GUIDELINE TO THE CODE OF MARKETING PRACTICE FEBRUARY 2015

1. The guidelines should not go beyond the Medicines and Related Substances Act and Regulations or what is stated in the Code of Marketing Practice except where necessary detail is called for by the Code.

2. Material of an educational nature should be in the training programme being developed by the MCA and not in the guidelines. Training programme will include examples.

3. These notes are intended as a guideline to the interpretation of the Code of Marketing Practice and are issued pursuant to Section 18C of Act 101 of the Medicines and Related Substance Act 101 1965, as amended (hereafter referred to as “the Act”).

4. Any person interpreting and applying the Code must consider the Guidelines issued thereunder in order to provide guidance as to the application of Code principles in practical situations. Previous rulings by Adjudication and Appeal Committees may also be considered. An interpretative approach that harmonises the Code and Guidelines should be followed. In cases of irreconcilable conflict the Code will prevail and recommendations may be made by structures of the MCA, including Adjudication and Appeal Committees as to adjustments that should be considered by the relevant MCA structures (Board and AGM) in correcting such irreconcilable conflicts.

5. Words and phrases that are defined in the Medicines Act shall bear the same meanings as they do in the Act and all regulations issued in terms of this Act. It is also intended that the guidelines be expanded on to include decisions of the Marketing Code Authority (MCA) after adjudicating complaints in order to build up a body of knowledge around the principles and implementation of the code. Such decisions will constitute precedent.
## AMENDMENT TO GUIDELINE TO THE CODE OF MARKETING PRACTICE February 2015

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INTRODUCTION

PART A: THE MARKETING AND PROMOTION OF HEALTH PRODUCTS TO HEALTHCARE PROFESSIONALS

Clause 2.2 Application of the Code

Note 1: Market extension
Activities which are designed to enlarge the market in a particular area such as disease awareness campaigns are permitted provided that these are carried out in a manner compatible with the Code.

Clause 4: Registration Status of Medicines

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 clause.

Note 2: 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.

Note 3: Unauthorised indications
The promotion of ‘off-label’ and/or unregistered indications in South Africa, is prohibited. This does not preclude discussing the merits of such unregistered, “off-label” indications in proper scientific discussions.

Note 4: Notification of new products and product changes to medical aids
Medical Aids need to have advance information about the introduction of new medicines or changes to the existing medicines in order to review the reimbursement status before approval. This information may be provided on the following basis:
- The information relates to:
  - Product that contains a new active substance, or active substances prepared in a new way (e.g. biotechnology)
  - Product that has a significant new indication
  - Product has a novel and innovative means of administration
- Information should be directed to policy makers
- The registration status of the product is clearly indicated
- Only factual information must be provided
- Company logos instead of product promotional logos should be used.
Clause 5: Advertising and Promotional Material of Medicines

Note 1: Individual promotional items and loose inserts
Each promotional piece for health products must be able to stand alone. A loose insert is regarded as a stand-alone promotional piece and must comply with the Code.

Note 2: Price lists
Price lists directed to the public may not contain pack shots of any health product in Schedule 2 or higher schedule. Only the name of the product, strength and pack size is allowed.

Note 3: Referencing
Referencing should be of a standard recognised by scientific journals.

Note 4: 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 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 of Clause 10.1 that promotional material and activities should not be disguised should also be borne in mind.

Note 5: Minimum information on audio-visual material
Where 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. 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. Audio-visual material and such like sent to healthcare professionals may be considered professional 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 6: Diaries and desk pads
Diaries and desk pads bearing advertisements of health products must comply with the provisions of Regulation 45 and the Code.

Note 7: Artwork
Artwork used in advertisements must not be misleading nor convey any information about a health product that is additional to that permitted under Regulation 45.

Note 8: Date of package insert
All package inserts referenced must include the date that the package insert was approved by MCC.
Note 9: Company controlled websites for Healthcare Professionals

A company may wish to provide promotional and educational material to healthcare professionals via a website. If this site contains promotional material it must be a secure site that is designed to allow access only to healthcare professionals. A mechanism such as a password protected site or other entry system would comply with the requirements of this section. An entry system such as a provider number would also be acceptable. The password to gain access to a restricted access site should not be a word that would be easily identifiable, such as the product name.

All material contained on a website directed to healthcare professionals must also comply with the provisions of the Code. This means that the standards applying to items such as advertising and printed promotional material apply to material included on a company sponsored website.

Any electronic forms of promotion must be considered in context. If the material is promotional it must include the reference to refer to the package insert for full prescribing information.

Companies should also take care when including references or links to other information sites. References or links to any non-compliant sites that may put the company at risk of being found in breach of the Code should be removed without delay. Links to international company websites should warn the reader they are leaving the local site and that they should refer to the local approved package insert.

Note 10: Use of healthcare professionals’ names on a company website

It is advised that companies should not include a list of individual doctor’s names or clinics on their corporate website or a company developed website for a condition or disease state. In consultation with an independent or society, and having sought their approval, it may be possible to provide a link to a society website where a list of physicians registered with the college or society is made publicly available.

