



AN INTRODUCTION TO THE CODE FOR HCP'S

The Marketing Code Authority (MCA) is a non-profit self-regulatory body with voluntary membership drawn from manufacturers of medicines, medical devices and *in vitro* diagnostics (IVDs). The MCA's Code of Marketing Practice lays down ethical rules for the marketing of medicines by its members.

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

- This Code of Marketing Practice (the “Code”) is the official Code of the Marketing Code Authority (MCA). Companies that are members of the MCA have committed to compliance with this Code, which is applicable to all Health Products which are subject to registration in terms of the Medicines and Related Substances Act 101 of 1965 as amended, irrespective of whether the products have been registered or called up for registration.
- Companies may have standards which are stricter in which case these standards will be applied by members.
- Membership of the MCA is either in collaboration with industry trade associations or as independent, non-association-aligned members.
- Guidelines to the Code assist in the interpretation and application of the Code.
- Contained in this booklet are excerpts from the Code and a few of the guidelines. *(Please note that numbering is not necessarily the same as in the Code.)*

The full Marketing Code v11 and Guidelines v9 can be accessed from www.marketingcode.co.za

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1 INDUCEMENTS, DONATIONS AND SPONSORSHIP

1.1 Inducements

- There shall be no personal and/or unjustifiable enrichment of HCPs or their staff.
- No gift, benefit in kind, rebate, discount, kickback, donation or any other pecuniary advantage shall be offered or given to

HCPs, administrative staff, government officials, or Consumers as an inducement to prescribe, lease, borrow, supply, stock, dispense, administer, use or buy any Health Product.

1.2 Donations and Corporate Social Investment

- Financial donations or other appropriate donations to charities or Institutions may be made, if properly recorded and approved by the responsible person in each Company or organisation.
- Donations, grants and benefits in kind to institutions, organisations or associations are only allowed provided:
 - they are made for the purpose of supporting healthcare or research;
 - they are documented and kept on record by the donor/grantor; and
 - they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific
 - that such donations are not made for Health Product promotional purposes
- Donations may only be made to organisations subject to applicable legislation.
- The donation shall be made directly to the relevant organisation and must not be paid directly to Healthcare Professionals or to healthcare administration staff.
- Acknowledgement by the recipient organisation of a donation must be restricted to an appropriate statement of support.
- Companies shall ensure there is no conflict of interest or potential conflict of interest between the Company and the organisation supported.
- A donation shall not constitute a payment that will otherwise be unacceptable under the Code. Companies shall have an agreement with the relevant organisation in terms of which disclosure of the donation is incumbent on both parties.
- Donations in lieu of FFS/Honoraria are not allowed.
- Companies are encouraged to make available publicly, information about donations, grants or benefits in kind made by them as covered in this section.



Guideline to Donations and Corporate Social Investment

Note 1: Donations to charities

- No donations may be made to hospitals or clinics as an incentive to prescribe any Health Product.
- Charitable donations must not be tied in any way to past, present or potential future use of the Company's Health Products or related services.
- All donations to a charity or non-profit organisation should be appropriately documented. For example, a written request should be submitted by the charitable organisation, detailing the purpose of the charity and the nature of its activities.
- Charitable donations to a bona fide organisation should not be made in response to requests made by HCPs unless the HCP is an employee or officer of the organisation and submits the request on behalf of the organisation.
- It would not be appropriate for a Company to support the favourite charity of a HCP in response to a request by that HCP.
- Companies should have no control over the final use of funds provided as charitable donations to charitable and other non-profit organisations.

1.3 Sponsorship

- Companies may sponsor medical education or training, or similar services provided by other organisations. Sponsorship material shall be accurate, contain balanced information on the subject and include a clear indication of which Company has produced the sponsored material.
- Nothing shall be offered or provided in a manner or on conditions that will interfere with the professional independence of an HCP.
- Refer also to Section 4.3 regarding the sponsorship of HCPs.

