The Medical Device Code of Ethical Marketing and Business Practice (the Code) in its entirety is applicable to medical device companies and their employees, healthcare professionals and employees of healthcare organisations – in the public and private sector – who are responsible for using devices and/or managing and administering the procurement of devices.

**Conference organisers and event organisers** should pay special attention to Chapters 1, 2 and 3 of the Code, dealt with in this summary on pages 5 to 7.

**Corporate social investment** managers and executives of *charitable and philanthropic organisations* should familiarise themselves with Chapter 4 of the Code, summarised on page 6.

**Nursing practitioners** involved in providing product support services on behalf of medical device companies are advised to pay special attention to Chapter 14 of the Code, summarised on page 9.
By developing the Medical Device Code of Ethical Marketing and Business Practice (the Code), the South African Medical Device Industry Association (SAMED) aims to provide leadership and clear guidance to medical device companies to enable them to uphold the ethical standards expected of the healthcare sector.

The Code was adopted by SAMED in February 2017 and is binding on all SAMED members. Current legislation allows the Minister of Health to recognise marketing codes for the pharmaceutical and medical device industries. Should this Code receive such recognition, it would apply to the entire industry, irrespective of membership of any industry association.

The adoption of the Code is a natural outcome of SAMED’s vision of developing a sustainable medical device industry by responsibly improving patient access to innovative medical devices.

**THE VALUES THAT UNDERPIN THE CODE ARE:**

- SAMED’s belief that the industry has a social responsibility that extends beyond our customers to patients and society in general.
- SAMED’s desire to foster cooperation and shared responsibility with healthcare professionals for the delivery of effective and efficient healthcare.

**RECONCILING HEALTHCARE AND BUSINESS ETHICS**

The medical device industry is so closely aligned with the mission of the healthcare professions that it must be bound by the encompassing professional ethos of putting the needs of the patient first. At the same time, the medical device industry is highly commercialised, competitive and innovative.

Traditional thinking has focused on the tension between the ethical commitments of healthcare professionals and the commercial imperatives that exist within the healthcare sector. The profit motive is often seen to undermine responsiveness to patient needs. While SAMED believes that this tension is real and must be addressed, we also believe that reconciling professional and business cultures is an achievable goal.

While the advancement of healthcare ethics is an end in itself, it also makes sound business sense in a world where companies need to take an integrated approach to value creation.
Medical devices are marketed in a manner that is distinct from the marketing of pharmaceuticals. Effective and safe use of medical devices often requires that healthcare professionals receive training specific to devices that are new to them and also to provide an opportunity for evaluation and practice before clinical application.

Some medical devices are costly items of equipment, designed for repeated use over a protracted period. They represent a considerable investment for the healthcare professional or healthcare organisation. In such circumstances, the stakes are high and the risk of unethical incentives to purchase is also increased.

The medical devices industry has therefore developed an Ethical Marketing and Business Practice Code that recognises and safeguards the benefits of an unusually close business relationship between Healthcare Professionals (HCPs) and companies, while at the same time prohibiting perverse business practices and imposing penalties on companies and individuals that engage in unethical practices.

**PRINCIPLES OF THE CODE**

The following general principles guided the formulation of the Code and inform interpretation of the Code:

**The principle of image and perception:** In their interactions with healthcare professionals, members of the medical device industry should consider public perceptions of the industry.

**The principle of (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.

**The principle of transparency:** Interactions between members of the industry and healthcare professionals must be transparent and comply with all applicable laws and professional codes of conduct.

**The principle of equivalence:** Whenever an HCP performs a service for a medical device company, payment for the service must represent fair market value.

**The principle of documentation:** Whenever a healthcare professional performs a service for a medical device company there must be a written agreement that provides details of the nature of the service. Remuneration and the performance of the service must be substantiated by financial records and activity reports.
GENERAL CHARACTER OF THE CODE

The Code is an instrument for self-regulation of the medical device industry and SAMED, as the representative industry association, is the custodian of the Code.