Note 11: 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 healthcare professionals 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 Africa 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 Africa audience and any discussion of products is consistent with local approved indications and 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 email providing the link to the webinar.
Note 12: Mobile media platforms and the use of applications (Apps)

A company may wish to provide promotional and educational material to healthcare professionals via an application downloaded on mobile media platforms (e.g. iPhone and iPad; Blackberry; Android based smartphones and other tablets). If the application contains promotional material it must be a secure application that is designed to allow access only to healthcare professionals. A mechanism such as a password protected application or other entry system would comply with the requirements of this section. The password to gain access to a restricted application should not be a word that would be easily identifiable, such as a product name.

All material contained on an application directed to healthcare professionals 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 electronic forms of promotion must be considered in context. That is, is the information medical education or promotion? If the material is promotional it must include a reference to the approved package insert or a direct hyperlink to the current package insert outside of the application or provide access to it via a package insert button within the application.

Companies should also take care when including references or links to other information sites. References to any non-compliant sites that may put the company at risk of being found in breach of the Code should be removed without delay. It must be made clear when the user is leaving the application or being directed to a site that the company is not responsible for and has not developed. 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.

A company may wish to provide promotional and educational material to healthcare professionals via Apps. 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 healthcare professionals. 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.

Note 13: QR codes /2D barcodes

A company may wish to provide promotional and educational material to healthcare professionals via QR codes or other 2D barcodes which link directly to applications or microsites. If the destination of these links is visible to the general public (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 14: Electronic detailing

The Guidelines Working Group acknowledges that an increasing number of companies are now using electronic devices to detail healthcare professionals. The principles from Clause 7 - 9 of the Code should apply to electronic detailing (“eDetailing” or “e Detail aid”). When writing the recommendations below, the Group made the assumption that such devices included iPads, other tablets, etc. If devices with smaller screens are used, care should be taken to ensure that all text is easily legible from a comfortable distance.

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

Text font, size and colour must be considered to ensure legibility. The resolution provided by different screen sizes should also be taken into account when accessing legibility. All text must be easily visible from a comfortable viewing distance prior to zooming or utilising other similar functions.

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 package insert for full prescribing information” is no longer mandatory if the full Package insert is directly accessible from within the eDetail aid. The table below for audiovisual material and the internet, where the need for the “reference to the approved package insert” is mandatory if the full package insert is immediately accessible.

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<th>Company Branded Pens and Notepads</th>
<th>Lanyards</th>
<th>Token Cost Bags</th>
<th>Brand Name Reminders (Not Permitted)</th>
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<tr>
<td>Company Educational Event</td>
<td>☑</td>
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<tr>
<td>Third Party Educational Event, A third party has the right not to allow a company to distribute these items</td>
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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 as per Clause 7 -9; 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 user has to scroll further down the page to see it.

Other mandatory information as per Clause 5.3 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.

**Note 15: Social media scenarios:**

- company initiated and controlled activities; and
- sponsorship of a third party (such as a health consumer organisation) to develop a social media portal.

Companies have full responsibility for their own initiatives. Through their contracts with third parties, the responsibilities of each party should be described.

Companies who 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;
  - describes whether any content would be excluded, and the process for excluding it;
  - discussion boards may be shut down at any time;
  - responsibilities for reporting of monitoring and reporting of Adverse Events reported via this media;

Information placed by South Africa on social media such as ‘YouTube’, ‘Facebook’, ‘Twitter’ or blogs must be aware that the company will be held liable for user generated content on Facebook may be considered to be a ‘marketing tool’ when used by an advertiser.

- Any business 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.

The need for companies to moderate social media content and the removal of inappropriate material within 24 hrs.

If using social media sites such as YouTube, Facebook etc. to make educational materials 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 in YouTube, the company should consider the “suggested clips” which may be associated with the video through similar tags.

Any electronic forms of promotion using Social Media must be considered in context. That is, is the information medical education or promotional? If the material is promotional it must include within the body of the advertisement and a reference to refer to the package insert before prescribing and/or a direct hyperlink to the Package insert must be included. When linking to a PDF of the Package Insert or Patient Information Leaflet on a third party site where the viewer cannot navigate away from the page displaying the PI or PIL, a pop-up box warning the reader they are leaving the company controlled site is not required.
Clause 6: Journal Advertising

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 product.

Advertising such as cards stapled to a journal and ‘wraparounds’ must not have a greater surface area than that outlined for loose inserts under Clause 6.2.

Note 2: Package inserts
A local package insert, approved in terms of the Medicines and Related Substances Act, is permitted as an insert or supplement.

Note 3: Inserts and supplements
Inserts and supplements, such as reports of conference proceedings are not advertisements as such, though they may be regarded as promotional material and are permitted, subject to the Legislative and Code provisions.

Clause 7: Information, Claims and Comparisons

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. It includes, inter alia, information or claims relating to current price lists and market share. It should be borne in mind that claims in promotional material must be capable of standing alone as regards accuracy etc. Claims should not be qualified by the use of footnotes and the like.

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. Care should be taken to ensure that relevant and current market share data is used.

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: 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
- 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;

- **absolute risk and relative risk**
  Risk reduction can make a medicine appear more effective than it actually is. In order to assess the clinical impact of an outcome, the absolute risk should 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.

- **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.

- **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.

