MCA

Marketing Code Authority

ethical marketing leadership for health products

THE SOUTH AFRICAN CODE OF MARKETING PRACTICE FOR HEALTH PRODUCTS

Version 11

GUIDELINES TO THE CODE

Guideline to Section 4.6

Note 1: Provision of Services by Company Representatives

The nature of the service provider, the person associated with the provision of medical and educational goods and services, is important i.e. is the service provider a Health Product representative of the Company or is the service provider some other appropriately qualified person, such as a sponsored registered nurse? If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then Health Product representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse, not employed as a Health Product representative, may undertake activities relating to patient contact and/or patient identification.

Health Product representatives could provide administrative support in relation to the provision of a screening service but must not be present during the actual screening and must not discuss or help interpret individual clinical findings.

Note 2: Promotional activities by Company Representatives

Promotional Activities include the activities of Company Representatives involved in promoting the use or sale of Health Products. This also includes activities in the FMCG arena.

All provisions in the Code including the need for accuracy, balance, fairness, good taste etc. apply equally to oral representations as well as to printed material.

Note 3: Value-added services

Company Representatives may provide value-added services (i.e. by assisting an HCP administratively to prepare motivations to medical schemes with respect to the compilation of documentation, case histories, records, etc.), only with informed consent from the patient and the consent of the HCP.

Note 4: Access to patient records

Access to patient records must comply with POPI Act and Companies must ensure that patient confidentiality is maintained at all times.

Neither the Company nor the Company Representatives may be given access to data/records that could identify, or could be linked to, a particular patient unless with the express written informed consent of the patient and HCPs.

Materials relating to the provision of medical and educational goods and services, such as internal instructions, external instructions, the written protocol for recipients and printed material, etc., must be examined and approved by the Company Code Compliance Officer. Companies must ensure that the requirements of the Code are met. A copy of the promotional materials must be made available to the MCA on request

Note 5: Reimbursement Services

If, during a promotional visit by a Company Representative, a change in medication to one of the Company's products is agreed, the Company Representative may not then offer a reimbursement service to facilitate the change as this will be seen as a way for the Company to ensure that the agreed change will in fact be made.

Guideline to Section 4.7

Note 1: Communications of scientific information to HCPs or Consumers

Information should not be proactively offered or provided by the Company.

Any information about a Health Product communicated to the HCPs or Consumers prior to approval of registration or regarding Off-label Use, must be carefully scrutinised to ensure it complies with the relevant regulations and the Code.

It is permissible for the Medical/Clinical/Regulatory Department of a Company to disseminate scientific information to keep HCPs updated with the latest scientific or clinical information.

Guideline to Section 4.11

Note 1: Operating Room or Clinical Environment

A Company Representative may only enter an operating room/clinical environment:

- Where feasible, with advanced permission of the patient
- upon permission from appropriate members of the medical staff of the facility,
- must wear appropriate attire as provided by the facility / or permitted by the facility, and
- may only advise on technical aspects of Company Health Products consistent with the approved Professional Information/Instructions for Use.

In the event that the Company Representative is attending the operating room/clinical environment in his capacity as a Company Representative and on Company time he may not use and/or apply Company Health Products, deliver patient or medical care directly to a patient even if they hold appropriate registration and/or licences.

In the event that the Company Representative is attending the operating room/clinical environment in his capacity as a trained HCP, he must have a written contract with the relevant facility and should be in a position to produce the contract, within a reasonable time, upon request.

Guideline to Section 5.1

Note 1: Weight management/slimming/body image

A weight reduction regime in which the intake of energy is lower than its output is the most common self-treatment for achieving weight reduction. Any claims made for the effectiveness of a weight reduction method or product must be backed by appropriate evidence. Testimonials that are not supported by trials do not constitute substantiation.

Marketers must show that weight reduction is achieved by loss of body mass before claims are made for a weight reduction aid or regimen. Combining a diet with an unproven weight reduction method does not justify making weight reduction claims for that that method.

A statement to the effect of: '*Only effective when used in conjunction with a kilojoule controlled balanced diet*' should be included on the label and in the advertisement for a product intended for weight loss/management.

