



SA CODE OF MARKETING PRACTICE v10

November
2016

This Code of Marketing Practice is the official code of the Marketing Code Authority (MCA). Member companies, as indicated on the MCA website, have committed to compliance with this code which is applicable to all health products subject to registration by the Medicines and Related Substances Act 101 of 1965.

Membership of the MCA is either in collaboration with industry trade associations or as independent, non-aligned members.

Guidelines to the code assist in the interpretation and application of the code www.marketingcode.co.za













The version control form a history of amendments to the code is referenced at the end of the code document.

V10 of the code was ratified at the AGM of the Marketing Code Authority on the 16th November, 2016.

For further information on the Marketing Code Authority or the code enforcement provisions please contact info@marketingcode.co.za

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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:

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.

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; Facebook, Twitter and other such mediums, 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.

Company means a company, closed corporation, organisation, firm, vendor or individual who may sell or promote health products.

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 with regard to Code compliance.

Complementary medicines means complementary medicines as defined in the Medicines and Related Substances Act 101 of 1965 as amended and Regulations.

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

Evaluation of medical devices and IVDs: The assessment and analysis of data pertaining to a medical device or in vitro diagnostics (IVDs) to establish or verify the clinical safety and/or performance of the device when used as intended by the manufacturer.

Faculty means active participants / HCPs who speak, present or serve another specific function at a third-party organised medical educational conference.

Health products. For the purpose of this Code, the term Health Products includes medicines, complementary medicines including health supplements (CAMs), medical devices, IVDs.

Health Supplements means health supplements as defined in the Medicines and Related Substances Act 101 of 1965 as amended, and Regulations

Healthcare Professional (HCP) includes individuals (clinical or non-clinical, including but not limited to, physicians, nurses, technicians, and research coordinators) 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 as well as Healthcare Facilities registered at the Department of Health or other regulatory or organisational body, such as hospitals, step-down facilities, managed care companies, etc.; which entities prescribe, purchase, lease, recommend, use, maintain or arrange for the purchase or lease of members' health products in South Africa.

Honorarium (or alternatively Fee for Service) means a payment or an award granted in recognition of a special service by a 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.

Institution: An organization, establishment, foundation, society, or the like, devoted to the promotion of a particular cause. This includes private hospitals and clinics.

For medical devices:

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
- supplied with such a container or pack

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 medicines, scheduled substances, medical devices and IVDs, as amended from time to time and includes any future legislation that amends or repeals and replaces the Medicines Act.

Medical devices and IVDs are defined in the Medicines and Related Substances Amendment Act, 2008,

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

Ordinary day means - any day other than a Saturday, Sunday or public holiday in terms of the laws of the Republic

Promotional aids means non-monetary items given away free of charge to promote a company or product.

Promotional material means detail aids; leave behind pieces, booklets, advertorials etc.

Registry is defined as an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes

Key



Medicines



All health products

CODE OF MARKETING PRACTICE

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 stake holders, to make regulations relating to the marketing of medicines, scheduled substances, medical devices or IVDs, 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 THE APPLICATION AND INTERPRETATION OF THE CODE

2.1 Introduction

The ethical promotion of medicines, scheduled substances, medical devices and IVDs 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.

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

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 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.

Considering the provision in terms of Section 18C of the Medicines and Related Substances Act No 101 of 1965, as amended, for an enforceable Code of Practice, the MCA intends that the MCA Code of Practice be acknowledged as such. The health products trade associations have adopted the MCA Code to signify the industry’s commitment to ensure that the marketing of health products to Healthcare Professionals and to the public is carried out in a responsible, ethical and professional manner which is 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

The Code is applicable to the following organisations and situations:

- 2.2.1 All medical devices, IVDs, registered health products, licence holders, their agents, contractors, third party distributors/marketers and/or contracted events' organisers. 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.
- 2.2.2 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.
- 2.2.3 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.
- 2.2.4 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.
- 2.2.5 Interactions between the industry and Healthcare Professionals (Part A) and the industry and the general public (Part B).
- 2.2.6. Wholesalers, distributors, medical/IVD devices importers and logistics companies to the extent that they may influence the demand for health products.

