



SAMED

south african medical device industry association

advancing **innovation** responsibly

THE SOUTH AFRICAN MEDICAL DEVICE INDUSTRY - FACTS



Index:

1.	About SAMED	2
1.1	Who is SAMED?	2
1.2	SAMED Members	2
1.3	Breakdown of Ordinary SAMED Members	3
2.	Medical Device Regulations	4
2.1	General	4
2.2	Definition of a Medical Device	4
2.3	Registration of Electromedical Devices	5
2.4	Registration of Combination Medical Devices	5
3.	South African Market	6
3.1	Growth Rates	6
3.2	South Africa's Medical Devices Sales by product category	7
3.3	Strengths and Opportunities	8
3.4	South Africa's Trade in Medical Devices	9
3.5	South Africa's Incentives	11
4.	Broad- Based Black Economic Empowerment	13
5.	Hospital Sector	14
5.1	Public hospital sector	14
5.2	Private hospital sector	14
6.	Procurement of Medical Devices in the private sector	15
7.	Codes of Practice to which SAMED members are bound	16

1. About SAMED

1.1 Who is SAMED?

SAMED - the South African Medical Device Industry Association – is a non-profit voluntary association representing the interests of 160+ companies operating in the Medical Device, Medical Equipment and In Vitro Diagnostics sector in South Africa.

SAMED's mission is to develop a sustainable medical device industry by responsibly improving patient access to innovative health technology.

SAMED is committed to:

- safeguarding and promoting the interests of its members,
- encouraging ethical principles and practices,
- promoting innovation and better patient outcomes and
- ensuring effective representation with all relevant authorities whether public or private.

SAMED membership comprises ordinary, association and associate members.

Our ordinary members include: multinationals, distributors, agents and local manufacturers of medical devices, medical equipment and IVD's.

Association members include: The South African Laboratory and Diagnostic Association (SALDA), The Medical Imaging Systems Association (MISA) and MDMSA (Medical Device Manufacturers of South Africa).

Associate members include: consultants, training providers and logistic companies operating in the medical device industry.

The industry we represent employs more than 4000 people and encompasses more than 300,000 different medical devices used in the diagnosis, prevention, treatment and amelioration of disease and disability. These range from sticking plasters and wheel chairs through to pacemakers and replacement joints.

1.2 SAMED Members

Ordinary Members:

3M South Africa (Pty) Ltd
Abbott Laboratories S.A. (Pty) Ltd
Adcock Ingram Critical Care
AEC-Amersham (Pty) Ltd
Affordable Medical (Pty) Ltd
Agfa Healthcare South Africa
AHG Health Solutions (Pty) Ltd (previously SM Specialist Solutions)
Akacia Medical
Amayeza Abantu
Angio Quip Medical Supplies (Pty) Ltd
Ariste Health (Pty) Ltd
Arjo Huntleigh Africa (Pty) Ltd

Atomo Australia (Pty) Ltd
Auckland Orthopaedics (Pty) Ltd
Axim
Bausch & Lomb
B Braun Medical (Pty) Ltd
Bard Medical
Baroque Medical (PTY) Ltd
Bayer (Pty) Ltd
Beier Drawtex Healthcare
BCC Pharmaceuticals Pty Ltd
Becton, Dickinson and Company (Pty) Ltd
BiotechAfrica
Biotronik SA (Pty) Ltd

Bliss Medical (Pty) Ltd
 BMK Orthopaedics
 BSN Medical
 Biomet
 BMG Orthopaedic Solutions (Pty) Ltd
 Bone SA
 Boston Scientific (SA) (Pty) Ltd
 Brittan Healthcare
 Browning Surgical CC
 CareFusion SA 319 (Pty) Ltd.
 Casene Agencies
 CE Mobility
 Centre for Tissue Engineering
 Clinipro (Pty) Ltd
 Coloplast SA
 Condor Medical Africa (Pty) Ltd
 Cossni Medical (Pty) Ltd
 Covidien (Pty) Ltd
 C-Therm Africa (Pty) Ltd
 Dräger Medical South Africa (Pty) Ltd
 Edwards Life Sciences
 EQOS Tech
 EndoAfrique (Pty) Ltd
 FS & NCP Medical Agency CC
 G E Healthcare
 Gabler Medical (Pty) Ltd
 Gentry Health CC
 GlaxoSmithKline
 Globus Medical
 Grobir Medical Supplies
 HemoCue SA (Pty) Ltd
 Heraeus South Africa (Pty) Ltd
 Hartmann Vitamed
 Hutz Medical
 Jalo Enterprise
 Johnson & Johnson Medical
 Karl Storz Endoscopy (South Africa)(Pty)
 Ltd
 Acelity (previously KCI Medical &
 Systagenix)
 Haylard Health (previously Kimberly Clark)
 Invula Healthcare Logistics
 Bidvest Medical (previously) Konica
 Minolta Medical SA
 Kunene Health Care (Pty) Ltd
 LifeAssay Diagnostics (Pty) Ltd
 Litha Medical
 Linette Bowen Agencies CC
 M & L Medical Suppliers CC (Viva Line)
 Malachite Medical (Pty) Ltd
 Maleho Medical Suppliers
 Marcus Medical (Pty) Ltd
 Macromed CC
 MDG Health Solutions (Pty) Ltd
 Medhold Medical (Pty) Ltd
 Medical International Orthopaedics
 Medtronic Africa (Pty) Ltd
 Neurophysics (Pty) Ltd
 Nuangle Medical (Pty) Ltd
 Obsidian Health (Pty) Ltd
 OmniMed (Pty) Ltd
 Orthomedics Pharmaceuticals
 Ortho Sol Development
 Ortho-Xact (Pty) Ltd
 Otto Bock South Africa
 Paragmed (Pty) Ltd
 Perryhill International (Pty) Ltd
 Philips Medical Systems South Africa (Pty)
 Ltd
 Professional Orthopaedics
 Respitek (Pty) Ltd
 Roche Products Pty Ltd - Diagnostics
 Division
 Rollybrush SA (Pty) Ltd
 Roth Medical (Pty) Ltd
 SA Biomedical (Pty) Ltd
 Safmed (Pty) Ltd
 Selective Surgical
 Siemens (Proprietary) Limited
 SleepNet BreatheNet
 Smith & Nephew (Pty) Ltd
 Smiths Medical South Africa (Pty) Ltd
 Southern Implants (Pty) Ltd
 Southern Medical (Pty) Ltd
 Specmed Medical Services Pty (Ltd)
 SteriTech
 Stratmed
 Stryker South Africa (Pty) Ltd
 Surgical & Ophthalmic Supplies (Pty) LTD
 Supra Latex (Pty) Ltd
 Surgitech (Pty) Ltd
 SxS Surgical Solutions (Pty) Ltd
 Teleflex Medical (Pty) Ltd
 Torque Medical
 Umsinsi Health Care
 Velani Medical (Pty) Ltd
 Vertec Scientific SA (PTY) LTD
 Viking Medical & Surgical (Pty) Ltd
 Vish Medical Supplies cc
 VitalAire
 Vuwani Medical Solutions cc
 Welch Allyn South Africa (Pty) Ltd
 Werkomed (Pty) Ltd
 Zimmer South Africa (Pty) Ltd