Guideline to Section 5.2

Note 1: Reply paid cards

Reply paid cards which are intended to be returned to Companies through the post must not include matters, which relate to a Health Product, which may not be legally advertised to Consumers. Reply cards may only bear the name of the Health Product. The inclusion of other information will constitute Advertising to Consumers.

Guideline to Section 5.3

Note 1: High standards, suitability and taste

The special nature of Health Products and the professional audiences to which the Advertising and Promotional material is directed require that the standards set for the promotion of Health Products are higher than those that might be acceptable for general commodity advertising.

It follows therefore that certain types, styles and methods of promotion, even where they might be acceptable for the promotion of products other than Health Products, are unacceptable. These include but are not limited to:

- the use of imagery of a sexual nature for the explicit purpose of attracting attention to the material;
- the provision of rubber stamps/stickers to HCPs for use as aids to prescription writing;

- the provision of private prescription forms pre-printed with the name of a Health Product; and
- teaser Advertising whereby Promotional Material is intended to "tease" the recipient by eliciting an interest in something which will be following or will be available at a later date without providing any actual information about the Health Product in question.

Note 2: Public interest criteria

The following should be taken into account:

- Consumers' or groups of Consumers' vulnerability when faced with disease, condition, ailment or defect
- whether the reference would be likely to result in Consumers not seeking professional advice where appropriate (such as where timely professional advice is important to prevent negative health consequences or irrevocable deterioration or progression of disease)
- whether the reference would be likely to have a negative impact on public health (or to have an effect on persons other than those to whom the Advertisement is directed).

Guideline to Section 5.6

Note 1: Artwork and visual representations

Artwork used in Advertisements must not be misleading nor convey any information about a Health Product that is additional to that permitted under the Medicines Act.

When showing before-and-after pictures of a patient using a Health Product, the visuals should not be exaggerated and should not imply or show complete eradication of the condition.

Anatomical drawings, graphs and tables must not mislead.

Differences that do not reach statistical significance must not be presented in such a way as to mislead.

Graphs and tables must be adequately labelled so that the information presented can be readily understood. If a graph or table is taken from a published paper, but has not been reproduced in its entirety, the graph must clearly be labelled as having been adapted from the paper in question. Any such adaptation must not distort or mislead as to the significance of that graph, table etc. It should also be noted that if a table, graph etc. in a paper is unacceptable in terms of the requirements of the Code then it must not be used or reproduced in Promotional Material.

Note 2: Price lists and pack shots for Schedule 2 and above

Price lists directed to Consumers may not contain pack shots of any Health Products in Schedule 2 or higher. Only the name of the product, strength, pack size and the price may appear on the price list.

Guideline to Section 5.7.1

Note 1: Hanging comparisons

Hanging comparisons must not be made, whereby a Health Product is described as being better or stronger or such like without stating the criteria against which the Health Product is compared.

Note 2: Price comparisons

Any comparison must be accurate, fair and must not mislead. A valid price comparison may only be made on the basis of the therapeutically equivalent dosage requirement for the same indication.

Guideline to Section 5.7.2

Note 1: Accuracy, balance and fairness of claims

The application of this clause is not limited to information or claims of a medical or scientific nature, but includes claims of a general nature, inter alia, information or claims relating to current price lists, sales, prescriptions and market share.

Note 2: Superlatives

Superlatives are those grammatical expressions that denote the highest quality or degree, such as best, strongest, widest etc. A claim that a product was 'the best' treatment for a particular condition, for example, cannot be substantiated as there are too many variables to enable such a sweeping claim to be proven.

The use of a superlative which can be substantiated is a simple statement of fact that can be very clearly demonstrated, such as that a particular Health Product is the most widely prescribed in South Africa for a certain condition, if this is not presented in a way that misleads as to its significance. Only relevant and current market share data may be used and must be fully referenced as to the source and the date.

Note 3: Use of the words 'the', 'unique' and 'ultimate'

In certain circumstances, the use of the word 'the' can imply a special merit, quality or property for a Health Product that is unacceptable under this clause if it cannot be substantiated. Great care needs to be taken with the use of the words 'unique' and 'ultimate'. Although in some circumstances the word

'unique' may be used to describe some clearly defined special feature of a Health Product, in many instances it may simply imply a general superiority, which is unacceptable.

