market share and export volumes remain anonymous.

37.5 It is acceptable to discuss public policy, educational and scientific developments, regulatory matters of general interest (including Government-imposed prices or reimbursement policies), demographic trends, publicly available information and historical information that has no impact on future business. Members may display or demonstrate new or existing products, but not discuss non-public R&D or production plans.

38. Abuse of a dominant position prohibited

38.1 Dominant firms have an added responsibility to behave in a way which does not exploit consumers or prevent or impede competitors from entering into or expanding within the market. A firm which has a market share of 45% or more is automatically dominant. A firm which has less than 45% of the market is dominant if it has 'market power' which means it can control prices, exclude competition, or behave to an appreciable extent independently of its suppliers, customers or competitors.

38.2 Members should be aware of the market in which they operate because the smaller the market, the easier it is for a firm to exercise market power and therefore be classified as dominant.

38.3 In the medical sector, markets tend to be highly concentrated (only a few, relatively big competitors). It is concentrated markets such as this where competition concerns are greatest.

38.4 As soon as a dominant firm's behavior has an anti-competitive object or effect, unless it can be justified on efficiency, technological or other pro-competitive grounds, it may result in fines and civil liability. There is no need to demonstrate the existence of an agreement or collusion. Examples of abuse of dominance which are specifically prohibited by the Competition Act include:

38.4.1 Charging an excessive price to the detriment of consumers;

38.4.2 Refusing to give a competitor access to an essential infrastructure or resource when it is economically feasible to do so;

38.4.3 Engaging in any act which impedes or prevents a firm entering into or expanding within the market;

38.4.4 Requiring or inducing a supplier or customer not to deal with a competitor;

38.4.5 Refusing to supply scarce goods to a competitor when supplying those goods is economically feasible;

38.4.6 Selling goods or services on condition that the buyer purchase separate, unrelated goods or services;

38.4.7 Forcing a buyer to accept a condition unrelated to the object of a contract;

38.4.8 Selling goods or services below cost in order to drive a competitor out of the market;

38.4.9 Buying up a scarce supply of intermediate goods or resources required by a competitor;

38.4.10 Charging different prices to different customers when the difference in price cannot be justified by cost considerations.

39. What to do if you suspect a breach of these guidelines?

Presence at meetings where anti-competitive conduct is discussed can be enough to incur liability under the Competition Act. Check the agenda, object in advance to impermissible discussion items and stay away if the agenda is not changed. As soon as you become aware of an infringement, contact your legal counsel, express your disagreement and ensure that a record is kept of your disagreement. If you miss a meeting, check the minutes upon receipt, and warn your legal counsel if these suggest an infringement. If there is a possibility that sensitive matters are discussed, consider having legal counsel present at meetings.

If you are uncertain whether a particular agreement, discussion or information exchange between competitors is allowed, immediately contact your company lawyer, who will take appropriate steps.

40. Do's and Don'ts: Guidelines on participation in SAMED meetings

40.1 DON'TS

40.1.1 Don't reach understandings or agreements or even hold discussions (especially with a competitor) on anything relating to commercially sensitive topics such as prices, credit terms and billing practices, production, inventory, supply volumes, sales, costs, future business plans, bids or matters relating to individual suppliers or customers.

40.1.2 Don't attend meetings without written agenda or clear indication of the purpose.

40.1.3 Don't attend unscheduled gatherings unless you know that they are for a bona fide purpose or that they are purely social gatherings.

40.1.4 Don't discuss business related topics at social functions.

40.1.5 Don't accept written non-public information or agree to the exchange of oral non-public information with Members who market competing products.

40.1.6 Don't participate in information exchanges, market surveys, or benchmarking exercises that allow access to individualized competitive information.

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

40.1.8 Don't agree to exclude competitors or engage in collective boycotts.

40.2 DO'S

40.2.1 Do read the SAMED Competition Law Compliance Guidelines that precede these guidelines.

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

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

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

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

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

41. Exchanging Data and Information

Any discussions where information is exchanged between competitors, whether in a formal or informal context, can constitute an anti-competitive agreement or practice.

If you are part of an information or benchmarking 'pool' or other market survey, ensure that individual manufacturers are not identifiable from the data, avoid meetings to discuss the results of the information gathering exercise, and allow open and voluntary participation in the exchange. Exchanging certain types of sensitive information may be more anti-competitive than is the case with other forms of information. Factors that could make for a high risk of infringement of the competition rules are set out in the table below.

Note that although the conduct listed in the right hand column is 'low risk', exchange of all types of information should be regarded with caution and if in doubt, legal advice should be sought.

High Risk of Infringement	Low Risk of Infringement
Supply, acceptance or exchange of information with competitors or potential competitors	Publication of information; exchange of information with customers or non-competitors
Supply/accept/exchange information on prices and discounts, individual bids, customer relations, supply volumes, costs, investment and general business strategy, production levels	Exchange information on public policy matters, educational and scientific developments, regulatory matters of general interest, demographic trends, publicly available information
Confidential information	Public information
Current information	Historic information
Individual company data	Aggregated industry data
Implied or explicit recommendations or agreements accompanying the exchange	No further discussion of the information exchanged

PART E: FREQUENTLY ASKED QUESTIONS AND ANSWERS

PREAMBLE & GENERAL QUESTIONS

- **Question 1**

Why did SAMED develop a code of business practice? How does this Code relate to the Code promulgated in terms of the 1997 and 2008-amendment to the Medicines and Related Substances Control Act? How does this Code relate to other Policy documents, such as the HPCSA's Perverse Incentives Policy or the Marketing Code for Pharmaceuticals?

SAMED's Code reflects the unique interactions between medical technology companies and HCPs. Distinguishing features in SAMED's Code arise primarily from the fact that Members interact with HCPs because of the complexity of medical technology and the importance of having HCPs understand how to use the technology safely and effectively. In other ways, however, SAMED's Code reflects similarities in the interactions between HCPs and medical technology companies as compared with other elements of the health care industry.

The SAMED Code aims to be in line 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

- **Question 2**

Who are "HCPs"? Does the term include non-clinical people who make product-purchasing decisions? Does it include decision-makers within Group Purchasing Organisations?

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 at 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 technology 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 e.g. The Foreign Corrupt Practices Act.

- **Question 3**

Are combination products covered by the Code?

Yes, interactions related to combination products (e.g. devices containing medicines) are covered by the Code.

- **Question 4**

Does the Code address arrangements between a Member and an HCP relating to licensing a new medical technology to the Member?

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.

- **Question 5**

What do the terms “modest,” “occasional” mean?

The Code seeks to balance an interest in civility with the desire to avoid even the appearance that meals and refreshments may be used as an inducement.

The code stipulates that meals and refreshments offered to HCPs must in all circumstances be modest in nature and subordinate to the purpose of the meeting.

“Modest” means moderate or low value and “occasional” means infrequent.