Associate Members:

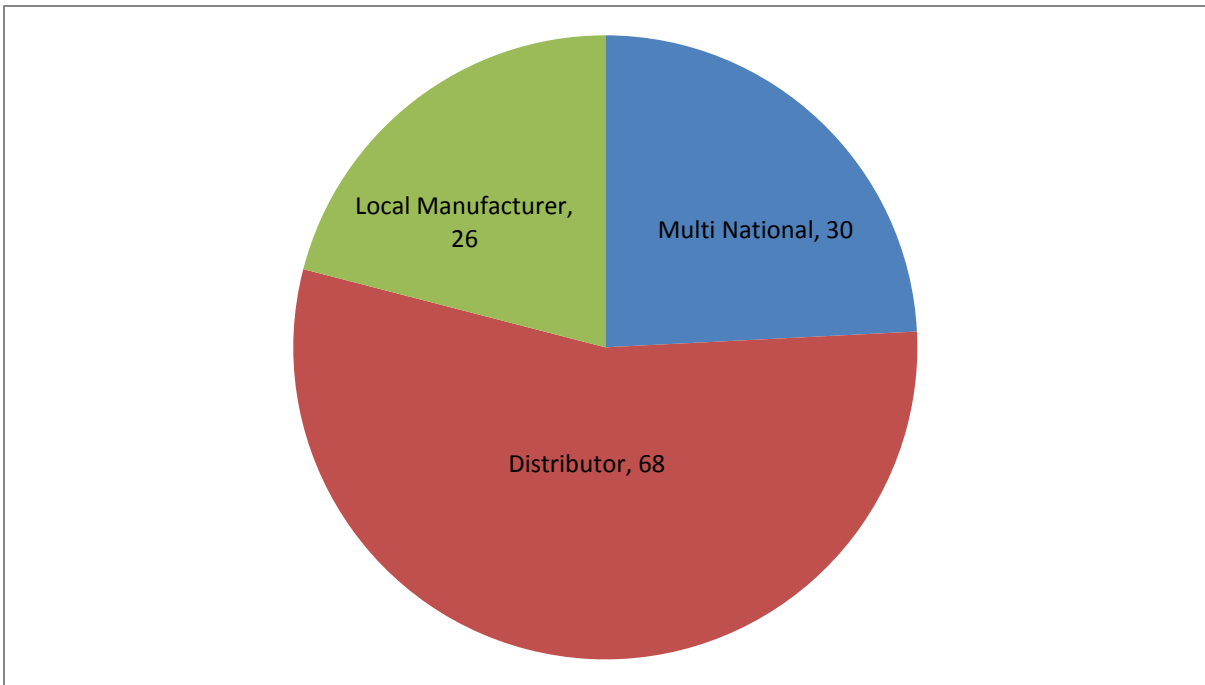
BRANDTECH
CEASA National
CSIR
DHL Supply Chain SA (Pty) Ltd
KD Consulting Pharmaceutical Solutions
Masoom Training Solutions
MC Pharma Consulting
Medical Project Dimensions (MPD)
Red Healthcare Learning

The Smart Group
Uti Pharma

Association Members:

MISA (Medical Imaging Society of South Africa)
SALDA (South African Laboratory and Diagnostics Association)
MDMSA (Medical Device Manufacturers Association of South Africa)

1.3 Breakdown of Ordinary SAMED Members



2. Medical Device Regulations

2.1 General

There are presently no regulations regarding the sale and use of medical devices in South Africa, save for electro medical devices, regulated by Radiation Control, an agency of the Department of Health. However, draft regulations have recently been released. [Click here](#) to view the draft regulations.

2.2 Definition of a medical device

SA legislation defines a medical device as:

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article-

(a) intended by the manufacturer to be used, alone or in combination, for human beings for-

- (i) diagnosis, prevention, monitoring, treatment or alleviation of 25 disease;
- (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- (iii) investigation, replacement, modification or support of the anatomy or of a physiological process; 3Q
- (iv) supporting or sustaining life;
- (v) control of conception;
- (vi) disinfection of medical devices; or
- (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;"

2.3 Registration of Electromedical Devices

The authority responsible for registration and licensing of Electro Medical Devices in SA is the Department of Health through its agency Radiation Control.

For more information please contact:

Leon du Toit, Director Radiation Control,

Email address: dutoil@health.gov.za

Radiation Control Website: <https://sites.google.com/site/radiationcontroldoh/>

2.4 Registration of Combination Medical Devices

If the device is classified and registered in the jurisdiction of manufacture (or in other jurisdictions where it is sold) as a medical device, then the general rule of thumb is that it would not require registration in South Africa. If however it is classified and registered as a medicine then the general rule of thumb is that it would need to be registered with the South African medicines control council.

General questions on medical device regulations – please contact:

For more information please contact:

Dr Joey Gouws, the Registrar of Medicines

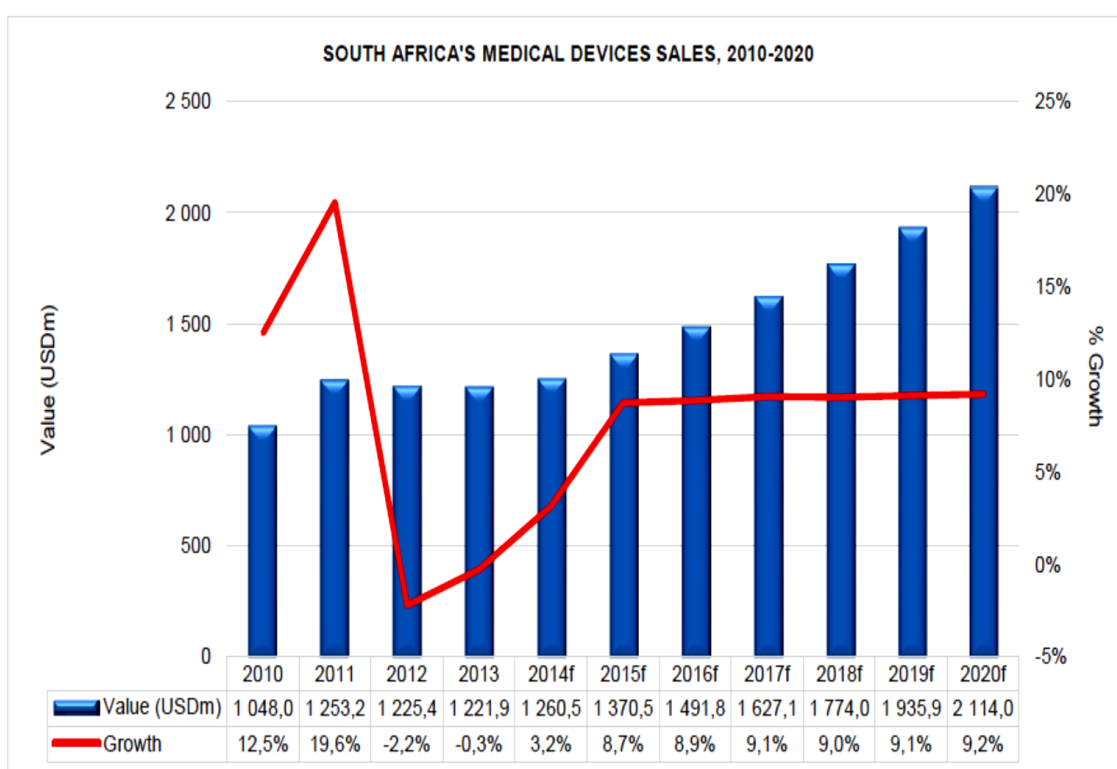
Email address: gouwsj@health.gov.za

Medicines Control Council Website: <http://www.mccza.com/>

3. South African Market (According to Wesgro Report 2014)

3.1 Growth Rates

Compared with the pharmaceutical market, where domestic manufacturers are now able to meet 50% of demand in volume terms, South Africa's domestic medical device industry remains underdeveloped, with imports catering for 90% of the market by value. The South African medical device market was estimated at USD1.2bn in 2013 generating revenues in excess of ZAR12.1bn and ranks among the top 30 largest in the world. The market is forecast to grow by a CAGR of 7.7% between 2013 and 2018, driven mainly by the development and upgrade of hospitals through public-private partnerships.



Source: BMI 2014

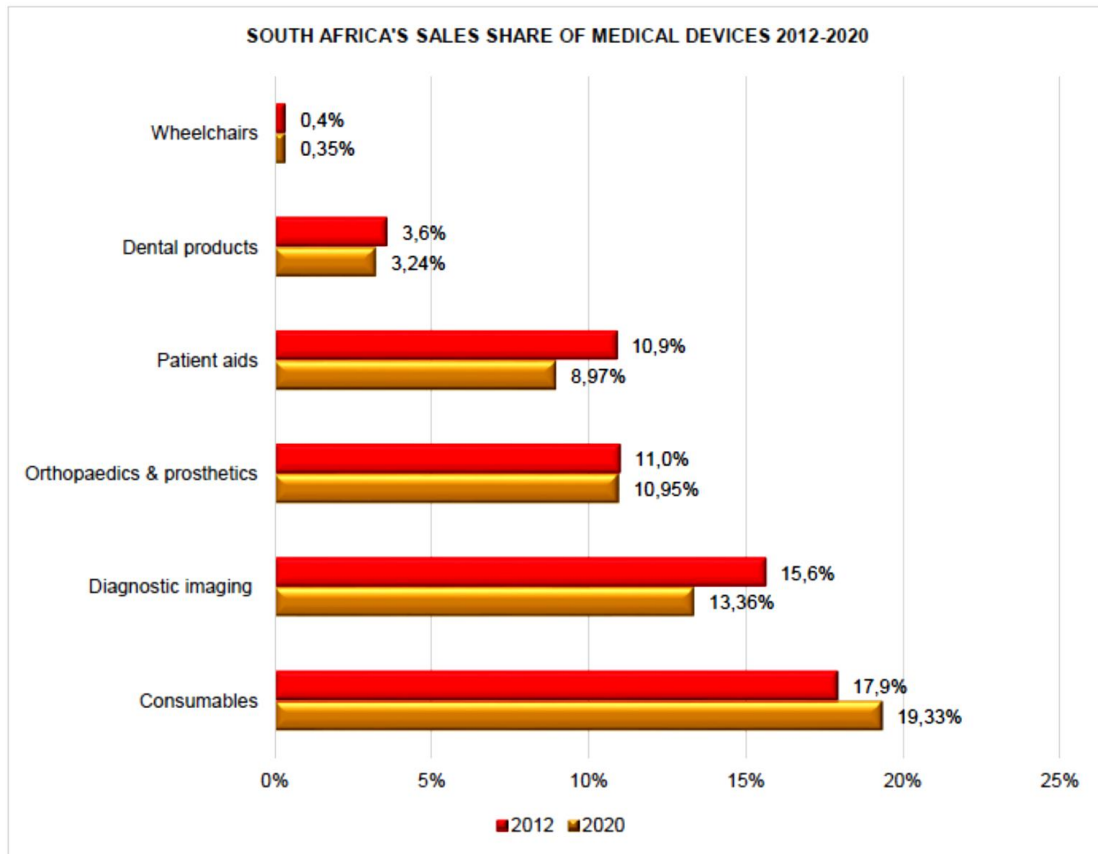
South Africa's medical device production firms tend to be small or medium sized businesses and often combine distribution activity with manufacturing. Multinational companies present in South Africa often operate in a joint venture capacity with local firms. Most South African manufacturers focus on producing basic medical equipment and supplies. Production is focused on bandages and dressings, medical furniture and low technology items.

A growing private sector is one of the key features of the South African medical device market. Close to 70% of the medical practitioners in the country work for the private

sector. Nevertheless, local players are likely to take a growing share of the South African market as they move into more high-tech areas, claiming much of the extra value from the predicted market growth.