1.4 Grants and Financial Support

- The Code recognises the significant contribution of the Industry to the knowledge of proper and effective use of Health Products through financial support of HCP activities.
- A Company may provide a grant or financial support provided that the grant or financial support is provided only to a healthcare practice, Institution or health related organisation and not directly to an individual HCP.
- The decision to provide a grant or financial support to a healthcare practice, Institution or health related organisation shall meet one or more of the following purposes:
 - education, training or academic;
 - medical research;

- activities that improve the quality use of Health Products; or
- improvement of patient outcomes.
- A grant or financial support shall not be conditional on an HCP, institution or health related organisation recommending, prescribing, dispensing or administering a Company's Health Product(s).
- Clear guidelines, which can be publicly disclosed, if required, shall be developed in relation to the awarding of grants and financial support.
- There shall be a written agreement in place outlining the nature of the grant or financial support provided.



Guideline to Grants and Financial Support

Note 1: Faculty expenses for HCPs visiting South Africa

- Grants to conference sponsors to cover the costs of reasonable honoraria, travel, lodging, and meals for HCPs visiting South Africa who are bona fide conference attendees and/or speakers are acceptable.
- HCPs should generally not be reimbursed directly for costs incurred related to the scientific components of the conference. Reimbursement of expenses may only be made through a practice account and on production of original invoices and subject to Section 4.3.

2 SAMPLES

2.1 Health Products

The supply of Health Product(s) as samples shall comply with relevant legislation.

2.2 Personal Care Products

- Personal care products may not be provided together with any scheduled Medicines.



Guideline to Samples

Note 1: Banded pack for Schedule 0 products

- Banded packs are permissible. The packs banded together must be the same Schedule 0 products e.g. 2 x Product syrups (Schedule 0).
- It is not permissible to band together different dosage forms or products e.g. Product X syrup and Product x lozenges or Product X and Product Y.
- Banded packs must comply with legal requirements e.g. Banding packs of paracetamol may result in the combined packs exceeding the maximum paracetamol limit in a pack for a Schedule 0 and as such will not be permissible.

3 COMPETITIONS

3.1 Competitions for HCPs

- Competitions for HCPs shall be permissible provided that:
 - the competition is based on medical or Health Product knowledge or the acquisition of scientific knowledge;
 - individual prizes or educational items offered benefit the patient and/or are relevant to the HCP's practice;
 - entry into a competition is not dependent upon prescribing, ordering or recommending a Health Product and no such condition shall be made or implied;
 - the value of the prize does not exceed the limits set by the MCA Board from time to time;
 - cash or cash equivalents (e.g. vouchers) are not allowed for completion of a survey, or as a prize for a competition; and
 - the competition complies with relevant legislation such as the Consumer Protection Act, if applicable.



Guideline to Competitions

Note 1: Competitions and quizzes for HCPs

- The use of competitions, quizzes and such like for the purposes of sales promotion is an acceptable form of promotion.
- Any competition must be in good taste and must not involve any subject matter that is inappropriate for the promotion of a health product as required under Clause 3.1.

- Participation in competitions and quizzes related to the promotion of Schedule 2-6 Health Products is limited to HCPs only.
- A competition is acceptable if its subject-matter as well as the prize(s) offered are clearly related to the HCP's practice.
- Entrance into the competition should not be linked to the sale, recommendation or prescription of the Health Product in any manner or form.
- The maximum value per prize in a promotional competition for HCPs is R 2 000 (inclusive of VAT) per event or Promotional Activity.
- The total value of all prizes for a competition for HCPs must not exceed R40 000 (inclusive of VAT).
- If the prize is congress sponsorship, it may cover bona fide conference fees, accommodation and travel for the winner only and will be subject to the Code requirements for sponsorship.

4 MEETINGS AND EVENTS WITH HCPs

4.1 General Principles

- Companies, organisations or individuals shall be permitted to organise or sponsor meetings and events, including CPD events and product launches, subject to the following requirements:
 - the merit and focus of the meeting or event is clearly of a scientific and/or educational nature;
 - no stand-alone entertainment or other leisure, social or sporting activities is planned, arranged or funded by Companies as these are unrelated to the promotion of scientific or educational objectives;
 - the venue and Hospitality is secondary to the meeting or event both in time allocation and focus;
 - programs and events are conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the scientific or educational objective of the event and the effective transmission of knowledge.
- hospitality is modest and appropriate;
- invitations are not extended to spouses or other guests of HCPs, i.e. any costs incurred by spouses or other guests shall not be reimbursed or paid for by the Company. In exceptional cases, such as clear health needs of the HCP (e.g. disability), the costs of travel, meals and accommodation and registration fees of an accompanying person who is considered to be a caregiver may be provided;
- inappropriate benefit or otherwise, including excessive Hospitality, is not offered and/or extended to HCPs; and
- any reasonable, actual costs related to the attendance of meetings, which may have been incurred by HCPs, may be reimbursed.



