SA CODE OF PRACTICE FOR THE MARKETING OF HEALTH PRODUCTS

October 2010
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SA CODE OF PRACTICE FOR THE MARKETING OF HEALTH PRODUCTS

1. PREAMBLE

WHEREAS

1.1 Section 18C of the Medicines Act 101 of 1965 ("the Act") empowers the Minister, after consultation with the pharmaceutical industry and other stakeholders, to make regulations relating to the marketing of health products, including an enforceable Code of Practice;

1.2 the companies in the healthcare industry have agreed to subscribe to a code of practice for the marketing of health products in South Africa based on the principle of self regulation as set out in this Code;

1.3 the enforcement of the Code will be entrusted to a MARKETING CODE AUTHORITY ("MCA") as herein provided.

2. INTRODUCTION TO-, APPLICATION AND INTERPRETATION OF THE CODE

2.1 Introduction

The ethical promotion of health products is vital in helping to ensure that healthcare professionals and the public have access to the information they need, that patients have access to the health products they need and that health products are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

All marketers of health products should maintain high ethical standards when conducting promotional activities and must comply with applicable legal, regulatory and professional requirements. Compliance with the Code will ensure that ethical promotional practices are established for all marketers, prescribers, dispensers, advisers and users of health products. The overarching philosophy is a principle of compliance with the spirit of the Code.

The “Code of Practice for the Marketing of Health products in South Africa” is referred to throughout as “the Code”.

The National Department of Health, the pharmaceutical industry and other stakeholders are committed to the provision of affordable and quality healthcare for all South Africans. High quality, effective and accessible health products are a cornerstone of healthcare. Accurate information about health products is integral to providing quality healthcare services.

This Code is issued in terms of section 18C of the Medicines and Related Substances Act No 101 of 1965, as amended, and is adopted by health products trade associations to signify the industry’s commitment to ensure that the marketing of health products to healthcare professionals and the public is carried out in a responsible, ethical and professional manner, based on practical and scientifically validated information.

The health products industry is committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the rational use of health products and fair competition in the marketing thereof. The industry seeks to preserve the independence of the decisions taken by healthcare professionals. The industry has an obligation...
and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of health products. Industry relationships with healthcare professionals must support, and be consistent with the professional responsibilities healthcare professionals have towards their patients.

This Code takes cognisance of other professional and industry codes applicable to the health products sector and professions with which the sector interacts.

2.2 Application of the Code

2.2.1 The Code is applicable to the following organisations and situations:

2.2.1.1 All registered health products licence holders, their agents, contractors, third party distributors/marketers and/or contracted events organisations. Companies that circumvent the Code by engaging or using other companies, agents, contractors or dispensing system software vendors or ordering systems will be infringing the Code.

2.2.1.2 All advertising and/or promotion and promotional activities and communication directed at influencing any member of the medical, dental, pharmacy, nursing or allied health professions or any seller of health products who in the course of his or her professional or other activities may prescribe, purchase, supply, administer, loan or lease a health product or recommend the use thereof.

2.2.1.3 All advertising and/or promotional material, which is directed to members of the public to inform the general public about the health products available for self medication.

2.2.1.4 All advertising and/or promotion and all activities directly or indirectly related to marketing which may reflect on the marketing practices of the industry, including but not limited to sponsorships, patient information-sharing, meetings and entertainment.

2.2.1.5 Interactions between the industry and healthcare professionals (Part A) and the industry and the general public (Part B).

2.2.2 The Code does not apply to the following situations:

2.2.2.1 Factual, accurate, informative announcements and reference material concerning registered health products and relating, for example, to adverse reactions and warnings.

2.2.2.2 The following documents are not covered by the Code:

2.2.2.2.1 Trade catalogues to suppliers including price lists.
2.2.2.2 Product labels, packaging materials and in-pack leaflets. These are subject to the labelling and package insert requirements in terms of the Regulations to the Medicines Act and the Guidelines pertaining thereto.

2.2.2.3 The marketing or promotion of complementary medicines and Stock Remedies as defined under Act 36 of 1947.

2.2.2.4 Issues relating to pricing, bonusing and perverse incentives governed elsewhere in legislation and in codes issued in terms of the Medicines Act, National Health Act No 61 of 2003, etc.

2.2.2.5 The Code is not applicable to wholesalers, distributors (excluding distributors of medical devices) and logistics companies except to the extent that they may influence the demand for health products.

2.3 Interpretation of the Code

2.3.1 The provisions in this Code should be interpreted in light of both the letter and spirit of the Code. Guidance notes, issued from time to time by the MCA will provide companies with an indication as to how the Code should be applied and adhered to, in practical terms. The rulings of the bodies established as part of the Marketing Code Authority, forms precedent on what constitutes acceptable practices in the marketing of health products.

2.3.2 The Code should not be construed to be in conflict with any existing law applicable to the marketing of Medicine, including but not limited to the Medicines Act, the Patents Act No 57 of 1978, the Copyright Act No 98 of 1978, the Trade Marks Act No 194 of 1993 and the National Health Act No 61 of 2003.

2.3.3 Any interpretation of the provisions of this Code as well as interaction with healthcare professionals not specifically addressed in this Code should be made in light of the following principle:

“Companies shall adhere to ethical business practices and socially responsible industry conduct and shall not use any unlawful or any unethical inducement or reward, including but not limited to those financial or material in nature, in order to sell, loan, lease, recommend or arrange for the sale, loan, lease or prescription of their products.”

2.3.4 In any review of advertising and/or promotional material or promotional activities covered by this Code, consideration will be given not only to the impression created by a careful study of an advertisement or activity, but also to the impression likely to be gained from a brief or partial exposure.

2.4 Status of the guidelines to the Code

2.4.1 Guidelines on the interpretation of the Code appear as supplementary information to the text in separate documents. The examples given are intended to illustrate and clarify the meaning of
the Code. They are not exhaustive and do not cover all possible situations to be covered by the provisions of the Code.

2.4.2 These guidelines will be updated regularly by the MCA, as part of its mandate to ensure education, application and enforcement of the Code. These guidelines will also be used to regularly update applicable monetary values and examples of conduct that constitutes violations of the Code.

2.5 Scope of application

2.5.1 PART A - The marketing and promotion of health products to healthcare professionals

PART A of the Code applies to the promotion of all health products to members of the healthcare professions, and to appropriate administrative staff by the industry or by other health professions such as those involved in managed healthcare or medical schemes, regardless of the scheduling status of the medicine.

It includes the marketing and promotion of self-medication products to healthcare professionals when such promotion is aimed at generating prescriptions or recommendations to patients.

Advertising and/or promotion of medicines in Schedules 0 and 1 to the general public is permitted but advertising and/or promotion of medicines in Schedules 2 to 6 to the general public is not allowed under the Medicines Act and Regulations. Therefore the provisions of PART A apply to all medicines (including Schedules 0 and 1) marketed to healthcare professionals, irrespective of the scheduling.

PART A is applicable to medical devices and IVD’s unless otherwise specified in PART C

2.5.2 PART B - The marketing and promotion of health products directly to the consumer

The advertising and/or promotion of medicines in Schedules 0 and 1, to the general public is permitted by law. The main purpose of the Code is to help ensure that advertising and/or promotion of self-medication medicines complies with applicable codes and laws. The Code is applied in spirit as well as in principle.

The scope of PART B relates to all self-medication (Schedules 0 and 1) medicines registered or sold in terms of the Medicines Act. PART B of the Code applies to advertising materials and promotional activities for medicines, as defined by the Medicines Act, which are aimed at the general public and persons who may legitimately purchase medicines on behalf of other consumers (e.g. parents, who purchase health products on behalf of their children). The provisions of PART B of the Code do not apply to advertising and/or promotion aimed at healthcare professionals, i.e. the advertisement of Schedules 0 and 1 medicines to professionals has to comply with the provisions of PART A of the Code.

The provisions in PART B have to be seen in the light of the exemption for Schedule 0 medicines from the provisions of section 18A to the Medicines Act.
PART B is applicable to medical devices and IVD’s unless otherwise specified in PART C”.

2.5.3  PART C - The marketing and promotion of medical devices.

2.6  PART D – PROVISION FOR ENFORCEMENT

2.6.1  The Code is based on the principle of self regulation of the industry through a procedure for handling complaints which is in line with international standards and practice, but made binding through the legislative recognition of the self-regulatory and subsequent processes which may include the medicines regulatory authority.

2.6.2  The process of enforcement and the relevant bodies responsible for such enforcement are set out in Part D of this Code.

2.6.3  The MCA has the power to refer issues not within the scope and ambit of this Code to the appropriate authorities, councils or bodies with the authority to deal with such issues.

2.6.4  The MCA has the power to outsource any of its enforcement functions in terms of the provisions set out in Part D of this Code and/or to align its administration with that of other Codes in force in the healthcare sector at any point in time.

2.7  Glossary

In this Code, 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.

The following additional definitions are provided to guide the interpretation of this Code:

2.7.1.  Advertisement includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

2.7.1 Advertising and/or promotion and promotional materials or activities, include, but are not limited to advertorials; branded materials relating to product sponsorship; aerial promotions such as on hot air balloons and/or blimps; booklets; cinema commercials; consumer leaflets; consumer broadsheets; direct mail materials; website and other Internet materials, including press releases intended for internet publication; on-pack statements; outdoor advertising; point of sale materials; posters; print advertisements (for use in newspapers, magazines, etc.); promotional aids including those used for direct selling activities; promotional scripts for use by telephone help lines; promotional text messages; consumer promoters; telephone help lines; television and radio/audio commercials; sports, art and other sponsorships; airport, washroom, shopping centre advertising and/or promotion; touch screen advertising; aisle, ceiling, floor advertising and other signs; counter top advertising; window displays; gondola end advertising; bunting; advertising on electronic ordering systems; bus, taxi and other vehicle advertising; and light box advertising.

2.7.2  Company means a company, closed corporation, organisation, firm, vendor or individual who may sell or promote health products.
2.7.3 Company Code Compliance Officer means anyone duly authorised by the company, or appointed by the company in writing, to sign documents or give instructions on behalf of the company.

2.7.4 Electronic journals mean electronic versions of journals that can be viewed online via any personal computer or other electronic device.

2.7.5 Health Care Professional (HCP) includes Healthcare Professional and Healthcare Facilities and includes, but is not limited to persons registered with the Health Professions Council of South Africa (HPCSA), South African Veterinary Council; Allied Health Professions Council, the Nursing Council, the Pharmacy Council, the Engineering Council for Clinical Engineers and includes institutions registered at the Department of Health or other regulatory or organisational body, such as a health facility (which includes hospitals, step-down facilities, etc), managed care companies, etc; which entities purchase, lease, recommend, use, maintain or arrange for the purchase or lease of, members’ medical technology products in South Africa.

2.7.6 Honorarium means a payment or an award granted in recognition of a special service by a professional person. Honoraria can be paid at fair market value for speeches, articles, appearances or other services rendered in terms of a written agreement, which may be subject to scrutiny by the MCA should such honorarium be the subject of a complaint in terms of the Code.

2.7.7 For medical devices:

2.7.8 Label means a display of printed information
- on or attached to the goods; or
- on or attached to a container or primary pack in which the goods are supplied; or

2.7.9 supplied with such a container or pack

2.7.10 Medicines Act (i.e. Medicines and Related Substances Act No 101 of 1965 as amended) means the body of legislation governing the registration and marketing of medicine, as amended from time to time and includes any future legislation that amends or repeals and replaces the Medicines Act.

2.7.11 Medical technology’, “Medical devices”, “Health Technology” refers to medical devices as defined in the Medicines and Related Substances Amendment Act, 2008, and include in-vitro diagnostics

2.7.12 Promotional item means merchandise given away free of charge in an effort to create awareness of a company or product.