The Code was developed by referencing relevant industry and healthcare professional codes within South Africa and internationally and has borrowed from many of these to create a unique code suited to the industry in this country.

The Code seeks to facilitate ethical behaviour across the industry, and to enforce compliance where necessary.

Where companies and individuals in the industry fail to observe the Code, there are provisions for achieving compliance and imposing sanctions. The compliance process is triggered by the receipt of a formal written complaint by SAMED. It therefore depends on people who are concerned about ethical healthcare practice and fair competition in business, taking that step to set the process of investigation and adjudication in motion.

The Code also sets in place procedures for recording information and evidence of ethical behaviour by contracting parties. These habits of transparency are a cornerstone of good governance and may provide valuable protection to the company should any complaints arise.

The Code is a living document and will be revised by SAMED from time to time in the light of experience and the evolving ethical culture in both business and healthcare.

The Code applies to the full range of companies within the medical device industry – manufacturers, importers, distributors and agents – and extends to their employees, agents and contractors working on their behalf.
This booklet provides a convenient introduction to the Code. Those who are expected to give effect to the Code – medical device companies and those who do business with them – should familiarise themselves with the full text of the Code available at: http://www.samed.org.za/Codes-of-Practice.aspx

3.1 ORGANISATION AND SPONSORSHIP OF EVENTS

One way in which the Code regulates the relationship between medical device companies and healthcare professionals is by providing guidance on the organisation of events.

The Code deals both with events organised directly by medical device companies and with third-party events which companies support through sponsorship of such events.

The Code insists that all events must fulfil a clear educational and/or device-marketing purpose that is evident in the programme and the choice of venue. It firmly closes loopholes that have allowed recreational and leisure activities to be disguised as educational and/or marketing events.

PROVISIONS APPLICABLE TO ALL EVENTS

The following general provisions apply to all events:

♦ Event programmes must relate directly to the field of professional expertise of healthcare professionals attending them. The programme may not include sport and leisure activities and other entertainment.

♦ Events should take place at conference facilities or meeting venues conducive to the exchange of scientific and medical information. Tourist and leisure resorts and luxury accommodation are considered unacceptable.

♦ Provision of reasonable hospitality for healthcare professionals attending events is acceptable, but this should be subordinate to the main educational/marketing focus of the event.

♦ There must be transparent criteria for selecting healthcare professionals to attend events.

♦ Payment of travel, accommodation and meals for spouses of healthcare professionals to attend events is not acceptable.

In terms of sponsorship of third-party events, such as local and international conferences, the following provisions apply:

♦ Purchase of satellite symposium packages at local and international conferences is endorsed provided that the symposium topic is related clearly to the topic of the main conference.

♦ Direct Sponsorship of registration, travel and accommodation of healthcare professionals to enable them to attend third-party events is permitted in the current Code. However, this practice will be prohibited as of 1 January 2018.
The Code endorses the invitation of healthcare professionals to **company events**, including:
- Product and procedure training and education events.
- Sales, promotion, product launch and business meetings.

The Code states that companies should provide product and procedure training and education to relevant healthcare professionals in order to facilitate safe and effective product use and good patient care. It specifies that personnel conducting such training must have appropriate expertise and indicates that company premises may be suitable venues.

The Code defines sales, promotional and business meetings and product launches as events “where the objective is to discuss product and related services, features and benefits, to conduct contract negotiations or to discuss sales terms”.

### 3.2 PROMOTIONAL ITEMS OF MEDICAL UTILITY, GIFTS AND COMPETITIONS

**GENERAL APPROACH**

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

In addition to this blanket prohibition of incentives or inducements – which have the potential to undermine decision-making in the patient’s best interests – the Code provides that:
- Items of medical utility, including, scientific medical reference books, journals, periodicals and anatomical models intended for teaching or patient benefit (value as determined from time to time by SAMED set out in the code), are allowed to be provided to HCPs.
- Member companies may not give gifts of any nature, including but not limited to those pertaining to cultural, religious or national events.
- Promotional items may be given to healthcare professionals, sales staff and appropriate administrative staff, provided that they are inexpensive, of educational and/or scientific value, not for personal use, and not in the form of cash or vouchers. Promotional items must be branded with Company name and/or Product and/or Logo.