Examples of **Inappropriate** hospitality include:

1. Sporting events: Members may not sponsor or host their own golf days or other sporting events for HCPs. Members may not invite or pay for HCP's to attend sporting events such as golf days, cricket and rugby matches etc. Members may not sponsor holes, prizes etc and advertise, put up branding / promotional material at any golf day

2. Sporting events at Congresses/Educational events: Members may not sponsor sporting activities which involve HCPs or pay for HCPs to participate in such activities at congresses or educational functions. Members may however pay for themselves to participate in such events, but may not promote/advertise their products/company during the event
3. Entertainment: Members may not entertain an individual or a Practice of HCPs and their staff. Meals may be offered provided that they are modest in nature, and provided that the hospitality is conducive to the exchange of information. No “stand-alone” entertainment may be offered.
4. Resort functions: It is inappropriate for Members to host HCPs at venues that would exclusively be considered as holiday destinations and which are distant from their normal place of practice, unless it is a bona fide educational meeting, conference or congress, endorsed by a Professional Healthcare Association. Venues such as Game Lodges, Dive resorts, Casino’s, Cruise ships, offshore islands and exclusive holiday resorts are some examples of inappropriate venues and would be viewed as a perverse incentive to HCP’s.
5. Receptions: It is inappropriate for Members to host or sponsor meals or receptions for large groups of HCPs that are entirely unconnected to any Congress, Business premises or educational event. This includes year end functions.
6. Spouses: It is inappropriate for Members to pay for the expenses of spouses/partners accompanying HCPs. Members should inform HCPs of this fact in advance of an event.
7. Company year end functions: it is inappropriate to invite HCP’s as guests to attend member company year end functions.

Examples of **Appropriate** hospitality include:

8. Members may pay for themselves to participate in a golf day, be it a charitable golf day or other
9. Members may play a social game of golf with an HCP provided that this is infrequent and that the member not pay for the HCP to play.

• **Question 6**

May a Member offer to provide laptop computers with independent value to a purchasing manager whose hospital purchases medical devices and technology that the Member has just introduced?

No. It is not appropriate for a Member to provide any item of value to an HCP that takes into consideration the value or volume of the business that is or may be generated by the HCP, unless permitted by law (e.g., appropriate discounts).

The Corruption Act and the ethical rules binding HCPs and managers in such situations (including but not limited to the obligatory disclosure of all gifts and support in terms of the Public Service Act and Regulations) have to be borne in mind.

These laws and rules prohibit the offering or acceptance of any object of value in return for an action (in this case an order), that the recipient is empowered to make, irrespective of whether the object did indeed influence the particular decision to purchase, lease, maintain or use.

MEMBER-SPONSORED TRAINING AND EDUCATION

- **Question 7**

Why may it be appropriate under the Code for Members to pay for travel to training and education sessions?

In order to efficiently deliver training at appropriate facilities, the Code contemplates that Members may bring HCPs together at a central location, which may make out-of-town travel necessary. Note that this section deals only with meetings focused on training and education on Member products, and only for persons who could legitimately benefit from the training.

Meetings focused on sales and promotion may not be sponsored under the Code, unless an educational aspect is central to the meeting.

- **Question 8**

May a Member pay for travel to a Member-sponsored general educational program not specific to the Member's products?

Members may sponsor travel to healthcare related educational sessions which are not necessarily specific to the Member's products.

SUPPORTING THIRD PARTY EDUCATIONAL CONFERENCES

- **Question 9**

May a Member designate attendees or faculty who will speak at third-party educational conferences?

No. The Code contemplates that an independent third party will select faculty and attendees. The Code does not preclude a Member from recommending a knowledgeable faculty Member. The conference sponsor or a professional association should make the ultimate selection.

- **Question 10**

Can a Member provide an educational grant to support the attendance of a Qualified HCP at a local third-party educational conference?

No. Only HCPs in training, nurses, technicians, registrars and other deserving persons may be sponsored.

- **Question 11**

May a Member organise the travel and accommodation arrangements of the spouse or other guest of an HCP attending a congress or training event, if the HCP pays for the spouse or guest?

No, unless that person qualifies as a proper delegate or participant at the meeting in their own right, it would not be appropriate for a member to organise the travel and/or accommodation arrangements of the spouse or guest of the HCP, irrespective of who pays.

- **Question 12**

What section of the Code applies to Member-sponsored off-agenda activities (e.g. sales and promotional meetings or educational programs) that are ancillary to a conference sponsored by a third party?

Section 5. In all cases however, it should be determined whether the conference sponsor has guidelines that cover that type of off-agenda activity, and if so, the sponsor's guidelines should also be honored.

- **Question 13**

What is the current limit set for prizes that may be offered as part of a competition promoted at a conference / congress?

R10 000

- **Question 14**

Would it be appropriate for a member to sponsor an HCP to attend a trade show e.g. Medica Trade Show held in Dusseldorf in November each year?

No.

SALES & PROMOTIONAL MEETINGS

- **Question 15**

Why does the Code not allow Members to extend business courtesies to spouses/partners in connection with sales and promotional meetings?

SAMED's Code is mindful of the desire to avoid even the appearance that business courtesies are being given as improper inducements to promote a Member's products.

On the other hand, it is appropriate for Members, as a matter of common courtesy and civility, to provide modest meals and receptions for HCPs in connection with these types of meetings.

To balance these considerations, the Code allows Members to provide “occasional and modest meals and refreshments for HCP attendees that are conducive to the exchange of information.”

Under the Code, such meals and refreshments are to be incidental and conducive to the underlying business purpose. The Code precludes the extension of these courtesies to persons, such as spouses/partners, without a bona fide professional interest in the meeting.

- **Question 16**

May a Member conduct a product sales or promotional meeting at a resort location and pay for an HCPs travel to the meeting for purposes of providing product information and negotiating sales terms?

This would be inappropriate.

Members are encouraged to hold any sales or promotional meetings as close to the HCPs place of business as possible.

Members are entitled to provide “modest meals and receptions” that are “conducive to the exchange of information.”

In the event that HCPs need to travel to such sales or promotional meetings, the cost of travel shall *not* be borne by the Member.

The Code does provide for limited special circumstances of “plant tours and demonstrations of non-portable equipment” as specific examples of when travel might be necessary.

ARRANGEMENTS WITH CONSULTANTS

- **Question 17**

Is a clinical investigator considered a “consultant” under Section 8?

Yes.

- **Question 18**

Is there a limit to the number of consultants a Member may retain under Section 8?

Members may retain only as many consultants as are legitimate and appropriate to provide *bona fide* services; moreover, the requirements of Section 8 must be satisfied for each consultant and the contracts should be similar in terms of remuneration, i.e. may not be scaled up or down depending on the relative support of the consultant for the Members’ products or events.

- **Question 19**

May a consultant be placed under retainer with services provided as requested?

Yes, provided the requirements of Section 8 are met. One should be mindful of labour legislation that currently takes a practical (and not a legal) view of employment, i.e. a person who works continuously and under the direction of the Member may be regarded as an employee in terms of the Basic Conditions of Employment Act, but which violates the Health Professions Act of 1974, that prohibits institutions and people not registered at the HPCSA from employing health professionals that are registered at the HPCSA.

