GUIDELINE TO THE CODE OF MARKETING PRACTICE -13 SEPTEMBER 2013

13/9/2013

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.

(Second edition as adopted at the Board Meeting on 11 July 2013 in Woodmead)

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Contents

First version for implementation	2010
Date for implementation	October 2010
Version 1: Updates proposed by SMASA, PIASA, SAMED, SALDA, Update according to ABPI, and EIPIA, IFPMA, EUCOMED	July 2012
Version 2: Clause 5 Note 2; 15 Note 3; 17 Note 3 and additional notes; 18 Note 12	February 2013
Version 3: Clause 4 Note 4; Clause 5 Note 2; Clause 15 Note 3; Clause 17 Note 3 – additional notes to cross check with IFPMA, note 6 – added definition of international and national event, Clause 18, Note 12; General recommendations	4 March 2013
Version 4: Grammer changes, Clause 17 – alternative wording proposed to Notes	16 April 2013
Version 5: Clause 18 – Note 3 Travel	28 May 2013
Version 6: Clause 15 – Note 3 for Devices only, Clause 36 - Note 3, Combined Guideline to Part A-C and D	3 June 2013

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 international meeting of high scientific standing with 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 country 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 re-imbursement 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

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 list 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.

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 and 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 7.2 which prohibits misleading information claims etc. in promotional material).
Attention is drawn to the provisions of Clause 7.5, 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 17 for more details.

Clause 15: Healthcare Sales Representatives

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 HCP's **only** for:
a. Faculty members presenting at a congress irrespective of day of arrival
b. HCP's 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 HCP's 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.
Programs 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 6 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 HCP's hospital administration (in the case of public sector HCP's / registrars) and as may be the case for HCP's 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 – The selected time of the year will be taken into account in determining if a geographic location is appropriate.

The Conference Venue – 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 reimburse directly for costs incurred directly related to the scientific components of the Conference, 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

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 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 or

healthcare professional. This does not apply to clinical researchers whose activities are controlled under the Good Clinical Practice Guidelines which is 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: Gifts -items of general utility

Items of general utility which have been held to be acceptable gifts 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 gifts should not exceed R300 inclusive of VAT.

Note 8: Gifts - items of medical utility

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

For individual practicing HCP or practices, the value should not exceed R 2 500 inclusive of VAT/year

For 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 / practice or institution.

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: Promotional aids

Some items distributed as promotional aids are intended for use by patients and these are acceptable provided that they meet the requirements of Clause 19.2 and 19.3 i.e. modest (not more than R50 including VAT).

Note 11: Items for patients

Other 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.

Note 12: 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 practice of medicine and pharmacy. 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, including 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 13: 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

Clause 20.6 Relations with the General Public and Media

Note 1: Advertising of health products to the general public
The advertising of S2 and above health products to the general public is prohibited by regulations under the Act. The promotion of health products in S0 or S1 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 S 2 and prescription-only health product are promotional in nature and are unacceptable. Competitions for S0 and S1 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 S2 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 20.6. The provisions of Clause 20.6 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 20.7 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.

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 24: Advertising and/or Promotional Material

Note 1: Children
For the purpose of the Code a child is someone under the age of twelve 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
S2 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 25: 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 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.

Clause 27: 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 supported by evidence. Bestselling claims must be carefully worded to avoid implying superior efficacy.

Clause 28: 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 not 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.

Note 4: 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 5: References to healthcare professionals

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

Clause 35: 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 S0 or S1 to the general public for self-medication purposes is permitted.

Clause 36: 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 (including VAT); and each individual prize may not exceed R5 000 (including 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 healthcare professional; with the same criteria applying – see Guidelines to Clause 18, Note 12**.**

Note 3: Banded pack for S0 products

Banded packs are permissible. The packs banded must be the same Schedule 0 products i.e. 2 X Product syrups (S0).

It is not permissible to band different dosage forms or products eg 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 SO 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 39: Healthcare sales representatives/Consumer Promoters

Note 1: Sales representatives

FMCG sales representatives, agents, merchandisers and promoters selling or promoting S0 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 IVD's 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 IVD's 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 HPCSA Ethical Rules.