Companies may run competitions, provided that entry is not dependent on prescribing, ordering or recommending a product. The competition should be based on medical or product knowledge and guidelines on the nature of prizes must be followed.

**CHARITABLE DONATIONS**

Charitable donations are gifts of a special kind and require a different approach. In the context of the Code, these donations refer to the “provision of cash, equipment, company product or relevant third-party product for exclusive use for charitable or philanthropic purposes”. 
The focus of the Code is to ensure:
- Only bona fide charities and non-profit organisations dedicated to charitable or philanthropic purposes receive such donations.
- There are no conditions attached to the donation that relate to the purchase, lease, recommendation, prescription, use, supply or procurement of the donor company’s products.
- The donation is not seen as a form of price concession to favoured customers.

Companies must undertake an independent process to identify, prevent and mitigate the potential risks of bribery and corruption arising from any charitable donation prior to the making of the donation and this assessment must be documented.

Donations, grants and benefits may also be made to institutions, organisations and associations for the purposes of supporting healthcare or research, provided:
- These are documented by the donor company and kept on record.
- They are not paid directly to healthcare professionals or administrative staff of healthcare organisations.

3.3 CONTRACTING PROFESSIONALS AS CONSULTANTS

The Code recognises that medical device companies may have a legitimate need to contract healthcare professionals as consultants for purposes such as research, product development, participation in advisory boards, and presenting at company events.

In all cases, the following conditions apply:
- Consulting arrangements shall not be contingent in any way on the purchase, lease, recommendation, prescription, use, supply or procurement of the contracting company’s products or services.
- The consulting contract must relate to a genuine need in the company and the consultant must be qualified to meet this need.

Where the consultant is paid, the fee must be determined in accordance with the fair market value of the specified service and be subject to the test of
commercial reasonableness. The latter refers to whether the deal makes business sense as a standalone contract, without any prospect of additional commercial engagement.

The Code provides clear guidelines on establishing the value of the service and compensation at fair market value.

3.4 RESEARCH: ROYALTIES AND REGISTRIES

Healthcare professionals, as individuals or in groups, often play a critical role in the development, evaluation and improvement of medical devices and the Code endorses fair compensation for their contribution.

The Code provides for companies to enter into royalty arrangements with healthcare professionals but only in instances where the professional “is expected to make or has made a novel, significant or innovative contribution to the development of a product, technology, process or method”.

The Code also requires that:

- This contribution needs to be appropriately documented.
- The compensation agreement must be in writing.
- The calculation of the value of royalties should take account of the need to “preserve the objectivity of medical decision-making and avoid the potential for improper influence”.
- The royalty arrangement should not be conditional on the healthcare professional purchasing, ordering or recommending any product of the company or participating in the marketing of the product upon its commercialisation.
- The arrangement must be compliant with intellectual property legislation.

Patient registries serve to collect uniform data on a large number of patients with the same disease or condition in order to evaluate health outcomes, including outcomes associated with the use of medical technologies or devices. The collection of such data requires the participation of healthcare professionals.

Medical device companies may utilise patient registries for a variety of purposes. For example: to understand the effects of products and improve patient care; to support regulatory approvals for extended use of products; to assess “real world” safety and effectiveness of products; to assess relative effectiveness of various technologies or products; and to comply with regulatory requirements for continued safety monitoring.