The Code does not apply to the following situations:

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

The following documents are not covered by the Code:

- Product labels, packaging materials and in-pack leaflets. These are subject to the labeling and package insert requirements in terms of the Regulations to the Medicines Act and the Guidelines pertaining thereto.
- The marketing or promotion of Stock Remedies as defined under Act 36 of 1947.
- Issues relating to pricing, bonusing, sampling 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.

2.3 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. The rulings of the bodies established as part of the MCA, forms

precedent on what constitutes acceptable practices in the marketing of health products.

- 2.3.2 Any person interpreting and applying the Code must consider the Guidelines issued thereunder in order to provide guidance as to the application of Code principles in practical situations. Previous rulings by Adjudication and Appeal Committees may also be considered. An interpretative approach that harmonises the Code and Guidelines should be followed. In cases of irreconcilable conflict the Code will prevail and recommendations may be made by structures of the MCA, including Adjudication and Appeal Committees as to adjustments that should be considered by the relevant MCA structures (Board and Annual General Meeting) in correcting such irreconcilable conflicts.
- 2.3.3 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, the Pharmacy Act No. 53 of 1974 and the National Health Act No 61 of 2003.
- 2.3.4 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.’*
- 2.3.5 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**

Guidelines on the interpretation of the Code appear as supplementary information to the text in a separate document. 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 that are covered by the provisions of the Code.

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 constitute violations of the Code.

2.5 **Scope of Application**

PART A - The marketing and promotion to Healthcare Professionals

PART A of the Code applies to the promotion to members of the healthcare professions, shareholders and to appropriate administrative staff in 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 and complementary and alternative medicines (CAMs) 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 and complementary medicines 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 complementary medicines and Schedules 0 and 1) marketed to Healthcare Professionals, irrespective of the scheduling.

PART B - The marketing and promotion directly to the consumer

The advertising and/or promotion of medicines in Schedules 0 and 1, and complementary medicines 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 and complementary and alternative medicines (CAMs) 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 and complementary and alternative medicines (CAMs) (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 all 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 light of the exemption for Schedule 0 medicines (Category A and D) from the provisions of section 18A and 22G as it relates to pricing to the Medicines Act.

PART C - The marketing and promotion of medical devices.

The principals of Interactions with Healthcare Professionals and the consumer and the advertising and promotion in Part A and B of the Code apply equally to Medical Devices and IVDs. Section C of the Code deals with specific activities related to Medical Devices and IVDs only.

Where indicated as such, certain provisions of Part A and Part B also apply to medical devices. Section C of the Code deals with specific activities related to medical devices and IVD's only.

Part D - provision for enforcement

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.

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

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.

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.

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 TO HEALTHCARE PROFESSIONALS

4 REGISTRATION STATUS OF MEDICINES

The promotion of a medicine must be in accordance with the Medicines and Related Substances Act 101 of 1965 and the terms of its registration, and must not be inconsistent with the particulars listed in its package insert.

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.

5 ADVERTISING AND PROMOTIONAL MATERIAL OF MEDICINES

- 5.1 Only registered and old medicines may be advertised and promoted (refer to Clause 4)
- 5.2 All advertising and/or promotional material must be based on the current approved South African package insert.¹
- 5.3 The minimum requirements must:
 - 5.3.1 Conform to the applicable regulations in terms of the Medicines Act.
 - 5.3.2 Form part of the promotional material and not be separate.
 - 5.3.3 Be included in all promotional material (except for promotional aids - see Clause 19.3).
 - 5.3.4 Be provided in a clear and legible manner.
 - 5.3.5 Be consistent with the most recently approved South African package insert for the medicine.
- 5.4 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 aids as referred to in Clause 19.3.
- 5.5 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.
- 5.6 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.
- 5.7 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.
- 5.8 Audio-visual or audio material such as films, video recordings, sound bites, interactive data systems and such like:
 - 5.8.1 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.

