

SAAPI CONFERENCE

Training of customer facing staff and service providers

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MCA Board Member



ethical marketing leadership for health products

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DISCLAIMER ON USE OF TRAINING MATERIAL



The Code remains the authoritative document on MCA policy.

This training material has been developed by the Marketing Code Authority for the training of customer facing staff and service providers to the health products industry on the marketing code, its implementation and enforcement.

The MCA would value details of groups trained on this material as well as feedback on the use and possible modifications to the slides.

The slides support Code v11 and Guidelines v9, the Sanctions Document dated Nov 2018 and the MCA Constitution (2015).

Notwithstanding anything in the slides or discussions, the master version of the Code v11 and Guideline v9 represents the total policy of the MCA in respect of ethical marketing and you are referred to that in the event of inconsistencies.

CONTENT

- Brief overview of MCA**
- Legislation vs marketing ethics**
- The Code – scope and general principles**
- Meetings, events, and contracting of HCP's
- CPD's
- Wrap up

THE MCA AND ITS PURPOSE

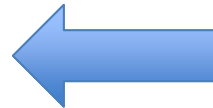
- Voluntary, not for profit, self-regulatory organisation, constituted to:
- promote the ethical marketing/promotion of health products,
 - adjudicate on complaints in terms of the Code, and
 - Update and publish a code of marketing practice for health products.

Key focus

The independence of HCPs and,
The protection of patients

[Link to MCA video](#)

[Link also on *www.marketingcode.co.za*](http://www.marketingcode.co.za)



ABOUT THE MCA



ethical marketing leadership for health products

WHO ARE WE AND WHAT DO WE STAND FOR?



Ethical marketing
of health products.



Companies marketing
medicines, devices,
in vitro diagnostics (IVDs).
Become a member

FUNDED BY
OUR MEMBERS



Adjudicate complaints against our members



COMPLAINT



LED BY A BOARD

A technical team maintains the Code



CODE OF **MARKETING
PRACTICE (CODE)**



Support for service providers

IN SUMMARY, THE MCA:

- Maintains and publishes a **Code** of ethical marketing practice
- Accepts and administers **complaints** from anyone in respect of marketing activities of members
- **Adjudicates** on complaints and appeals (Expert Panelists)
- Advocacy towards:
 - **ethical marketing of health products by companies**
 - **compliance by HCPs**
 - **reporting of unethical promotion**
- **Training** & certification in competence in Code implementation
- **Website** www.marketingcode.co.za

COMPLIANCE WITH THE LAW* – NOT NEGOTIABLE



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* The Medicines and Related Substances Act, 101 of 1965, and Regulations General Regulations to the Act (General Regulations), GG41064, 27 Aug 2017, Regulations relating to Medical Devices and IVDs (Device Regulations), GG40480, 9 Dec 2016.