2.7.13 Minimum Requirements means the legislated requirements for written advertisements as stated in Regulations to the Medicines Act.

3. OBJECTIVES OF THE MCA

The objectives of the MCA shall be:
3.1 to ensure and maintain the ethical promotion and advertising of health products by all parties and entities, including companies and their employees and agents as described in clause 2.2 and who are or may be subject to the Act (hereinafter referred to as the “Companies” and the company);

3.2 to ensure that those bound by the Code maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements.

3.3 to adjudicate on complaints and disputes in terms of the Code.
PART A --- MARKETING AND PROMOTION OF HEALTH PRODUCTS TO HEALTHCARE PROFESSIONALS

4. REGISTRATION STATUS OF MEDICINES
A medicine must not be advertised or promoted:

4.1 prior to the product being registered by the medicines regulatory authority or
4.2 unless an application has been submitted in terms of Section 14(3) of the Medicines Act (“old medicine”), which permits its sale, supply and use in South Africa.

The promotion of a medicine must be in accordance with the terms of its registration, and must not be inconsistent with the particulars listed in its package insert.

5. ADVERTISING AND PROMOTION MATERIAL OF MEDICINES
5.1 All advertising and/or promotional material must be based on the current approved South African package insert.

5.2 The minimum requirements must:
5.2.1 Conform with the applicable regulations in terms of the Medicines Act.
5.2.2 Form part of the promotional material and not be separate.
5.2.3 Be included in all promotional material (except for promotional items - see Clause 18.3).
5.2.4 Be provided in a clear and legible manner.
5.2.5 Be consistent with the most recently approved package insert for the medicine.

5.3 In all forms of advertising and/or promotion i.e. written, audio, audio-visual, internet, the statement “For full prescribing information refer to the package insert approved by the medicines regulatory authority” should appear or be stated. This does not apply to promotional items as referred to in Clause 18.3.

5.4 In the case of an advertisement included as part of independently produced information on the internet, the statement should be in the form of a direct link between the first page of the advertisement and the minimum information.

5.5 In the case of printed promotional material consisting of more than two pages, the minimum information can appear either on the first or last page.

5.6 Promotional material other than advertisements appearing in professional publications must include the date or a code number identifying the version on which the promotional material was drawn up or last revised.

5.7 Audio-visual or audio material such as films, video recordings, sound bites, interactive data systems and such like:
5.7.1 The minimum information must be provided either by way of a document that is made available to all persons to whom the
material is shown or sent, or by inclusion on the audio-visual recording or in the interactive data system itself in line with the general provisions in Clause 5.2.

5.7.2 When the minimum information is included in an interactive data system, instructions for accessing it must be clearly displayed.

5.7.3 If the material consists of sound only, the minimum information may be provided by the way of a document that is made available to all persons to whom the material is played or sent.

6. JOURNAL ADVERTISING
6.1 An advertisement which contains two or more pages must not be false or misleading when each page is read in isolation.

6.2 An advertisement taking the form of a loose insert in a journal may not be of a size larger than the page size of the journal itself.

6.3 Advertisements in journals must not resemble editorial matter unless clearly identified as advertorial or as a sponsored feature.

6.4 In the case of a journal advertisement where the prescribing information appears overleaf, a reference to where it can be found must appear in a type size which is legible at either the beginning or the end of the advertisement.

7. INFORMATION, CLAIMS AND COMPARISONS
7.1 Accuracy, balance, fairness of claims.
Information, claims and comparisons whether in advertisements, promotional items, product detailing and all information relating to health products, whether verbal or in writing, must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence, and must reflect that evidence clearly. Such information or the manner in which it is portrayed, must not mislead either directly or by implication by distortion or undue emphasis. Material must be sufficiently complete to enable the recipients to form their own opinion of the therapeutic value of the health product.

Any information, claim or comparison must be capable of substantiation. No substantiation is required for claims in the package insert which has been approved by the medicines regulatory authority.

7.2 Exaggerated or misleading claims
Promotion material must encourage the rational use of health product by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a health product. Claims should not imply that a medicine, active ingredient or health product has some special merit, quality or property unless this can be substantiated.

7.3 Comparisons
A comparison in the marketing and promotion of health products is only permitted in promotional material if:

7.3.1 It is not misleading or disparaging.
7.3.2 Health products or services for the same needs or intended for the same purpose are compared.

7.3.3 One or more material, relevant and representative features which is capable of substantiation is compared.

7.3.4 No confusion is created between the health product advertised and that of a competitor or between the advertisers’ trademarks, proprietary names, other distinguishing marks and those of a competitor.

7.3.5 The trademarks, proprietary names, other distinguishing marks, health products, services, activities or circumstances of a competitor are not discredited or denigrated.

7.3.6 Trademarks/trade names or company names of another company may only be mentioned with written permission from the other company.

7.3.7 No unfair advantage is taken of the reputation of a brand, trademark, proprietary name or other distinguishing marks of another company.

7.3.8 Health products or services are not presented as imitations or replicas of goods or services bearing another company trademark or trade name.

7.3.9 Hanging (open ended) comparisons are not allowed.

7.4 Substantiation

Substantiation for any information, claim or comparison must be provided without delay at the request of members of the health professions or appropriate administrative staff. It need not be provided in relation to the validity of a health products regulatory authority approved indication(s) in the package insert.

7.5 References

When promotional material refers to published studies, clear and complete references must be given.

7.6 Unpublished supporting data

When promotional material refers to (unpublished) data on file, the relevant part of this data must be provided without delay at the request of members of the health professions or appropriate administrative staff.

If confidential information, such as information relating to trade secrets, sensitive commercial information or information of a competitive nature is involved, the material may be given to an independent arbitrator acceptable to both parties or a person appointed by the MCA from its Adjudication Panel for assessment, in the case of a dispute. The arbitrator or person appointed by the MCA will make an assessment as to whether the unpublished data in fact support the statement(s) made in the promotional material.

7.7 Artwork

All artwork, including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters
with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.

7.8 Use of the word ‘safe’

The word ‘safe’ or words containing references to safety must not be stated in such a way as to imply that a product has no side effects, toxic hazards or risk of addiction. The word ‘safe’ must not be used without scientific qualification and substantiation.

7.9 Use of the word ‘new’

The word ‘new’ must not be used to describe any product or presentation, which has been generally available or any therapeutic indication, which has been available for more than twelve months in South Africa.

7.10 Other claims

It must not be stated that a product has no side-effects, toxic hazards or risk of addiction or dependency.

8. DISPARAGING REFERENCES

8.1 The health products, products and activities of other companies, including manufacturers of generic health products, must not be disparaged in any way, including:

8.1.1 safety, quality and efficacy;
8.1.2 the effectiveness of the official registration process by which the product obtained market authorisation;
8.1.3 disparaging references relating in general terms to generic or originator health products.

8.2 The health professions and the clinical and scientific opinions of their members must not be disparaged.

9. HIGH STANDARDS, FORMAT, SUITABILITY AND ENDORSEMENT BY HCP’S

9.1 All materials and activities must recognise the special nature of health products, and the professional standing of the audience to which they are directed and must not be likely to cause offence. High standards must be maintained at all times.

9.2 The name or photograph or film of a member of a health profession must not be used in any way that is contrary to the applicable professional codes for that profession and all endorsements, where permitted by professional codes, have to be done within the scope of such codes.

9.3 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

9.4 Promotional material must not include any reference to the medicines regulatory authority unless this is specifically required by the medicines regulatory authority, through the applicable legislative and other provisions. This provision does not preclude references to important medicines regulatory authority Guidelines and Policies, such as those on the reporting of adverse events, which serves as important regulatory frameworks for the utilisation of medicines.
9.5 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.

9.6 The telephone, SMS, e-mail, telex or facsimile machines must not be used for promotional purposes, except where, when first contact is made, the option to opt out is given and the decision is subsequently respected. The option to opt out should also be provided on all subsequent communications, even if the addressee has not opted out after the first contact.

9.7 All material relating to health products and their uses, which is sponsored by a company, must clearly indicate the details of the company that sponsored it. The only exception to this clause is market research material that need not reveal the name of the company involved but must state that a company sponsors it.

9.8 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which may be regarded as advertising and/or promotion to the general public contrary to relevant legislation.

10. DISGUISED PROMOTION

10.1 Promotional material and activities must not be disguised.

10.2 Market research activities, post-marketing surveillance studies, post-authorisation studies, clinical trials and the like must not be disguised promotion, nor contain or lead to disparaging comments about competitors or their products. Such trials/studies must be conducted with a primarily scientific or educational purpose. Material relating to health products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.

10.3 Clinical trials should not be undertaken for the purpose of promotion of health products intended for administration to human beings.

10.4 Observational/Non-interventional studies of registered medicines are studies where the medicinal product(s) is(are) prescribed in the usual manner in accordance with the approved medicines regulatory authority package insert. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data. This clause is not applicable to veterinary medicines.

10.5 Observational/Non-interventional studies involving health products that are intended for administration to humans, that are prospective in nature and that involve the collection of patient’s data from or on behalf of an individual, or groups of healthcare professionals specifically for the study must comply with all of the following criteria:

10.5.1 The study is conducted with a scientific purpose and there must be:

10.5.1.1 a written study plan (protocol) and

10.5.1.2 written contracts between healthcare professionals and/or the institutions at which the study will take place, on the one hand, and the company sponsoring
the study on the other hand, which specify the nature of the services to be provided and, subject to what is stated below, the basis for payment of those services.

10.5.2 Remuneration provided must be reasonable and of fair market value to the work performed.

10.5.3 The study protocol must be submitted to the appropriate ethics committee for review.

10.5.4 Personal data privacy including the collection and use of personal data must be respected.

10.5.5 The study must not constitute an inducement to participate, recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.

10.5.6 The study protocol must be approved by the company’s scientific/medical department, who must also supervise the conduct of the study.

10.5.7 The study results must be analysed by or on behalf of the contracting company and summaries thereof must be made available within a reasonable period of time to the company’s scientific service, which service shall maintain records of such reports for a reasonable period of time. The company should send the summary report to all healthcare professionals that participated in the study and should make the summary report available to the MCA upon request. If the study shows results that are important for the assessment of benefit-risk, the summary report should be immediately forwarded to the medicine regulatory authority. In addition, companies are encouraged to publicly disclose the summary details and results of non-interventional studies in a manner that is consistent with the parallel obligations with respect to clinical trials.

10.5.8 Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company’s scientific service that will also ensure that the Medical Sales Representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product or used as a pretext to obtain access to the healthcare professional for any purpose.

10.6 Material issued by companies that relates to health products but which is not intended as promotional material for those health products per se, for example corporate advertising, press releases, market research material, financial information to inform shareholders, the stock exchange, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.

11. PROVISION OF REPRINTS AND THE USE OF QUOTATIONS

11.1 Reprints of articles in journals must not be provided unsolicited to any healthcare professional unless the articles have been published in a peer reviewed publication in line with good principles of scientific review and publication. When providing a reprint of an article about a health product, it should be accompanied by prescribing information. If a non-peer-reviewed
article is requested by a healthcare professional, a copy may be provided on
written request.

11.2 Quotations from medical and scientific literature must accurately reflect the
intention and meaning of the author(s). If unpublished, “personal
communications” shall not be used unless the company, organisation or
individual is able to supply written substantiation based on scientific data
upon request.

11.3 Quotations taken from public broadcasts, for example radio, television or the
Internet, and from private occasions, such as medical conferences or
symposia relating to health products, must not be used without the formal
permission of the speaker unless there is a published record of the
proceedings and this is accurately given as a reference.