- **Question 20**

What happens if a consultant is engaged but the project is cancelled or modified without using the consultant's services?

The Code contemplates that if the requirements of Section 8 were met when the consultant was engaged and then unanticipated circumstances prevented performance, then the question of whether or how much payment is made to a consultant would be a matter determined by the underlying agreement.

- **Question 21**

What factors should a Member consider when evaluating the venues and circumstances for meetings with consultants?

A Member should assess:

- a. whether there is a *bona fide* business justification for holding the meeting
- b. whether the location and venue are suitable for and conducive to the exchange of information between Member and consultant
- c. whether the value of any Member-sponsored lodging is modest, whether any ancillary meals and refreshments are modest in value (or alternatively, the fair market value of such meals and refreshments are taken into consideration when determining the fair market value of the compensation to be provided to the consulting HCP) and are subordinate in time and focus to the business part of the meeting; and
- d. whether the overall meeting has a genuine business purpose and tenor and does not represent improper inducement of the HCP.

Venues such as Game Lodges, Dive resorts, Casino's, Cruise ships, offshore islands and exclusive holiday resorts are some examples of inappropriate venues.

GIFTS

- **Question 22**

What is the current maximum value per annum set for gifts and what are some examples of branded promotional items of minimal value that are “related to an HCPs work or for the benefit of patients”?

R300 incl vat

Pens and notepads that could be used in the HCPs work environment are examples of minimal value, branded promotional items appropriate as gifts. Items such as branded golf balls and tee shirts would be inappropriate, as would a gift of wine or spirits.

- **Question 23**

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

Yes. It would be considered acceptable to recognise a life event by offering a gift such as flowers, fruit basket or a card.

- **Question 24**

May a Member provide snacks and refreshments to HCPs and their staff?

If food is provided in connection with sales and promotional meetings, conferences, or training and education, it is acceptable to provide snacks and refreshments of a modest nature to only those persons attending the event.

- **Question 25**

Is the R300 limit determined on a per-gift or per-year basis?

Members may occasionally provide modest gifts to HCPs. Other than the gift of medical text books or anatomical models used for educational purposes, any gift from a Member should have a fair market value of no more than R300 incl vat.

The R300 limit is intended to be a per-year amount.

REIMBURSEMENT SUPPORT PROGRAMS

- **Question 26**

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

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.

GRANTS & OTHER CHARITABLE DONATIONS

- **Question 27**

What is an example of a grant or donation to individuals engaged in genuine charitable missions for the support of that mission”?

One example is providing medical devices to individuals who perform volunteer disaster relief abroad. Supporting disaster relief work may be appropriate under the Code, notwithstanding that the individuals or group are acting as independent volunteers and not under the umbrella of a not-for-profit, charitable organisation, registered as such in terms of applicable legislation.

Donations in cash or supplies may also be made to organisations, foundations and other institutions dedicated to a specific charitable cause.

Corporate Social Investment donations may also be made in keeping with the principles of the BBBEE Act

- **Question 28**

May grants be given to a for-profit organisation, such as a legitimately sponsored research grant to a for-profit hospital? What about a research grant to an individual HCP?

This section of the Code addresses charitable giving. Funding a research project at a for-profit institution, or paying an individual researcher, would not qualify as a charitable gift. However, that does not, by itself, mean that the funding would violate the Code. For example, if the funding constituted payment for a legitimate service, it could be appropriate under Section 14. Equally, donations made to for-profit organisations in terms of corporate social investment are legitimate.

- **Question 29**

May a Member make a charitable contribution to a not-for-profit institution to pay the registration or seminar fees and travel expenses for one or more of its affiliated HCPs to attend a third-party educational conference?

If the HCP is in private practice elsewhere, then No.
If the HCP is a public employee, then yes.

- **Question 30**

May a Member make a charitable contribution to a not-for-profit or state hospital for construction of a new wing?

Yes. Members have historically supported the delivery of healthcare services through charitable contributions. As with any other contribution, this type of contribution may be appropriate if (a) the recipient of the contribution is a charity; (b) the purpose of the donation is charitable in nature and (c) it is not offered with the intent of providing an inducement to order, sell, lease, recommend, arrange for the sale or lease of, or prescribe Members' products.

Many factors would be involved in considering whether such a contribution is appropriate, including ensuring that the amount of the donation is not dependent upon the volume of business or anticipated business conducted with or referred to the Member. Legislative and policy provisions have to be considered as well, particularly in the context of state facilities.

- **Question 31**

May a Member make a contribution to pay for a clinical fellow?

Yes. A Member may make a contribution to subsidize a clinical fellow if he/she is in a genuine fellowship program affiliated with a teaching institution.

- **Question 32**

Public hospital service excellence awards: it would be considered appropriate for a member company to sponsor a public hospital service excellence award program provided that the award is modest in nature.

CLINICAL TRIALS AND PRODUCT EVALUATIONS

- **Question 33**

Must the patient consent to the Trial or Evaluation?

Yes - in the case of a Clinical Trial. No - in the case of an Evaluation.

- **Question 34**

Can payment be made to a patient for participation in a Trial or Evaluation?

Certain patient expenses may be reimbursed, as provided for in the Trial protocol. Small gifts given to child participants after completion of a research project shall be allowed. Any payments to be made should be declared to and scrutinized by the appropriate Research Ethics Committee.

- **Question 35**

Is the practice of offering inducements directed towards the investigators acceptable or perverse?

Expenses

Where researchers incur personal expense as a direct consequent of undertaking research, it is quite proper that they be reimbursed against production of original invoices for that expenditure by the sponsor of the research. Expenses should be moderate and reasonable and where a healthcare practitioner is reimbursed by a Funder or patient for the procedure, it would be inappropriate to enrich the healthcare practitioner further for his/her skill.

Fees

Sponsors of research involving patients may properly engage healthcare practitioners to assist in that research, and it is proper for these healthcare practitioners to be paid a fee for their services. It is inappropriate that a healthcare practitioner should be paid a fee for carrying out research work in sessions for which he or she is already being paid from another source. Sponsorship must be declared in a participant information sheet.

Again, the rates should be moderate and in line with the time, not for the procedure, but for actual time taken for conducting the research.

- **Question 36**

Can healthcare practitioners be reimbursed for evaluating a product – not conducting a formal trial?

No. It is not appropriate to reimburse a healthcare practitioner for time spent evaluating a product not under the scope of an ethics committee, registry or without appropriate acknowledgement.

- **Question 37**

What about products developed in South Africa?

Currently no Medical Device regulation exists in South Africa, with the exception of electro-medical devices. There is nothing to stop a manufacturer from releasing untried products into the market. However, the rules for Clinical Trials and Product Evaluations apply equally to such products.