Note 4: Absolute risk and relative risk

Statements relating to risk reduction: Absolute risk must be stated. The relative risk should never be referred to without referring to the absolute risk. The absolute risk can be referred to in isolation.

Note 5: Use of pharmaco-economic data

Economic evaluation of Health Products: Care must be taken that any claim involving the economic evaluation of a Health Product is borne out by the data available and does not exaggerate its significance.

Note 6: Emerging opinions

Emerging clinical or scientific opinion; Where a clinical or scientific issue exists that has not been resolved in favour of one generally accepted viewpoint, particular care must be taken to ensure that the issue is treated in a fair and balanced manner in Promotional Material.

Note 7: Use of statistical data

There must be a sound statistical basis where data is used to support comparisons used in Promotional Material. Differences that do not reach statistical significance must not be presented in such a way as to infer significance or mislead. Before statistical information is included in Promotional Material it must have been subjected to statistical appraisal. Claims based on published papers in which the arithmetic and/or statistical methodology was incorrect or questionable must not be used in Promotional Material. Statistical significance must not be used to infer the clinical significance of an outcome or study.

Guideline to Section 5.7.4

Note 1: Speed of absorption claims (6.7.4.4)

All speed of absorption and speed of action claims must be in line with the approved Professional Information. For indications such as pain and fever,

- 'fast' is taken to mean that the Health Product works within about 30 minutes,
- 'immediate benefit' as within 10 seconds,
- 'all day relief' if the Health Product works for at least 10 hours, and
- 'all night relief' if the Health Product works for at least 8 hours.

Guideline to Section 5.7.7

Note 1: Exaggerated or misleading claims

Claims for superior potency in relation to mass are generally meaningless and best avoided unless they can be linked with some practical advantage

Note 2: Use of data derived from *in vitro* studies, studies in healthy volunteers and in animals.

Care must be taken with the use of such data so as not to mislead as to its significance. The extrapolation of such data to the clinical situation should only be made where there is data to show that it is of direct relevance and significance.

Note 3: Sales claims

Sales claims must be based on volume of sales and must be supported by evidence. Best-selling claims must be carefully worded to avoid implying superior efficacy.

Guideline to Section 5.8.

Note 1: Advertisers must hold evidence for all claims made in advertising

Advertisers should be able to demonstrate that they have taken a systematic approach to reviewing the available evidence. The following types of evidence are likely to be acceptable:

- published data in a peer-reviewed journal
- standard textbooks, such as 'Martindale: The Complete Drug Reference' and 'British National Formulary'
- unpublished company data that has been approved by the company's medical or regulatory departments.
- The following are unlikely to be acceptable as supporting evidence:
- evidence which is out of date because it has been superseded by more recent studies and a progression in scientific understanding
- reports of poorly designed research
- books and information on the Internet that do not reflect available scientific evidence
- editorial material such as newspaper reports, as this is often anecdotal and not backed by clinical evidence
- animal studies where this is the only evidence submitted.

Note 2: Data in support of a claim

Evidence gathered to support a claim must be factual, unambiguous, not vague or emotive, or immeasurable, and must be able to be substantiated and stand up to scrutiny. The use of relative rather than absolute benefits may overemphasize the benefit of medicines which may leave HPCs susceptible to misinterpreting information and as such extreme caution must be taken when presenting such data. Data used must be independently reviewed.

Guideline to Section 5.9

Note 1: Use of HCPs' names on a Company website

Companies should not include a list of individual HCPs' names, hospitals or clinics on their corporate website or a Company developed website for a condition or disease state. In consultation with representatives of a society, and having sought their approval, it may be possible to provide a link to a society website where a list of HCPs affiliated to the society is made publicly available.

Note 3: Testimonials

Testimonials older than 3 years will require to be substantiated as being current.