- **statistical information.** Care must be taken to ensure that there is a sound statistical basis for all information, claims and comparisons in promotional material. Differences that do not reach statistical significance must not be presented in such a way as to mislead. Instances have occurred where claims have been based on published papers in which the arithmetic and/or statistical methodology was incorrect or questionable. Accordingly, before statistical information is included in promotional material it must have been subjected to statistical appraisal. Care should also be taken if there is statistical significance but no obvious clinical significance.

**Note 5: Comparisons**
Comparisons must be substantiated and must not be left up to interpretation.

- **hanging comparisons** must not be made, whereby a health product is described as being better or stronger or suchlike without stating against which criteria against which the health product is compared;

- **price comparisons** as with any comparison must be accurate, fair and must not mislead. A valid comparison may only be made where a price comparison is made on the basis of the therapeutically equivalent dosage requirement for the same indication.

**Note 6: Artwork illustrations, graphs and tables**
Care must be taken to ensure that artwork does not mislead as to the nature of a health product or any claim or comparison and that it does not detract from any safety aspects. Depictions of children should not be used in relation to products not authorised for use in children. Pictograms must not be used to depict opinions or interpretations. Particular care must be taken with anatomical drawing, graphs and tables to ensure that they do not mislead. Differences that do not reach statistical significance must not be presented in such a way as to mislead. Refer also to note 4 above on statistical information.

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 7: Use of the word ‘safe’**
The restrictions on the word ‘safe’ apply equally to grammatical derivatives of the word such as ‘safety’.
Clause 9: High Standards, Format, Suitability and Endorsement by HCPs

Note 1: High standards, suitability and taste
The special nature of health products and the professional audiences to which the 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 doctors for use as aids to prescription writing
- the provision of private prescription forms pre-printed with the name of a health product
- 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 product in question.

Note 2: 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 the public. Reply cards may only bear the name of the product. The inclusion of information would constitute advertising to the public.

Clause 10: Disguised Promotion

Note 1: Disguised promotional material
Promotional material sent under the guise of personal communications is inappropriate. Envelopes must not be used for the dispatch of promotional material if they bear words implying that the contents are non-promotional.

Care must be taken with company-sponsored reports on meetings and the like to ensure that they are not disguised promotion. Sponsorship must be declared in accordance with Clause 10.2.

Note 2: Market research
Where market research is carried out by an agency on behalf of a company, the agency must reveal the name of its client to the Marketing Code Authority or MCC if requested. When commissioning market research, companies must take appropriate steps to ensure such information is provided on request.

Note 3: Provision of non-promotional material: Guidelines for Clinical Trials in South Africa
Companies must comply with the “Guidelines for good practice in the conduct of clinical trials in human participants in South Africa” and Good Clinical Practice-ICH Guidelines. Clinical trials or safety studies should not be undertaken solely for purposes of promotion. Approval by an Ethics Committee and, where required, approval by the MCC, must be obtained for post-marketing trials.

Note the requirement [locally and internationally] for all clinical trials to appear on a Register of Clinical Trials. The South African Dept. of Health clinical trial register appears on the www.sanrr.gov.za.

Clause 11: Provision of Reprints and the Use of Quotations

Note 1: Provision of reprints
The provision of an unsolicited reprint of an article about a health product constitutes promotion of that health product and all relevant requirements of the Code must therefore be observed. Clause 11.1 does not preclude the provision of scientific data on non-registered medication if the healthcare professional...
requests the information provided this information is given in a non-promotional manner (Refer to Guidance Notes on Clause 13). Particular attention must be paid to the requirements of Clause 4 [health product must be registered in South Africa].

**Note 2: Quotations**

Any quotation chosen by a company for use in promotional material must comply with the requirements of the Code itself. Care should be taken when quoting from any study or the like to ensure that it does not mislead as to its overall significance. (See Clause 7.4 which prohibits misleading information claims etc. in promotional material).

Attention is drawn to the provisions of Clause 7.7, which requires that when promotional material refers to published studies, clear references must be given as to where they can be found.

**Clause 13: Scientific Information Service**

**Note 1: Communications of scientific information to healthcare professionals or public.**

Information should not be proactively provided and should not be prompted by the company or proactively offered.

Any information about a health product communicated to the health professions or the public 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 Department of a company or organisation to disseminate scientific information to keep healthcare professionals updated with the latest scientific or clinical information. The company should keep a record of the unsolicited requests for literature from healthcare professionals. This information should not be conveyed by the Marketing or Sales Department or the medical representative.

**Clause 14: Certification of Promotional Material and Other Activities**

**Note 1: 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 is sold.

It follows therefore that the companies, organisations or individual 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.

**Note 2: 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. Refer to Clause 18 for more details.

**Clause 15: Marketing and Sales Personnel**

**Note 1: Promotional activities by healthcare sales representatives or other company employees**
Promotional activities include the activities of healthcare sales representatives (including contract representatives) or any other company employee 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 2: Briefing material**
The detailed briefing material referred to in this clause consists of both the training material used to instruct healthcare sales representatives about health product and the instructions given to them as to how the products should be promoted. Note the need for certification of all briefing and training materials. This item should be part of the company SOP as well as part of the training material.