FREE EQUIPMENT, PAYMENT FOR CONSUMABLES / DISPOSABLES

- **Question 38**

Is it acceptable that one enter into a contract with a provider that associates the placement/loan of equipment with the purchase of a **finite** or minimum number of consumables?

No, in general this would be considered unacceptable and unethical since the stipulation that a finite number of consumables must be purchased has the potential to result in over-servicing.

PAYMENT FOR SHELF SPACE

- **Question 39**

Is it acceptable to pay for shelf space?

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

PAYING AN HCP TO USE/SELL MY PRODUCT

- **Question 40**

Is paying an HCP not in my full time employ, to use/sell my product considered perverse e.g. commission per product used?

Yes

- **Question 41**

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

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 local courier companies or by the member themselves.

EMPLOYEE ATTENDANCE IN OPERATING ROOM / CLINICAL ENVIRONMENT

- **Question 42**

May a company representative who is a registered Theatre Sister work in a hospital after hours?

Company representatives may not work as HCP's in their spare time. Guidance should be sought from DENOSA or SANC and the hospital policy will prevail. It could be a conflict of interest for the member

- **Question 43**

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

No, this is inappropriate due to infection control policies.

- **Question 44**

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

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

- **Question 45**

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

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.

CODE BINDING IN OTHER COUNTRIES

- **Question 46**

Is the Code binding on those Members who sell products in other countries e.g. Angola etc.

No, however should the Member sell or engage with a South African HCP outside of South Africa, the SAMED Code will be applicable.

HANDLING INFRINGEMENTS AND ENFORCEMENT OF THE CODE

- **Question 47**

What is the current fee that must be paid when lodging a complaint with regard to a possible contravention of the code?

R2500 incl vat

- **Question 48**

Does the SAMED Code offer legal advice?

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.

- **Question 49**

Will SAMED provide advice on how specific provisions of the Code would apply to specific practices that a Member is contemplating?

Yes. Members are at liberty to address any questions about specific practices to the SAMED Code Advisory Committee. Note, the SAMED Code Advisory Committee bears no responsibility for the advice provided should the Member fail to fully disclose all details / specifics relating to the contemplated practice.

- **Question 50**

Does the Code govern the actions of Members' agents, distributors and Associate Members of SAMED?

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.

PART F: EXAMPLE TEMPLATES

(a) Consulting Agreements

Process to be followed:

Each member company that hires HCPs as consultants should firstly complete the Needs Assessment document which generates a documented trail of clinical education and training needs analysis required by the member.

From this an Agreement is generated which then forms the basis of a contract between member company and HCP which spells out the terms of the agreement and remuneration details.

Procedure

- a) Any business need for an HCP to carry out an activity should be captured in an annual Needs Assessment.
- b) All paid HCP services must have a fully executed contract in place before the HCP provides the service. In order for a contract to be created, the Corporate Sponsor must justify this by using the HCP Consulting Contracts Request Form. The request will clearly indicate the following:
 - . Scope of work to be carried out
 - . Breakdown of time for work (e.g. preparation time, travel time, meeting time etc)
 - . Clinical expertise required for completion of the work
 - . Healthcare Professional nominated to carry out the work
 - . Evidence to demonstrate the suitability of the proposed HCP to carry out the work
 - . Country of origin of the HCP
 - . Proposed payment rate (including payment intervals and maximum contract value)
 - . Any expenses or hospitality associated with the proposed activity, with evidence to demonstrate compliance with relevant local industry code of practice (e.g. meeting agenda/schedule, meeting location, attendees list, details of hotel accommodation and travel arrangements).
- c) Corporate Sponsors should submit contract requests to the In-Country/Regional Compliance Committee within a reasonable time (at least 21 days) before the intended commencement of the activity in order to allow for proper consideration of the request and contract preparation prior to the initiation of any activity under the agreement.
- d) Payments to HCPs should be in accordance with fair market value in the country of residence of the HCP for the service(s) to be provided. All requests must include evidence to demonstrate that the proposed payment rate meets FMV. Any request which exceeds FMV must be supported by a written justification for the excursion.
- e) Contracts/engagement letters must be signed by the HCP before the initiation of any work under the contract. All contractual documentation must be retained for audit purposes.
- k) On completion of the work, or at defined intervals as outlined in the contract, the HCP will submit a request for payment to the Corporate Sponsor using the Work Activity Report (WAR). Any expenses claimed by the HCP in association with the work must be documented on the WAR or local claim form. Expenses claims by HCPs must take into account the SAMED Code.

EXAMPLE OF A CONSULTING AGREEMENT

This Consulting Agreement (“Agreement”) is entered into by and between:

And

XYZ

Insert Name

Physical Address

(hereinafter “the Consultant”).

With effect from **INSERT DATE**

PREAMBLE

WHEREAS, XYZ markets, sells and distribute their own range of imported medical devices; and

WHEREAS, the Consultant is an orthopaedic surgeon specialising in INSERT and desires to consult with XYZ regarding surgeon education on products and procedures for INSERT FIELD (the “Field”); and

WHEREAS, XYZ desires to have the Consultant perform consulting services with respect to the Field; and

WHEREAS, in consideration of consulting fees to be paid to the Consultant by XYZ, the Consultant desires to provide the specified consulting services with respect to the Field and to assign to XYZ all rights in and to the results of such service with respect to the Field, as specified more fully as follows;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the parties agree as follows:

1. Definitions

In this Agreement, the following terms shall have the following meanings:

- 1.1 “Affiliated Company” in relation to any party shall mean any corporation, partnership, proprietorship, or other entity controlled by, controlling, or under common control with such party, and shall include any corporation, or partnership, proprietorship or other entity directly or indirectly owning, owned by or under common ownership with the party in question to the extent of fifty percent (50%) or more of the equity or voting shares, including shares owned beneficially by such party.

2.2 "Training-Day" shall mean a standard eight (8) hour day, or, if less than eight (8) hours of service is provided in any one day, then such term shall mean service performed on various days so that the aggregate amount of time equals eight (8) hours.

2. Services

2.1 During the term of the Agreement, the Consultant shall provide to XYZ up to NUMBER (0) Training-Days of consulting and advisory services in the Field. Such services shall include, without limitation, those listed in the Statement of Work which is attached hereto and made a part of this Agreement as Schedule A.

2.2 Consulting services will be performed personally by the Consultant at XYZ's request and subject to the Consultant's availability. The Consultant shall not enter into this agreement if the Consultant has previously entered into a currently effective exclusive or restrictive arrangement or agreement to provide advisory or consulting services to another entity in the Field, nor shall the Consultant during the term of this Agreement enter into any sort of exclusive or restrictive arrangement or agreement to provide advisory or consulting services to another entity in the Field.

2.3 Consulting services hereunder will be coordinated at XYZ by the General Manager, Surgical or a named designee (the "Corporate Sponsor").