Guideline to Meetings and Events with HCPs

Note 1:

The following is a tabulated summary of what would be regarded as acceptable or not acceptable when interacting with HCPs. Please note that the table provides a set of examples only and is not intended as an exhaustive list.

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

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.

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.

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 centre or centres 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.

Note 6: Any other travel

For any other travel, economy class travel is the standard class travel that companies may offer HCPs to attend both local and international events, including congress attendance and site visits.

Note 7: Conference programme

International events:

- An event is 'international' when participants are practicing in different countries. A national meeting with international speakers will still be considered national if all the participants are practicing in the same country.

The schedule of the scientific conference programme:

- For a full day event, the detailed programme should contain a minimum of six hours of medical educational content (excluding lunch and other breaks).

The availability of the programme in advance:

- The programme should be available at least 60 days prior to the event and contain sufficient information to enable an evaluation of the scientific value of the sessions and permit Companies to notify each sponsored HCPs hospital administration (in the case of public sector HCPs / registrars) and as may be the case for HCPs working for private sector hospitals, superiors or HCP societies / associations.

The relevance of the programme:

- The programme content should directly relate to the specialty and/or medical practice of the HCP who will attend the conference or have a sufficiently reasonable relationship to justify the attendance of the HCP. Agenda content relating to non-scientific topics, such as leadership skills, practice management, and speaking and presentation skills are acceptable if they are kept to a minimum.

Note 8: Geographic location

No Company may organise or sponsor an event that takes place outside its home country unless:

- most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country, or;
- given the location of the relevant resource or expertise that is the object or subject-matter of the event, it makes greater logistical sense to hold the event in another country.

The time of the year should be taken into account in determining if a geographic location is appropriate.

The geographic location should not be the main attraction of the conference. The image of the location among Consumers, media and authorities may not be perceived as a purely luxury, touristic/holiday and/or entertainment venue.

Note 9: Meals

Modest meals may be provided as an occasional business courtesy consistent with the following limitations:

- the meal should be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.
- Meals may occur at the HCPs' place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions.

In other cases, it may be impractical or inappropriate to provide meals at the HCPs' place of business, for example,

- where the medical technology cannot easily be transported to the HCPs' location,
- when it is necessary to discuss confidential product development or improvement information, or
- where a private space cannot be obtained on-site.

Meals may only be provided to HCPs who actually attend the meeting. Meals for guests of HCPs or for any other person who does not have a bona fide professional interest in the information being shared at the meeting is not allowed.

Note 10: Hospitality and accommodation at congresses

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

The appropriateness of accommodation: Companies may not pay for or reimburse HCP lodging expenses at top category or luxury hotels.

The accommodation must be limited to the duration of the conference – accommodation and/or other services provided to HCP delegates should not cover a period of stay beyond the official duration of the conference.

The registration fee: The registration fee should cover only the scientific programme and authorised activities and hospitality.

Note 11: HCPs unconnected to any congress

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

4.2 CPD Meetings

- 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 may only use the International Non-Proprietary Name (INN) of Health Products during CPD events. Companies shall inform speakers that the use of trade names is not permitted;
 - Health Product Promotional Material displayed outside of the meeting room is not visible to Consumers if it is not permissible to market such Health Product directly to Consumers;
- for local CPD events and Health Product launches, which are held in major cities, reasonable travel arrangements or reimbursement of actual travel expenses may be made to ensure that the HCPs who do not reside/practise in major cities are able to access the applicable information;
- the 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.