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

5.8.3 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, printed on one or both sides.

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

7.2 Upon reasonable request, a company must promptly provide Healthcare Professionals and appropriate administrative staff with accurate and relevant information relating to claims and comparisons about the products which the company markets.

7.3 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.

For medicines: No substantiation is required for claims in the package insert which has been approved by the medicines regulatory authority.

7.4 Exaggerated or misleading claims

Promotional material must encourage the rational use of a 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 an active ingredient or health product has some special merit, quality or property unless this can be substantiated.

7.5 Comparisons

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

- 7.5.1 It is not misleading or disparaging.
- 7.5.2 Health products or services for the same needs or intended for the same purpose are compared.
- 7.5.3 One or more material, relevant and representative feature(s) which is/are capable of substantiation is/are compared.
- 7.5.4 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.
- 7.5.5 The trademarks, proprietary names, other distinguishing marks, health products, services, activities or circumstances of a competitor are not discredited or denigrated.
- 7.5.6 Trademarks/trade names or company names of another company may only be mentioned with written permission from the other company, unless doing so is permitted by intellectual property law and / or common law, as amended and developed from time to time.
- 7.5.7 No unfair advantage is taken of the reputation of a brand, trademark, proprietary name or other distinguishing marks of another company.
- 7.5.8 Health products or services are not presented as imitations or replicas of goods or services bearing another company trademark or trade name.
- 7.5.9 Hanging (open ended) comparisons are not allowed.

7.6 Substantiation

7.6.1 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.

7.6.2 For complementary and alternative medicines (CAMs), substantiation for any product claim must be in accordance with the requirements of the applicable regulations to the Medicines Act and associated guidelines, where such exist, insofar as they relate to the level of evidence required for a low risk versus a high risk type of claim. If the product is already registered, substantiation need not be provided in relation to the validity of approved indications in the package insert.

7.7 References

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

7.8 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 supports the statement(s) made in the promotional material.

7.9 **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.

7.10 **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.

7.11 **Use of the word 'new'**

The word 'new' may be used to describe any product, presentation or therapeutic indication, which has not been available in the market for more than 12 months in South Africa.

7.12 **Other claims**

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

7.13 **Personal medical matters**

In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a Healthcare Professional.

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, efficacy/effectiveness and performance

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 HCPS**

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 / video, television advertisement, radio advertisement or any other reproduction of a member of a Healthcare Professional must not be used in

any way that is contrary to the applicable professional Code(s) 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, mobile messaging, telex, facsimile machines, or any form of electronic communications as defined in the Electronic Communications and Transactions Act, No 25 of 2002, as amended from time to time, 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. This provision shall be subject to all national legislation in force from time to time, to the extent applicable.
- 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, observational / non-interventional studies and the like must not be disguised promotions, 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 data from or on behalf of an individual, or group 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:
 - 10.5.2 A written study plan (protocol) and
 - 10.5.3 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.
 - 10.5.4 Remuneration provided must be reasonable and of fair market value to the work performed.
 - 10.5.5 The study protocol must be submitted to the appropriate ethics committee for review.
 - 10.5.6 Personal data privacy including the collection and use of personal data must be respected.
 - 10.5.7 The study must not constitute an inducement to participate, recommend, prescribe, purchase, supply, sell or administer a particular product.
 - 10.5.8 The study protocol must be approved by the company's scientific/ medical department, who must also supervise the conduct of the study.
 - 10.5.9 The study result 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 relevant 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.
 - 10.5.10 Sales and marketing personnel 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 sales and marketing personnel are adequately trained. Such involvement must not be linked to the promotion of any 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.

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.

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 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 Code.
- 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 MCA 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 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 product.

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 MARKETING AND SALES PERSONNEL

15.1 Training

Each company shall ensure that its Marketing and Sales personnel, 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 health 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 health products they promote or services offered.