**Do not promote
or sell
unregistered
product if it
should be
registered**

**Get details
required on
advertisements
correct**

**Do not make
claims not
allowed by law**

**Follow rules for
conference
exhibitions**

**No
Sampling,
bonusing,
discounts**

**Only supply to
authorised
persons**

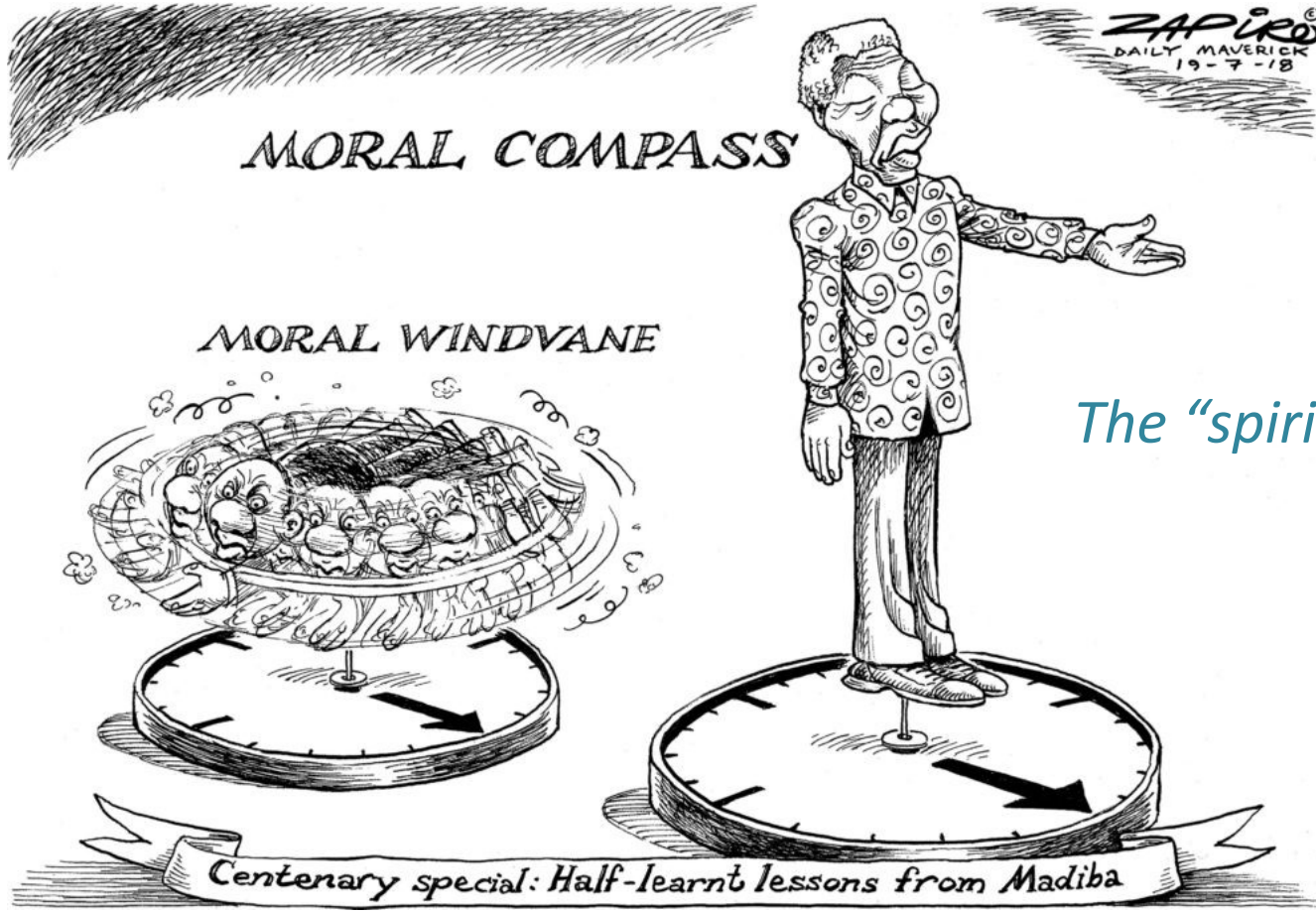
CODE 

**Break the law
and face the
consequences**

ZAPIRO®
DAILY MAVERICK
19-7-18

MORAL COMPASS

MORAL WINDVANE



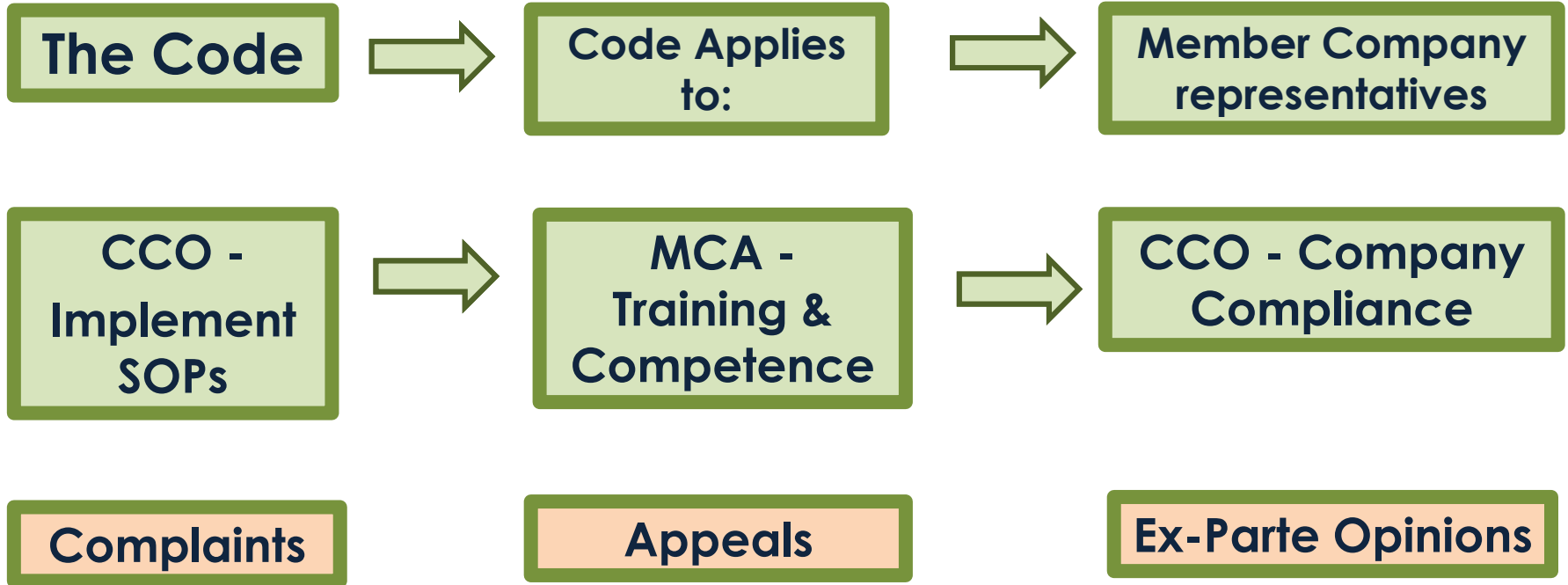
The “spirit” of the Code

Centenary special: Half-learnt lessons from Madiba

THE SPIRIT OF THE CODE

- NDoH, Industry, stakeholders: provision of affordable, quality healthcare. Accurate information a cornerstone.
- HCPs and consumers must have access to accurate and substantiated information on HPs to ensure HPs are prescribed and used in a manner that provides maximum healthcare benefits.
- Industry obligation & responsibility:
 - Accurate information & education about health products (HPs)
 - Industry relationships with HCPs shall support and be consistent with, the professional responsibilities they have towards their patients.

MCA CODE – FRAMEWORK FOR AN ETHICAL APPROACH



Updated Code and Guideline June 2018. Guideline is supplementary to the Code

- Addresses all products subject to Medicines Act. Note: complementary medicines and medical devices have recently regulated and therefore subject to the Act
- Common ethical principles – HCPs and consumers
- Complete editorial refresh – user friendly
- Move to values based from rules based on compliance
- Complaints and Appeals processes can withstand scrutiny