2.4 If hosting of visiting surgeons or others in the Operating Room are included in the Statement of Work attached as Schedule A, XYZ shall pay the Consultant only for the incremental additional time per case required to welcome and host visiting surgeons, including incremental additional time actually spent pre- intra- and post-operatively, per case, as required to review case history, instruct on and demonstrate surgical equipment, instruments, implants and technique, "Incremental additional time" means the additional time spent per case due to the instruction and demonstration aspect of the case. Prior approval for such hosting under this Agreement is required from XYZ by the Corporate Sponsor.

3. Consulting Fee

3.1 XYZ shall pay, and the Consultant shall accept, as consideration for the consulting services to be provided hereunder, and the assignment in Paragraph 6, a fee in the amount of AMOUNT Rands (R----) per Training-Day up to a maximum amount of AMOUNT Rands (R---) for the term of this Agreement. Payments shall be made quarterly for work performed in the preceding quarter on the receipt and approval, pursuant to XYZ's compliance standards, as may be amended from time to time, of each report to be provided under Section 3.2 hereof. All payments shall be made to the Consultant into the following bank account, unless otherwise agreed in writing between the parties.

Name of Account:

Bank:

Branch Code:

Account Number:

Type of Account:

- 3.2 During the term of this Agreement, the Consultant shall submit report to XYZ after the completion of any work, setting forth the nature and extent of the consulting services performed, including the number of Training-Days services were provided, the description of the services provided and the result or outcome of that service. The format for the report to be submitted by the Consultant is attached hereto as Schedule B. Additional reports may be required.
- 3.3 Material and equipment approved by XYZ in advance and used by the Consultant in the course of the consultation will be reimbursed by XYZ on presentation of receipts or other evidence of payment. All travel arrangement will be booked and paid for directly by XYZ. Reasonable domestic travelling time shall be included when calculating Training-Days upon the prior written approval of the Corporate Sponsor.
- 3.4 All Parties represent that the terms of this Agreement are commercially reasonable and the payment provided is consistent with a fair market value for general commercial transactions generated or which could in the future be generated between the Parties.

4. Relationship

- 4.1 The Consultant is an independent contractor and not an employee or agent of XYZ. The Consultant shall provide services to XYZ at such a place and in such time and manner as deemed appropriate, and shall be responsible to XYZ only for the results of the services. The Consultant shall have no right to incur any obligations whatsoever on the part of XYZ. Payments to be made to the Consultant shall not be subject to any withholdings, such as for income tax, unless and until the applicable laws or regulations with respect thereto require such withholdings to be made with respect to payments to bona fide independent contractors. The Consultant shall not be entitled to any compensation other than as stated herein. Nor shall the Consultant be entitled to any benefits that would otherwise accrue if the Consultant were an employee of XYZ. The Consultant acknowledges that XYZ may be required to report payments made to the Consultant to appropriate authorities.

5. Confidentiality

- 5.1 All information disclosed by XYZ to the Consultant and identified as confidential and all information generated by either XYZ or the Consultant under this Agreement shall be proprietary information of XYZ and shall be treated as confidential. The Consultant shall only use such information for the benefit of XYZ.
- 5.2 t Consultant shall not use, disclose or publish any proprietary or confidential information of XYZ without the prior written consent of XYZ.

5.3 The above limitations of confidentiality shall not apply to (i) information which at the time of disclosure to the Consultant was already in the public domain, (ii) information which after disclosure to the Consultant becomes part of the public domain through no fault of the Consultant, (iii) information subsequently received by the Consultant from a third party not owing a duty of confidence to XYZ; or (iv) information required to be disclosed by the Consultant pursuant to subpoena or other lawful process, provided the Consultant first notifies XYZ in a timely manner to allow XYZ to seek an appropriate order or take such other action as it deems reasonably necessary to protect its interests.

5.4 Except as may be required by law, the Consultant agrees to keep the terms of this Agreement confidential, and the Consultant shall not disclose the terms hereof to any person entity or other association, other than the Consultant's attorney, accountant or similar professional pursuant to seeking personal services, without the prior written consent of XYZ.

5.5 The provisions of this Clause 5 shall survive any expiration or termination of this Agreement.

6. Disclosure and Assignment of Inventions

All results of the consulting services provided hereunder, including training materials, presentations, documents, publications or other information conceived, prepared, created, compiled, presented or otherwise used by the Consultant during the term of this Agreement in providing services with respect to the Field hereunder shall be the sole and exclusive property of XYZ, and XYZ shall have the unencumbered and exclusive rights to use all results of the consulting services, with respect to the Field, performed hereunder without additional compensation to the Consultant. The Consultant shall promptly disclose and periodically deliver the latest versions and iterations of any such material to XYZ, without encryption or other protective devices not authorised by XYZ, and irrevocably assign and hereby does assign, to XYZ all of the Consultant's rights, title and interest in and to any such material to XYZ and assist XYZ in applying for, maintaining, or otherwise securing legal protection including copyrights and the like for the same. The Consultant shall execute any papers necessary to vest title in these materials in XYZ. Upon any termination or expiration of this Agreement, the Consultant shall return to XYZ all notebooks, writings, drawings, recordings, photographs and records of every type (including all copies thereof) embodying, in any form, any confidential or proprietary information of XYZ, including all results of the consulting services provided hereunder. The parties acknowledge that this Section 6 does not apply to any inventions, concepts or other information of the Consultant arising outside the services provided under this Agreement. The Consultant may submit any such inventions, concepts or other information to XYZ for its consideration under arrangements separate from this Agreement.

7. Representations and Warranties

The Consultant represents and warrants that, with respect to any information, knowledge or data disclosed to XYZ under this Agreement, including all results of the consulting services, the Consultant has the full and unrestricted right to disclose and assign the same without incurring legal liability to others, and that XYZ shall have the full and unrestricted right to own, use and publish the same as it may see fit.

The Consultant warrants and represents that he has the unrestricted right and freedom to provide the consulting services to be provided hereunder. The Consultant further warrants and represents that he has the full right unrestricted by obligations to third parties to assign all rights, title and interest in and to the results of such services to XYZ.

The Consultant warrants and represents that he has the full right, power and authority to enter this Agreement and perform its obligations, unrestricted by obligations to third parties.

The Consultant represents and warrants that in furnishing services pursuant to this Agreement he will conform to all applicable laws and regulations, and applicable codes of professional conduct.

8. Indemnities

XYZ shall, at its own expense, defend any lawsuit or proceeding brought against the Consultant as a result of XYZ's use of the Consultant's work under this Agreement, provided that XYZ is notified promptly in writing and given authority, information, and assistance for the defence of the lawsuit or proceeding. XYZ will pay all damages and costs awarded in any such suit or proceeding made with its written consent. XYZ is not obligated to reimburse the Consultant for expenses (including fees for legal services) incurred without XYZ's prior written authorisation. The decision either to defend or to settle a suit or proceeding is at the sole discretion of XYZ. The foregoing represents the entire liability of XYZ with respect to these matters.

The Consultant shall defend and indemnify XYZ and hold XYZ harmless from and against any and all demands, claims, causes of action or damages, including reasonable attorney fees and expenses, arising out of, resulting from, or related to, the breach of any representation, warranty or agreement by the Consultant.