15.2 Compliance with Codes and laws by 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 to the provisions of Clause 18 (Interaction with Healthcare 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, where applicable. 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, Sales 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 sales 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 Representatives must be appropriately trained on operating room/clinical environment protocol(s).

16 MEDICAL SCIENTIFIC LIAISONS (MSL)

16.1 Company MSL should have a scientific or medical background or experience. They provide scientific and medical information to HCP and customers to ensure appropriate and safe use of medicines.

16.2 MSL should not report into Marketing and Sales and should comply with Section 15 and 18 of the Code.

17 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.

18 INTERACTIONS WITH HEALTHCARE PROFESSIONALS

18.1 Hospitality/venues of meetings and events

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

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

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

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

18.1.4 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.

18.1.5 Invitations should not be extended to spouses or other guests except if they

- are Healthcare Professionals or administrative staff and form part of the trainees or invited attendees at such a meeting / event i.e. any costs incurred by spouses or other guests cannot be reimbursed or paid for by the company.
- 18.1.6 Inappropriate financial benefit or material benefits including excessive hospitality cannot be offered and/or extended to Healthcare Professionals.
 - 18.1.7 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.
 - 18.1.8 CPD meetings:
 - 18.1.8.1 No product promotion is allowed in the CPD meeting room. Company-branded items/promotions are permissible.
 - 18.1.8.2 Speakers should use the International Non-Proprietary Name (INN) names of products during CPD events. Companies must make it known to speakers that the use of trade names is not permitted.
 - 18.1.8.3 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.
 - 18.1.8.4 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.
 - 18.1.8.5 The criteria for selection of attendees/invitees must be transparent and available to the MCA on request for scrutiny.
 - 18.2 For medical or scientific congresses, conferences or seminars held in South Africa, internationally or international meetings held overseas and held in South Africa:
 - 18.2.1 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.
 - 18.2.2 The rationale for any meeting or sponsorship to attend a meeting is to be transparent, valid and cogent.
 - 18.2.3 Consideration must be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, hospitality provided and the like.
 - 18.2.4 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.
 - 18.2.5 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.
 - 18.2.6 Sponsored speakers may receive reasonable honoraria.

- 18.2.7 Advertisement and promotion is 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.
- 18.2.8 Sponsorship of congress organised events, other than recreational and sporting events, is permitted. Sponsorship of any stand-alone social or entertainment event is however not permitted.
- 18.2.9 Invitations should not be extended to spouses or other guests except if they are Healthcare Professionals or administrative staff and form part of the trainees or delegates at such a meeting / event i.e. any costs incurred by spouses or other guests cannot be reimbursed or paid for by the company. The meeting and event should be appropriate to all delegates' scope of practice.

18.3 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.

18.4 Stand-alone entertainment, leisure, social or cultural events with Healthcare Professionals

Meetings organised for patients, the 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 are not permitted.

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

18.5 The use of consultants

- 18.5.1 It is permitted to use Healthcare Professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing of meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:
- a) A written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to Clause (g) below, the basis for payment of those services;
 - b) A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
 - c) The criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular Healthcare Professionals meet those criteria;
 - d) The number of Healthcare Professionals retained is not greater than the number reasonably necessary to achieve the identified need;
 - e) The contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants;

- f) The hiring of the Healthcare Professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and
- g) The compensation for the services is reasonable and reflects the fair market value of the services provided.

18.5.2 In written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that employ, on a part-time basis, Healthcare Professionals that are still practising their profession are strongly encouraged to ensure that such persons have an obligation to declare his/her employment arrangement with the company whenever he/she writes or speaks.

18.5.3 If a Healthcare Professional attends an event (an international event or otherwise) in a consultant or advisory capacity the relevant provisions of Clause 18.5 shall apply.

18.6 Medical and educational services / goods

Medical and educational goods and services which enhance patient care and/or maintain patient care, can be provided subject to the provisions of Clause 19.1. and Clause 19.2. They must not be provided to individuals for their personal benefit. Medical and educational goods must not bear the name of any medicine but may bear the name of the company providing them.