The following specific guidelines apply in the specific situations outlined below:

- 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 of the products under the circumstances.
- Multiple Use/Capital Equipment: Multiple use products / Capital Equipment provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation 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 period unless the HCP purchases or leases the products.

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 Healthcare Professional' location at the conclusion of the evaluation appraisal period unless the HCP Healthcare Professional 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 Health Care 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 HCP
- Charitable donations
- Fee for service with health care 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

PART D: ENFORCEMENT

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 EO 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**

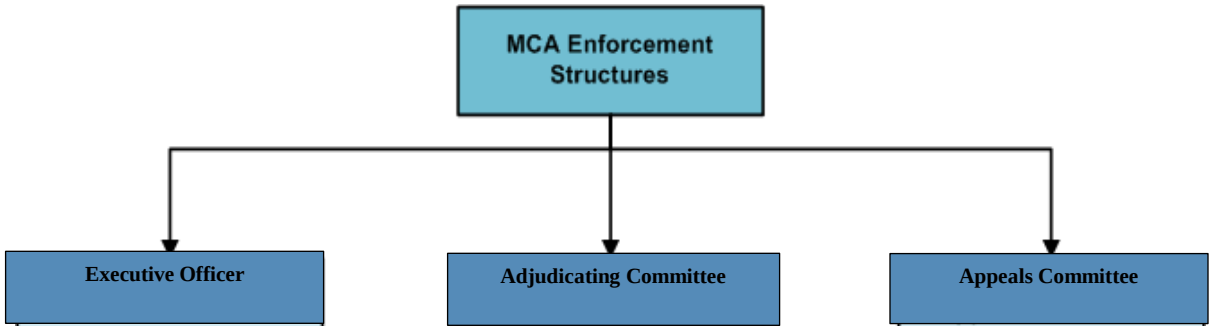
Recommended for adoption by the Code Technical Advisory Committee on: 9 July 2013

Adopted by the Board of the Marketing Code Authority on: 11 July 2013

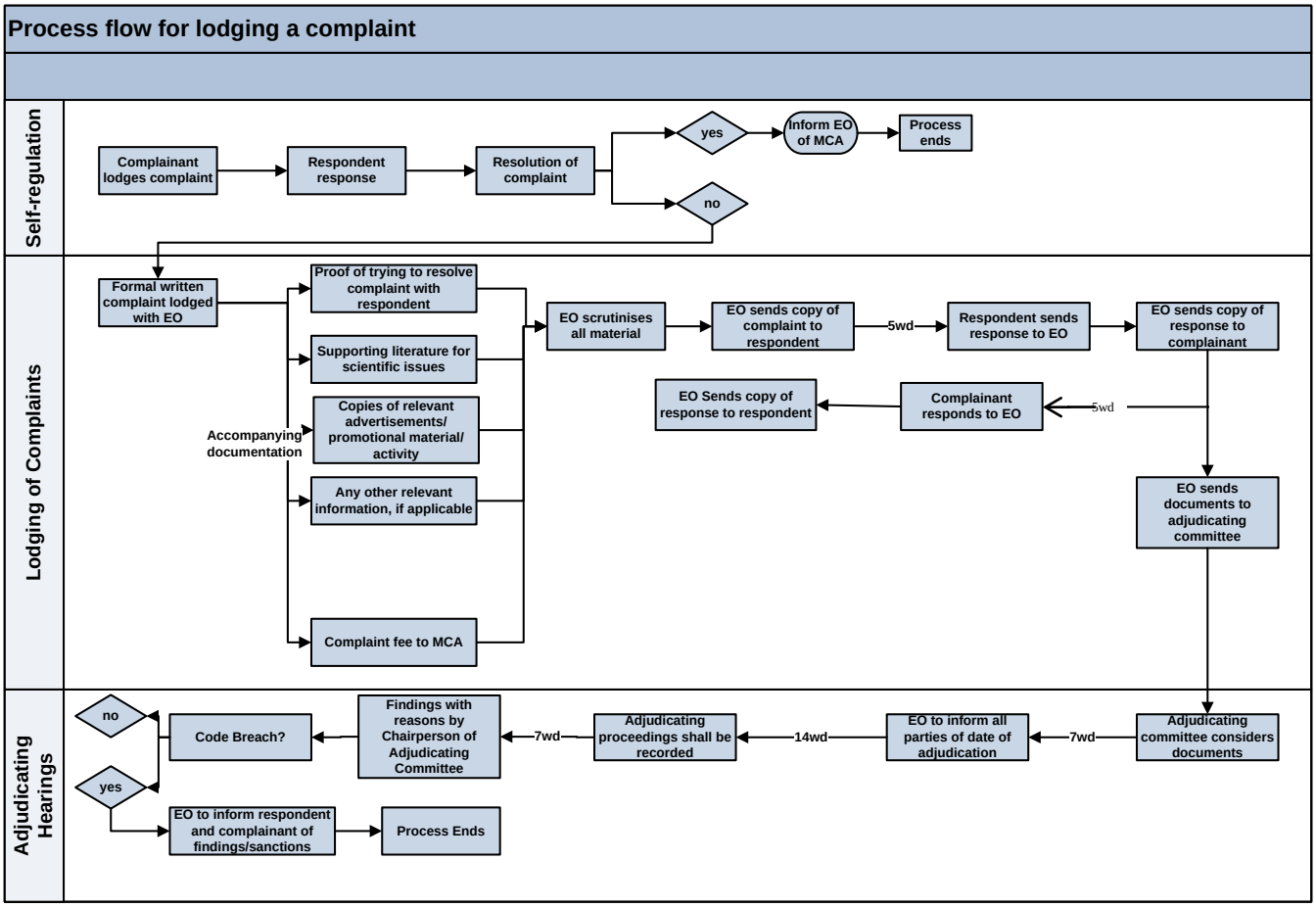
PROCEDURE FOR LODGING A COMPLAINT WITH THE MCA