3.2 South Africa's Medical Devices Sales by product category

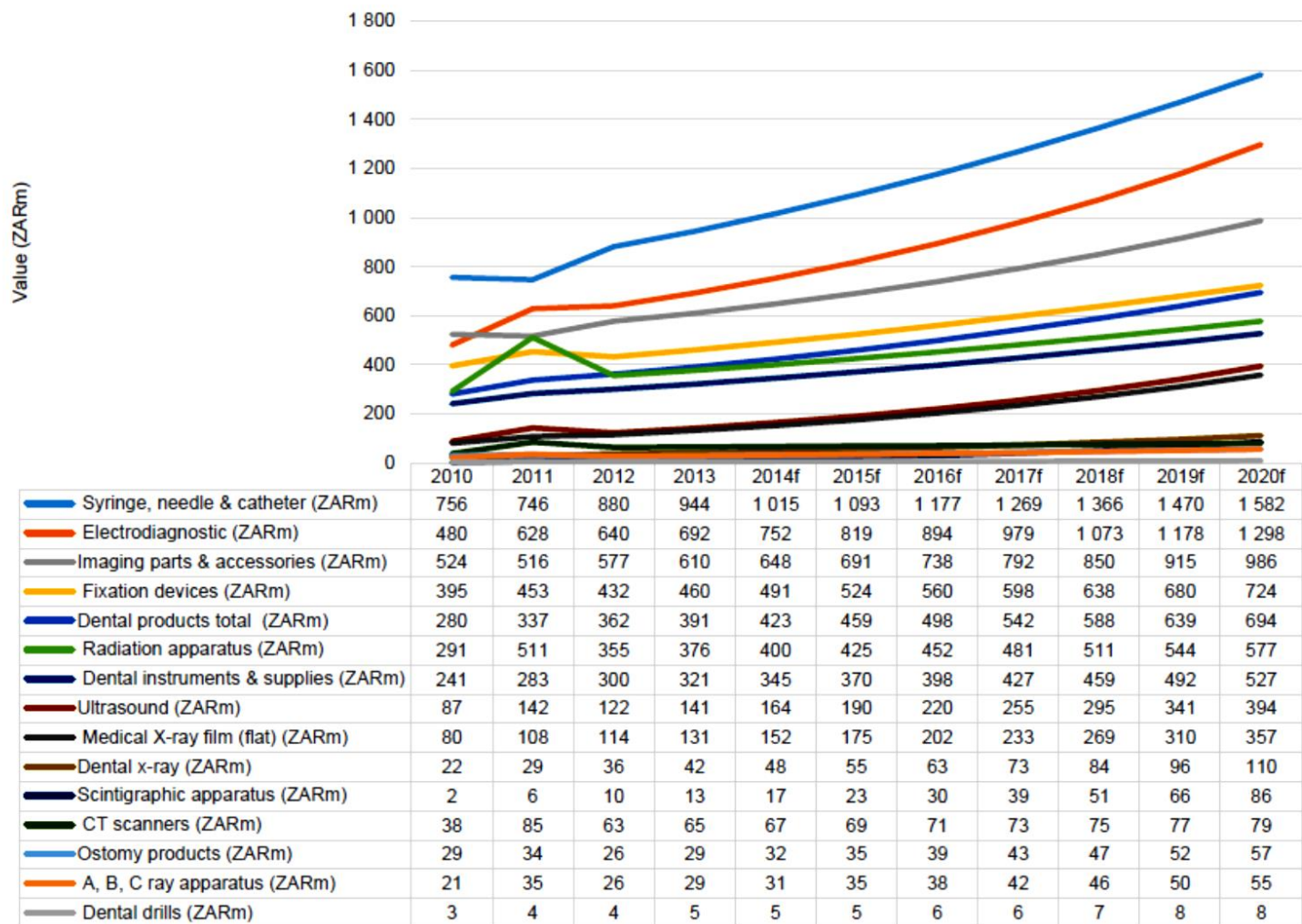
Consumables will continue to make up the largest share of South Africa's sales of medical devices, estimated at 18% in 2012 and 19% in 2020. This is closely followed by diagnostic images accounting for 16% in 2012 and 13% in 2020.



Source: BMI 2014

Syringes, needles and catheters continue to account for the largest share of medical devices sales in South Africa for the period 2010 to 2020. It is estimated to increase from ZAR756m in 2010 to ZAR1.6bn in 2020. Electro- diagnostic devices and imaging parts and accessories rank second and third in 2013, valued at ZAR692m and ZAR610m respectively. All the medical devices in the diagram below are expected to increase during the forecast period.

SOUTH AFRICA'S SALES OF SELECTED MEDICAL DEVICES, 2010-2020



Source: BMI, 2014

3.3 Strengths and Opportunities

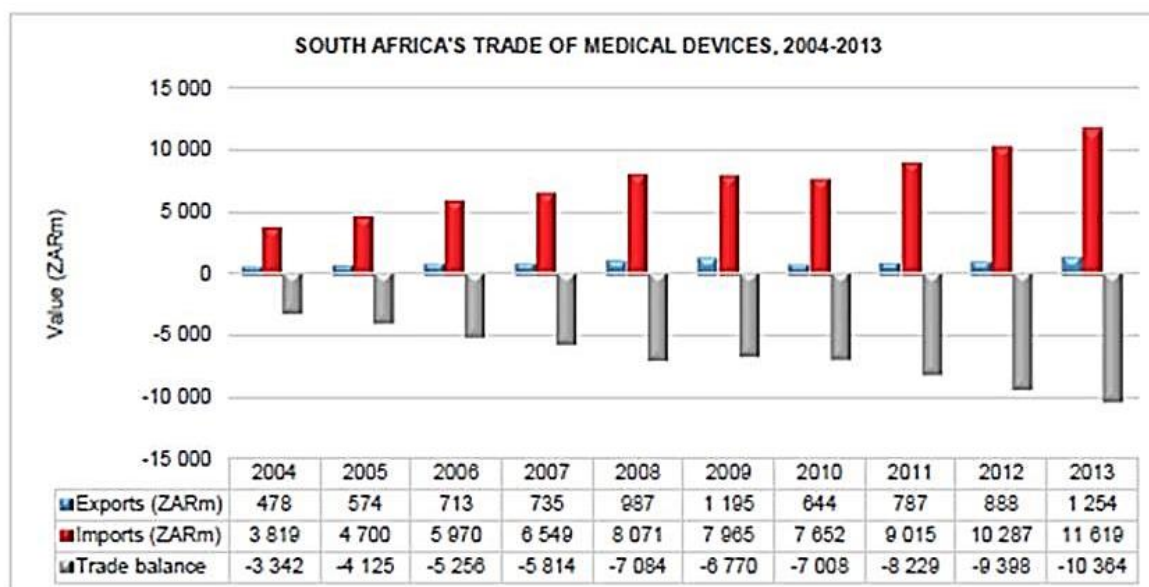
The table below shows strengths and opportunities within South Africa's medical devices industry:

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> ➤ Wealthiest African economy whose healthcare system is envied by other African nations ➤ Strong, sizeable private sector 	<ul style="list-style-type: none"> ➤ Poor infrastructure, particularly in the extensive rural areas, limiting efficiency of healthcare delivery as well as the shortage of medical personnel
OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> ➤ Public-private partnership growth ➤ Imports account for around 95% of market ➤ Emergence of affluent, middle class 	<ul style="list-style-type: none"> ➤ Inadequate public funding for development of public health system ➤ Depreciating Rand is making imports less affordable

Source: Business Monitor International, 2014

3.4 South Africa's Trade in Medical Devices

South Africa's trade in medical devices experienced strong growth from 2004 to 2013. Over the ten year period both exports and imports were at their highest level in 2013. South Africa's exports increased by 41% in 2013, while imports increased by 13%. This is a clear indication of the high global demand for South Africa's medical devices. The trade balance has been negative over the ten year period as South Africa has remained a net importer.



Source: TradeMap, 2014

The top 10 destination markets for medical device exports from South Africa in 2013 lists 5 African markets, showing the prominence of Africa as a key export region for South Africa's medical devices. Zimbabwe was the leading export market for medical devices from South Africa in 2013, valued of ZAR155m. Zambia and Kenya rank second and third at ZAR117m and ZAR116m respectively. Other top export markets were the United States (ZAR90m), the Netherlands (ZAR77m) and Mozambique (ZAR58m).

The United States was the leading import market for medical devices from South Africa in 2013, valued at ZAR3bn, followed by Germany and China valued at ZAR1.8bn and ZAR1.1bn respectively.

South Africa's Top 10 Export Markets for Medical Devices, 2013				South Africa's Top 10 Import Markets for Medical Devices, 2013			
Rank	Market	Value 2013 (ZARm)	% Growth 2013	Rank	Market	Value 2013 (ZARm)	% Growth 2013
1.	Zimbabwe	155.1	63.12%	1.	United States	3024.4	14.93%
2.	Zambia	116.6	127.29%	2.	Germany	1828.3	7.68%
3.	Kenya	115.5	227.09%	3.	China	1068.8	20.86%
4.	United States	89.6	33.29%	4.	Switzerland	648.1	19.96%
5.	Netherlands	77.3	98.38%	5.	United Kingdom	466.3	10.79%
6.	Mozambique	58.1	17.48%	6.	Japan	435.2	12.64%
7.	United Kingdom	57.1	23.40%	7.	Mexico	384.0	22.69%
8.	Germany	54.3	2.99%	8.	Ireland	360.4	-6.11%
9.	Australia	43.3	19.57%	9.	France	327.8	10.24%
10.	Nigeria	42.0	22.09%	10.	Netherlands	317.9	8.29%
Total Exports		1254.5	41.21%	Total Imports		11618.6	12.95%

Source: Quantec 2014

Instruments, appliances for medical was the leading medical devices export from South Africa in 2013, valued at ZAR293m, followed by medical dressings having an adhesive layer (ZAR150m) and electro-diagnostic apparatus (ZAR142m). Breathing appliances and gas masks (124%); suture materials, sterile surgical and dental goods (174%) and orthopaedic appliances (124%) showed strong growth in 2013. Instruments, appliances for medical was also the largest medical device import product into South Africa in 2013, valued at ZAR3.7bn followed by needles, catheters and cannulae and orthopaedic appliances, valued at ZAR719m and ZAR567m respectively. Parts and accessories for radiation apparatus was the fastest growing medical device import product, growing by 41% in 2013.

South Africa's Top 10 Export Products for Medical Devices, 2013				South Africa's Top 10 Import Products for Medical Devices, 2013			
Rank	Market	Value 2013 (ZARm)	% Growth 2013	Rank	Market	Value 2013 (ZARm)	% Growth 2013
11.	H901890: Instruments, appliances for medical, etc science	292.6	55.48%	1.	H901890: Instruments, appliances for medical, etc science	3672.0	10.25%
12.	H300510: Medical dressings etc. having an adhesive layer	149.9	29.71%	2.	H901839: Needles, catheters, cannulae etc, (medical)	719.4	13.20%
13.	H901819: Electro-diagnostic apparatus	142.1	48.62%	3.	H902190: Orthopaedic appliances	566.6	29.42%
14.	H902000: Breathing appliances and gas masks	93.4	234.90%	4.	H902110: Orthopaedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances	474.8	11.66%
15.	H300590: Medical dressings etc except those with adhesive layer	69.5	19.12%	5.	H902131: Orthopaedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances	394.1	11.37%
16.	H902190: Orthopaedic appliances,	50.2	124.11%	6.	H902290: Parts and accessories for radiation apparatus	356.3	40.49%
17.	H902290: Parts and accessories for radiation apparatus	38.8	3.30%	7.	H901819: Electro-diagnostic apparatus	342.3	13.87%
18.	H300610: Suture materials, sterile surgical and dental goods	36.0	174.26%	8.	H902139: Orthopaedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances	326.1	5.56%
19.	H902219: Non-medical X-ray equipment	31.3	-18.66%	9.	H901850: Ophthalmic instruments and appliances	324.4	20.18%
20.	H300660: Contraceptive preps based on hormones or spermicides	30.7	17.13%	10.	H300660: Contraceptive preps based on hormones or spermicides	302.2	-8.78%
Total Exports		1254.5	41.21%	Total Imports		11618.6	12.95%

3.5 South Africa's Incentives

South Africa has a range of incentives available to qualifying investors. The more commonly used incentives (dti Investor handbook 2014) in the medical devices sector are given below:

Selected Incentives for South Africa's Medical Devices Sector, 2014			
Incentive	Objectives	Applicability	Benefits
(ECA) Healthcare (Managed by the IDC)	Support and develop businesses in both the healthcare and education sectors in South Africa and the rest of the continent. These include the financing of Greenfield projects, expansions and acquisitions and combinations thereof.	Focus areas are: <ul style="list-style-type: none"> ➤ Manufacturing of medical equipment. ➤ Medical schemes administration and medical schemes management. ➤ Medical and dental practice activities. 	Competitive, risk-related interest rates based on the prime bank overdraft rate. Requirement: Minimum loan amount is R1million at a prime linked interest rate.
Manufacturing Investment Programme (MIP)	Stimulate investment in manufacturing; <ul style="list-style-type: none"> ➤ Increase employment opportunities; and ➤ Sustain enterprise growth. 	Investors in new and expanding projects in the South African manufacturing industry.	Investment grants of 15% to 30% of the investment cost of qualifying assets (machinery and equipment, buildings and commercial vehicles) for new establishments or expansions.
(CRD) Innovation Fund (IF) (Funded by the Department of Science and Technology)	Advancement Programme (TAP); Missions in Technology Programme (MiTech); Seed Fund; Patent Support Fund for SMEs; Patent Support Fund-Technopreneur; Patent Support Fund for Research Institutions; Patent Incentive Scheme	N/A	The IF uses a flexible returns structure be it royalty, equity, convertible loans or combinations thereof, structured as appropriate for each investment.
Foreign Investment Grant (FIG)	Foreign investors that have been approved for the MIP.	Compensate qualifying foreign investors for the costs of moving qualifying new machinery and equipment from abroad to South Africa.	A cash grant, to a maximum of R10 million, but the lower cost of: <ul style="list-style-type: none"> ➤ 15% of the value of new machinery and equipment; or ➤ the actual relocation cost of new machinery and equipment.
(CRD) Support Programme for Industrial Innovation (SPII)	Promote technology development in South Africa through provision of financial assistance to all South African registered enterprises in manufacturing or software development that engage in development of innovative, competitive products and/or processes.	All private sector enterprises engaged in a manufacturing or an IT-related project.	A conditional repayable grant of 50% of the qualifying cost incurred during development activity with a minimum grant amount of R3 million per project, repayable on successful commercialisation of the project.

4 Broad-Based Black Economic Empowerment

South Africa's first democratic government was elected in 1994, with a clear mandate to redress the inequalities of the past in every sphere: political, social and economic. Since then, government has embarked on a comprehensive programme to provide a legislative framework for the transformation of South Africa's economy. The government devised various policies which are aimed at reducing the effects that the previous government's unequal policies had on the masses. In particular in the formal business environment, it was necessary that formal steps be taken to help the previously disadvantaged people to positively contribute and participate in the economy. Broad-Based Black Economic Empowerment (B-BBEE) is a specific government policy to advance economic transformation and enhance the economic participation of black people in the South African economy.

The Department of Trade and Industry's (**the dti's**) growth strategy includes a focus on broadening participation, equity and access to redress for all economic citizens, particularly those previously marginalised. The Black Economic Empowerment (BEE) Act, No. 53 of 2003, facilitates **the dti's** work in this area by establishing a legislative framework for the promotion of BEE; empowering the Minister to issue Codes of Good Practice and publishing Transformation Charters; establishing the BEE Advisory Council; and making provision for matters connected therewith. The B-BBEE Codes of Good Practice emerged in February 2007 as an implementation framework for the B-BBEE policy and legislation. After the implementation thereof, institutional mechanisms were established for the monitoring and evaluation of B-BBEE in the entire economy. Both the Codes of Good Practice and the B-BBEE Act have subsequently been revised.

All organs of state, public entities and any private enterprise that undertakes business with a public entity must implement the Codes. That is not the limit of those who must comply; any business providing goods or services to another business that is subject to BEE compliance may also be required to provide evidence of its own BEE compliance. The size of a business is particularly relevant in determining the necessary levels of BEE compliance.

The Codes provide for three levels of compliance based on the size of a business:

- Exempted Micro Enterprises (EMEs) are businesses with an annual turnover of less than R5,000,000 (this is a new amendment; previously, EMEs were businesses with a turnover of less than R300,000 p.a and less than 5 staff);
- Qualifying Small Enterprises (QSEs) are businesses with an annual turnover of less than R35,000,000; an
- Medium to large enterprises (M&Ls) with an annual turnover of more than R35,000,000.

[Click here](#) to view Broad-Based Black Economic Empowerment Amendment Act, 2013

[Click here](#) to view Broad-Based Black Economic Empowerment (B-BBEE) Codes of Good Practice

For more information, please visit the DTI's website:

http://www.thedti.gov.za/economic_empowerment/bee.jsp

5 Hospital Sector

5.1 Public:

South Africa has a number of public (government run) hospitals within its nine provinces. These are split into three categories: Academic, District and Regional Hospitals.

For a list of all these hospitals and their contact details, please follow the following links to each provincial department of health:

National Department of Health: <http://www.health.gov.za/>

Gauteng Department of Health: <http://www.health.gpg.gov.za/Pages/default.aspx>

Free State Department of Health:

<http://www.fshealth.gov.za/portal/page/portal/fshp/intranet>

Eastern Cape Department of Health: <http://www.ecprov.gov.za/Pages/default.aspx>

KwaZulu Natal Department of Health: <http://www.kznhealth.gov.za/>

Limpopo Department of Health: <http://www.doh.limpopo.gov.za/>

Mpumalanga Department of Health: <http://www.mpuhealth.gov.za/>

North West Department of Health: <http://health.nwpg.gov.za/dohnw/>

Northern Cape Department of Health: <http://www.northern-cape.gov.za/>

Western Cape Department of Health: <https://www.westerncape.gov.za/dept/health>

The Preferential Procurement Policy Framework Act (PPPFA) governs all government procurement within South Africa. The PPPFA stipulates that when government assesses contracts, it must take into account a preference point system which prescribes functionality, price and reconstruction development programme (RDP) goals. Please [Click Here](#) for a copy of the Act.

5.2 Private:

There are a number of private hospital groups within South Africa.

For more information please contact the following:

Life Healthcare Hospitals: www.lifehealthcare.co.za

The Hospital Group has 48 Facilities with 7 713 beds.

National Hospital Network (NHN): www.nhn.co.za

NHN has 165 members, consisting of 52 Hospitals, 37 Day Clinics, 25 Psychiatric Facilities, 18 Ophthalmology Facilities, 33 Sub-Acute Facilities.

Netcare Ltd: www.netcare.co.za

Netcare Ltd runs 31 Hospitals in Gauteng, 9 Hospitals in KwaZulu Natal, 1 Hospital in Mpumalanga, 1 Hospital in North West Province, 4 Hospitals in Free state, 4 Hospitals in Eastern Cape and 6 Hospitals in the Western Cape.

Mediclinic: <http://www.mediclinic.co.za/Pages/default.aspx>

Mediclinic runs 49 private hospitals throughout South Africa and 3 in Namibia with more than 7 000 beds in total.

6 Procurement of Medical Devices

If you wish to sell a device that requires reimbursement by medical aids, into the private sector, you would need to apply for a nappi code. MediKredit has over the years undertaken to facilitate the adoption of NAPPI (National Pharmaceutical Product Interface) as a national standard.