11.4 Utmost care must be taken to avoid ascribing claims or views to authors
when these no longer represent the current views of the authors concerned.

11.5 The provision of articles and the use of quotations are also subject to the
provisions of Clause 8.

12. DISTRIBUTION OF PROMOTIONAL MATERIAL

12.1 Promotional material should only be sent or distributed to those categories of
persons whose need for, or interest in, the particular information can
reasonably be assumed.

12.2 A company that is requested by an addressee to cease or limit the volume of
promotional material should respect the wishes of the addressee.

12.3 Mailing lists must be kept up-to-date. Requests from healthcare
professionals to be removed from promotional mailing lists must be complied
with promptly and no name may be restored except at their request or with
their permission.

Note: For medical devices refer to Part C: Sales and Marketing Programs

13. SCIENTIFIC INFORMATION SERVICE

Every company must compile and collate information about the health products they
market, and must be able to provide such information to authorities, members of
healthcare professions or the general public, where appropriate. This may include
information about adverse events.

14. CERTIFICATION OF PROMOTIONAL MATERIALS, MEETINGS AND OTHER
ACTIVITIES

14.1 Appointment of person(s) responsible as Company Code Compliance Officer
for approval of promotional material, meetings or activities.

14.1.1 Promotional material and activities must not be approved nor
issued unless its final form, to which no subsequent amendments
will be made, has been certified by an individual on behalf of the
company i.e. the Company Code Compliance Officer. Company
Marketing Personnel and Medical Sales Representatives must
ensure they obtain the necessary approval from the Company Code
Compliance Officer prior to placing adverts in any publications and/or forums.

14.1.2 The appointed Company Code Compliance Officer should either be the responsible pharmacist and/or a natural person responsible for the enforcement and compliance with the Act.

14.1.3 Each company or individual should have a Standard Operating Procedure (SOP) for the approval process. The SOP and documentation must be available for auditing by the Marketing Code Authority or the medicines regulatory authority according to the medicines regulatory authority’s auditing requirements.

14.1.4 Activities which would be subject to certification include, but are not limited to, Continued Professional Development (CPD) or similar professionally-required educational events, the presentation of scientific or promotional material, journal club meetings organised and/or sponsored by the company, the use of observational/non-interventional studies for promotional purposes, etc.

14.1.5 Meetings that fall within the ordinary scope of the day-to-day activities of company Healthcare Sales Representatives, and/or where the events, parts of the event, a speaker or an attendee is not sponsored by the company, are not subject to certification.

14.2 The Certificate

The Certificate must state that the Company Code Compliance Officer has examined the final form of the material or arrangements for an event and that it is in accordance with the requirements of the relevant advertising and/or promotional regulations and this Code, is not inconsistent with the product registration and the package insert and is a fair and truthful presentation of the facts about the medicine.

14.3 Recertification of promotional material

Promotional material that is still in use must be re-certified at intervals of no longer than two years to ensure that it continues to conform to the relevant regulations and the Code.

14.4 Retention of documentation

14.4.1 Companies, organisations or individuals shall preserve all certificates and the relevant accompanying information for not less than five years after the final use of the promotional material or the date of the meeting and produce them on request from the MCA or the medicines regulatory authority.

14.4.2 In relation to certificates for promotional material, the material must be preserved in the form certified with information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination. It is, however, in the interest of storage space, acceptable to store accurate photographic or other electronic representations of material, information or items.

14.4.3 All documents/material relating to marketing and promotion, including the agenda for the event, irrespective of the nature of the campaign or event, have to be retained for the minimum period.
15. HEALTHCARE SALES REPRESENTATIVES

15.1 Training of Healthcare Sales Representatives

Each company shall ensure that its Healthcare Sales Representatives, including personnel retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of healthcare products (each, a “Healthcare Sales Representative”) are familiar with the relevant requirements and all applicable laws and regulations related to the promotion and advertising, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the healthcare products they promote or services offered.

15.2 Compliance with codes and laws by Healthcare Sales Representatives

Healthcare Sales Representatives must comply with all relevant requirements of the applicable professional and good practices codes and all applicable laws and regulations, and companies are responsible for ensuring their compliance.

15.3 Gaining interviews

Healthcare Sales Representatives must not employ any inducement or subterfuge to gain an interview. No fee should be paid or offered for the granting of an interview. Donations to charities in return for Healthcare Sales Representatives gaining interviews are prohibited. Offering or making donations in lieu of hospitality are unacceptable. In an interview, or when seeking an appointment for one, Healthcare Sales Representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or the company that they represent.

15.4 Organising meetings

Healthcare Sales Representatives organising meetings are permitted to provide appropriate hospitality and/or to meet any reasonable, actual costs, which may have been incurred. All meetings have to conform with the provisions of Clause 17 (Interaction with Health Care Professionals).

15.5 Consideration for healthcare professionals and others

Healthcare Sales Representatives must ensure that the frequency, timing and duration of calls on healthcare professionals, pharmacies, hospitals, other healthcare facilities, medical schemes or funders and the like, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom Healthcare Sales Representatives wish to call, and the arrangements in force at any particular establishment, must be observed.

15.6 Information to scientific service of company

Healthcare Sales Representatives must transmit to the scientific service of their companies (Clause 13) any information that they receive in relation to the use of the health products that they promote, particularly reports of adverse events.

15.7 Information to be provided to healthcare professionals
When Healthcare Sales Representatives introduce a medicine to a healthcare professional for the first time, they should provide a copy of the latest medicines regulatory authority approved package insert. On subsequent occasions, such information should be available on request.

15.8 Follow up on requests for information

If discussion on a medicine is initiated by the person or persons on whom a Healthcare Sales Representative calls, the medical representative should make available the information on that medicine referred to in Clause 15.7, as soon as possible after the request.

15.9 Detailed briefing materials

Companies may prepare detailed briefing material for Healthcare Sales Representatives on the technical aspects of each healthcare product that they will promote. Briefing material must comply with the relevant requirements of the Code and must be approved by the Company Code Compliance Officer in the company, where applicable.

15.10 Company responsibility for Healthcare Sales Representatives

Companies are responsible for ensuring that the activities of their Healthcare Representatives comply with the Code and all applicable laws and regulations.

15.11 Healthcare Sales representatives in an Operating Room or Clinical Environment.

Healthcare Sales representative must be appropriately trained on operating room / clinical environment protocol(s).

16. TRAINING

All personnel, including members of staff concerned in any way with the preparation or approval of promotional material or of information to be provided to members of South African health professions and to appropriate administrative staff or of information to be provided to the public, must be fully conversant with the requirements of the Code.

17. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

17.1 Hospitality/Venues of meetings and events

Companies, organisations or individuals are permitted to organise or sponsor meetings and events including Continuing Professional Development (CPD). The following should be adhered to:

17.1.1 The merit and focus of the meeting should be clearly scientific and/or educational.

17.1.2 The venue and hospitality should be secondary to the meeting both in time allocation and focus.

17.1.3 The venue should be appropriate and conducive to the scientific or educational objectives and the purpose of the event or meeting.

17.1.4 Hospitality, meals and entertainment should be modest. As a general rule, hospitality must not exceed what the healthcare professionals would normally be prepared to pay for themselves.
17.1.5 Invitations should not be extended to spouses or other guests except if they are healthcare professionals or administrative staff i.e. any costs incurred by spouses or other guests cannot be reimbursed or paid for by the company.

17.1.6 Inappropriate financial benefit or material benefits including excessive hospitality cannot be offered and/or extended to healthcare professionals.

17.1.7 For speakers, payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel are permissible provided it is in terms of a written contract.

17.1.8 CPD meetings:

17.1.8.1 No product promotion is allowed in the CPD meeting room. Company-branded items/promotion are permissible.

17.1.8.2 Speakers should use the INN names of products during CPD events. Companies must make it known to speakers that the use of trade names is not permitted.

17.1.8.3 Product promotional material displayed outside of the CPD meeting room should not be accessible to the general public, if it is not permissible to market such product directly to the public.

17.1.9 For local CPD events and product launches which are held in major cities, reasonable travel arrangements or travel reimbursement can be made to ensure that the healthcare professionals that do not reside/practice in major cities are able to access the applicable information.

17.1.10 The criteria for selection of attendees/invitees must be transparent and available to the MCA on request for scrutiny.

17.2 For medical or scientific congresses, conferences or seminars held in South Africa, internationally or international meetings held overseas and held in South Africa:

17.2.1 Meetings organised by companies, other organisations or individuals at venues outside South Africa, that are educational and scientific in nature and involve South African healthcare professionals are acceptable.

17.2.2 The rationale for any meeting, or sponsorship to attend a meeting, is to be transparent, valid and cogent.

17.2.3 Consideration must be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, hospitality provided and the like.

17.2.4 As with any meeting, it should be the programme that attracts delegates and not the associated hospitality or venue and all entertainment and events have to be subordinate in time and nature to the sponsored meeting, congress, conference or seminar.

17.2.5 Payment of registration fees, travel and accommodation must be made to the professional associations/organisers and not directly to
the healthcare professional or appropriate administrative staff, unless proof is received that the amounts spent are in the name of the sponsored person and which corresponds to each and every line item as per the agreed sponsorship. No payment may be made to the professional/staff for time spent at the event.

17.2.6 Sponsored speakers may receive reasonable honoraria.

17.2.7 Advertisement and promotion are subject to domestic legislation, i.e. if a product is not registered in South Africa, it cannot be promoted, even if the congress is international in nature, unless exemption has been granted in terms of applicable legislation.

17.2.8 Sponsorship of congress organised events, other than recreational and sporting events, is permitted. However sponsorship of any stand alone social or entertainment event is not permitted.

17.3 Transparency
When meetings are sponsored by companies, other organisations or by individuals, the fact must be disclosed in the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

17.4 Stand-alone entertainment, leisure, social or cultural events with healthcare professionals

17.4.1 Meetings organised for patients, general public, individual or groups of doctors, other healthcare professionals and/or for administrative staff that are wholly or mainly of an entertainment, leisure, social or sporting nature is not permitted.

17.4.2 No stand-alone entertainment or other leisure, social or sporting activities may be planned, arranged or funded by companies as these are unrelated to the promotion of scientific or educational objectives.

17.5 Other interactions with healthcare professionals

17.5.1 Consultancy services

17.5.1.1 The engagement of a healthcare professional to provide genuine consultancy or other genuine services to a company is permitted. Healthcare professionals that provide consulting services to a company and are still practicing their profession must declare their employment arrangement with the company whenever they write or speak in public about a matter that is the subject of the employment or any other issue relating to that company. Such arrangement must be formalised in a written agreement, which may be subject to scrutiny by the MCA if such interaction forms part of a complaint lodged in terms of this Code.

17.5.2 No direct payments to healthcare professionals for any other services

17.5.2.1 Payments may not be made to doctors or groups of healthcare professionals, either directly or indirectly, for rental for rooms or other services.
17.5.2.2 Healthcare professionals involved in *bona-fide* and if relevant, peer reviewed research, are not subject to 17.5.2.1.

17.5.3 Certification of Meetings
For the purposes of certification envisaged in Clause 14, the following details have to be retained:

17.5.3.1 Details of the programme, both scientific/education and entertainment/ hospitality, if any.
17.5.3.2 Invitations, the choice of venue(s).
17.5.3.3 Documentation as to the rationale for the meeting or sponsorship.
17.5.3.4 Participant selection processes and criteria.
17.5.3.5 The anticipated costs associated with the event, as well as that associated with all entertainment and hospitality. Records of actual costs will be retained by the company’s finance department and be available for auditing purposes.