The provisions of this Clause 8 shall survive any termination or expiration of this Agreement.

9. Term and Termination

The term of the obligation of the Consultant to provide consulting services hereunder shall commence upon the effective date written above and shall continue in effect for and up to and including 31 December 2009, and may be extended thereafter by a mutual written agreement of the parties.

If at any time XYZ shall be in default of a payment as provided herein, the Consultant may, by written notice specifying such default, demand payment thereof; upon failure by XYZ to cure the specified default within thirty (30) days after such demand, the Consultant shall have the right to terminate this Agreement.

XYZ shall have the right to terminate if the Consultant is in breach of any material representation, warranty, agreement or other obligation of this Agreement, and except as otherwise provided herein, the Consultant shall have failed to cure such breach within thirty (30) days after receipt of written notice thereof from XYZ.

XYZ may terminate this Agreement if XYZ or an Affiliated Company of XYZ experiences a Change in Control; provided that XYZ gives the Consultant notice in writing within ninety (90) days after the effective date of such Change in Control. For purposes of this section, "Change in Control" shall mean any occurrence or condition which causes substantially all of the assets or the business of XYZ or an Affiliated Company to be assigned to or come under the control of a third party that is not an existing Affiliate of XYZ, whether by operation of law, disposition of assets or stock, by merger or otherwise.

If this Agreement is terminated within the initial twelve (12) months of its initial term, then neither party shall renegotiate the terms of this agreement or enter into other or further agreements with the other party for the duration of such initial twelve (12) month term.

10. Notices

Any notice required under this Agreement shall be in writing sent by, registered mail, courier, hand delivery or by facsimile addressed as follows and deemed to have been received as stated:

If to the Consultant:

If to XYZ (Pty) Ltd

xxxxxxxxxxxxxxxx

Fax:

Attention: General Manager Surgical

Hand Delivery and courier are deemed to be received on delivery
Registered post is deemed to be received within 7 days of posting
Facsimiles are deemed to be received on despatch provided they are confirmed by registered post by not later than the following business day. .

11. Disputes

The parties agree that, in the event of any disputes arising out of or in connection with this Agreement, both parties will use their commercially reasonable efforts to reach an amicable and prompt resolution of such dispute, including mediation and arbitration, if the parties agree. Failing amicable resolution, either party will have recourse in law.

The cost of arbitration or mediation of disputes hereunder shall be borne as follows: fifty percent (50%) by the Consultant and fifty percent (50%) by XYZ.

In the event of a breach or default hereof, neither party shall receive, and each party hereby waives any entitlement to, consequential, exemplary or punitive damages.

12. Continuing Performance

Payments payable under Section 3 hereof shall be contingent upon XYZ's receipt of corresponding reports as provided therein; provided however, in all other respects, the obligations of each party hereunder are independent of the others, such that a breach hereof by one party does not excuse the non-breaching Party from performance hereunder.

13. Force Majeure

Neither party shall be responsible for, and the terms of this Agreement shall be inapplicable to, any delays in or non-performance of the terms of this Agreement which are due to circumstances beyond the control of the party responsible for performance, including but without limitation, acts of God or public enemy, acts or any order of government, fire, flood or other natural disaster, embargoes, accidents, explosions, strikes or other labour disturbances (regardless of the reasonableness of the demands of labour), shortages of fuel, power or raw materials, inability to obtain or delays or transportation facilities, incidents of war, or other events causing the inability of such party acting in good faith with due diligence, to perform its obligations under this Agreement.

14. Severability

In the event that any provision of this Agreement shall be determined by an arbitrator or court of competent jurisdiction to be unenforceable, invalid or illegal for any reason, or inapplicable as a result of force majeure, then such arbitrator or court may strike any such provision or substitute any enforceable, valid and legal provision that approximates the original intent of the parties hereto.

If as a result of any material change in law or regulation which relates to the subject matter of this Agreement, either party's legal counsel determines, in an opinion reasonably acceptable in form and substance to the other party's legal counsel, that this Agreement or any part thereof is contrary to applicable law or will cause either party to be in violation of applicable law, then the parties shall meet to discuss such provision(s) and shall substitute therefore a lawful and enforceable provision which so far as possible results in the same commercial effects. If the parties fail to negotiate a mutually agreed resolution within thirty (30) days, then either party may terminate this Agreement upon thirty (30) days written notice to the other party.

15. Applicable Law and Jurisdiction

- 15.1 This agreement shall be interpreted and implemented in accordance with the law of the Republic of South Africa.
- 15.2 Either party shall be entitled, but not obliged, to institute any proceedings arising out of or in connection with this agreement in the magistrates' courts.
- 15.3 Should a party elect to institute proceedings in the supreme court the parties consent to the jurisdiction of the Local Division.

16. Compliance - No Purchase, Use or Referral Requirement

The parties acknowledge that this Agreement in no way and under no circumstances, either directly or indirectly, covertly or overtly, requires the Consultant to refer, recommend, order, or prescribe, or to influence the referral, recommendation, ordering, or prescribing of, any product or service developed, marketed, manufactured, distributed, and/or sold by or on behalf of XYZ or any Affiliated Company thereof, with respect to any patient of the Consultant, to any patient of the Consultant's medical group or a member of the Consultant's medical group, or to any patient of a health care facility at which the Consultant holds medical staff privileges or otherwise provides medical services to patients.

No adjustment to the compensation to be paid to the Consultant under this Agreement shall be made due to the presence or absence of any such referral, recommendation, ordering, or prescribing. Further, in the performance of this Agreement, the Consultant shall comply with the requirements of all applicable laws, rules and regulations, including without limitation those relating to payments or reimbursements. The provisions of this paragraph shall survive any termination or expiration of the Agreement.

17. Entire Agreement

This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and may not be changed, modified or rescinded except by a written instrument executed by all parties hereto.

18. No Adverse Construction

This Agreement shall be construed neutrally and with no presumption favouring or disfavouring either party by virtue of its authorship.

19. Successors and Assigns; No Third Party Beneficiaries

This Agreement shall insure to the benefit of the parties, and their permitted successors and assigns. This Agreement may not be assigned by either party hereto without prior written consent of the other party; provided however, XYZ may assign this Agreement, upon notice to the Consultant, to a party purchasing substantially all of the business or assets of XYZ.

20. No Waiver

No waiver by either party of a breach, failure of condition, or any right or remedy contained in or granted by the provisions of this Agreement shall be effective unless it is in writing and signed by the party waiving the breach, failure, right or remedy. No such waiver by either party shall be deemed a waiver of any other breach, failure, right or remedy, whether or not similar, nor shall any waiver constitute a continuing waiver unless the writing so specifies.

21. Counterparts

This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties, intending to be legally bound, have executed this Agreement with effect from the date written above.