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

Enforcement Structures

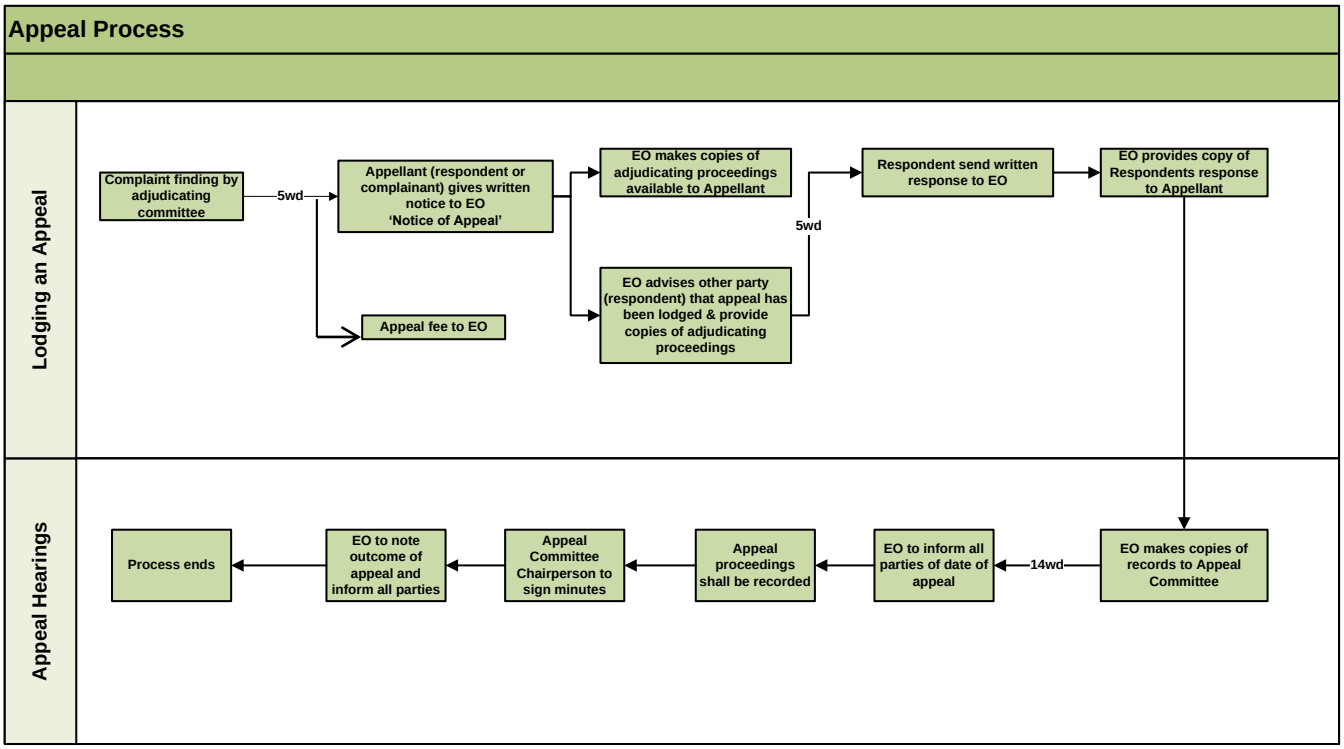


Simplified Process flow for lodging a complaint



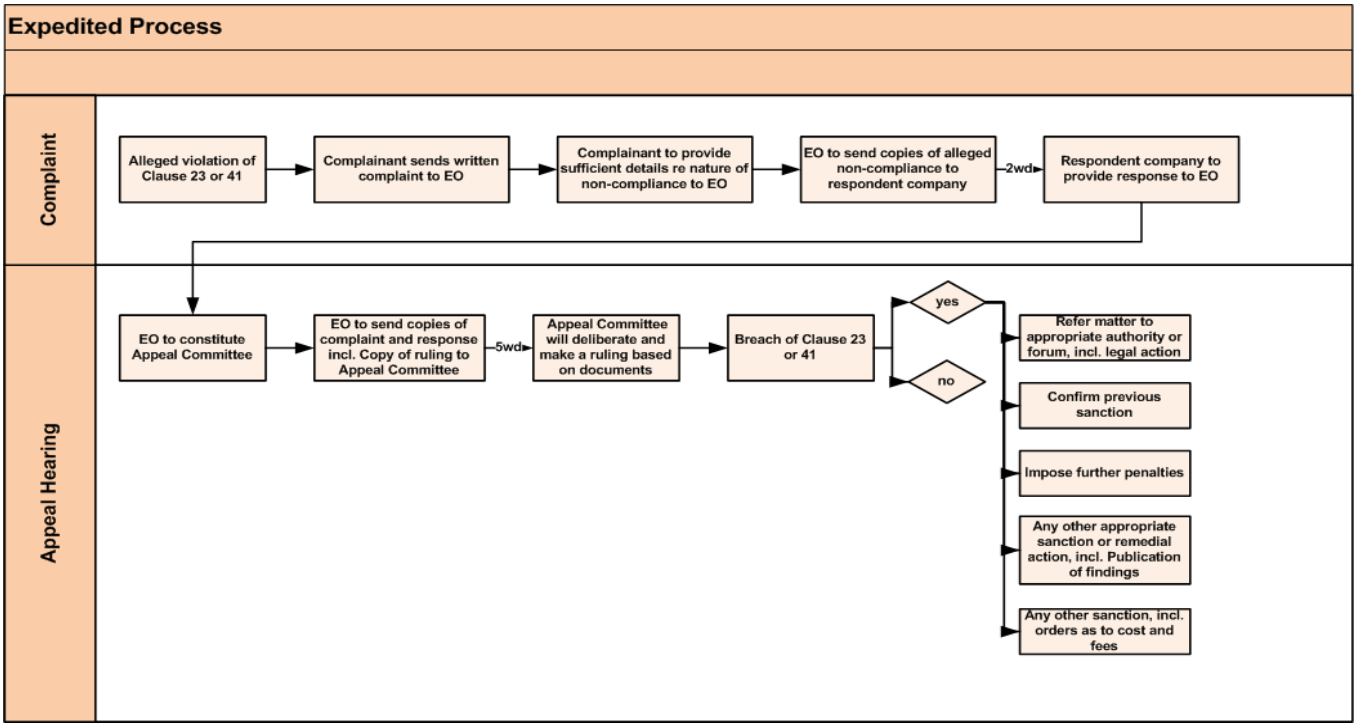
*Ref (Code Clause 54 to 57) for full process

Simplified Appeal Process



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

Expedited Process (Clauses 23 or 41 violated)



*Ref (Code Clauses 23 or 41 violated)