4.3 Medical or Scientific Congresses, Conferences or Seminars

- The Code recognises the contribution of the Industry to provide medical education that will facilitate better patient care and outcomes through sponsorship of HCPs to attend local and international medical educational and scientific events.
- Meetings organised by Companies or any Person on their behalf at venues outside of South Africa that are educational and scientific in nature and involve South African HCPs shall be acceptable.
- Sponsorship shall be provided to an HCP to attend an educational event provided the event is directly related to the HCP's area of expertise.
- Where a Company undertakes the sponsorship of an HCP, the following requirements shall be met:
 - the sponsorship shall be set out in a written agreement;
 - the sponsorship shall not be conditional on the HCP recommending, prescribing, dispensing or administering a Company's Health Product(s);
 - the sponsorship may cover registration fees as well as travel, accommodation, and Hospitality costs of the HCP;
 - documented criteria shall be in place for determining which HCPs should receive support; and
 - the final approval as to which HCP is sponsored shall be made by the Company's Code Compliance Officer.

- The decision to sponsor an HCP must be able to withstand public and professional scrutiny.
- For medical or scientific congresses, conferences and seminars held in South Africa or internationally, whether arranged by a South African or international group, the following rules must be observed:
 - the rationale for any meeting or sponsorship to attend a meeting shall be transparent, valid and cogent;
 - consideration shall be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, Hospitality provided and the like;
 - as with any meeting, it shall be the program that attracts delegates and not the associated Hospitality or venue;
 - any associated events shall be subordinate in time and nature to the sponsored meeting, congress, conference or seminar;
 - payment of registration fees, travel and accommodation cost shall be made to the professional associations/organisers or the appropriate administrative staff and not directly to the HCP, unless proof is received that the amounts spent are in the name of the sponsored person and which corresponds to each and every line item as per the agreed sponsorship;
 - no payment shall be made to the HCP or administrative staff for time spent at the event;
- sponsorship of congress organised events, other than recreational and sporting events, shall be permitted;
- invitations shall not be extended to spouses or other guests i.e. any costs incurred by spouses or other guests may not be reimbursed or paid for by the Company;
- the meeting and event shall be appropriate to the field of practice of the HCPs invited to attend;
- sponsored HCPs shall not be involved in the direct promotion of specific Health Products; and
- the program shall be available at least 60 (sixty) days prior to the event and contain sufficient information to enable an evaluation of the scientific value of the sessions.
- Companies sponsoring an HCP to speak at a Company-sponsored educational event or congress shall ensure, as a condition of the sponsorship, that the HCP is familiar with the approved indications for relevant Health Products and is aware of the obligation not to promote unapproved Company Health Products or indications. This does not apply to independently organised third-party educational events or Company-sponsored educational events, which are non-promotional, and where an independent scientific faculty has chosen the topics and speakers.
- In the case of international congresses held in South Africa, unapproved Health Products or indications shall not be promoted unless Section 14(3) of the Medicines Act applies.



Guideline to Medical or Scientific Congresses, Conferences or Seminars

Note 1: Entertainment at conference

A Company may not fund attendance at a concert, purchase of entertainment tickets or pay for entertainment (including sport and hunting activities) in any form. However, if there is background music or a local performance at the venue where the event is taking place, which is not paid for by a Company, this may be permitted.

4.4 Transparency Related to Sponsorship

- When meetings are sponsored by Companies or any Person on their behalf, the sponsorship shall be disclosed in the papers relating to the meetings and in any published proceedings.
- The declaration of sponsorship shall be sufficiently prominent to ensure that readers are aware of it at the outset.

4.5 Hospitality for Administrative Staff during Meetings

- Companies may provide Hospitality to appropriate administrative staff attending professional, scientific and promotional meetings/events, provided that it is reasonable and subordinate to the main purpose of the meeting or event.

MAKE CODE COMPLIANCE a condition of licensing?



LEGISLATION PROVIDES
FOR CODE ENFORCEMENT



No regulations
published



MCA Code depends
on voluntary
commitment



Compliance with a code should be a
condition for a manufacturer licence



ADVOCATES FOR
APPROPRIATE REGULATIONS:



→ Prescribe standards for code
authorities and codes



→ Mandate code authorities to
enforce their codes



→ Second level enforcement by
the regulator



Provision for penalties for
non-compliance
e.g. loss of product or company licence

Need for enforceable
**CODE OF
MARKETING
PRACTICE**



NPO

FOUNDED IN
2012



**CODE OF MARKETING
PRACTICE (CODE)**



**BEST
PRACTICE**

LED BY A BOARD A technical team maintains the Code



Support for service providers



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