Guideline to Section 5.10

Note 1: Journals with an international distribution

The Code applies to the Advertising of Health Products in professional journals that are produced in South Africa and/or intended for a South African audience. International journals that are produced in South Africa are subject to the Code if any proportion of their circulation is to a South African audience. In these circumstances the advertiser should indicate that the information in the Advertisement is consistent with the South African registration of the Health Product.

Advertising such as cards stapled to a journal and 'wraparounds' must not have a greater surface area than that outlined for loose inserts

Note 2: Professional Information and Patient Information Leaflet

Local Professional Information Patient Information Leaflet and Instructions for Use approved by the Regulatory Authority, is permitted as an insert or supplement.

Guideline to Section 5.16

Note 1: Electronic detailing

The principles embodied in the Code apply equally to electronic detailing ("eDetailing" or "e-Detail aid") using such devices as iPads, tablets, etc. Care

should be taken to ensure that all text complies with the requirements of the legislation and the Code and is easily legible from a comfortable distance.

Care should be taken when each page is viewed separately that the information is not false or misleading when read in isolation.

Placement of mandatory requirements such as, generic names, p-values, statements of significance, etc. should follow the same principles of the Code and should be clearly visible on the screen – they cannot only be visible within an animated feature such as a pop-up, etc.

The reference "*refer to approved Professional Information for full prescribing information*" is no longer mandatory if the full Professional Information is directly accessible from within the eDetail aid.

It is possible to give emphasis to a specific part of the content/area of a tablet screen through the use of light boxes, stretching/enlarging graphs etc.

Content must not be constructed in such a way that there is loss of context by obscuring critical elements, for instance, a claim remains visible, but a related qualifier statement, or other descriptive text that provides context, is hidden by a pop-up screen.

Qualifying statements should follow the same principles embodied in the Code. They should be linked to the relevant claim with a readily identifiable asterisk or similar device.

Qualifying statements must appear directly below or adjacent to the claim, and must be in prominent text such that the text size for the qualifying statement is larger than the other minimum text size on the screen. A qualifying statement should always be visible when its corresponding claim is on the screen.

The qualifying statement must not be hidden by pop-ups, if a section of the screen is enlarged, or positioned such that a person has to scroll further down the page to see it.

Other mandatory information should all be no more than 2 clicks away from any one screen (i.e. could access via a menu bar) or appear as part of the e-detailer e.g. at the end of each 'chapter/section' of information where an e-detailer is so designed.

Guideline to Section 5.17

Note 1: Electronic journals

The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the Advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the minimum information can be found. This should be in the form of a direct link.

The first part is often linked to other parts and in such circumstances, the linked parts will be considered as one advertisement. If the first part mentions the Health Product name, then this is the most prominent display of the brand name and the non-proprietary name of the Health Product or a list of the active ingredients using approved names where such exist, must appear immediately adjacent to the most prominent display of the brand name. The size must be such that the information is easily readable.

The requirement that Promotional Material and activities should not be disguised should also be borne in mind.

Note 2: Mobile media platforms and the use of digital applications (Apps)

A Company may wish to provide promotional and educational material to HCPs via an application downloaded on mobile media platforms (electronic devices). If the application contains Promotional Material it must be a secure application that is designed to allow access only to HCPs. Examples of acceptable Smartphone Apps include, but are not limited to medical dictionaries, access to clinical papers, conference proceedings or planners, and dose calculators.

If an App contains Promotional Material it must only be accessible via a secure App Store/Site or process that is designed to allow access only to HCPs. A mechanism such as a password or other restricted entry system would comply with the requirements of this section. The password to gain access to the App should not be a word that would be easily identifiable, such as the product name.

All material contained on an application directed to HCPs must also comply with the Code. This means that the standards applying to items such as Advertising and printed Promotional Material apply to material included on applications for mobile media platforms.

Any references or linkages to other reputable information sources must be to sources which provide valuable educational material that would enhance the quality use of products in South Africa.

The type size and graphics used in all application Advertisements must be such that allows easy and clear legibility.

