



# Update: Medical Device Code of Ethical Marketing and Business Practice: “The Code”

**SAMED**

south african medical device industry association

advancing **innovation** responsibly



# SAMED: Who we are and what we do

- Established 1985, grown significantly in recent years
- 151 member companies, 4 associations, 14 associate members
- The majority of medical device companies in South Africa are small to medium in size
- SAMED members must comply with Medical Device Code of Ethical Marketing and Business Practice
- Close ties with other international bodies e.g. GMTA, AHWP, Advamed, Medtech Europe
- First Code 1994

## BACKGROUND

# The view through a wide-angle lens

Ethical conduct of government and business organisations under  
*close scrutiny*

Ethos of *good governance*, where fair conduct, value creation and sustainability are linked

Global trend, aligning with *international* best practice and approaches



‘The overarching objective of King IV is to make corporate governance more accessible and relevant and to be the catalyst for a shift from a compliance-based mindset to one that sees corporate governance as a lever for value creation’

- Mervyn King



‘It was to me never reason for irritation when these bodies – the Public Protector, Human Rights Commission, Auditor-General . . . Constitutional Court and others – were asked to adjudicate on actions of my government . . . and judged against it . . . I drew reassurance that the ordinary citizens of our country would be protected against abuse’

- Nelson Rolihlahla Mandela

## IN HEALTHCARE REGULATION

# It's all about the patient

- **Expansion** of health sector regulators since 1994
  - Council for Medical Schemes
  - Office of Health Standards Compliance
  - Proposed SA Health Products Regulatory Authority
  - SA Research Ethics Council
- In these, as in older regulatory bodies, the aim is to **safeguard the patient and improve healthcare ...**
- The healthcare industry is one of the most carefully **scrutinized** industries in the world

## KEY FEATURES OF CODE

# Instrument of self-regulation

- Based on ‘insider’ appreciation of unique features of devices industry
  - Practices that must be protected – in patients’ interests
  - Practices that must be eradicated – also in patients’ interests
- Voluntary – to a point
  - Membership of SAMED dependent on acceptance of the Code
  - Vision is for a responsible industry, not isolated companies
- Complaints-driven approach
  - Mutual monitoring by members as well as stakeholders and public
- Ministerial recognition possible
  - Draft regulations provide for Ministerial recognition of industry codes

# SAMED VISION

To develop a sustainable medical device industry  
by responsibly improving patient access to  
innovative health technology



## SAMED's overarching principles

- Support an industry that is **responsible to patients** and broader public
- Pursue **best interests of members** while respecting needs and rights of patients
- Promote **ethical principles and practices**, as agreed by members, and oppose inappropriate inducements to healthcare professionals
- Promote **fair competition** among members based on value of products and ethical marketing acumen
- Contribute to developing a **people-centred, equitable and efficient** healthcare system
- Advance compliance with **spirit and letter of applicable laws**

# PRINCIPLES OF THE CODE

## Guide for interpretation of the Code's provisions

- The Principle of Image and Perception
- The Principle of Separation (patient best interest)
- The Principle of Transparency
- The Principle of Equivalence
- The Principle of Documentation

# Snapshot of The Code

## Part 1: Interactions with healthcare professionals

Events, gifts & charitable donations

Demo products, samples, loaned & placed devices

Bonusing, rebates, incentives, consultant fees & royalties

Patient registries

False claims to medical schemes

Conduct of healthcare representatives

Utilisation of nursing professionals

Advertising of medical devices

## Part 2: Dealing with infringements

SAMED-selected Ethics Committee

Complaint procedure

Independent investigation

Conduct of hearings

Sanctions

## Part 3: Questions and answers

## Part 4: Complaint form

## Part 5: Addendums

# Unique interactions with healthcare professionals

- Close working relationships with healthcare professionals are lifeblood of devices industry
- Beyond any question, these relationships are indispensable to good patient care and progressive practice
- Strength of this interdependence puts devices industry in special league
- But strong interdependence breeds possible risk of manipulation or collusion that has negative impact on patient
- Clear rules and the guidance (and possible sanction) of peers and competitors are essential safeguards for industry, healthcare professionals and patients

# Multiple platforms for unique interactions

<b>Platform</b>	<b>Devices</b>	<b>Pharmaceuticals</b>
Advancement of products	Developed in collaboration with HCPs	R&D in labs by scientists
Product life-cycle	Short (2-4 years), ongoing evolution	Long, unchanging compound
Clinical evaluation & RCT standardisation	Difficult to blind and standardise, no placebo, multiple users, training long & ongoing, influenced by settings / users	Easy to blind and standardise, usually one end-user, shorter training, less dependent on setting / user
Safe & effective use	Outcomes depend critically on skills/experience of user, requiring intensive & ongoing training / education	Outcomes less dependent on skill / experience of user
Additional support provision	Service & maintenance for many high-tech devices	Mostly, little or no training, service or maintenance

## Code draws the ethical line

- Essence of Code is drawing the line between essential value of key practices and distortion of practices for unethical gain
- Code gives clear guidance on where the line lies in each set of circumstances

## Code protects members and industry

- Clearly describes and limits role of company representatives in the clinical environment
- Also defines role of nursing professionals retained by members to ensure correct product use
- In so doing, assists members to:
  - Meet legal obligation to ensure correct product use
  - Remain within appropriate scope of work
- And thereby reduces exposure to risk

## Approach to enforcing the Code

- **Complaints-driven:** no investigation or hearing without a complaint
- **Conciliation** the first line of response in many cases
- **Investigation** is conducted by an **independent** investigator
- **Hearings** are conducted by **ethics committee**
- **Legal representation** only in particularly **complex** matters
- Matters involving **advertising** referred to Advertising Standards Authority
- Schedule of **sanctions agreed by members** as part of Code



## The way forward

- Code ratified by **SAMED Board** on 23 Feb 2017
- Code **available on** **SAMED** website
- **Formal launch** of the Code to key stakeholders
- **Regional Code training** for member companies to facilitate member compliance and support
- Certification
- Advocating for **official recognition** of the Code
- Regular **review** of Code due to dynamic aspects of our industry

Thank you  
[www.samed.org.za](http://www.samed.org.za)