18.7 Other interactions with Healthcare Professionals

18.7.1 No direct payments may be made to Healthcare Professionals for any other services

18.7.1.1 Payments may not be made to doctors or groups of Healthcare Professionals, either directly or indirectly, for rental for rooms or other services.

18.7.1.2 Healthcare Professionals involved in *bona-fide* and if relevant, peer reviewed research, are not subject to 18.7.1.

18.7.1.3 No cash or cash equivalents (e.g. vouchers) are allowed for completion of a survey or as a prize for a competition.

18.7.2 Certification of meetings

For the purposes of certification envisaged in Clause 14, the following details must be retained:

18.7.2.1 Details of the programme, both scientific/education and entertainment/ hospitality, if any.

18.7.2.2 Invitations, the choice of venue(s).

18.7.2.3 Documentation as to the rationale for the meeting or sponsorship.

18.7.2.4 Participant selection processes and criteria.

18.7.2.5 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.

18.8 Patient Registries

- 18.8.1 With regard to Healthcare Professionals providing information to registries, remuneration must be commensurate with the work performed i.e. must be reasonable and of fair market value.
- 18.8.2 Registries may not be disguised as promotion, and should be of scientific and/or healthcare policy merit, and relate to a legitimate and defensive project to obtain data/information. Proof of such *bona fide* registry data and documentation, including protocols, research ethics committee approval and agreements may be called for from time to time.
- 18.8.3 Registries should comply with all applicable laws, including but not limited to the privacy protections, the prescribed consent of the person whose information it is as provided for in the National Health Act, Protection of Personal Information Act and the Consumer Protection Act.

19 INDUCEMENTS, GIFTS AND PROMOTIONAL ITEMS, COMPETITIONS

19.1 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 health product, subject to the provisions of Clause 19.2. No donation should unjustifiably enrich Healthcare Professionals performing a health related service.

19.2 Promotional aids

- 19.2.1 Occasional items to Healthcare Professionals, appropriate administrative staff, sales and other staff are acceptable provided that they are:
 - 19.2.1.1 Inexpensive and of modest intrinsic value i.e. within the cost limit set from time to time per annum by the MCA.
 - 19.2.1.2 Not for personal use e.g. no entertainment CDs/DVD, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.
 - 19.2.1.3 Educational and/or of scientific value, benefit the patient and/or be relevant to the practice.
 - 19.2.1.4 No cash or cash equivalents (e.g. vouchers) are allowed.
- 19.2.2 It is permissible to brand promotional aids. 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.
 - 19.2.2.1 The items should be inexpensive and of minimal intrinsic value i.e. within the cost limit set from time to time per annum by the MCA.
- 19.2.3 The following information may be included on such items:
 - 19.2.3.1 The proprietary name of the product.
 - 19.2.3.2 An indication that the name of the product is a trademark.
 - 19.2.3.3 Relevant company name, company logo and/or product logo.

19.3 **Cultural courtesy gifts**

An inexpensive gift not related to the Healthcare Professionals' practice, the value of which will be 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.

19.4 **Competitions**

Competitions should fulfill the following criteria:

- 19.4.1 The competition is based on medical/product knowledge or the acquisition of scientific knowledge;
- 19.4.2 Individual prizes or educational items offered should benefit the patient and / or be relevant to the practice; and within the cost limit set from time to time by the MCA;
- 19.4.3 The prize cannot comprise cash or a cash equivalent (e.g. vouchers) and
- 19.4.4 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.

19.5 **Donations and grants to charities**

19.5.1 Financial donations or other appropriate donations to 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:

- 19.5.1.1 They are made for the purpose of supporting healthcare or research;
- 19.5.1.2 They are documented and kept on record by the donor/grantor; and
- 19.5.1.3 They do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific products.
- 19.5.1.4 Donations must not be paid directly to Healthcare Professionals or to healthcare administration staff.
- 19.5.1.5 Companies are encouraged to make available publicly, information about donations, grants or benefits in kind made by them as covered in this section.