A NAPPI code is an unique identifier for a given product which enables electronic transfer of information throughout the healthcare delivery chain. The allocation of a NAPPI Code by MediKredit does however, not serve as an endorsement or accreditation of the product in question by MediKredit.

MediKredit as an independent player in the healthcare industry that is not owned by either providers or funders of healthcare, is responsible for the management and maintenance of the NAPPI file subject to the governing authority of the NAPPI Advisory Board (NAB). NAB establishes policies regarding the allocation of NAPPI codes. The standard for electronic information exchange in the healthcare industry are tariff codes for procedure and consultation claims and NAPPI codes for surgical products, ethical products and consumables.

MediKredit is responsible for the day-to-day management of the NAPPI file and to make it available in the public domain. The public domain file has been available free of charge since the inception of NAPPI as a coding standard and contains information on the NAPPI code, product description, strength, pack size and manufacturer. Product information that is not available in the public domain, is available from MediKredit at a fee, subject to certain conditions.

For further information please contact:

Krish Pather

Medikredit

GM: Performance Health and Clinical Services

011-770-6013 (D)

082 498 7293

<http://www.medikredit.co.za>

7 Codes of Practice to which SAMED Members are bound

7.1 Purpose of the Codes

SAMED members are bound by two codes of Practice:

- A. The South African Code of Practice for the Marketing of Health Products and
- B. The SAMED Code of Business Practice.

The fundamental purpose of the Codes of Practice is to promote and encourage among SAMED Members, ethical principles and practices. As such it is envisaged that the Codes will become an essential guide and support for SAMED members in their interactions with their customers.

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

7.2 Application of the Codes

Both Codes are binding on all SAMED Members and are a condition for new and ongoing membership. The Codes are applicable to all SAMED Members and their employees, their agents, contractors, third party distributors/marketers and/or contracted events' organisers. The Codes relate to interactions between SAMED members and healthcare professionals and SAMED members and the general public.

Healthcare Professional (HCP) includes Healthcare Professional and Healthcare Facilities and includes, but is not limited to persons registered with the Health Professions Council of South Africa (HPCSA), South African Veterinary Council; 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 prescribe, purchase, lease, recommend, use, maintain or arrange for the purchase or lease of, SAMED members' health products in South Africa.

7.3 Where can I find the Codes and who to contact?

7.3.1 The SA code of Practice for the Marketing of Health Products

This code is governed by the Marketing Code Authority (MCA). The MCA is unique globally, as it has been formed and agreed to by members from the innovative, generic and self-medication sectors of the pharmaceutical industry as well as the medical devices, in-vitro diagnostics and veterinary medicines. They are a voluntary organisation built on a constitution that was signed in 2012. The Code ensures that the health industry advertises

and promotes their products according to the high ethical standards of the Code and aligned with international best practice. This indicates the commitment of the local industry to fair and ethical business practices in dealings with patients, healthcare practitioners and other stakeholders in this sector.

Click here for: [The SA code of Practice for the Marketing of Health Products](#)

Click here for the: [Guidelines to the SA code of Practice](#)

Enquiries:

All enquiries with regard to the SA Code of Practice for the Marketing of Health Products are to be submitted, preferably, in electronic format to:

Dr Haseena Gani

Marketing Code Authority (MCA) Executive Officer

Mobile: +27 074 208 6100

Email: marketingcodesa@gmail.com

Website: www.marketingcode.co.za

7.3.2 The SAMED Code of Business Practice

Click here for: [The SAMED Code of Business Practice](#)

Enquiries:

All enquiries with regard to the SAMED Code of Business Practice are to be submitted, preferably, in electronic format to:

Tanya Vogt

SAMED Executive Officer

Mobile: +27 83 601 0343

Email: tanya@samed.org.za

Website: www.samed.org.za

7.4 What the Codes cover

7.4.1 SAMED Code of Business Practice

7.4.1.1. Bonusing, Rebates and Incentive Schemes

SAMED Members are expected to provide accurate, transparent and responsible billing information to HCPs, reimbursement authorities and other payors. Members are also expected to follow the principles of acceptable invoicing procedures.

No SAMED Member may offer a bonus, free goods or other incentive scheme deemed to be perverse, to an HCP in relation to the acquisition of goods and services.

SAMED members must ensure that the following appear on the invoice when charging their customer:

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

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

Sampling must be in accordance with the provisions of the SA Code for Marketing of Health Products.

Special Requests and pro bono supplies:

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.

7.4.1.2 Contracting Private Nursing Practitioners

If a registered nurse is in the full time employ of a SAMED Member, that nurse is considered a company representative. Any interactions with a patient will be subject to the SAMED protocol governing Sales Professionals in the Clinical Environment as well as the professional rules and regulations of the Nursing Council. If a nurse is employed or contracted as a nurse by the Member, the contract may not be exclusive i.e. the nurse must have the right to also provide competitive products to the patient. Any agreements that are in place must be in writing and clearly outline what the nurses' responsibilities are. Any remuneration must be set out in advance and under no circumstances may it be connected to volumes as this would be considered perverse and de facto illegal.

7.4.1.3 Company representatives in the clinical environment

SAMED Member Company representatives may only enter an operating room/clinical environment in accordance with permission from appropriate members of the medical staff of the facility. They are expected to wear appropriate attire, as provided by/or approved by the facility. Representatives should be prepared to advise on technical

questions related to the assembly and operational performance of Company products consistent with the labelling and instructions for use, but 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 their company, company products may not be used and/or applied directly to a patient by them even if they hold appropriate certification/licenses.

They may not deliver patient care or perform medical services of any type, even if they possess an appropriate medical license/certification. The representative's 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. The representative may not have any hands on contact with the patient or any part of the patient during surgery or clinical event.

It is strongly recommended that healthcare facilities request that company representatives that enter the clinical environment have undergone the SAMED endorsed CRICE (Company Representative in the Clinical Environment) training course. See: [www. http://masoom.co.za/samed/](http://masoom.co.za/samed/)

See also Addendum 1 - MCA communication on concerns with interactions with healthcare professionals (HCPs).

7.4.1.4 Royalty arrangements

SAMED Members 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. Arrangements involving the payment of royalties to an HCP must be formalised in a written agreement.