**Note 3: Healthcare representative in operating room / the clinical environment**

**Devices only**
- must be trained on operating room / clinical environment protocol
- may only enter an operating room/clinical environment 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
- may only advise on technical aspects of company products consistent with the approved package insert / instructions for use
- may not give clinical diagnostic advice, surgical advice or recommend treatment, even as the result of a direct request from the surgeon, operating room staff, or any other healthcare professional.
- In the event that the Healthcare Representative is attending the operating room/clinical environment in his/her capacity as a Company Representative and on company time he/she may not use and/or apply company product, deliver patient or medical care directly to a patient even if they hold appropriate certification/licences.
- In the event that the Healthcare Representative is attending the operating room/clinical environment in his/her capacity as a trained Healthcare Professional, he/she must have a written contract with the Hospital and should be in a position to produce the contract, within a reasonable time, upon request

**Clause 18: Interactions with healthcare professionals**

**Note 1: Public perception of the healthcare industry**
The healthcare industry should refrain from creating a perception or giving the incorrect impression about the industry to other stakeholders including patient and consumer associations, the press, healthcare professionals, government officials and also the general public by offering excessive hospitality or in any other manner.

**Note 2: Honoraria**
A written agreement with regards to honoraria should be determined at a company level and must take into consideration the expertise of the speaker.
**Note 3: 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.

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. 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, this may include arriving 48 hours before the meeting, and departing soon thereafter).

An official agenda should be prepared for the meeting.

**Note 4: 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.

The only exception for economy class travel locally would 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 5: Venues**

Programs and events should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge.

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 6: Conference programme**

**International events:** An event is ‘international’ when participants are practicing in different countries.

A national meeting with international speakers would still be considered national if all the participants are practising 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 events 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 society / association.
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 7: Geographic location
No company may organise or sponsor an event that takes place outside its home country unless:

a. 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;

b. 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 (an “international event”).

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

The Conference Venue should be a business or commercial centre providing conference facilities conductive to the exchange of scientific and medical information and the transmission of knowledge. It should not be the main attraction of the conference. The image of the location among the public, media and authorities cannot be perceived as purely luxury, touristic/holiday and/or entertainment venue.

Note 8: 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 can 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 9: Accommodation
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 adopt when paying for themselves.

Note 10: Hospitality and accommodation at congresses
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.

Spouses, partners, family and/or other guests may not benefit from hospitality sponsored by signatories to the Code.
The appropriateness of accommodation – companies may not pay for or reimburse HCP lodging expenses at top category or luxury hotels.
The accommodation to 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 authorized activities and hospitality.

Note 11: Entertainment
Companies may not provide or pay for any stand-alone entertainment or any recreational event or activity for any HCP.
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.
Light entertainment in the form of e.g. background music at events connected to a bone fide function for the exchange of information is acceptable.

Note 12: Entertainment at conference
A company cannot 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 pharmaceutical company, this may be permitted.

Note 13: 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 is acceptable.
HCP should generally not be reimbursed directly for costs incurred directly related to the scientific components of the Conference. However, it is realised that there may be bona fide occasions where direct payments are justified. Reimbursement of expenses may only be made on production of original invoices.

Note 14: Scientific advisory boards
If companies have scientific or advisory board meeting, there shall be bona fide consulting services agreements with the HCPs.
Companies may not pay HCPs for their time whilst attending the CPD events under the guise that such events are scientific meetings or advisory board meetings. The general rules relating to spouses/partners, meals and refreshments and entertainment also apply in this context.

Note 15: Company sponsored product training and education
Companies have a responsibility to make product education and training available to HCPs in the interest of ensuring the appropriate, safe and effective utilisation of a particular type of medical technology. “Training” means training on the safe and effective use of medical technologies. “Education” means communicating information directly concerning or associated with the use of a company’s medical technologies, e.g. information about disease states and the benefits of medical technologies to certain patient populations.

Note 16: Corporate hospitality
Individual healthcare professionals and other prominent professionals and business persons may be invited to corporate events associated with corporate or charitable programmes which are non-
promotional in nature. Company Code Compliance Officers should carefully scrutinise the nature of the event including the purpose stated in the invitation to ensure this is not disguised promotion.

**Note 17: Consulting services**
Consulting services should be legitimate, have a business need and be governed by a written service level agreement. The contract for consulting or other services can 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

**Note 18: Medical and educational goods and services**
The following guidance is intended to assist companies in relation to medical and educational goods and services.

1. a) The role of Health Sales 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.

   b) If Health Sales Representatives provide, deliver or demonstrate medical and educational goods and services then this must not be linked in any way to the promotion of products.

   c) In order to comply with this stipulation the representative must not carry out both activities at the same visit.

   d) 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 products are promoted.

   e) If, during a promotional visit by a representative, a change in medication to one of the company’s products is agreed, the representative may not then offer a re-imbursement service to facilitate the change as this would be seen as a way for the company to ensure that the agreed change would in fact be made.

   f) The acceptability of the role of Health Sales Representatives will depend on the nature of the goods and services provided and the method of provision.

   g) 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 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.

   h) Neither the company nor its health product 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.

   i) Sponsored health professionals should not be involved in the promotion of specific products.
2. Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.

3. Service providers must operate to detailed written instructions provided by the company. These should be similar to the briefing material for 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.

4. 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.

5. 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 pharmaceutical company must be given.

Clause 19: Inducements, Gifts and Promotional items, Competitions

Note 1: 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 healthcare sales representatives must not be involved, unless with the express written permission of the patient and healthcare professional. Healthcare Sales 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.