The Code requires that:

- There must be a legitimate need for creating/supporting a registry: the data collected must be of scientific significance or of value for healthcare policy-making.
- Proof that the registry is fulfilling such a need must be available, for example, in the form of protocols and ethics committee approvals.
- Payment of healthcare professionals for participating in patient registries must be in accordance with fair market value and the nature of work performed.
3.5 DEMONSTRATION/EVALUATION PRODUCTS AND LOANED/PLACED EQUIPMENT

The Code states: “No member may offer a bonus, free goods or other incentive scheme deemed to be perverse to a healthcare professional in relation to the acquisition of goods and services in contravention to regulations issued in terms of 18C of the Medicines and Related Substances Act.”

It requires companies to provide accurate and transparent billing to healthcare professionals and others responsible for payment and to make this documentation available should a formal complaint in terms of the Code be lodged.

The Code clarifies that:

- **Demonstration products** are provided free of charge by companies to equipped and qualified healthcare professionals or organisations solely for the purpose of demonstrating their functionality and safe and effective use. They are not intended for clinical use.

- **Evaluation products** are provided free of charge by companies to healthcare institutions for the sole purpose of obtaining their feedback and evaluation on the product when it is used as intended over a stipulated period of time.

The Code endorses all the above practices subject to the following conditions:

- Provision of these products must not improperly reward, induce or encourage healthcare professionals and organisations to purchase, lease, recommend, prescribe, use, procure or supply the company’s products.

- The quantity of single-use products or time-period for which multi-use products are made available must be suited to the purpose of evaluating or demonstrating the product or familiarising healthcare professionals with the product.

- Delivery and return of products (in the case of multi-use equipment) must be carefully managed and clearly documented.

Equipment may also be **loaned, rented or placed** with a healthcare provider in order to cross-merchandise this capital equipment through the sale of consumables or disposables that are specific to the equipment in question, subject to the HCPSA’s Guidelines for Good Practice – Booklet 5, item 3.6 Technological Equipment as applicable to Healthcare Professionals.

3.6 CONDUCT OF HEALTHCARE REPRESENTATIVES

The Code stipulates that companies are responsible for ensuring that healthcare representatives have the training necessary to provide them with scientific understanding of the medical devices that they promote and enable them to offer precise and complete information about these products.
It deals specifically with the conduct of healthcare representatives in the operating room and other clinical environments. Of particular significance are the provisions that healthcare representatives:

- Require the permission of medical staff of the healthcare facility and written consent of the patient in order to enter these areas.
- May only advise on technical aspects of company products in accordance with the approved package insert or instructions for use.
- May not give clinical advice relating to diagnosis, clinical procedure or treatment even when directly requested to do so by surgical or other healthcare staff.
- May not use or apply the company product or deliver care directly to the patient even if licensed and capable of providing such care.

In instances where a healthcare representative is present in an operating theatre or healthcare facility in his/her capacity as a trained healthcare professional (and is not, at the time, representing the company), s/he must have a written contract with the healthcare organisation for such professional service.

### 3.7 UTILISATION OF NURSING PROFESSIONALS

The Code provides for medical device companies to employ or contract nursing professionals to provide product support to individual patients after a specific product has been consented to and prescribed for the patient. The scope of their service is very specific and does not extend to general nursing care.

This practice responds to the reality that specialised nursing care is often unavailable within hospitals and after patient discharge. This gap poses a risk to quality patient care and also represents a risk to medical device companies because they are legally obliged to ensure that their products are correctly used.

While nursing professionals employed or contracted by companies may offer product support, the Code emphasises that the principle of informed patient consent is inviolable. Each patient must be provided with a description of the service being offered as well as other options, and the benefits, risks and costs of various options.

The nursing professional’s first responsibility throughout product support is to the patient:

- S/he should be able to advise the patient of alternative products in event of allergies or difficulties arising in relation to the original product. There should not be overt loyalty to any company’s product.
- S/he should be free to express dissent with the company without fear of reprisal if this is in the patient’s interests.