Recognition/enforcement of the code by SAHPRA/ACT in terms of S18C of Medicines Act is key

CODE APPLIES TO MEMBERS AND ANY THIRD PARTY ACTING ON THEIR BEHALF



- Licence holders
- Agents
- Contractors
- Third party distributors
- Event organisers
- All health products
- Promotional activities directed at HCPs and consumers
- Interactions with HCPs and consumers
- Software and ordering systems

MEMBER COMPANY REPRESENTATIVES MUST BE CODE CERTIFIED (C)



- 4.1 Professionalism – refrain from negative impression of industry
- 4.2 Training – all customer facing staff Code certified & product knowledge – training material CCO approved
- 4.3 Medical Scientific Liaison (MSL) – qualified & not reporting to marketing dept
- 4.4 Compliant (Code/Law/ POPI/other)
- 4.5 Companies responsibility for Product Information
- 4.6 Provision of Services by Company Representatives – written instructions – don't combine service with promotion – no reimbursement services – protect patient data

COMPANY REPRESENTATIVES CONT'D

- 4.7 Scientific/Product Queries
Inquiries managed by qualified personnel, unsolicited queries ex HCPs to medical/reg/other, queries on off-label use or diagnosis from consumers to HCPs, specific requests – clarity only (PI), responses not promotional, maintain record of unsolicited requests.
- 4.8 Transmit info on Adverse Events/Product Technical Complaints/Usability Issues to scientific services
- 4.9 Gaining Interviews with HCPs: no payment/benefit, subterfuge, donation, misleading on company represented
- 4.10 Respect for HCPs and Others
- 4.11 Operating Room or Clinical Environment – properly trained and not give advice