Note 2: Value added services
Healthcare Sales Representatives may provide value added services, with informed consent from the patient and the consent of the medical practitioner, by assisting a medical practitioner administratively to prepare motivations to medical schemes with respect to the compilation of documentation, case histories, records etc.

Note 3: Access to patient records
Neither the company nor its healthcare sales 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 healthcare professional. This does not apply to clinical researchers whose activities are controlled under the Good Clinical Practice Guidelines which is 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 - 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.

Note 4: Good practice guidelines for healthcare professionals
All healthcare professionals are required to comply with their respective Codes of Professional Conduct of their professional bodies. These codes require, inter alia, that the healthcare professional’s registration status is not used in the promotion of health products or services.
Healthcare professionals should not ask for or accept any material rewards from companies, organisations or individuals that sell or market health products. Sponsorship of healthcare professionals to attend congresses and the like, should not be used to influence them to promote specific health products.

**Note 5: Terms of trade**

Schemes that enable healthcare professionals to obtain personal benefits in relation to the purchase of health products are unacceptable even if they are presented as alternatives to financial discounts.

**Note 6: Package deals**

Clause 18.1 does not prevent the offer of package deals for patients wherein 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.

**Note 7: items of general utility**

Items of general utility which have been held to be acceptable items to doctors as being inexpensive and of relevance to their work include but are not limited to pens, pads, diaries, nail brushes, desk trays, calendars, and desk clocks. Names of health products should not be used on promotional aids when it would be inappropriate to do so, for example, when it might mislead as to the nature of the item. The value of item should not exceed R300 (inclusive of VAT).

**Note 8: - items of medical utility**

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

- For scientific medical reference books / journal and periodical
  - individual practicing HCP 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.

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

**Note 9: Items on long term loan**

Items provided on long term or permanent loan to a healthcare profession or a practice are regarded as gifts and are subject to the requirements of this clause.

**Note 10: Competitions and quizzes**

The use of competitions, quizzes and suchlike 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 and prescription-only health products is limited to healthcare professionals only. A competition is acceptable if its subject matter is clearly related to the healthcare professional practice as is the prize(s) offered. Entrance into the competition should not be linked to the sale, recommendation or prescription of the product in any manner or form. The maximum per prize in a promotional competition is R 2 000, (inclusive of VAT)/ event or promotional activity.

If the prize is congress sponsorship, it will cover bona fide conference fees, accommodation and travel for the winner only.

**Note 11: Donations to charities**

Any donation to a charity must not constitute a payment that would otherwise be unacceptable under the Code. Companies are encouraged to have an agreement with the charity whereby disclosure is incumbent on both parties.

No donations may be made to hospitals or clinics as an incentive to prescribe any health product. Members may make donations for charitable or other philanthropic purposes. Donations may be made only to charitable organisations or other non-profit entities entitled to receive them under applicable national or local laws and regulations. Donations may be made to support the general activities of a bona fide organisation or may be made to support general fund raising drives for projects undertaken by such an organisation.

Charitable donations must not be tied in any way to past, present or potential future use of the member’s products or 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. The payment should be made out in the name of the charity and paid directly to the charity. Charitable donations to a bona fide organisation should not be made in response to requests made by healthcare professionals unless the healthcare professional is an employee or officer of the organisation and submits the request on behalf of the organisation. It would not be appropriate for a member to support the favourite charity of a Healthcare Professional in response to a request by that healthcare professional.

Members should have no control over the final use of funds provided as charitable donations to charitable and other non-profit organisation.

**Clause 20: Items for Patient or Patient Organisations**

**Note 1: Patient support items**

Patient support items may be provided to health professionals by representatives during the course of a promotional call and representatives may deliver such items when they are requested by health professionals, for example on reply paid cards.

Examples of items which might 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.

Patient support items may be made available for the use of health professionals even though they are not to be passed on to patients for them to keep. This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a health professional. 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 health professional and the patient must be similar.

**Note 2: Items for patients**
Items that may be made available to patients should meet the relevant principles set out in Clause 19.2, that is they should be inexpensive and be related to either the condition under treatment or general health. Care must be taken that any such activity meets all the requirements of the Code and in particular Clause 20 i.e. no advertising of Schedule 2 - 6 only health products to the public.

No gift or promotional item for use by patients must be given for the purpose of encouraging patients to request a particular health product.

**Clause 20.9 Relations with the General Public and Media**

**Note 1: Advertising of health products to the general public**
The advertising of Schedule 2 and above health products to the general public is prohibited by regulations under the Act. The promotion of health products in Schedule 0 or Schedule 1 to the general public for self-medication purposes is permitted.

- Invitations to the public to participate in competitions or quizzes which are linked directly or indirectly to a Schedule 2 and prescription-only health product are promotional in nature and are unacceptable. Competitions for Schedule 0 and Schedule 1 should not be linked to the purchase or sale of the product in any manner or form.

**Note 2: Information to the public**
This clause allows for the provision of non-promotional information about Schedule 2 and above to the general public 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 Medicines Regulatory Authority. Any information so provided must observe the principles set out in this clause, that is, it should be factual, balanced and must not encourage members of the public to ask their doctors to prescribe a specific health product. It must not constitute the advertising of health products to the general public prohibited under Clause 20.9. The provisions of Clause 20.9 must be observed if an inquiry is from an individual member of the public.