7.4.2 The SA code of Practice for the Marketing of Health Products

Areas relating to interactions between SAMED members and HCP's in terms of The SA Code of Marketing Practice include:

- Sponsorship
- Training and education
- Hospitality/venues of meetings and events
- Stand-alone entertainment, leisure, social or cultural events with Healthcare Professionals
- The use of consultants
- Medical and educational services / goods
- Patient Registries
- Gifts, Promotional Items and Competitions

- Donations and grants to charities
- Corporate Social Investment
- Items for patients and patient organisations
- Training and Education
- Healthcare Sales Representatives/ Consumer Promoters
- Incentives to Pharmacy Assistants and other non-healthcare professional sales
- Loan and placed equipment
- Evaluations and Demonstrations

A summary is included as Addendum 1. For further detail please review both the Code and Guidelines to the Code.

7.5 Infringements of the Codes and Lodging a complaint

Infringements of the Codes are dealt with through documented and legally compliant processes. Any HCP or customer of a SAMED member may lodge a formal written complaint upon payment of the stipulated fee. These forms are available at:

SAMED: <http://www.samed.org.za/Codes-of-Practice.aspx>
MCA: <http://www.marketingcode.co.za/Lodgeacomplaint.aspx>

7.6 Disclaimer

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

Addendum 1

MCA communication on concerns with interactions with healthcare professionals (HCPs)

1. From time to time, the Marketing Code Authority (MCA) is approached by both members and non-members for interpretative opinions, advice and/or clarification of various aspects and clauses of the SA Code of Marketing Practice (Marketing Code). Often the MCA is requested to confirm whether a specific practice by a member or non-member is in line with the Marketing Code and / or acceptable in respect of the said Code. As the MCA is not an entity with statutory authority, the MCA cannot provide legally binding opinions; it can only provide guidance in respect of the requirements of the Marketing Code.

For any specific activity within the scope of the Marketing Code to be determined as acceptable or not, a formal complaint needs to be lodged with the MCA in order for the MCA to investigate and obtain the facts after which, the complaint follows a specific adjudication process. This process is clearly defined on the MCA website. See <http://www.marketingcode.co.za>

The purpose of this communication is to impress upon members and non-members alike the spirit of the Marketing Code and to highlight practices that appear to be prevalent in the health products' industry; such practices being in contravention substantively or

against the spirit of the Marketing Code. It should be noted that the Marketing Code does not have jurisdiction over matters directly relating to commercial sales activities such as in bonusing, incentives and rebates. These are governed by Act 101 18A.

An important aspect of selling health products to Healthcare Professionals (HCPs) is the ability to meet with HCPs and to detail and promote the quality and value of products for the patient. It is this aspect of meeting with the HCP that is raising concerns for the MCA.

In terms of Clause 2.3.4 of the MCA Code:

“Companies shall adhere to ethical business practices and socially responsible industry conduct and shall not use any unlawful or any unethical inducement or reward, including but not limited to those financial or material in nature, in order to sell, loan, lease recommend or arrange for the sale, loan, lease or prescription of their products”

2. In terms of Clauses 15.3 and 15.4 of the MCA Code:

Gaining interviews

Healthcare Sales Representatives must not employ any inducement or subterfuge to gain an interview. No fee should be paid or offered for the granting of an interview. Donations to charities in return for Healthcare Sales Representatives gaining interviews are prohibited. Offering or making donations in lieu of hospitality are unacceptable. In an interview, or when seeking an appointment for one, healthcare sales representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or the company that they represent.

Organising meetings

Healthcare Sales Representatives organising meetings are permitted to provide appropriate hospitality and/or to meet any reasonable, actual costs, which may have been incurred. All meetings have to conform to the provisions of Clause 17 (Interaction with Healthcare Professionals).”

3. To support the provisions of the Code set out above, it is informative to note that the Ethical Policy Guidelines of the Health Professions Council of South Africa, and specifically Booklet 5, concerning perverse incentives, over-servicing and related matters is fully aligned with these provisions and we have set them out below.

2.4 ‘Endorse’ means any action whereby a person or body attaches approval to or sanctions any health establishment or orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance or other health related product or health related service with a view to encouraging or promoting the preferential use or preferential sale thereof for the purpose of financial gain or other valuable consideration.

2.9 ‘Improper financial gain or other valuable consideration’ means money, or any other form of compensation, payment, reward or benefit which is not legally due or which is given on the understanding, whether express, implied or tacit, that the recipient will engage or refrain from engaging in certain behaviour in a manner which is either:

2.9.1 Illegal; and/or

2.9.2 Contrary to ethical or professional rules; and/or

2.9.3 Which, in the opinion of a the HPCSA, may adversely affect the interests of a patient or group of patients, in order to procure some direct or indirect advantage, benefit, reward or payment for the person offering or giving the said money, compensation, payment, reward or benefit, and 'perverse incentive' has the same meaning.

3.9.1 Accepting commission Health care practitioners shall not accept commission or any financial gain or other valuable consideration from any person or body or service in return for the purchase, sale or supply of any goods, substances or materials used by the health care professional in his or her practice...

3.10.2 For seeing representatives Health care practitioners shall not charge a fee or receive any financial gain or other valuable consideration for seeing medical representatives...

3.13.1 Collaborative efforts Historically there has been a close collaboration between health care practitioners and the pharmaceutical and health supply industry that extended particularly to CPD. Health care is to a large extent self-governing and practitioners must ensure that their participation in such collaborative efforts is in keeping with their ethical duties towards patients and society.

It is suggested that the entire booklet be scrutinised at www.hpcs.co.za, as there is a large section concerning the funding and sponsoring of conferences and meetings, and a distinction made between education and product marketing.

4. Applicability of the Marketing Code

Clause 2.2.1 of the Marketing Code is applicable to: "...their agents, contractors, third party distributors / marketers and / or contracted event's organisers..."

It is clear from this clause that the scope of the Marketing Code is wider than just the industry's interaction with HCPs, it includes parties along the entire medical value chain.

5. Conclusion

The Marketing Code and its applicability consist of more than just the application of the provisions. There is a moral and ethical requirement to support the efforts of the Marketing Code Authority as the overarching philosophy is a principle of compliance with the spirit of the Marketing Code[1] . This philosophy is based on the patient's right to "...ensure that the marketing of health products to HCPs...is carried out in a responsible, ethical and professional manner..."[2]

The MCA can only act when issues of unethical and unprofessional behaviour are brought to its attention via a formal complaint. We urge all members to be ambassadors of the SA Code of Marketing Practice and to support the MCA to identify unacceptable practices in the health products' industry, to benefit the patient and patient care.

[1] SA Code of Marketing Practice: Clause 2.1 Para 3, page 7/55

[2] SA Code of Marketing Practice: Clause 2.1 Para 5, page 7/55