18. **INDUCEMENTS, GIFTS AND PROMOTIONAL ITEMS, COMPETITIONS**

18.1 Inducements
There should be no personal enrichment of healthcare professionals or other healthcare providers. No gift, benefit in kind, rebate, discount, kickback or any other pecuniary advantage shall be offered or given to members of the health professions, administrative staff, government officials, or the general public as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any healthcare product, subject to the provisions of Clause 18.2. No donation should unjustifiably enrich healthcare professionals performing a health related service.

18.2 Gifts and promotional items
Occasional gifts and promotional items to healthcare professionals, appropriate administrative staff, sales and other staff are acceptable provided that they are:

18.2.1 Inexpensive and of minimal intrinsic value i.e. within the cost limit set from time to time per annum by the MCA.
18.2.2 Not for personal use e.g. no entertainment CD’s/DVD’s, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.
18.2.3 Educational and/or of scientific value, benefit the patient and/or be relevant to the practice.
18.2.4 No cash or cash equivalents is allowed.

18.3 Promotional items
It is permissible to brand promotional items. The minimum information for a medicine as required under Clause 5 does not have to be included on a promotional aid provided that no promotional claims are made. The following information may be included on such items:
18.3.1 The name of the medicine.
18.3.2 An indication that the name of the medicine is a trademark.
18.3.3 Relevant company name, company logo and/or product logo.

18.4 Cultural courtesy gifts
An inexpensive gift not related to the practice of medicine, the value of which will determined by the MCA, may be given as a maximum of one gift per year to healthcare professionals, in recognition of significant national, cultural or religious days. The maximum value of the gift must be in line with the value of general gifts.

Note: The Medical Device and IVD industry may not give gifts pertaining to cultural, religious or national events.

18.5 Competitions
18.5.1 Competitions should fulfil the following criteria:
18.5.2 the competition is based on medical/product knowledge or the acquisition of scientific knowledge;
18.5.3 the prize is relevant to the practice of medicine, dentistry or pharmacy; and
18.5.4 individual prizes or educational items offered and within the cost limit set from time to time by the MCA;
18.5.5 entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.

18.6 Donations and grants to charities
18.6.1 Financial donations or other appropriate donations to registered charities or other institutions may be made if properly recorded and approved by the responsible person(s) in each company or organisation. Donations, grants and benefits in kind to institutions, organisations or associations are only allowed provided:

   18.6.1.1 They are made for the purpose of supporting healthcare or research;
   18.6.1.2 They are documented and kept on record by the donor/grantor; and
   18.6.1.3 They do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

18.6.2 Donations must not be paid directly to healthcare professionals.
18.6.3 Companies are encouraged to make available publicly, information about donations, grants or benefits in kind made by them as covered in this section.

18.7 Corporate Social Investment
18.7.1 Donations to meet identified corporate social responsibility projects may also be made if judged on its merits, approved by the
responsible person(s) in each company or organisation and documented.

18.7.2 Corporate social investment is excluded from the operation of the Code in so far as such donations do not induce the overall over or under utilisation of a medicine.

19. RELATIONS WITH THE GENERAL PUBLIC AND THE MEDIA

19.1 Health products must not be advertised to the general public if they are prescription only products.

19.2 Patient support group meetings, events and patient support materials may be sponsored provided that proper records are kept and that no product promotion takes place. The fact that sponsorship or support has been provided should be displayed on the materials and/or at the meeting or event.

19.3 Information that is made available to the general public either directly or indirectly about health products must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading or disparaging with respect to the safety of the product and may not refer to a medicine's safety, quality or efficacy. Statements, representations or tie-off lines must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific health product. Clause 19.1 does not prohibit education or information relating to substitution of a health product or information on safe use, storage of health products in general.

19.4 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer should be recommended to consult with his or her own healthcare professional.

19.5 Companies are responsible for information that is issued by their public relations agencies about their products.

19.6 Patient education (‘help-seeking advertisements’) directed at general public is acceptable, provided that it:

19.6.1 Does not contain the name of the specific health product.
19.6.2 Does not make or allude to a medicinal or therapeutic claim.
19.6.3 Does not provide any risk information.
19.6.4 Lets the public know that treatment exists for a medical condition.
19.6.5 “For more information, refer to your doctor or pharmacist (or healthcare professional)” is mentioned.

20. SAMPLES

The supply of samples is not permitted to extend beyond the conditions as prescribed under the Medicines Act.

Note: Medical devices and IVD

Sampling may only take place within the ambit of the Medicines Act and applicable regulations, and includes the provision of devices for product evaluations / appraisals as outlined in this Code, and for purposes of exhibition.
Demonstration products which are not intended to be used in patient care should be accompanied by designations such as “Sample - Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompany the product.

21. **THE INTERNET**

21.1 Access to promotional material directed at the South African public provided on the Internet in relation to Schedule 02 to Schedule 06 should be limited through a password protection scheme to healthcare professional.

21.2 Information or promotional material covered by Clause 21.1 about medicines which is placed on the Internet outside South Africa will be regarded as within the scope of the Code if it was placed there by a South African company, or an affiliate of a South African company, or at the instigation or with the authority of such a company and it makes specific reference to the availability or use of the medicine in South Africa.

21.3 Medicines covered by Clause 21.1 may be advertised in a relevant, independently produced electronic journal intended for healthcare professionals or appropriate administrative staff which cannot be accessed by non-healthcare professionals.

21.4 Package inserts for medicines covered by Clause 21.1 above may be included on the Internet and be accessible by members of the public provided that they are not presented in such a way as to be promotional in nature.

21.5 It should be made clear to an internet user when he/she is leaving any of the company sites, or sites sponsored by the company, or is being directed to a site, which is not that of the company.

22. **COMPLIANCE WITH UNDERTAKINGS AND RULINGS**

When an undertaking has been given in relation to a ruling under the Code or when a ruling is made under the Code, the company concerned must ensure that it complies with that undertaking and/or the specific ruling.
PART B: --- MARKETING AND PROMOTION OF HEALTH PRODUCTS DIRECTLY TO THE CONSUMER

23. REGISTRATION STATUS OF MEDICINES

A medicine must not be promoted:

23.1 prior to the product being registered by the medicines regulatory authority or;

23.2 unless an application has been submitted in terms of Section 14(3) of the Medicines Act (“old medicine”) which permits its sale, supply and use in South Africa.

The promotion of a registered self-medication product must be in accordance with the terms of its registration and must not be inconsistent with the particulars listed in the package insert or approved text.

24. ADVERTISING AND/OR PROMOTION

24.1 Advertisements must be consistent with the requirements of the Medicines Act and other applicable legislation.

24.2 Advertisements shall not mislead or disparage either directly or by implication. Information, claims and comparisons must be accurate, balanced, fair, objective, unambiguous and supportable and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. The use of medical terminology is acceptable provided that this does not confuse or mislead the consumer.

24.3 Advertising and/or promotion shall not be misleading as to the nature of the product, its ingredients or indication(s).

24.4 Advertisements must not contain any other express or implied exaggerated claims as to the benefits that can be obtained from use of the health product.

24.5 Efficacy claims should clearly state if health products are intended to be used over extended periods of time or where the health product is indicated for disease risk reduction or prevention.

24.6 Advertising and/or promotion can refer to the prevention of symptoms and use of a product in chronic conditions, if in line with the registered indication. The advertisement shall make it clear under what circumstances use of the product is appropriate. This is particularly important in therapeutic areas where individuals may be asymptomatic.

24.7 Advertising and/or promotion shall not cause consumers unwarranted anxiety with regard to any condition. Nor should it suggest that suffering might arise if a consumer fails to respond to the advertisement’s claim. Advertising and/or promotion must not suggest that the condition will deteriorate or that it will become more severe if the individual does not use the medicine featured. Language which causes fear or distress should not be used.

24.8 Advertisements should not suggest that using a health product could enhance normal good health or be a substitute for a healthy diet and lifestyle.
24.9 Advertising and/or promotion shall not be aimed principally or exclusively at children (under the age of twelve years).

24.10 Advertising and/or promotion shall not show children using, or within reach of, health product without adult supervision.

24.11 Advertising and/or promotion shall encourage responsible self-medication and should not encourage individuals to exclusively self-diagnose. Nor should it encourage self-diagnosis where medical intervention is required. Particular care should be taken where symptoms are generalised and a diagnosis is made by exclusions of more serious complaints or where use of the health product could mask the symptoms of a more serious condition. Advertising should encourage individuals to share information with the pharmacist or healthcare practitioner so that they can ensure the health product will be suitable for the intended user.

24.12 Advertising and/or promotion shall not suggest that a medical consultation or surgical operation is unnecessary nor shall it discourage consumers from seeking medical or pharmaceutical advice. Consideration should be given to the inclusion of information concerning the availability of professional advice.

24.13 Advertising and/or promotion shall not offer to diagnose, advise, prescribe or treat personally by correspondence.

24.14 Advertising and/or promotion shall not claim guarantees on a product’s effects, safety or quality.

24.15 Advertising and/or promotion shall not encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of any health product.

24.16 Advertisements should not be flippant or use inappropriate imagery or imagery out of context. Advertisers are encouraged to convey the message that health products should be treated with respect and may not be suitable for some people.

24.17 Sponsored advertorials shall be appropriately identified as such in the particular publication at the place where it appears, in order to be distinguished from editorials.

24.18 Advertising and/or promotion should not encourage consumers to discontinue the use of prescribed health products.

24.19 Advertising and/or promotion shall not contain recommendation of a product by scientists or health professionals unless substantiated.

24.20 Advertising and/or promotion shall not include recommendation by a person who, because of their celebrity status, may encourage consumers to use a particular health product.

25. INFORMATION, CLAIMS AND COMPARISONS IN ADVERTISING AND/OR PROMOTION

25.1 All advertising and/or promotion must be consistent with the provisions of the Medicines Act i.e. all advertising and/or promotion must give the information necessary for the correct use of a product as approved by the medicines regulatory authority and may not deviate from, be in conflict with or go beyond the evidence submitted in the application for registration with regard to its safety, quality and efficacy in respect of what has been approved by the
medicines regulatory authority and incorporated in the approved package insert.

25.2 In the case of an advertisement for a health product which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the medicines regulatory authority for inclusion in the package insert of the medicine.

25.3 A written advertisement for a medicine shall comply with Regulation 45 of the Medicines Act.

25.4 Advertising and/or promotion shall not unfairly denigrate or discredit, either directly or by implication, a competitor product, ingredient or treatment type.

25.5 Advertising and/or promotion should not suggest that a product’s effects are better than or equal to another identifiable product or treatment.

25.6 Advertising and/or promotion shall not state that a product does not contain an active ingredient or ingredients used in competitor products other than as permitted by the medicines regulatory authority.

25.7 Trade names of products of other companies shall not be used without permissions of the owner.

25.8 Hanging (open ended) comparisons are not allowed.

25.9 Comparisons are only permitted in advertising and/or promotion or promotional material if:

25.9.1 they are not misleading or disparaging;

25.9.2 health products or services for the same needs or intended for the same purpose are compared;

25.9.3 one or more materials, relevant and representative features, capable of substantiation, are compared;

25.9.4 no confusion is created between the health product advertised and that of a competitor or between the advertiser’s trademarks, proprietary names, other distinguishing marks and those of a competitor;

25.9.5 the trademarks, proprietary names, other distinguishing marks, health product, services, activities or circumstances of a competitor are not discredited or denigrated. Trademarks/proprietary name of a competitor may only be mentioned with written permission from the competitor;

25.9.6 no unfair advantage is taken of the reputation of a trademark, proprietary name or other distinguishing marks of a competitor;

25.9.7 health products or services are not presented as imitations or replicas of goods or services bearing a competitor’s trademark or trade name.