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 clause, 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 clause. Package inserts may be provided to members of the public on request. Companies may provide members of the health professions with approved package inserts or patient information leaflets concerning a health product with a view to their provision to patients to whom the health product has already been prescribed.

**Note 3: Financial information**
Information made available in order to inform shareholders on the Johannesburg Stock Exchange and the like by way of annual reports and announcements etc. may relate to both existing health products and those not yet marketed / registered. Such information must be factual and presented in a balanced way.

**Note 4: Replies intended for use in response to individual enquiries**

Replies intended for use in response to enquiries that are received on a regular basis may be drafted in advance provided that they are used only when they directly and solely relate to the particular enquiry. Documents must not have the appearance of promotional material.

**Note 5: Requests for information or advice on personal medical matters**

This clause prohibits the provision of information or advice on personal medical matters to individual members of the public requesting it. The intention behind this prohibition is to ensure that companies, organisations or individuals do not intervene in the patient/doctor relationship by offering advice or information that should professionally be in the domain of the doctor. However, information may be given including information on health products prescribed for the enquirer, provided that it complies with the requirements of Clauses 20.9 and 20.11 and does not impinge on the principles behind this clause.

All requests from members of the public need to be handled with great care and a decision taken as to whether the company, organisation or individual can responsibly answer the inquiry.

Requests from patients for information may in some instances best be handled by passing the information to the patients’ doctors for discussion with them rather than providing the information directly to the patients concerned.

**Clause 22.2: Internet**

It must be made clear when the reader is leaving the site or being directed to a site that the company has not developed. 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. When making such a reference or linkage a clear screen displaying the following statement must appear before the reference material is accessed:

“The information a reader is about to be referred to may not comply with the South Africa regulatory requirements. For information relevant to the South Africa environment is available from the company or via the Package Insert.”
PART B: THE MARKETING AND PROMOTION OF HEALTH PRODUCTS TO THE GENERAL PUBLIC

Please note that it is imperative to take cognisance of the Guidelines to Part A, as there is duplication of Clauses. The Guidelines to Part A must therefore be read in conjunction to the Guidelines to Part B.

Clause 25: Advertising and/or Promotion

Note 1: Children
For the purpose of the Code a child is someone under the age of 12 years. The way in which children perceive and react to marketing communications is influenced by their age, experience and context in which the message is delivered; marketing communications that are acceptable for young teenagers will not necessarily be acceptable to young children. These factors must be taken into account.

Note 2: Misleading advertising
Although it is acceptable to indicate that a self-medication product is palatable, advertising shall make it clear that it is a health product. Advertising shall not state that a product does not contain an active ingredient or ingredients used in competitor products other than permitted by the MCC. Advertising shall not use misleading, alarming or improper visuals to represent changes in the human body.

Note 3: Advertising of Schedule 2 health products
Schedule 2 health products may not be advertised to the public however, the use of point of sale advertising materials, such as dummy boxes, gondola ends (without product), may be used within the confines of the pharmacy.

Note 4: Product recommendations by healthcare professionals
It is acceptable to state that a product’s active ingredients, formulations or preparations have been used or prescribed or recommended by a healthcare professional/s, provided that there is evidence that this is the case and that it does not contravene the product’s package insert and condition/s of registration.

Note 5: Type of claims
The following claims are allowed provided there is clinical data to support the statements.

- ‘Fast’ claims: For most indications such as relief of pain, fever, cold and flu symptoms, allergy symptoms, indigestion, travel sickness and sleeplessness, ‘fast’ is currently taken to mean ‘within about 30 minutes’.
- ‘Immediate’ and ‘instant’ claims: In order to claim that a product has an ‘immediate’ or ‘instant’ benefit, advertisers must be able to demonstrate that the product has the advertised effect within 10 seconds.

Clause 26: Information, Claims and Comparisons in Advertising and/or Promotion

Note 1: Information to appear in advertisements
The application of this clause is not limited to information or claims of a medical or scientific nature. It includes, inter alia, information or claims relating to pricing and market share all of which need to be substantiated.

Note 2: The use of the word ‘new’
This includes new formulations, flavours, new pack presentation/sizes and design.

Note 3: Use of the word ‘natural’
Does not preclude that a product contains natural ingredients.
Note 4: 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 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.

Note 5: Speed of absorption claims
All speed of absorption and speed of action claims must be line with the approved package insert. For indications such as pain, fever, ‘fast’ is taken to mean that the product works within about 30 minutes, ‘immediate benefit’ as within 10 seconds, ‘all day relief’ if product works for at least 10 hours and ‘all night relief’ if the product works for at least eight hours.

Note 6: 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.
Clause 28: Suitability and Taste

Note 1:
Care should be taken to avoid causing offense on the grounds of race, religion, sex, sexual orientation or disability. Examples that are unacceptable:

- portrayal of dangerous behaviour such as alcohol drinking and driving
- full nudity
- imagery of an overtly sexual nature
- portrayal of persons in vulnerable situations
- cruelty to animals
- shocking analogies or visual portrayals the consumer may find offensive

Note 2: Sales claims
Sales claim must be based on volume of sales and must be supported by evidence. Bestselling claims must be carefully worded to avoid implying superior efficacy. Examples to be included

Clause 29: Prohibitions or Restricted Representations

Note 1: Use of the term 'serious'
'Serious' in the context of this clause will mean forms of those diseases, conditions, ailments or defects which are:

- generally accepted not to be appropriate to be diagnosed and or treated without consulting a suitably qualified healthcare professional, and/or
- generally accepted to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.