Note 3: QR Codes/2D Codes

A Company may wish to provide Promotional and educational Material to HCPs via QR codes or other 2 D barcodes which link directly to applications or microsites. If the destination of these links is visible to Consumers (e.g. iTunes store, Google Play store or a non-secure website), then a mechanism such as a password protected application/microsite or other entry system would comply with the requirements of this section. The password to gain access to a restricted application/microsite should not be a word that would be easily identifiable, such as a product name.

Note 4: Social Media

Companies have full responsibility for their own initiatives, which must comply with the Code. In the case of sponsorship of a third party (such as a consumer organisation) to develop a social media portal, the contracts with the third parties must clearly describe the responsibilities of each party.

Companies which engage in social media activities that include discussion boards and sharing of audio and visual content should consider:

whether discussion boards need to be monitored and how regularly;

how to manage inappropriate conversation;

establishing rules for participants joining a discussion forum that:

- outline what is inappropriate conversation (e.g. offensive language, racist comments, promotion of a product) and that conversations may be monitored;
- describe whether any content would be excluded from the media, and the process for excluding it;
- provision for discussion boards to be shut down at any time;
- responsibilities for reporting of monitoring and reporting of Adverse Events reported via this media.

A Company will be held responsible for user-generated content placed in South Africa on social media such as 'YouTube', 'Facebook', 'Twitter' or blogs. It may be considered to be a 'marketing tool' when used by an advertiser.

Any Company that decides to leave public testimonials or other comments on their Facebook and Twitter pages will be held responsible if they are false, misleading or deceptive.

Companies must moderate social media content and remove inappropriate material within 24 hrs.

If using social media sites such as YouTube, Facebook, etc. to make educational material available to consumers, Companies should give consideration to any potential associated content, links or Advertisements irrespective of whether the Company can control them, for example if displaying a video on YouTube, the Company should consider the "suggested clips" which may be associated with the video through similar tags.

Note 5: Company-controlled websites for HCPs

A mechanism such as a password protected site or other entry system will comply with the requirements of this section. An entry system such as a provider number will also be acceptable. The password to gain access to a restricted access site should not be a word that will be easily identifiable, such as the product name.

Note 6: Minimum information on audio-visual material

Where details of the requirement for inclusion of "minimum information" is shown in the audio-visual material as part of the recording, it must be of sufficient clarity and duration to be heard or seen by the listener/viewer. The minimum information must be an integral part of the Advertisement. It is not acceptable for the Advertisement and the minimum information to be separated by any other material.

Publications and Advertisements may be affixed to the side of the audio-visual device or included on the box containing the audio-visual material. The minimum information must, however, be made available for any Advertisement for a Health Product appearing on audio-visual material or in an interactive data system or on the Internet, including journals on the Internet.

Note 7: Webinars

Webinars may be broadcast from a meeting at which a speaker is presenting to an audience or may be broadcast only as a webinar, whereby all audience members are 'virtual'.

Companies should consider the following when engaging with HCPs via webinar:

- Speaker briefing and slides: The same principles for briefing a speaker and review of slides for face-to-face presentations should also apply to webinars.
- Moderation by the Company: Based on the nature of the content of the session, Companies should make an assessment for the need for moderation. For transparency, a Company should consider including a statement alerting the audience if a session will be moderated and include any action that may be taken by the Company e.g. removal of any inappropriate 'material'/posts/questions.
- Delayed broadcast: Webinars may be recorded for later broadcast.
- International broadcasts that are made available by the South African affiliate/Company: The same principles apply for international broadcasts/webinars as for those initiated locally. Companies should ensure that the content is appropriate for a South African audience and any discussion of products is consistent with local approved indications and Health Product information. If the content is promotional, all mandatory requirements should be communicated to the audience. For example, text embedded around the viewing frame, a holding slide at the beginning and/or end of the webinar presentation, or including the information in an e-mail providing the link to the webinar.

Guideline to Section 5.18

Note 1: Provision of information during medicine development

The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited whether the event is of a national or international nature, provided that any such information or activity does not constitute promotion, which is prohibited under this or any other section.