25.10 Substantiation for any information, claim or comparison must be provided at the request of the marketing code authority. It need not be provided, however, in relation to the validity of indications approved in the product registration.
25.11 When a written advertisement refers to the medicines regulatory authority approved package insert as well as scientific, published studies, clear and complete references must be listed on the advertisement.

25.12 When a written advertisement refers to unpublished data on file, the relevant part of this data must be provided at the request of the MCA.

25.13 All artwork including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code.

25.14 Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.

25.15 Information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side effects, toxic hazards or risks of addiction. It is acceptable to highlight the absence of a specific side effect, e.g. 'no drowsiness'. The word 'safe' or phrases containing reference to safety must not be used without adequate scientific substantiation.

25.16 Exaggerated, all-embracing claims or superiority claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a health product. Claims should not imply that a health product or an active ingredient has some special merit, quality or property unless this can be substantiated.

25.17 The word 'new' must not be used to describe any product or presentation, which has been generally available or any therapeutic indication, which has been available on the market for more than twelve months in South Africa.

25.18 Advertising and/or promotion of a self-medication medicine shall not suggest that a product is a foodstuff, cosmetic or other non-medicinal product.

25.19 Although it is acceptable to indicate that a self-medication medicine is palatable, advertising and/or promotion shall make clear that it is a medicine.

25.20 Advertising and/or promotion shall not suggest, directly or indirectly, that a product contains an unknown active ingredient.

25.21 A product, or any of its attributes, shall not claim to be unique unless substantiated.

25.22 Advertising and/or promotion shall not mislead about the novelty of a preparation.

25.23 Advertising and/or promotion claims relating to speed of absorption, dissolution, distribution or other pharmacokinetic particulars are acceptable if supported evidence and if in line with the product's registration dossier. However, such evidence may not be extrapolated to claims that a product offers improved efficacy or speed of efficacy, without supporting evidence to substantiate such claims.

25.24 Advertising and/or promotion shall not suggest that the safety, quality or efficacy of a product is due to the fact that it is natural. Advertising and/or promotion shall not claim that a product is ‘natural’.

25.25 Advertising and/or promotion shall not suggest that a product is herbal, unless all the active ingredients are plants or extracts of plants. ‘Herbal’ can
only be used to describe those elements that are of plant origin e.g. ‘herbal ingredient’.

25.26 Claims for weight management, meaning weight loss, measurement reduction, clothing size reduction and weight control/maintenance, can only be made in conjunction with reference to sensible lifestyle factors including a diet and exercise.

26. DISPARAGING REFERENCES

26.1 The medicine, health products and activities of other companies must not be disparaged.

26.2 The health professions and the clinical and scientific opinions of their members must not be disparaged.

27. SUITABILITY AND TASTE

27.1 All material and activities must recognize the special considerations relating to the promotion of the health product and must not be likely to cause offence.

27.2 The name or photograph or film of a member of a health profession must not be used in any way that is contrary to the conventions of that profession.

27.3 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies, organisations or individuals, in a way that is likely to mislead or confuse.

27.4 Promotional material must not include any reference to the medicines regulatory authority unless this is specially required by the medicines regulatory authority.

27.5 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.

27.6 All material relating to health products and their uses, which is sponsored by a company, must clearly indicate that the company, organisation or individual had sponsored it. Market research material need not reveal the name of the company, organisation or individual involved but must state that a company, organisation or individual sponsors it.

28. PROHIBITIONS OR RESTRICTED REPRESENTATIONS

An advertisement for a self-medication medicine must not refer, expressly or by implication, to products during or assisting in the treatment of serious forms of disease, conditions, ailments or defects unless prior approval is given under the Medicines Act.

29. QUOTATIONS

Quotations relating to a medicine taken from public broadcasts, for example radio, television or Internet, and from private occasions, such as medical conferences or symposia, must not be used without the written permission of the speaker.
30. TESTIMONIALS

30.1 Testimonials shall comply with the approved package insert and with the other principles of this Code.

30.2 Testimonials should be less than three years old and be the genuine views of the user.

30.3 The use of healthcare professionals for marketing, promotion, endorsements or testimonial has to take place within the scope set by the professional codes applicable to such professionals.

31. HEALTHCARE PROFESSIONALS

31.1 Advertising and/or promotion shall not claim that a product is, or has been available on prescription. However, it is acceptable to state that a product’s active ingredient, formulation or preparation has been prescribed by a health professional, provided there is evidence that this is the case.

31.2 Advertising and/or promotion shall not refer to a ‘college’, ‘hospital’, ‘institute’, ‘laboratory’ or similar establishment, unless the establishment genuinely exists.

32. VIEWS OF AUTHORS

The utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

33. SCIENTIFIC INFORMATION SERVICES

All companies, organisations or individuals must compile and collate all information about the health products that they market, and must be able to provide such information to authorities, members of healthcare professions or the general public, where appropriate. This may include information about adverse drug reactions.

34. CERTIFICATION OF PROMOTIONAL MATERIAL

The same process and principals stipulated in Clause 14 of Part A of the Code applies in the context of Part B.

35. RELATIONS WITH THE GENERAL PUBLIC AND THE MEDIA

35.1 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer advised to consult his or her own health professional.

35.2 Companies are responsible for information about their products that is issued by their public relations agencies.

36. PROMOTIONS, GIFTS, PRIZES AND INDUCEMENTS

36.1 No company shall be involved in promotional schemes which are hazardous to the public or which bring the industry into disrepute.

36.2 Entry into consumer competitions shall not be dependent on the conditional purchase of a health product nor shall a medicine be offered as a prize. The value of the prize shall not exceed the limits set by the Marketing Code Authority from time to time.
37. HOSPITALITY AND MEETINGS

Companies may provide hospitality to persons or appropriate administrative staff in association with professional, scientific and promotional meetings/events, provided that it is reasonable and subordinate to the main purpose of the meeting or event.

38. TRAINING AND EDUCATION

Companies may provide training or education for the general public and may also sponsor training provided by other organisations. Such materials should offer accurate, balanced information on the subject area and include a clear indication of which company has produced or sponsored the material.

39. HEALTHCARE SALES REPRESENTATIVES / CONSUMER PROMOTERS

39.1 Companies should ensure that Healthcare Sales Representatives/consumer promoters have adequate training to ensure sufficient scientific knowledge of the health products which they promote to enable the provision of precise and complete information about such health products.

39.2 All materials including slides and handouts shall comply with the requirements of the Code.

39.3 Product training must be consistent with the package insert of a medicine.

39.4 Healthcare Medical Sales Representatives/consumer promoters must notify their company regarding any information received in relation to the use of health products which they promote, particularly any information relating to adverse event reporting.

39.5 Healthcare Sales Representatives/consumer promoters are to conduct the promotion of product in a professional manner, and are not permitted to disparage any opposition products.

40. COMPLIANCE WITH UNDERTAKINGS AND RULINGS

When an undertaking has been given in relation to a ruling under the Code or when a ruling is made under the Code, the company concerned must ensure compliance with that undertaking and/or specific ruling.
PART C: MEDICAL DEVICES

41. ADVERTISEMENTS AND PROMOTIONS

General Principles

All technology has to be advertised and promoted according to any applicable laws and regulations which exist or may be set for the promotion and advertisements of medical devices and IVDs.

Advertisements and promotions have to portray the technology in line with the approved uses and attributes of the technology. Where products are not registered in South Africa or any other jurisdiction, advertisements and promotions have to be in line with the known uses and attributes of the technology, and the appropriateness of promoted or advertised uses or attributes may be investigated on receipt of a complaint in this regard.

The use of all artwork (logos, tables, graphics, illustrations, etc) should reflect the principles of fairness, balance and accuracy and should not distort, mislead, etc.

The use of words such as safe, new and other claims should be within the relevant legal frameworks, and should not be used in contravention of the above principles, i.e. should be subject to substantiation, be accurate and balanced.

All promotions and advertisements should be of a high standard and respect HCP’s and patients.

41.1 Promotions or advertisements to the public have to take place within the applicable regulatory frameworks, and where such advertisement or promotion relates to help-seeking behaviour amongst the public, conform to the following:

41.1.1. Should not make or allude to inappropriate healthcare claims associated with a particular product;

41.1.2. Should not use risk or safety information in a distorted way to scare members of the public or to induce a sale based on fear, exaggerated, distorted or misleading information or in a manner that leads consumers to make deductions on the comparative safety or risk of competitor products;

41.1.3. May let the public know of a particular disease or condition and that treatment exists for such disease or condition.

41.2 An advertisement must:

41.2.1. contain correct and balanced statements only and claims which the supplier has already verified;

41.2.2. include the phrase: “For more information, refer to your HCP”.

41.3 An advertisement must not:
41.3.1 be likely to arouse unwarranted and unrealistic expectations of product effectiveness;
41.3.2 be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases;
41.3.3 mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions;
41.3.4 abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress;
41.3.5 contain any matter which is likely to lead persons to believe: that they are suffering from a serious ailment; or
41.3.6 that harmful consequences may result from the technology not being used.
41.3.7 encourage, or be likely to encourage, inappropriate or excessive use;
41.3.8 contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
41.3.9 contain any claim, statement or implication that it is effective in all cases of a condition;
41.3.10 contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects.

42. INCENTIVES TO PHARMACY ASSISTANTS AND OTHER NON-HEALTHCARE PROFESSIONAL SALES
An advertisement must not offer any personal incentive to a pharmacy assistant, or other non-healthcare professional sales person at retail level, to recommend or supply medical devices.

43. SCIENTIFIC INFORMATION
Any scientific information in an advertisement should be presented in a manner that is accurate, balanced and not misleading.
Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.
Publication of research results must identify the researcher and financial sponsor of the research.
Any statement made may be subject to scrutiny for its scientific validity, and independent experts may be called upon in the case of a complaint, to verify such statement(s).

44. COMPARATIVE ADVERTISING
Comparative advertisements must be in alignment with South African law, be balanced and must not be misleading or likely to be misleading, either about the technology or classes of technology, with which it is compared.
Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the technology, or classes of technology, with which comparison is made, are harmful or ineffectual.

45. **PROFESSIONAL RECOMMENDATION**

Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and is not presented as an endorsement of a medical device.

Advertisements must not contain or imply endorsement by:

- any government agency;
- hospitals and other facilities providing healthcare services;
- individual or groups of healthcare professionals, other than where the emphasis is on the availability, which may include the price of the technology through his/her retail business; or
- by individuals, who are healthcare professionals by way of their representation in advertisements or academic qualifications, and / or who are likely to be known as healthcare professionals by the reasonable person.

Advertisements must not contain or imply endorsement of the goods by bodies or peak healthcare professional associations that:

- represent the interests of health consumers;
- conduct or fund research into a disease, condition disorder or syndrome; or represent healthcare professionals;

unless:

- the advertisement names the body or association;
- the endorsement is authenticated;
- the nature of the endorsement is clearly disclosed; and
- the endorsement is based upon an objective assessment of available scientific data supporting the use of that product.

Where this is not the case and where the body or association has received valuable consideration for the endorsement, the advertisement must acknowledge that consideration.

46. **TESTIMONIALS**

Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.

47. **SAMPLES**

An advertisement for technology must not contain an offer of a sample.

48. **CONFORMITY**

The conformity of an advertisement with this section will be assessed in terms of its probable impact upon the reasonable person to whom the advertisement is directed.
PART D --- PROVISION FOR ENFORCEMENT OF THE CODE

49. SELF-REGULATORY ENFORCEMENT OF THE CODE OF MARKETING PRACTICE

49.1 The MCA is hereby recognised as the self-regulatory authority for health products, which authority is properly constituted by means of a Constitution as a juristic body.