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).

Note 3: Responsible self-medication
The World Health Organisation notes that responsible self-medication can:

- help prevent and treat symptoms and ailments that do not require medical consultation;
- reduce the increasing burden on medical services for the relief of minor ailments, especially when financial and human resources are limited;
- increase the availability of healthcare to populations living in rural or remote areas where access to medical advice may be difficult and
- enable patients to control their own conditions.
Clause 32: Healthcare Professional

Note 1: References to establishments
Reference to a 'college', 'hospital', 'institute', 'laboratory' or similar establishment, may only be made if the establishment is a bona fide establishment as named.

Note 2: References to healthcare professionals
Reference to healthcare professionals in advertisements should refer only to those registered in the country in which they practice.

Clause 36: Relations with the General Public and the Media

Note 1: Requests for information or advice on personal medical matters
This clause prohibits the provision of information or advice on personal medical matters to individual members of the general public requesting it. The intention behind this prohibition is to ensure that companies, organisations or individuals do not intervene in the patient/healthcare professional relationship by offering advice or information that should be in the domain of the healthcare professional. Answering requests by members of the public as to whether a particular health product contains sucrose or some other inactive ingredient, or whether there would be problems associated with drinking alcohol whilst taking the health product or whether the health product should be taken before or after a meal, is acceptable.
The promotion of health products in Schedule 0 or Schedule 1 to the general public for self-medication purposes is permitted.

Clause 37: Promotions, Gifts, Prizes and Inducements

Note 1: Provision of medical and educational goods and services
The provision of medical and educational goods and services which will enhance patient care or benefit the South African health system are acceptable. The provision of such goods and services must not be done in such a way as to be an inducement to prescribe, supply, administer or buy any health product or to recommend its use, prescription or purchase.

Note 2: 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.

Competition 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 healthcare professional; with the same criteria applying – see Guidelines to Clause 19, Note 12.

Note 3: Banded pack for Schedule 0 products
Banded packs are permissible. The packs banded must be the same Schedule 0 products i.e. 2 X Product syrups (Schedule 0).
It is not permissible to band different dosage forms or products e.g. Product X syrup and Product X lozenges or Product X and Product Y.
Banding packs of paracetamol may result in the combined packs exceeding the paracetamol limit for a Schedule 0 and as such would not be permissible.
A giveaway item such as plastic dosage spoons, sponges for Schedule O products should be of nominal value and not mislead the patient or encourage the inappropriate use of the health product, as per the local approved package insert.

No branding of children’s medicines should take place so as to advertise to or encourage the use of medicines by children e.g. a giveaway teddy-bear or toy with an OTC medicine.

**Clause 40: Healthcare sales representatives/Consumer Promoters**

**Note 1: Sales representatives**

FMCG sales representatives, agents, merchandisers and promoters selling or promoting Schedule 0 health products are included in the description of medical representatives.
PART C: MEDICAL DEVICES

Clause 49.2: Evaluations and demonstration

Note 1: Product evaluations should be conducted in accordance with the following general guidelines:
- The provision of equipment for free has to take place within the applicable legislative provisions.
- No payment may be made to the healthcare provider wishing to conduct a product evaluation for their own purposes.
- Reasonable compensation payments may be made to the healthcare provider involved in a product evaluation that has been requested by a company for justifiable medical or scientific reasons - provided that this reasonable compensation relates to the HCP’s resources spent on the evaluation (e.g. personnel costs, lab infrastructure, like electricity/water etc.) and this must be documented in a formal agreement.
- Where an evaluation is conducted and monies exchanged due to the evaluation being part of a clinical trial or registered/approved research project, as per the relevant provisions under the Medicines Act and National Health Act and the regulations thereto, including but not limited to:
  - There must be a written contract
  - Written evaluation results must be provided; and
  - All evaluations must have a finite time period or alternatively a finite number of procedures to be performed.
  - Each evaluation must pursue a scientific and therapeutically relevant aim. Where the evaluation constitutes a research project, an Equipment Evaluation protocol must be drafted and approved by an accredited Ethics Committee before the evaluation commences.
  - It is recommended that appropriate indemnities are in place, even if the evaluation is not a clinical trial or research project.
  - All costs for the duration of the equipment evaluation will be borne by the equipment supplier. This is to be documented, and may be required to be provided as part of regulatory requirements or on receipt of a valid complaint in terms of the Code.
  - Should the evaluation lead to publications, lectures and other presentations the sponsor must be disclosed.
  - 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 technology medical devices and IVDs and subject to the patient providing informed consent for the specific procedure, which includes disclosure of the arrangement between the member company and the HCP on the 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 products under the circumstances.

Note 3: Multiple use/capital equipment:
Multiple use 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 products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation appraisal period and should have a process in place for promptly removing such
multiple use products from the HCPs location at the conclusion of the evaluation appraisal period unless the HCP purchases or leases the products.