XYZ (PTY) LTD
SOUTH AFRICA

CONSULTANT'S NAME

By: _____

By: _____

Print Name: _____

Date: _____

Title: _____

Date: _____



2009 International
Needs Assessment v1

(b) Donations and Grants

DONATION AGREEMENT

THIS AGREEMENT (this "Agreement"), effective as of the last date indicated below, is made between _____ (Company), located at _____ and the _____ ("Receiver"), located at _____, for the donation of the material identified in Section C herein ("Material").

This Agreement is for a donation of certain Material from _____ (Company) to be used by Receiver for the medical care of patients.

The parties agree as follows:

Section A

1. Qualified Charity. Receiver is a qualified charity and has provided proof of its charitable non-profit status to _____ (Company).
2. Use of Material. The use of the Material by Receiver will be related to the charitable purpose of Receiver.
3. Material Donated. The Material has not been transferred by _____ (Company) to Receiver in exchange for money, other property or services.
4. Not for Resale. Receiver is not accepting the Material for the purpose of resale and intends to use the Material in its charitable function.

Section B

1. Indemnity. Receiver shall indemnify and hold _____ (Company) harmless from and against any and all claims, demands, or actions which are hereinafter made or brought against _____ (Company) by any person, firm, corporation or association for the recovery of damages which is caused or alleged to have been caused by (1) Receiver's failure to meet any of its obligations or representations under this Agreement, and (2) the possession, handling, use, consumption, transportation or disposal of the Material.
2. Shipment and Title. Unless otherwise agreed, transfer shall be F.O.B. _____ (Company) and title shall vest in Receiver when loading is completed.

3. No Warranty. Receiver acknowledges that _____ (Company) warranties are not transferred with the Material. **THE MATERIAL IS "AS IS" AND TO THE EXTENT PERMITTED BY APPLICABLE LAW, THERE ARE NO OTHER WARRANTIES, TERMS, CONDITIONS OR REPRESENTATIONS AND _____ (Company) DISCLAIMS ANY AND ALL TERMS, CONDITIONS, REPRESENTATIONS, WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY TERMS, CONDITIONS, REPRESENTATIONS OR WARRANTY OF SATISFACTORY QUALITY, NON-INFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE, OF THE MATERIAL.**

4. Disposables. Receiver will be responsible for obtaining, at its own cost, the disposable products (such as IV administration sets or probe covers) that are used in conjunction with the Materials. _____ (Company) reserves the right to discontinue at any time the manufacture of such disposable products, with no liability to _____ (Company) _____.

5. Compliance with Laws. Receiver will comply with all pertinent laws.

6. Advertisement/Publicity. Receiver will not advertise about the fact or nature of this Agreement without _____ (Company) prior written permission. Neither party will make any press release or other public disclosure regarding this Agreement unless required under applicable law or by any governmental agency, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

7. Permits/Licenses. Receiver confirms that all applicable licenses and permits have been obtained to receive, transport and use the Material. Upon request, Receiver will submit to _____ (Company) copies of all applicable existing and new or renewed permits, licenses, and other written approvals which it must hold in order to legally: (1) receive; (2) transport (if transported by Receiver); and (3) use, and if necessary, dispose of the Material.

8. Medical Devices. In the event that the donated materials are medical devices, Receiver certifies that the devices will be used as prescribed in their labeling.

9. Complete Agreement. This Agreement shall constitute the entire Agreement between the parties as to the Material. Any modifications or deletions must be accepted in writing by both parties. The subject matter of this Agreement shall be governed by the terms of this Agreement rather than by terms set forth in any purchase order or confirmation by Receiver or _____ (Company) _____.

Section C

List each product, include quantity, full product name and model #

RECEIVER

COMPANY

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

(b)

(c) FCPA Donation Requests

Date: _____

FOR ATTENTION (to be completed)
CUSTOMER (to be completed)
CUSTOMER ADDRESS (to be completed)

Dear Sir/madam

RE REQUEST FOR DONATION

I refer to your letter dated (to be completed) for a request of a donation.

Unfortunately the company is unable to consider your request due to corporate governance restrictions placed on all U.S. registered companies operating in South Africa.

According to the U.S. Foreign Corrupt Practices Act ("FCPA"), Company and its officers, directors, employees, contract workers and agents (including consultants, distributors and sales representatives) must comply with the U. S. Foreign Corrupt Practices Act ("FCPA "). The FCPA prohibits companies such as Company from directly or indirectly (e.g. through an agent or distributor) giving money or anything of value (including gifts, sponsorships, and donations) to a non-U.S. government official if the purpose is to win or retain business or influence these officials' decisions. Because many countries have nationalized health care systems, this law also applies to physicians, purchasing officers, nurses or other employees of government hospitals, clinics or pharmacies.

According to this act no person employed by the company or representing the company, shall offer, promise to pay, give, promise to give and/or authorize the paying or giving of anything of value, directly or indirectly, to a government official, a political party or official thereof, or a political candidate.

(Company) is committed to compliance with this law. Additional information on the FCPA can be found in the company's Ethics Policy Guide.

Please be assured of our continued high level of customer service.

Yours faithfully

General Manager
(Company) – South Africa

(d) Letter of regret re Funding / Sponsorship Requests

Date (to be completed)

Address (to be completed)

Dear Sir/Madam,

RE: REQUEST FOR FUNDING

Thank you for your letter, dated (to be completed) appealing for funding.

Unfortunately, due to (Company) compliance with the SAMED Code of Marketing and Business Practice we regret to advise you that we are not able to assist with this request for funding / sponsorship.

The SAMED Code prohibits healthcare companies from giving money or anything of value which is not for approved medical educational purposes, such as a Year-end function/Christmas party as you have requested.

We do hope that you understand and accept our position on this issue and would like to take the opportunity of wishing you a successful function.

Please be assured of our continued commitment to providing the highest possible levels of customer service and care.

Yours sincerely,

(e) Sponsorship to Congresses and Conferences

It is recommended that a letter / document be created for circulation to relevant HCP's and contain the following:

1. Information on the event to be sponsored.
2. Paragraph on the importance of complying with the law, including the company's own Business Conduct Standards, SAMED Code of Business Practice, etc
3. What is to be sponsored: travel costs, lodging, etc.
4. Reimbursement rules: i.e., only original receipts, no spouses, children, etc
5. Acceptance: request for signed acceptance of the offer, including a statement that the sponsoree is acting in accordance with the rules/policies of his/her Professional Association.
6. Mention re no obligation i.e. the sponsorship does not create any obligation for the sponsoree to buy/use any products of the sponsoring company.

(f) Payment for spouses

Date

Dr A. Bcdefg,
ABC Hospital,
Cape Town

Dear Dr Bcdefg,

Spouse/partner attendance at Local Event / Congress

We wish to remind you that, in line with the SAMED Code of Marketing and Business Practice, we are unable to pay for spouses/partners. All costs (including meals and entertainment) incurred by our Company on your spouse's/partner's behalf will be invoiced to yourself.

Please sign acceptance of these conditions and return.