49.2 The MCA shall have the power to create the required enforcement mechanisms in line with the provisions of this Code and in line with its Constitution and shall have all the powers necessary to ensure an efficient and effective self-regulatory mechanism.

49.3 The MCA processes constitute the first steps in any dispute or complaint relating to the provisions of this Code, and any aggrieved party may, after exhausting all the internal remedies provided in this Code, approach the relevant regulatory authority for resolution of a matter which it deems not to have been resolved satisfactory and the MCA has the power to refer any matter prior to its final internal resolution to any relevant Authority should it deem the matter to warrant such a referral.

49.4 All signatories to the Code shall apply to be members of the MCA and shall have the rights and responsibilities as set out in the MCA Constitution.

50. ENFORCEMENT STRUCTURES

50.1 The following officers and structures are responsible for the enforcement of the Code, as outlined in this Code and as established by the Constitution of the MCA:

50.1.1 The Executive Officer of the MCA acts as the custodian of the Code and the enforcement processes described in this Code;

50.1.2 An Adjudicating Committee, as appointed from time to time acts as the structure of the first instance, the appointment of which takes place in terms of the MCA Constitution.

50.1.3 An Appeals Committee, to deal with appeals on matters regarded by any of the parties as not resolved to its satisfaction by the Adjudicating Committee, the appointment of which takes place in terms of the MCA Constitution.

50.2 Any part or all of the enforcement processes may be outsourced by the MCA to any competent body in line with the provisions of the MCA Constitution and shall not affect the validity of any process undertaken or outcome facilitated by such out-sourced body.

50.3 Non-members of the MCA may agree to abide by, or by required by law to abide by, the enforcement mechanisms created by the Code.
51. **LODGING OF COMPLAINTS**

51.1 As a first course of action, parties have to attempt to resolve any Code matter by means of the complainant approaching the respondent directly in an amicable fashion.

51.2 Should a Company, Member or any individual person or entity ("the Complainant") be of the view that there has been a breach or contravention of any of the provisions of the Code by a Company ("the Respondent") and wishes to lodge a complaint, it shall lodge a formal written complaint with the Executive Officer, clearly setting out details of the complainant and the complaint, and shall be accompanied by:

51.2.1 proof that the company and complainant have made all reasonable attempts to resolve the matter between themselves;

51.2.2 if the complaint is based on scientific issues, supporting literature and any studies relied on;

51.2.3 copies of any advertisements and/or promotional material and/or any other material (such as invitations, agreements, correspondence, etc) which may be relevant;

51.2.4 any other information the Complainant considers relevant to the determination of the complaint.

51.3 The complaint shall make reference to the sections of the Code which may have been contravened and shall in addition be accompanied by:

51.3.1 the prescribed complaint fee applicable at the time;

51.3.2 proof that the Complainant had, as soon as the reason for the complaint became known to him, approached the Respondent with the view of resolving the dispute amicably between them without the need of intervention by the MCA and that such approach proved unsuccessful;

51.3.3 if the complaint is based on scientific issues, supporting literature and any studies relied on;

51.3.4 copies of any advertisements and/or promotional material which may be relevant;

51.3.5 any other information the Complainant considers relevant to the determination of the complaint.

51.4 The Executive Officer shall on receipt of the complaint, send a copy of the complaint to the Respondent and request a formal response within five working days from the date upon which the Respondent receives the complaint.

51.5 The Executive Officer shall upon receipt of the response, send a copy of the response to the Complainant and invite a reply to be submitted within five working days from the date upon which the Complainant receives the response. The reply, if any, will on receipt be sent to the Respondent.

51.6 During the above exchange of documents, the Executive Officer shall cause the constitution of the Adjudicating Committee in terms of the provisions for such constitution as set by the MCA Constitution. After receipt of the reply, if any, the Executive Officer will forward the documents to the members of the Adjudicating Committee adjudication as provided for in this Code.
51.7 A complaint may be withdrawn by the Complainant at any time in writing, addressed to the Executive Officer, in which case the complaint fee will be forfeited.

52. NOMINATED COMPLAINANT

52.1 The Executive Officer shall scrutinise promotional material and advertisements issued by companies on an ongoing basis to ensure that the advertisements do not contravene the provisions of the Code. The Executive Officer shall also monitor such further conduct by Companies as s/he deems fit.

52.2 Should the Executive Officer be of the opinion that there has been a breach s/he will immediately bring this to the attention of the Executive Board, who will appoint from amongst the members an individual, not conflicted, who will become the nominated complainant in the matter.

52.3 The nominated complainant will act as complainant and in accordance with the processes outlined in this Code and no complaint fees will be payable.

53. ADJUDICATING HEARINGS

53.1 The Adjudicating Committee shall consider the documents placed before it by the Executive Officer at a date occurring within 7 working days after the last exchange of documents between the Parties.

53.1.1 Where documents are subject to amongst others Clause 7.6 (arbitration of confidential information), Clause 17 (evaluation of agreement between company and healthcare professional, including that of an honorarium) or Clause 18 (donation or support agreements) the Executive Officer will nominate an independent member of the Adjudication Panel as arbitrator in the matter of the specific document or agreement and such agreement may be subject to confidentiality protections and may, in such cases, not be disclosed to the other party in the matter or any other third party and only the finding of the independent arbitrator will be made known to the Committee prior to the date of the hearing or at any time prior to the Adjudicating Committee making its finding.

53.2 An Adjudicating Committee will request the Executive Officer to advise the Complainant and Respondent of the date of the hearing of the complaint, which date has to be set at least 14 ordinary days after the exchange of documents, and invite them to appear before the Adjudicating Committee to make such further submissions as may be allowed by the Adjudicating Committee.

53.3 Although an Adjudicating Committee shall be entitled to adopt such procedures and formalities as it in its sole discretion, may from time to time determine, it shall adhere to the principles of natural justice and shall:

53.3.1 allow a party to state its case in writing;

53.3.2 ensure that no member of the Adjudicating Committee has any direct or indirect interest in the matter which is being adjudicated upon.
53.4 No Party shall have legal representation at Adjudicating proceedings unless the Adjudicating Committee, having regard to, *inter alia*, the complexity of the evidence and the legal issues likely to be involved, the serious nature of the matter enquired into and the penalty which may be imposed, in its sole discretion determines that legal representation is desirable in the light of the above factors and other factors deemed relevant by the Committee. In such case a Party shall be entitled to legal representation by only a practising attorney or practising advocate or both.

53.5 Adjudicating proceedings shall be recorded either manually or by means of recording equipment. The Chairperson of the Adjudicating Committee shall ensure that the proceedings are transcribed as soon as possible after the conclusion of the hearing and shall thereafter certify the transcript as an accurate record of the proceedings.

54. **POWERS OF AN ADJUDICATING COMMITTEE**

54.1 Should an Adjudicating Committee determine that there has been a breach or contravention of the Code or that no breach or violation has occurred, it shall make such a finding and furnish reasons therefore. The finding and reasons shall be communicated to the Parties. Such determination and penalty, if applicable, has to be made within 7 working days of the date of the hearing or adjudication of the matter.

54.2 Without fettering the discretion of the Adjudicating Committee, in circumstances where it has found that the Respondent had committed a breach of the Code in respect of advertising and/or promotional activities, the Adjudicating Committee will have regard to *inter alia* the following factors in deciding on a suitable penalty: whether the publications have ceased; how widely the offending material had been distributed; what steps have been taken to withdraw the published material; whether corrective statements have been issued; whether the breach was deliberate, negligent or inadvertent; whether there were or are safety implications; whether the material or publication was or is misleading and the extent thereof; the manner in which the perception of health care professionals or consumers have been or will be effected; whether commercial damage or harm, and the extent thereof, has been caused; whether the Respondent had previously breached the Code.

54.3 An Adjudicating Committee shall, in cases of a breach or contravention of the Code, have the power to impose on a Party any one or more of the following penalties:

54.3.1 a reprimand; caution or warning;

54.3.2 a fine, within limits set from time to time by the MCA in terms of its Constitution;

54.3.3 issue a directive that the Respondent's internal procedures be audited by a representative of the MCA and that a report be furnished to the Executive Officer after the conclusion of such audit;

54.3.4 issue a directive that any offending promotional activity or material or advertisement be ceased and/or withdrawn forthwith and that satisfactory proof be provided, within a stipulated time period, to the Executive Officer that this has been done;
that the Respondent, as represented by himself, or in the case of a company by its Chief Executive Officer, Country Manager, Company Code Compliance Officer or other senior member of management, furnish a written undertaking within a stipulated time period that the Respondent will avoid similar breaches of the Code in the future;

54.3.6 that such action be taken by the Respondent to publicly undo the damage or potential damage caused by or as a result of the breach of the Code;

54.3.7 that the Respondent pay such costs and expenses as the Adjudicating Committee considers just and equitable in the circumstances including an order that the Respondent refund the Complainant the amount of the complaint fee;

54.3.8 that the finding of the Adjudicating Committee be published to the Members;

54.3.9 such other order as may be considered appropriate to the Adjudicating Committee in the circumstances.

54.4 Should the Adjudicating Committee find that there is no merit in the complaint, or that the complaint was vexatious, frivolous or malicious, the Adjudicating Committee may order the Complainant to pay such costs and expenses as the Adjudicating Committee considers just and equitable in the circumstances including an order that the Complainant pay the costs, or portion of the costs and expenses incurred by the Respondent.

54.5 An Adjudication Committee, shall, should the time period for an appeal have lapsed, be entitled to order that the outcome of the appeal hearing be published on the MCA website in a summarised version, including a summary of the violation and the penalty imposed.

55. LODGING AN APPEAL

55.1 An appeal against a decision by the Adjudicating Committee shall lie to an Appeal Committee and to no other body. All decisions, penalties, rulings, determinations or findings of an Appeal Committee shall be final and binding on the Party or Parties concerned.

55.2 Should either the Complainant or the Respondent wish to appeal the finding, decision or penalty imposed by the Adjudicating Committee (“the Appellant”), the Appellant shall give notice in writing of his intention to appeal (“Notice of Appeal”) within five working days from the date on which the finding, decision penalty to be appealed against has been communicated to him. The Notice of Appeal shall be addressed to the Executive Officer and shall be delivered within the prescribed time limit to the Executive Officer.

55.3 Every Notice of Appeal shall be accompanied by the prescribed appeal fee.

55.4 Once an Appeal has been lodged, the Executive Officer shall:

55.4.1 as soon as possible thereafter make a copy of the record of the Adjudicating proceedings to which the appeal relates available to the Appellant;
55.4.2 advise the other party (hereinafter referred to as the Respondent) that an appeal has been lodged and also furnish the Respondent with the copy of the record.

55.5 Should a Notice of Appeal not be lodged within the prescribed time period, the right of appeal or the appeal as the case may be shall lapse; provided that the Executive Officer may, on written application to him, in his sole discretion and on such terms and conditions as he may determine, condone the late lodging and reinstate any appeal which has lapsed.

55.6 Where an appeal has been lodged, the Respondent may within 5 working days after being provided with a copy of the Appellant's Notice of Appeal, lodge a written response with the Executive Officer. A copy of such response by the Respondent, if any, shall be furnished to the Appellant upon receipt of it by the Executive Officer.

55.7 During the above exchange of documents, the Executive Officer shall cause the constitution of the Appeal Committee in terms of the provisions for such constitution as set by the MCA Constitution. After receipt of the reply, if any, the Executive Officer will forward the documents to the members of the Appeal Committee adjudication as provided for in this Code.

55.8 An appeal may be withdrawn by the Appellant at any time in which case the appeal fee will be forfeited.

55.9 In the event of the Executive Officer being the nominal complainant, the discretion to extend the time periods as provided for in Clauses Error! Reference source not found. and 55.5 will be delegated to the Chairperson of the Adjudicating Committee which made the ruling forming the subject matter of the appeal.