**Note 4: Demonstration:**
Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Healthcare Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as “Sample,” “Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

**GENERAL RECOMMENDATIONS:**

**Suggested list of company procedures**
- Travel, hospitality and meals to HCPs
- Charitable donations
- Fee for service with Healthcare Professionals
- Patient organisations support
- Promotional materials review process
- Gifts / promotional items approval
- Medical education events
- Educational grants
- Market research review
- HCP support to congresses
- Congress stands and promotional booths
- Event review process (advisory board, launches etc.)
- Textbooks and subscriptions approval
Appendix 1: Values / limits

Items of general utilities:
Modest: R 300 inclusive of VAT

Items of medical utilities:
For scientific medical reference books / journal and periodical
- individual practicing HCP 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 2 500 (inclusive of VAT)/ practice or institution.

Competition prizes
The maximum per prize in a promotional competition is R 2 000, (inclusive of VAT)/ event or promotional activity.
If the prize is congress sponsorship, it will cover bona fide conference fees, accommodation and travel for the winner only.
PART D: PROVISIONS FOR THE ENFORCEMENT OF THE CODE

The purpose of this guideline is to provide guidance on the procedure to be followed by companies prior to lodging complaints via the MCA, visual representation of processes in Part D.

PROCEDURE FOR COMPLAINTS HANDLING PRIOR TO REFERRAL TO MCA

This procedure outlines the process for the handling of complaints relating to the Marketing Code on a company to company level, prior to referral of the complaint by either the complainant or the respondent to the MCA for adjudication.

BEFORE LODGING A COMPLAINT WITH THE MCA

1. Compliance with the Code is at its most effective when companies develop internal procedures for the development and approval of company activities and materials and ensure operations are based on an explicit risk management strategy. Companies should focus their efforts on good regulatory compliance rather than reliance on the complaints process.

2. When parties are involved in dispute, the complainant and respondent must attempt to resolve the matter prior to lodging a formal complaint with the MCA.

3. The Complainant and Respondent must comply with the following procedure:
   i. The complaint must be conveyed to the respondent (Company Code Compliance Officer to Company Code Compliance Officer or suitable senior company person) in writing, requesting a written response in five working days.
   
   ii. If a response is received and the complaint is resolved, then the complaint will not progress any further. The complaint will be considered as closed. The complainant and respondent must keep all documentation on record.
   
   iii. Should the matter be resolved between the disputing parties, the Executive Officer may* be provided with the names of the companies involved, the infringement with reference to the specific clause(s) in the Code. This information will be confidential and will not be published. It is solely for the records of the EO specific clause(s) in the Code. This information will be confidential and will not be published. It is solely for the records of the EO.

4. If a response is not received or the complaint is not resolved to the satisfaction of both parties, the complaint may progress to the next stage.

5. The complainant may then submit a formal complaint in writing, signed by the person in the company authorized to do so, to the Executive Officer of the MCA.
6. The complaint will only be accepted by the Marketing Code Authority if the Executive Officer is satisfied that the complainant has previously informed the respondent that it proposed to make a formal complaint and offered inter-company dialogue at a senior level in an attempt to resolve the matter, but that this offer was refused or dialogue proved unsuccessful.

7. If no resolution is agreed upon only then may the complainant write to the Executive Officer of the MCA.

8. The Marketing Code Authority shall, in accordance with the MCA Constitution and Code, not adjudicate a complaint without compliance to the above procedure, insofar as that procedure is consistent with the Constitution and Code. In the event of inconsistency, the provisions of the Code and Constitution will be given effect to.

* SAMED members should

Recommended for adoption by the Code Technical Advisory Committee on: 24th November 2014

Adopted by the Board of the Marketing Code Authority on: 3rd February 2015
PROCEDURE FOR LODGING A COMPLAINT WITH THE MCA

Refer to Part D of the Marketing Code (Provision for Enforcement of the Code) and process diagrams below.

**Enforcement Structures**

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<table>
<thead>
<tr>
<th>MCA Enforcement Structures</th>
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<td>Executive Officer</td>
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<tr>
<td>Adjudicating Committee</td>
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<tr>
<td>Appeals Committee</td>
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Simplified Process flow for lodging a complaint

*Ref (Code Clause 54 to 57) for full process*
**Appeal Process**

- **Complain filed to adjudicating committee**
- **Respondent provides reasons for complaint to IO**
- **IO provides reasons to complainant**
- **IO asks another party/respondent that appeal has been lodged & sends copies of adjudicating proceedings**
- **Respondent sends written response to IO**
- **IO provides copy of respondents response to appellant**

**Appeal Hearing**

- **IO to Constitue Appeal Committee**
- **IO to send copies of complaint & response to Appeal Committee & complainant**
- **Appeal Committee to deliberate & make a ruling based on documents**
- **Ruling**
  - Refer matter to appropriate authority or courts, incl legal action
  - Confirm previous sanction
  - Imposed further penalties
  - Any other appropriate sanctions or remedial action, incl Termination of Contract
  - Any other sanctions, incl orders as to costs and fees

*Ref (Code Clause 58 to 60 for full process)*

**Expedited Process**

- **IO to send copies of appeal & compliance to respondents company**
- **Respondent to provide compliance to IO**

*Ref (Code Clauses 23 or 41 violated)*