Note 2: Notification of new product and product changes to medical schemes

Medical schemes require advance information about the introduction of new medicines or changes to the existing medicines in order to review the reimbursement status before approval for reimbursement. Information that may be provided includes:

- Health Product that contains a new active substance, or active substances prepared in a new way (e.g. biotechnology)
- Health Product that has a new registered indication
- Health Product that has a novel and innovative means of administration

Information may be directed to policy-makers in which case the registration status of the product, must be clearly indicated

Only factual information and Company logos instead of product promotional logos should be used.

Note 3: Promotion at international conferences

The display and provision of Promotional Material for unregistered medicine and/or indications is permitted at international meetings in South Africa provided the following conditions are met:

- Meeting is truly an international meeting of high scientific standing with a significant proportion of the attendees from countries outside South Africa in which the product is registered
- Medicine or indications must be relevant and proportional to the purpose of the meeting
- The registration status and/or approved indications in South Africa must be clearly and prominently displayed in the Promotional Materials
- The names of the countries where the medicine / indication is registered must include one major developed country and it must state that registration conditions differ from country to country.

Guideline to Section 6.2

Note 1: Certification of travel arrangements

When certifying meetings that involve travel inside or outside South Africa, the Company Code Compliance Officer must ensure that all the arrangements are examined, including the programme, the venue, the reasons for using that venue, the intended audience, the anticipated cost and the nature of the hospitality and the like.

This would include travel arrangements for speakers. It would also include any arrangements to sponsor travel or accommodation for delegates to a local conference where the money is paid to the professional body organising the conference, or sponsorship of travel or accommodation for delegates to an international conference.

Note 2: Joint ventures and co-promotion

In a joint venture in which a third party provides a service on behalf of a number of Companies, or other organisations, or an individual, the responsibility for any activity carried out by that third party on their behalf remains that of the companies, or other organisations or individuals. This includes the FMCG (Fast Moving Consumer Goods) arena in which a Schedule 0 Medicine and Complementary medicine is sold.

It follows therefore that the Companies, organisations or individuals involved, should be aware of all aspects of the service carried out on their behalf and should take this into account when certifying the material or activity involved.

Similarly, if two or more Companies or other organisations or individuals organise a joint meeting, each should ensure that the arrangements for the meeting are acceptable. Under co-promotion arrangements whereby Companies jointly promote the same Health Product and the Promotional Material bears both Company names, each Company should certify the involved Promotional Material or Activity, as they will be held jointly responsible for it under the Code.

Guideline to Section 7.2

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.

Guideline to Section 7.4

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 10.3.

Guideline to Section 8

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.

Guideline to Section 9.1

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 9.1.
- 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

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Guideline to Section 9.2

Note 1: Value of competition prizes

The total value of the prizes for a consumer competition must not exceed R100 000 (inclusive of VAT); and each individual prize may not exceed R5 000 (inclusive of VAT).

A donation of any nature linked to the competition needs to be included in the total prize money.

Competitions to wholesalers, the FMCG trade, spaza store owners, retailers, forecourt owners and the like are to be treated in the same manner as a competition to a HCP with the same criteria applying.

Note 2: Competitions open to Consumers

Invitations to Consumers to participate in competitions or quizzes which are linked directly or indirectly to a Schedule 2–6 Health Product are promotional in nature and are unacceptable.

Guideline to Section 10.1

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	√	√	X	X
Third-party educational event (dependent on 3rd party agreement)	√	√	X	X
Advisory Board meeting	√	√	X	X
Clinical Investigator meeting	√	√	X	X
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.

Guideline to Section 10.3

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.

Guideline to Section 11.1.1

Note 1: Items of medical utility

Scientific medical reference books, journals, periodicals and anatomical models intended for teaching or patient benefit:

For scientific medical reference books / journals and periodicals

- individual practicing HCPs or practices, the value should not exceed R 2 500 (inclusive of VAT)/year
- training or academic institutions, the value should not exceed R 10 000 (inclusive of VAT)/year

The value of medical devices should not exceed R300 (inclusive of VAT) / per item with a cap of R 2500 (inclusive of VAT)/ practice or institution per annum.

Other items of medical utility may be offered or provided if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.

Items might include an anatomical model for use in an examination room, or medical textbooks, as both primarily involve a patient benefit. A DVD or CD player however will not be permissible.

Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

Note 2: Medical and educational goods and services

The following guidance is intended to assist companies in relation to medical and educational goods and services.

- The role of Company Representatives in relation to the provision of goods and services supplied in accordance with the Code needs to be in accordance with the principles set out below. In this context Companies should consider using staff other than Health Product representatives.
- If Company Representatives provide, deliver or demonstrate medical and educational goods and services then they must not be linked in any way to the promotion of Health Products.
- In order to comply with this stipulation the Company Representative must not carry out both activities at the same visit.
- Company Representatives may introduce a service by means of a brief description and/or delivering materials, but may not instigate a detailed

discussion about the service at the same time as a call at which Health Products are promoted.

- The acceptability of the role of Company Representatives will depend on the nature of the goods and services provided and the method of provision.
- The nature of the service provider, the person associated with the provision of medical and educational goods and services, is important i.e. is the service provider a Health Product Company Representative or is the service provider some other appropriately qualified person, such as a sponsored registered nurse? If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then Health Product representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse, not employed as a Health Product representative, may undertake activities relating to patient contact and/or patient identification. Health Product representatives could provide administrative support in relation to the provision of a screening service, but must not be present during the actual screening and must not discuss or help interpret individual clinical findings.
- Neither the Company nor Company Representatives may be given access to data/records that could identify, or could be linked to, particular patients unless healthcare professional and patient consent is received in writing.
- Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.
- Service providers must operate according to detailed written instructions provided by the Company. These should be similar to the briefing material for Company Representatives as referred to in Clause 15. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed, etc. should be included. The written instructions must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.
- Service providers must abide by the principle set out in Clause 15 that in an interview, or when seeking an appointment, reasonable steps must be taken to ensure that they do not mislead as to their identity or that of the Company they represent.
- A recipient of a service must be provided with a written protocol to avoid misunderstandings as to what the recipient has agreed. The identity of the sponsoring Company must be given.

Guideline to Section 11.1.2

Note 1: Occasional items

Items of general utility, which have been held to be acceptable items to HCPs as being inexpensive and of relevance to their practices, include but are not limited to pens, pads, diaries, nail brushes, desk trays, calendars, and desk clocks.

Diaries and desk pads bearing advertisements of Health Products must comply with the provisions of Regulation 42 and 21 (in respect of medical devices and IVDs) and the Code.

Note 2: Detail on promotional Aids

Names of Health Products should not be used on Promotional Aids/items when it would be inappropriate to do so, for example, when it might mislead as to the nature of the item.

Note 3: Value of occasional items

The value of item shall not exceed R300 (inclusive of VAT).

Note 4: Package deals

Clause 12.1.2 does not prevent the offer of package deals for patients in terms of which the purchaser of particular Health Products receives with them other associated benefits, such as apparatus for administration, provided that the transaction as a whole is fair and reasonable and the associated benefits for the patient are relevant to the Health Products involved.

Guideline to Section 11.2

Note 1: Patient support items

Patient support items may be provided to HCPs by Company Representatives during the course of a promotional call and Company Representatives may deliver such items when they are requested by HCPs, for example on reply paid cards. Examples of items which will be acceptable include a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise, perhaps for obese patients subject to the provisions of relevant legislation.

Patient support items may be made available for use by HCPs even though they may not be passed on to patients for them to keep. Their purpose is to allow patients to gain experience in using their Health Products whilst under the supervision of a HCP. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject. The perceived value to the HCP and the patient must be similar.

Note 2: Items for patients

Items that may be made available to patients must meet the relevant principles set out in the Code and must be inexpensive and be related to either the condition under treatment or general health. Any such activity must meet all the requirements of the Code and in particular no Advertising of Schedule 2 to S6 Medicines and Category C and D Medical Devices and IVDs to the public.

Note 3: Direct patient contact

If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then Company Representatives must not be involved, unless with the express written permission of the patient and the HCP. Company Representatives may provide administrative support in relation to the provision of a screening service, but must not be present during the actual screening and must not discuss or help interpret individual clinical findings.