56. **APPEAL HEARINGS**

56.1 An Appeal Committee, when hearing an appeal, shall adopt such procedures as it, in its sole discretion, may determine.

56.2 The Executive Officer will set a date for the hearing by the Appeal Committee within 14 ordinary days after the exchange of documents and shall notify all interested parties of the date, venue and time of such hearing.

56.3 No Party shall have legal representation at appeal proceedings unless the Appeal Committee, having regard to, *inter alia*, the complexity of the evidence and the legal issues likely to be involved, the serious nature of the matter enjoined into and the penalty which may be imposed, in its sole discretion determines that legal representation is desirable in the light of the above factors and other relevant factors. In such case a Party shall be entitled to legal representation by only a practising attorney or practising advocate or both.

56.4 The Appellant and the Respondent (and their respective legal representatives, if any) shall be bound by and confined to the record of the Adjudicating proceedings and shall not be entitled to introduce new evidence save with the permission of the Appeal Committee, which may determine such matter in its sole discretion and on such terms and conditions as it may deem fit.

56.5 Appeal proceedings shall be recorded either manually or by means of recording equipment. The Chairperson of the Appeal Committee shall ensure
that the proceedings are transcribed as soon as possible after the conclusion of the hearing and shall thereafter certify the transcript as an accurate record of the proceedings.

56.6 The operation of the finding, penalty or decision of the Adjudicating concerned shall be suspended:

56.6.1 during the appeal process; and/or

56.6.2 when a Notice of Appeal has been lodged, pending the final determination of such appeal by an Appeal Committee, or the lapsing of the appeal or the withdrawal thereof.

56.7 The Appeal Committee may, in its sole discretion, without hearing any Party or individual and without giving any reasons, postpone or adjourn any appeal for such periods as it deems fit.

57. POWERS OF AN APPEAL COMMITTEE

57.1 An Appeal Committee, on hearing an appeal, shall have the powers:

57.1.1 to allow the appeal;

57.1.2 to dismiss the appeal;

57.1.3 to substitute any finding or decision as it deems fit or substitute such sanction as it deems fit, including any amended penalty;

57.1.4 to make such order as in its opinion the circumstances may require including an order to remit the matter for the hearing of further evidence or an order for the hearing de novo;

57.1.5 to hear further evidence or receive any documents on such terms and conditions as it in its discretion may decide;

57.1.6 at any time to order a Party to pay all or a portion of the actual costs and other expenses reasonably incurred by the MCA in connection with an appeal or any postponement thereof, in addition to any other sanction, if it is of the opinion that such order is warranted and to determine the amount of such costs and other expenses;

57.1.7 to order that the prescribed appeal fee, or any portion thereof, be forfeited or be refunded as it may determine having regard to the outcome of the appeal;

57.1.8 an order that the matter be reported to the appropriate authorities including, but not limited to any appropriate statutory regulatory authority with a request or recommendation that further action be taken against the any of the parties.

57.1.9 to make such rulings as it in its sole discretion shall determine.

57.2 An Appeal Committee, in addition to any of the powers set out above, shall be entitled to order that the outcome of the appeal hearing be published on the MCA website in a summarised version, including a summary of the violation and the penalty imposed.
58. **FAILURE TO REPLY, PROVIDE FURTHER INFORMATION OR TO ATTEND A MEETING OR HEARING**

58.1 A failure by any party to, without good cause shown, reply to a request to respond to a complaint, failure to provide further evidence of an alleged breach or violation of the Code, failure to make any submissions or presentation and/or a failure to attend a meeting or hearing as provided for in this Code, shall not *per se* invalidate any proceedings undertaken in terms of this Code.

58.2 The Executive Officer, Adjudicating Committee or Appeal Committee shall, in such cases, consider the possibility- and impact of a party frustrating the Code processes, and should act in the interest of ensuring Code compliance; and the Executive Officer or Committee may proceed with the matter without such further evidence, reply, response, presentation, submission or attendance, or dismissing the complaint or appeal on the basis of insufficient evidence.

59. **EXPEDITED PROCESS WHEN PARTY IN BREACH OF RULING OR UNDERTAKING**

59.1 Should the Executive Officer receive a complaint from any party, including a nominated complainant, based on an alleged violation of Clause 22 and/or Clause 40 of the Code, that a company against which a ruling has been made by either an Adjudicating- or Appeal Committee, or where a company has provided an undertaken to act or cease to act in any particular manner, has failed to honour such ruling or commitment, the Executive Officer will institute an expedited process described in this Clause.

59.2 The complainant has to provide sufficient details as to the nature of the non-compliance with the ruling or undertaking, a copy of which details will be provided to the company allegedly in non-compliance upon receipt by the Executive Officer.

59.3 The respondent company shall, within two working days after receiving the complaint, provide a response to the Executive Officer, who shall have constituted an Appeal Committee to decide on the matter.

59.4 The complaint and response, as well as a copy of the ruling or undertaking will be provided to the Appeal Committee without delay, and the Committee will deliberate and make a ruling on the matter based on the documents before it, within five working days after receiving all the documents. No rights of appearance of any party will be granted, unless on exceptional cause shown.

59.5 The Appeal Committee shall regard the ruling or undertaking as valid and shall not re-open the matter, shall not consider the matter *de novo* and shall not hear any evidence or defence relating to the validity or correctness of the ruling or undertaking previously made.

59.6 The Appeals Committee shall provide a substantiated ruling as to whether a breach of clause 22 or clause 40 has indeed occurred, and shall have the power to:

59.6.1 Refer the matter to any appropriate forum or authority for consideration, including a recommendation that legal action be taken; and/or
59.6.2 Confirm any previous sanction imposed; and/or
59.6.3 Impose any further penalties, sanctions or fines on the respondent company within the limits set by the MCA from time to time; and/or
59.6.4 Impose any other appropriate sanction or remedial action, including the publication of its findings in the public domain in a format deemed appropriate by it;
59.6.5 Any other sanction, including orders as to cost and fees.

60. VARIATION OF TIMELINES AND WAIVER OF FEES

60.1 The Executive Officer may, on good cause shown and subject to such conditions as s/he may impose, vary the time periods referred to in this Part of the Code, after considering the impact of such variation on both parties, including the need to ensure expeditious resolution of Code matters, the interest of justice and fairness.

60.2 The Executive Officer may, based on policy set by the MCA, waive any complaints or appeal fees for any person or company when s/he deems any situation to fall within the circumstances envisaged by such policy.
TRADE ASSOCIATIONS AND COMPANIES INVOLVED IN DEVELOPMENT OF THE SOUTH AFRICAN MARKETING CODE

INNOVATIVE MEDICINES SA (IMSA)

CONTACT DETAILS:
Postal Address: P.O. Box 2008, Houghton, 2041
Physical Address: 52 Glenhove Road, Melrose, 2196.
Tel: 011 880-4644
Fax: 011 880-4644
E-mail: imsacom@imsa.org.za
Website: www.imsa.org.za

List of IMSA members
Boehringer Ingelheim (Pty) Ltd
Fresenius Kabi
GE Healthcare (Pty) Ltd
Genzyme Biopharmaceuticals (Pty) Ltd
Eli Lilly SA (Pty) Ltd
Norge (Pty) Ltd
Novartis South Africa (Pty) Ltd
Nycomed (Pty) Ltd
Pfizer Laboratories (Pty) Ltd
Roche Products (Pty) Ltd
Sanofi-aventis (Pty) Ltd

NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS (NAPM)

CONTACT DETAILS:
Postal Address: P.O. Box 32361, Kyalami, 1684
Physical Address: 1342 Howick Mews, Waterfall Park, Bekker Road, Midrand 1685
Tel: 011 312-6966
Fax: 086 529 4245
E-mail: napm@mweb.co.za
Website: www.napm.co.za

List of NAPM members
Abex Pharmaceutica (Pty) Ltd
Activo Health
Arrow Pharma (Pty) Ltd
Aurobindo Pharma (Pty) Ltd
Austell Laboratories (Pty) Ltd
Be – Tabs Pharmaceuticals (Pty) Ltd
Bodene (Pty) Ltd
Caps Pharmaceuticals SA (Pty) Ltd
Columbia Pharmaceuticals
Di Medicine Registration Consultants
Dr Reddy’s Laboratories (Pty) Ltd
Cipla-Medpro (Pty) Ltd
Ferring Pharmaceuticals (Pty) Ltd
Litha Healthcare (Pty) Ltd
MC Pharma (Pty) Ltd
Medreich S.A
Mylan (Pty) Ltd
Pharma Dynamics (Pty) Ltd
Ranbaxy (SA) (Pty) Ltd
Sandoz SA (Pty) Ltd
Septapharma (Pty) Ltd
Teva Pharmaceuticals(Pty) Ltd
Thebe Medicare (Pty) Ltd
Zydus Group
PHARMACEUTICALS MADE IN SA (PHARMISA)

CONTACT DETAILS
Postal Address: P O BOX 1587, Gallo Manor, 2052
Physical Address: Building 7 Health Care Park, Woodlands Drive, Woodmead
Secretariat: Phoebe Phaka
Tel: 011 239-6549
Fax: 011 239-6530
Email: pphaka@aspenpharma.com

List of PHARMISA members:
Sekpharma (Pty) Ltd
Specpharm Holdings (Pty) Ltd
The Biovac Institute
Bodene (Pty) Ltd
National Bioproducts Institute
Phambili Hospital Products (Pty) Ltd
Pharmacare Limited trading as Aspen Pharmacare
Biolclones (Pty) Ltd

PHARMACEUTICAL INDUSTRY ASSOCIATION OF SA (PIASA)

CONTACT DETAILS:
Postal Address: P O Box 12123, Vorna Valley, 1686
Physical Address: Building 5, Thornhill Office Park, 94 Bekker Street, Vorna Valley, 1686
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Citymed  
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GUIDELINES TO THE SOUTH AFRICAN CODE OF PRACTICE FOR THE MARKETING OF HEALTH PRODUCTS

These notes are intended as a guideline to the interpretation of the Code of Practice for the Marketing of Health products 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”). 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. The responsibility of ensuring the currency of the guidelines rests with the MCA

Principles Underlying the Guidelines:

- The guidelines should not go beyond the Medicines and Related Substances Act and Regulations or what is stated in the Code of Practice for the Marketing of Health products except where necessary detail is called for by the Code
- The guidelines should not duplicate the code or legislation
- 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.
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Note 1:
PART A: MARKETING AND PROMOTION OF HEALTH PRODUCTS TO HEALTHCARE PROFESSIONALS

Clause 4: Registration Status of Medicines

Note 1: Provision of information during health product 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 is not permitted in South Africa, whether the meeting is national or international in nature.

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.

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 contain pack shots of any health product in Schedule 2 or higher schedule provided no indications/claims are made.

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.

**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.
- **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. Pictogram 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.

Note 2: Reply paid cards

Reply paid cards which are intended to be returned to the 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.


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 health products 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.

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. 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

- 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
- may only advise on technical aspects of company products consistent with the approved package insert.
- 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.
- may not use and/or apply company product, deliver patient or medical care directly to a patient even with appropriate certification/licences

Clause 17: 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

Business class travel is permitted for both incoming and outgoing faculty members (i.e. HCPs that are presenting scientific papers at the congress, educational events or local CPD accredited meetings/events).

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. 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: 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 7: 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 8: 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 background music at events connected to a bone fide function for the exchange of
information is acceptable.

Note 9: 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 10: 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 11: 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 Companies’ Medical Technologies, e.g. information about disease states and the benefits of Medical
Technologies to certain patient populations.