MCA CODE – ADDRESSES PRINCIPLES OF:



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**Advertising &
promotion**

**Inducements,
donations &
sponsorship**

Sampling

Competitions

**Promotional items
& gifts**

**Meetings &
events with HCPs**

**Contracting &
reimbursing HCPs**

**Meetings &
events patient
organisations**

**Relations with
consumers &
media**

BREACH THE CODE AND FACE THE CONSEQUENCES (C)



Sanctions or Fine

Remedial Action

Report on Internet

Report to regulator

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MEETINGS & EVENTS & CONTRACTING WITH HCPS (CHAPTER 10 & 12)



(10.1) General principles – sponsorship of events acceptable provided:

- * scientific in nature,
- * no stand-alone entertainment/sport arranged or funded,
- * suitable venue, modest hospitality,
- * no spouses/guests,
- * reasonable costs may be reimbursed.
- * Substantial detail in guidelines.

(10.3) Medical or scientific congresses,

- * conferences and seminars
- * linked to area of expertise,
- * written agreement, registration & travel/accommodation, documented selection criteria, CCO approval, etc

Guideline to

Guideline to Section Note 1

The following is considered acceptable when examples only are

	Medical Education content	Company branded event-related pens, notepads, lanyards, token bags	Promotional product content	Product branded promo aids, brand reminders
Company educational event	√	√	X	X
Third-party educational event (dependent on 3 rd party agreement)	√	√	X	X
Advisory Board meeting	√	√	X	X
Clinical Investigator meeting	√	√	X	X
Trade display	√	√	√	√
Medical representative detailing healthcare professional	√	√	√	√



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acceptable or not
provides a set of

Guideline to Section 10

Note 2: Venues

Programmes requiring 'hands on' training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities.

It is **inappropriate** 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

Note 3: The reasonableness of hospitality

Hospitality should be limited to reasonable hotel accommodation and meals, coffee breaks, and a conference dinner or cocktail reception which all HCP delegates are expected to attend.

Guideline to Section 10

Note 4: International travel

- * Companies may sponsor business class travel for HCPs **only for:**
 - Faculty members presenting at a congress irrespective of day of arrival.
 - HCPs attending advisory boards and clinical investigations irrespective of day of arrival.
- * Business class airfares may not be exchanged for two Economy tickets so that a companion/spouse may accompany the HCP.

It is not appropriate to pay for travel 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.

- * Travel should be arranged by the sponsoring company (or their designated travel agent), and should be restricted to the designated meeting dates (dependent on the travelling time involved, which may include arriving 48 hours before the meeting, and departing soon thereafter).
- * An official agenda should be prepared for the meeting.

Guideline to Section 10

Note 5: Local travel

Where there are objective reasons to support the need for out-of-town travel to facilitate the exchange of information,

* reasonable travel costs, including economy class airfares for the attending HCPs who reside outside of the main center or centers where such training takes place, may be reimbursed. The only exception for economy class travel locally will be a documented medical condition that necessitates business class travel.

It is **not appropriate** to pay for travel 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.

Guideline to Section 10

- **Note 6: Any other travel**
- **Note 7: Conference programme**
- **Note 8: Geographic location**
- **Note 9: Meals**
- **Note 10: Hospitality and accommodation at congresses**
- **Note 11: HCPs unconnected to any congress**

MEETINGS & EVENTS & CONTRACTING WITH HCPS (CHAPTER 10 & 12)



- (10.1) General principles – sponsorship of events acceptable provided:
scientific in nature, no stand-alone entertainment/sport arranged or funded, suitable venue, modest hospitality, no spouses/guests, reasonable costs may be reimbursed. Substantial detail in guidelines.
- (10.3) Medical or scientific congresses, conferences and seminars linked to area of expertise, written agreement, registration & travel/accommodation, documented selection criteria, CCO approval, etc
- (10.4) Transparency on sponsorship
- (10.5) Hospitality for administrative staff during meetings if reasonable & subordinate

CPD VS PROMOTION (10.2)

- CPD meetings shall meet the following requirements in addition to other requirements stipulated in the Code:
 - No Health Product promotion is allowed in the meeting room. Company-branded items/promotions are permissible;
 - Speakers -(INN) name. No trade names;
 - Promotional Material displayed outside not visible to Consumers S2 and up;
 - For local CPD events and Health Product launches in major cities, reasonable travel arrangements or reimbursement of actual travel expenses may be madeThe criteria for selection of attendees/invitees are transparent and available to the MCA on request for scrutiny.
- Companies shall not pay HCPs for their time whilst attending the CPD events under the guise that such events are scientific meetings or advisory board meetings.