Should you require any further information, please do not hesitate to contact XXXX on +27 11 XXX-XXXX.

Yours sincerely,

XXXX XXXXXXXX
Managing Director

I have read, understood and agreed to the above

Signature

Date

Date

Dr A. Bcdefg,
ABC Hospital,
Cape Town

Dear Dr Bcdefg,

Spouse/partner attendance at Congress

We wish to remind you that, in line with the SAMED Code of Marketing and Business Practice, we are unable to pay for spouses/partners. All costs (including meals and entertainment) incurred by our Company on your spouse's/partner's behalf will be invoiced to yourself on your return to South Africa.

Please sign acceptance of these conditions and return.

Should you require any further information, please do not hesitate to contact XXXX on +27 11 XXX-XXXX.

Yours sincerely,

XXXX XXXXXXXX
Managing Director

I have read, understood and agreed to the above

Signature

Date

(g) Complaint lodging form

SAMED Code of Marketing and Business Practice Complaint Form

Date: _____

1	Name of complainant:	
2	Representative body or company of complainant:	
3	Name of alleged infringing company/person:	
4	Provision of the SAMED Code that has allegedly been infringed:	
5	Field in which infringement has occurred (e.g. cardiology, wound care, orthopaedics etc):	
6.1	Circumstances of the infringement: What:	
6.2	When:	
6.3	Where:	
6.4	How:	
7	Supporting evidence, where available:	

Name: _____

Designation: _____

Company: _____

Signed: _____

Date

Dear Health Care Professional (HCP)

As you may be aware the healthcare industry is one of the most carefully scrutinized industries in the world.

Recently ADVAMED and EUCOMED - the medical device industry bodies in the United States and Europe respectively - updated their Codes, and Multi National Companies doing business out of these regions have adjusted their Internal Codes of Business Practice accordingly. The FCPA (Foreign Corrupt Practices Act) is enforceable on US and foreign companies that are required to file reports under the Securities and Exchange Act of 1934.

As a result of this SAMED (The South African Medical Device Industry Association) has decided to align its Code of Business and Marketing Practice to be in harmonization with the rest of the world.

Any company that is a member of SAMED, is bound by this code. From the outset, it is important to emphasize that the updated Code underpins SAMED's vision i.e.:

'The responsible and ethical advancement of the interests of the medical devices industry within the SA healthcare environment while promoting better patient outcomes'.

The fundamental purpose of the Code is to promote and encourage among SAMED Members ethical principles and practices. The underpinning principle of the Code is that SAMED Members will not offer any inducement to a HCP or other customer in order to sell, lease, recommend, or arrange for the sale or lease of their products.

In particular we would like to draw your attention to the following clauses of the code relating to attendance at International and local congresses:

1. International Congresses

1.1 Members may sponsor HCPs, both qualified and in training, to attend international events like congresses, conferences and scientific meetings, subject to the following:

1.1.1 Members may pay registration fees and may only offer economy travel, modest accommodation and meals. The level of accommodation offered must be appropriate, modest in nature, and the costs involved must not exceed that level that the recipients would normally adopt when paying for themselves.

1.1.2 Spouses and other accompanying persons, unless qualified as HCPs and registered as delegates, may not attend the actual meeting and may not receive any associated meals and refreshment at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany.

2. Local Congresses

Members may only sponsor HCPs in the public sector, HCP's in training, registrars, nursing staff, technicians and other deserving persons to attend local CPD accredited events like congresses, conferences and scientific meetings. In this regard, Members may pay registration fees and only offer economy (upgradeable) travel and modest accommodation.

3. Congress organized events and sporting activities

Members may sponsor only congress organized events e.g. an opening dinner, but not any add-on recreational events or entertainment, such as sporting events (ski, golf, etc), sight-seeing tours, etc.

In other words, members may not sponsor sporting activities which involve HCPs or pay for HCPs to participate in such activities at congresses or educational functions. Members may however pay for themselves to participate in such events.

4. Faculty

Members may pay for business class flights for incoming and outgoing faculty, but only if they are presenting on the day of arrival.

We trust that this communiqué offers a better insight into the dealings of our Members with yourselves, the HCP's that we deal with on a daily basis.

The full document is available at www.samed.org.za.

You are also welcome to contact your local representatives from all SAMED Member companies for a full copy of the code.

Sincerely,



T.M.Vogt
Chief Operating Officer
SAMED

Addendum 1

SAMED Policy and Procedure - Transparent Invoicing Model

Issue Date: 13 September 2007

Updated 14 April 2008

Prepared by:

Tanya Vogt (COO of SAMED)

And

Approved by the SAMED Board of Directors

Important Note:

This document is to be initialed on all pages, by the COO and/or duly designated representative and a signed copy faxed to the SAMED offices at

fax nr: 011 467 1697

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 mainly transparency and affordability within the health care 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 compliant with Competition Law (see the Competition Act [Act No. 89 of 1998]).

2 Purpose:

To ensure that all off invoice rebates are eliminated from the invoicing process by suppliers of Medical Devices to their customers.

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 **Maximum List Price:** that price which is the supplier's benchmark price and the maximum price at which the item will be sold at to a customer.

Note: this price replaces the previous list price that *may* reflect inflated pricing to accommodate rebates.

- 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 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.**
- 3.5 **Other inducements:** shall include payment for information or shelf space, supply of bonus or free goods, and the like, as specified in the SAMED Code of Business Practice.
- 3.6 **Settlement discount:** that discount which is granted for timeous settlement of an account and which reflects the normal ‘cost of money’.
- 3.7 **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.
- 3.8 **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 elimination of off invoice rebates 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:

- Revised Maximum 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 (i.e. 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 spiraling 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 revised 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 i.e. payment for information or shelf space, supply of bonus or free goods and the like, where such payments are deemed to be perverse. Sampling must be in accordance with the provisions of the SAMED Code of Business Practice.

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.

Signatories shall be published on the SAMED website.

10 Compliance:

This document will be incorporated into the SAMED Code of Business Practice 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: tanya@samed.org.za or fax 011 467 1697.

Signed:

I _____ duly authorized and representative of
_____(Company) hereby commit to implementing and
adhering to
this policy from this day _____ (date) forward.

Witness _____

Addendum 2

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 training on operating room/clinical environment protocol provided by SANC/SAOA/SATS etc 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 status⁵
- 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 the facility. You should be prepared to advise on technical questions related to the assembly and operational performance of Company products consistent with the labeling and instructions for use.

⁵ This applies primarily to communicable diseases e.g. flu, hepatitis B etc, not those conditions you need not disclose by law

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

When acting on behalf of your company, company products may not be used and/or applied directly to a patient by you even if you hold appropriate certification/licenses, You may not deliver patient care or perform medical services of any type, even if you possess an appropriate medical license/certification.

Your purpose in the operating room/clinical environment is to provide expertise relating to the preparation, assembly and use of instrumentation / devices which must be facilitated by communicating with the appropriate healthcare professional performing the procedure.

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