Note 12: Patient Support Groups
Companies may work with patient organisations but in doing so must ensure that the involvement of the company is made
clear so that all of the arrangements comply with the Code. This includes the need to declare sponsorship and the
prohibition of advertising prescription only health products to the public. The requirements which cover meetings for
healthcare professionals and appropriate administrative staff also apply to companies supporting patient organisation
meetings.

Companies should ensure compliance with the following requirements if they are considering becoming involved in any
patient support program:
- No incentives, other than material that will enhance positive health outcomes and compliance, are provided to patients to become involved in these programs;
- The data collected from these programs will not be used for any purpose other than to increase positive health outcomes and never for promotional activities; and
- The duration of these programs is appropriate to the disease state treated by the product involved.

Note 13: 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 14: 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 18: 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 practising HCP or practises, it should not exceed R 2 500 inclusive of VAT/year
  - For training or academic institutions, it 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 / practise 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 items – intended for use by patients
Some items distributed as promotional aids are intended for use by patients and these are acceptable provided that they meet the requirements of Clause 18.2 and 18.3 i.e. inexpensive (not more than R300 including VAT) and relevant to the practice.

Other items that may be made available to patients should meet the relevant principles set out in Clause 18.2, 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 19 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 11: 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 12: Donations to charities
Any donation to a charity must not constitute a payment that would otherwise be unacceptable under the Code. Companies are encourages 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.

Clause 19: 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 Schedules 0 or 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 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 19.1. The provisions of Clause 19.3 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 fulfils 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 19.1 and 19.2 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 of age. 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.

Clause 25: Information, Claims and Comparisons in Advertising and/or Promotion

Note 1: Information to Appear in Advertisements and Package Inserts
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.

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 Schedules 0 or 1 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 (Fast Moving Consumer Goods) 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. A giveaway item should be of nominal value, must not mislead the patient and does not encourage the inappropriate use of the health product, as per the local approved package insert. Giveaway items could include a spoon, sponge, etc.

Clause 39: Healthcare sales representatives/Consumer Promoters

Note 1: Sales Representatives

Fast Moving Consumer Goods Sales representatives, agents, merchandisers and promoters selling or promoting S0 health products are included in the description of medical representatives.
Guidelines to Part D of Marketing Code – 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, principles to be considered when determining sanctions as a result of breach findings.

1. 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.

1.1 Before lodging a complaint with the MCA

1.1.1. 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.

1.1.2. The Complainant and Respondent must comply with the following procedure:

1.1.2.1. The complaint must be conveyed to the respondent (Company Code Compliance Officer to Company Code Compliance Officer) in writing, requesting a written response in five working days.

1.1.2.2. 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.

1.1.2.3. Should the matter be resolved between the disputing parties, the MCA should, as a matter of courtesy, be informed.

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

1.1.2.5. If the respondent does not agree with the complaint then both parties (Company Code Compliance Officer and/or CEO to Company Code Compliance Officer and/or CEO) should be encouraged to have a face to face or via another medium meeting in order to try and resolve the dispute within five working days.

1.1.2.6. If the respondent does not agree with the complaint, then both parties should agree within two working days on a date for a meeting to resolve the dispute in question. Meeting should take place within a further ten working days and the meeting should be face-to-face or via another medium.

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

1.1.2.8. The Marketing Code Authority shall not adjudicate a complaint without compliance to the above procedure (1.1.2.1 - 1.1.2.7).
2 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.

2.1 Enforcement Structures

2.2 Complaints Process

Process flow for lodging a complaint
2.3 Appeal Process

**Appeal Process**

- **Lodging an Appeal**
  - Complainant lodging complaint
  - EO can review time line
  - Appeal fee to EO
  - EO advises other party (respondent) that appeal has been lodged & provide copies of adjudicating proceedings

- **Appeal Hearings**
  - EO to make recording of hearing & issue outcome of appeal
  - Appellant Committee Chairperson to certify transcript
  - Chairperson to ensure proceedings are transcribed
  - EO to inform all parties of date, time & venue of hearing
  - EO makes copies of records to appeal committee

- **If no satisfactory outcome**
  - EO refers to Board
  - Process ends

2.4 Expedited Process

**Expedited Process**

- **Complaint**
  - Alleged violation of Clause 22 or 40
  - Complainant (incl. nominated complainant) sends written complaint to EO
  - EO to send copies of alleged non-compliance to EO
  - EO to send copies of alleged non-compliance to respondent company

- **Appel Hearings**
  - EO to constitute Appeal Committee
  - EO to convene appeal on written complaint & respond incl. copy of ruling to Appeal Committee
  - Appeal Committee will deliberate & make a ruling based on documents
  - Breach of Clause 22 or 40?

- **Yes**
  - Refer matter to appropriate authority or forum incl. legal action
  - Confirm previous sanction

- **No**
  - Imposes further penalties
  - Any other appropriate sanction or remedial action incl. Publication of findings
  - Any other sanction, save orders as to costs and fees
3 Principles for determining sanctions

Companies should provide evidence that they have exhausted all options to resolve complaint at company level, as per Part D of the Marketing Code. The principles for determining a sanction should be transparent to both the complainant and subject company. These principles are not a list of procedural rules but the foundation upon which the level of sanction is determined. Sanctions should be based upon clear principles and applied in a predictable and consistent manner without unnecessary rigidity. 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.

It must be acknowledged that sanctions are not static. The upper limits of monetary sanctions will be reviewed as part of the annual review of the Code. However, within the limits identified in the Code, the MCA has the discretion to apply a range of monetary fines and other sanctions based on consideration of these principles.

The following is a set of principal factors which will be taken into consideration by the MCA in determining a sanction following a finding of breach/es of the Code.

3.1 Principal factors in determining a sanction:

- The nature and extent of the activity/material
- whether the breach should have been clearly evident to the Company;
- breadth of activity or campaign;
- length of time that the materials have been in use;
- the number and type of alleged breach/es; and
- circumstances in which the activity took place – and whether any explanation offered by the subject company.

3.2 Double Jeopardy

The MCA will not rehear a complaint against a particular section or sections of the Code in relation to the same activity or same material irrespective of whether there was a finding of a breach of the Code, unless there is an allegation that the material has not been withdrawn or the activity has not ceased. If a complaint is received in relation to an activity or material already considered by the MCA the complainant will be referred to the outcome of the previous complaint.

4 Factors to Consider for Sanctions

- extent of breach – how misleading, damaging, disparaging;
- potential for patient harm – such breaches usually require corrective action and may attract a higher sanction; direct to consumer advertising or misleading information to the general public – in general, activities directed to the consumer found in breach of the Code attract a higher sanction. Direct to consumer advertising is in breach of the SA Marketing Code for S2 and upwards;
• promotion of an un-approved indication or product also attract a higher sanction in recognition that this would also breach the SA Marketing Code; and
• extent of dispute resolution dialogue – demonstration of significant attempts to resolve a complaint prior to proceeding to the MCA may result in a lower sanction being applied;
• potential costs to be incurred by a company for corrective action – the MCA will consider the overall monetary cost of the package of sanctions, for example the cost of issuing a corrective letter in combination with a fine.

• In the case of a corrective letter the MCA will specify to whom the letter must be sent. This will reflect the audience who may have received the material found in breach of the Code.
• Where the sanction includes a corrective advertisement the placement must be in the same journal as that of the advertisement found in breach of the Code. The corrective advertisement must be of the same size and prominence as the original advertisement.
• A copy of the distributed corrective letter (on company letterhead bearing the signature of the company Chief Executive Officer or Code Compliance Officer) and published corrective advertisement should be provided to MCA for the file records. (Refer to Section 24.2 of Code)
• The number, format, size, wording, mode of publication, prominence, timing (including duration of publication) and method of distribution of corrective statements must be approved by the MCA prior to release.

4.1 Company History
• history of previous breaches of the Code in relation to a specific therapeutic area;
• sanctions previously imposed on the company by the MCA in relation to the same or similar types of breach/es or in comparable circumstances;
• repeated or multiple breaches;
• any evidence that previous breaches or sanctions have not successfully encouraged improved compliance within the company (not necessarily within the same therapeutic area);
• any evidence that the breach related to an activity that was not sanctioned by the company’s operating procedures or training of personnel; and
• Cooperation/acknowledgement of offence and evidence of internal procedures implemented to avoid similar breaches in future.

5 Sanctions
The Adjudicating Committee will make a decision regarding the fines and any applicable complaints fees payable by the respondent or complainant. Refer to Sanctions document.
<table>
<thead>
<tr>
<th>Breach Classification</th>
<th>Expanded definition</th>
<th>Corrective Action/Public Disclosure</th>
<th>Fine</th>
<th>Timelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minor</strong></td>
<td>No safety implications for patients’ wellbeing No effect on how healthcare professionals will use product</td>
<td>Immediate withdrawal of material/activity from market Company to issue a corrective statement, as determined by MCA, including target audience Written reprimand to company by MCA Notify HCP of breach, if relevant</td>
<td><strong>R6K-R100K</strong></td>
<td><strong>30 days</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>No safety implications to patients’ wellbeing May have effect on how healthcare professionals will use product</td>
<td>Immediate withdrawal of material/activity from market Company to issue a corrective statement, as determined by MCA, including target audience Written reprimand to company by MCA Notify HCP of breach, if relevant Publication of corrective advertisement, as determined by MCA, including target audience</td>
<td><strong>R100K-R200K</strong></td>
<td><strong>30 days</strong></td>
</tr>
<tr>
<td><strong>Serious/Severe</strong></td>
<td>Will have safety implications to patients’ wellbeing Will have effect on how healthcare professionals will use product Commercial impact on relevant market Activities that bring disrepute to industry or reduce confidence in the industry</td>
<td>Immediate withdrawal of material/activity from market Written reprimand to company by MCA Publication of corrective advertisement, as determined by MCA, including target audience</td>
<td><strong>R200K-R300K</strong></td>
<td><strong>30 days</strong></td>
</tr>
</tbody>
</table>

**Additional Sanctions/Fines**

| Fines not paid | When a monetary fine is not paid within the required time period from receipt of the decisions and the reasons for the decisions of the MCA | Further fine of R50K | **60 days** |
| Corrective Action not implemented | Where corrective action has not been actioned within required timelines Any other sanction including orders as to cost and fees | The matter will be raised by MCA with the subject company and may be taken to MCA for consideration | Further fine of R100K | **60 days** |

| Repeated Breaches | >3 infringements in 1 year When a company repeats any breach, as classified by MCA, in the promotion/activity of any of the company’s products/activity | The MCA may publish the decision in a newspaper with national circulation along with the name of the offending company. Publication of the infraction on MCA website All postings will remain on website for 12 months. Inform the MCC of infringement and recommend cancellation of registration of product | First: R10K + original fine; Second: R15K + original fine; Third: R25K + original fine R200K max MCC can cancel product registration | **60 days** |

| Multiple breaches | Where the MCA, through monitoring, finds a number of breaches of the Code by a company: MCA will usually consider the aggregate of the breaches to determine whether a sanction should be imposed | The MCA may publish the decision in a newspaper with national circulation along with the name of the offending company. Publication of the infraction on MCA website Inform the MCC of infringement and recommend cancellation of registration of product/s involved MCA may impose a sanction in respect of each breach of the Code, but may choose to impose an additional financial sanction | MCC can cancel product registration | **60 days** |

| Invalid / unjustified / vexatious complaints | Does not comply with requirement of complaint as defined in Code | MCA informs complainant in writing | R10K | **60 days** |
| Bringing the Code into disrepute | When a company brings the Code into disrepute or misrepresents the Code | The MCA may publish the decision in a newspaper with national circulation along with the name of the offending company. Publication of infraction on MCA website | R200K max | **60 days** |