CONTRACTING & REIMBURSING HCP'S (Chapter 12)



Contracted services

12.1.2.2 A written agreement must be in place prior to the commencement of the services, which specifies

- the nature of the services to be provided and
- the details of the payment of those services.
- Transparency regarding the process

CONTRACTING & REIMBURSING HCP'S (Chapter 12)



Contracted services

12.1.3 A Company shall have **a documented process for determining** the value of the FFS/Honorarium for HCP's, which shall include:

- 12.1.3.1 A **written record** of the basis on which the FFS/Honorarium was determined;
- 12.1.3.2 A description of the **legitimate need identified** for contracting the services prior to requesting the services;
- 12.1.3.3 **Documented details** of arrangements entered into with the prospective consultants/advisers;
- 12.1.3.4 A **written signed undertaking** by the consultant/adviser that he will declare that he is a consultant/adviser to the Company whenever he writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that Company.

12.1.5 The **criteria for selecting consultants/advisers** shall be directly related to the identified need of the Company for their services and the persons responsible for selecting the consultants/advisers shall have the expertise necessary to evaluate whether the particular HCPs meet those criteria. **The rationale shall be documented.**

CONTRACTING & REIMBURSING HCP'S (Chapter 12)



- 12.1.6 The number of consultants/advisers retained shall not be greater than the number reasonably necessary to achieve the identified need.
- 12.1.7 The contracting Company shall maintain records concerning, and makes appropriate use of, the services provided by consultants/advisers.

CONTRACTING & REIMBURSING HCP'S (Chapter 12)



(12.1) Contracted services

Subject to written contract, transparency, FMF. Actual costs retained.

(12.2) Payment Exclusions

No payments other than as outlined in Code. No payment for rental of rooms or other services.

(12.3) Patient Registries – may not be disguised promotion

Value of Code training and certification



- All customer facing staff
- **Certification online**
- **Certificate valid for 2 years**
- 3 types: medicines, medical device and IVDs, combined
- Required when lodging or defending complaints
- CPD for HCPs 2 credits
 - Future - HCP's 2 ethics points
- Videos to support

IMPORTANT TO TAKE HOME

- Critical for Industry to make a success of the implementation and enforcement of the Code
 - To retain the key privilege of self-regulation
 - To prevent enforced Government regulation
 - To ensure adherence and respect of the Code by all stakeholders so that the commercial ‘playing fields’ are levelled
 - To ensure that reliable scientific information is made available to healthcare practitioners, patients...consumers in general
- Essential to have fair and balanced promotion of medicines for both Healthcare professionals and patients
- Essential for the image of the industry
- Mechanism for compliance with Medicines Act

SAVE THE DATE!

Marketing Code Training Workshop

The Marketing Code Authority (MCA) and The South African Association of Pharmacists in Industry (SAAPI) are pleased to announce their second session in training towards achieving competence in the implementation of the Code of Marketing Practice.

This training is applicable to:

- Manufacturers and service providers of medicines (including complementary medicines), medical devices and IVD's
 - We welcome all interested parties

Cost:

- R890 (incl VAT) per person
- R790 (incl VAT) per additional person (3 or more – could include service providers)

Attendees completing the Code online certification within a month of the course will get 30% discount on the assessment fee

Training Details:

2nd November 2018

08h30-13h30

More information to follow soon



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Marketing Code Training Workshop

- Medicines, Devices & IVD's and Combined Assessment (3 types offered)
- R252 incl. VAT per assessment unit (3 attempts)
- 80% pass mark
- Certificate available upon successful completion
- Certificate valid for 2 years
- Study material: Code, Guideline and any relevant legislation
- Comprises 30 MCQ's, 60 minutes time limit
- Certificate holders show competence in the sector where they work
- If you attend the training on 2nd November, you will receive a 30% discount if completed within one month of the training
-