Guideline to Section 12.1

Note 1: Acceptable consulting services

Consulting/advisory services should be legitimate, have a business need and be governed by a written service level agreement. The contract for consulting or other services may include, but is not limited to:

- speakers for conferences and congresses
- presentation and demonstrations at Company sponsored product training
- advisory boards
- training services
- development of educational material / software or programmes
- development and/or management of patient compliance software/programs

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Guideline to Section 12.3

Note 1: Consent for access to patient data

Neither the Company nor its Company Representatives may be given access to data/records that could identify or could be linked to a particular patient unless with the express written consent of the patient and the HCP. This does not apply to clinical researchers whose activities are controlled under the Good Clinical Practice Guidelines, in line with the best international practice viz.

patient confidentiality. Companies must ensure that patient confidentiality is maintained at all times.

approval by Company Code Compliance Officer of materials relating to the provision of medical and educational goods and services, such as internal instructions, external instructions, the written protocol for recipients and printed material etc., must be examined by the Company Code Compliance Officer. Companies are to ensure that the requirements of the Code are met.

A copy of the materials must be made available to the SA Marketing Code Authority on request.

Guideline to Section 15.4

Note 1: Information to Consumers

This section allows for the provision of non-promotional information about Schedules 2 and above Medicines and Classes C and D to Consumers either in response to a direct inquiry from an individual, including inquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like. It also includes information provided by means of posters distributed for display in surgery waiting rooms etc.

This prohibition does not apply to vaccination campaigns or other public health campaigns carried out by Companies and approved by the Department of Health and/or the Regulatory Authority.

Any information so provided must observe the principles set out in this section, that is, it should be factual, balanced and must not encourage Consumers to ask their HCPs to prescribe a specific Health Product. It must not constitute the Advertising of Health Products to the general public prohibited under the Medicines Act which must be observed if an inquiry is from a Consumer.

Particular care must be taken in responding to requests from the media to ensure that the provisions of the Code are upheld.

In the event of a complaint which relates to the provisions of this section, Companies may be asked to provide copies of any information supplied, including copies of any relevant press releases and the like. This information will be assessed to determine whether it fulfills the requirements of this section. Professional Information/Patient Information Leaflets/Instructions for Use may be provided to Consumers on request. Companies may provide HCPs with approved Professional Information/ Patient Information Leaflets /Instructions for Use concerning a Health Product for supply to their patients to whom the Health Product has already been prescribed.

Note 2: Requests for information or advice on correct use of Medicines

This section prohibits the provision of information or advice on personal medical matters to individual Consumers requesting it. The intention behind this prohibition is to ensure that Companies, organisations or individuals do not interfere in the

patient/HCP relationship by offering advice or information that should be in the domain of the HCP. Answering requests of Consumers as to whether a particular Health Product contains sucrose or some other inactive ingredient, or whether there will be problems associated with drinking alcohol whilst taking a particular Health Product or whether the Health Product should be taken before or after a meal, is acceptable.

Guideline to Section 15.2

Note 1: Technology

Medical Devices and IVDs may only be provided to hospitals, healthcare facilities or HCPs for evaluation, as such evaluations have to be undertaken by lawful and legitimate, trained users of the Medical Devices and IVDs and subject to the patient providing informed consent for the specific procedure, which includes disclosure of the arrangement between the Company and the HCP in respect of the Medical Device to be used in line with the Healthcare Professional Council of South Africa Ethical Rules.

Note 2: Single use/consumables/disposables

The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation appraisal of the Health Products under the circumstances.

Note 3: Multiple use/capital equipment

Multiple use Health Products / Capital Equipment provided without transfer of title for evaluation appraisal purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation appraisal. The terms of an evaluation appraisal of such multiple use Health Products should be set in advance in writing. Companies should retain title to such multiple use Health Products during the evaluation appraisal period and should have a process in place for promptly removing such multiple use Health Products from the HCPs location at the conclusion of the evaluation appraisal period unless the HCP purchases or leases the Health Products.

Guideline on Section 15.3

Note 1: Items on long term loan

Items provided on long term or permanent loan to an HCP or an HCP practice are regarded as promotional items or gifts and are subject to the requirements of section 12