The remuneration of nursing professionals as employees or independent contractors should be at fair market value for services rendered in the following areas: advising the patient on correct product use, issuing adverse event reports, ensuring compliance with consumer protection legislation and medical scheme requirements.
No incentives, rebates or discounts may be provided by the company to contracted nursing professionals as a reward for attaining particular volumes or frequency of product use.

3.8 ADVERTISING OF MEDICAL DEVICES

The Code does not deal with advertising of medical devices and will not investigate complaints related to advertising. The Code highlights the obligation of companies to comply with all Acts and regulations related to the advertising of medical devices and IVD’s i.e. the Advertising Standards Authority (ASA) Code, the Consumer Protection Act and the Medical Device and IVD regulations. Complaints regarding any unethical advertising of medical devices will be referred to the ASA.
Members of the industry, healthcare professionals, civil society “watchdogs” and the general public all have a role to play in ensuring the Code becomes an effective instrument for ethical conduct. A complaints process is the engine of Code enforcement and it is implemented jointly by members of the industry, independent experts and the SAMED office.

The main role players and their responsibilities are described below while the steps in the process of complaint registration, investigation and adjudication are set out in the figure on page 14.

4.1 COMPLAINT LODGING PROCESS

Important features of the process should be noted:

- Complainants must identify themselves and be in a position to provide written information on the nature of the alleged infringement. This requirement is intended to limit unsubstantiated complaints.

- The key natural justice principle of hearing both sides of an issue forms part of the procedure from the point that the complaint is received through to the hearing conducted by the Ethics Committee.

- The mechanism is one of self-regulation by the industry with elements of independent investigation and adjudication built in. As such, it attempts to view alleged infringements through the lens of individuals with a sound knowledge of the industry, while introducing experts with an understanding of legal principles and investigational methods.

- The process is designed to be relatively inexpensive. Legal representation at hearings will only be permitted in exceptional cases.

- The process is designed to take up to three months from complaint receipt to final outcome. Precise time-frames are stipulated in the Code for every step in the process.

- A commitment to strict confidentiality will be required of all role-players responsible for the receipt, administration, investigation and adjudication of complaints under the Code.

- The range of sanctions is clearly set out in a schedule which forms part of the Code. Sanctions have been approved by SAMED and include the options of restitution, monetary fines and publication of confirmed infringements together with the name of the company or individual transgressing the Code.
4.2 FROM COMPLAINT TO FINDING: THE RESPONSE TO ALLEGED BREACHES OF THE CODE

Secretariat receives complaint, asks respondent to respond and complainant to reply to response. Sends documents to Independent Investigator.

Investigator conducts investigation and produces report. May recommend conciliation in some cases.

Ethics Committee receives Investigator’s report. Adjudicates all cases with merit through formal hearing.

Complainant, respondent and possibly witnesses and experts participate in hearing. Committee delivers finding, imposes penalties where applicable.

Secretariat facilitates conciliation. Some matters settled. Others referred back to adjudication.
4.3 COSTS

Any SAMED member, a member of the public, HCP 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. **Note there is no lodging fee required to be paid by a member of the public, HCP or regulatory body.**

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

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

4.4 SANCTIONS

The Code includes a detailed schedule of sanctions, which links specific sanctions to particular types of infringements. The aim is to ensure that both complainant and respondent should understand why a particular approach to sanctions has been taken.

Within this framework, the Ethics Committee has discretion to impose fines, order action to rectify damage done, or direct the publication of details of infringements and the names of the parties responsible.

The following factors will be considered by the Ethics Committee when weighing the sanctions to be imposed:

- The nature and extent of the breach, including its impact on the market and reputation of the industry.
- The nature and number of breaches and the time period over which they occurred.
- The extent to which the breach should have been evident to the company.
- A previous history of similar breaches and/or failure to implement previously imposed sanctions.
- The impact of the breach on patients, healthcare providers and competitors in the industry.
- Potential costs that would be incurred by the company if corrective action were required.