19.6 **Corporate social investment**

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.

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 health product.

20 **ITEMS FOR PATIENTS AND PATIENT ORGANISATIONS**

20.1 Healthcare Professionals may be provided with items which are to be passed on to patients and which are part of a formal patient support programme, the details of

which have been appropriately documented and certified in advance as per the Code.

20.2 The items provided must be inexpensive and directly benefit patient care. In the case of the product being recommended or prescribed for the patient, the item may bear the name and / or logo of the company and / or product.

20.3 Joint working between one or more companies is acceptable provided that this is carried out in a manner compatible with the Code. Joint working must always benefit patients and be in accordance with competition law.

20.4 **Written agreements**

When companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement which states the amount of funding and also the purpose thereof.

20.5 **Use of logos and proprietary materials**

The public use of a patient organisations logo and/or proprietary material by a company requires written permission from that organisation.

20.6 **Editorial control**

Companies must not seek to influence the text of patient organisation material they sponsor in a manner favorable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies.

20.7 **Contracted services**

Contracts between companies and patient organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research.

It is permitted to engage patient organisations as experts and advisors for services such as participation at advisory board meetings and speaker services provided a written contract or agreement is in place.

20.8 **Events and hospitality**

All events sponsored or organised by or on behalf of a company including scientific, business or professional meetings must comply with Clause 18.1.

Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases, in case of clear health needs (e.g. disability), the travel meals, accommodation and registration fees cost of an accompanying person considered to be a care giver can be provided.

21 **SAMPLES** 

The supply of product(s) as samples is not permitted to extend beyond the conditions as prescribed under any relevant health legislation or any exemption/s thereto.

CAMs and personal care products may not be provided together with any medicines scheduled.

22 **THE INTERNET** 

Note: For Medical devices and IVDs, please refer to Part C

- 22.1 Promotional material accessible by the South African public provided on the Internet in relation to Schedule 2 to Schedule 6 medicines should be provided through a password protection scheme to Healthcare Professionals only.
- 22.2 Information or promotional material covered by Clause 22.1 about medicines that is placed on the Internet outside of South Africa, will not be considered in scope, unless the information or promotional material is specifically placed on the web to target South African consumers.
- 22.3 Medicines covered by Clause 22.1 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.
- 22.4 Package inserts and patient information leaflets (PILs) for health products covered by Clause 22.1 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.
- 22.5 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.

23 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 within the specified timeframe. Refer to Part D of the Code.

PART B: MARKETING AND PROMOTION DIRECTLY TO THE CONSUMER / PUBLIC








24 REGISTRATION STATUS OF MEDICINES

The promotion of a registered self-medication and complementary and alternative medicine (CAM) 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.

A medicine must not be promoted:

- 24.1 Prior to the product being registered by the medicines regulatory authority or;
- 24.2 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.

25 ADVERTISING AND/OR PROMOTION

- 25.1 Only registered and old medicines may be advertised and promoted (refer to Clause 24) 
- 25.2 Advertisements must be consistent with the requirements of the Medicines Act and other applicable legislation and in line with the approved package insert. 
- 25.3 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. 
- 25.4 Advertising and/or promotion shall not be misleading as to the nature of the product, its ingredients or indication(s). It shall not contain any exaggerated claims either direct or implied as to the benefits that can be obtained from use of the health product. 
- 25.5 When showing before-and-after pictures of a patient using a health product, the visuals should not imply or show complete eradication of the condition, nor may the visuals imply that a health product can be used to treat more serious forms of disease than the registration of the product would allow. 
- 25.6 Efficacy / effectiveness or performance claims should clearly state if health products are suitable for use over extended periods of time or where the health product is indicated for disease risk reduction or prevention. 
- 25.7 Advertising and/or promotion can refer to the prevention of symptoms and use of a health product in chronic conditions, if in line with the registered indication¹. The advertisement shall make it clear under what circumstances use of the health product is appropriate. This is particularly important in therapeutic areas where individuals may be asymptomatic. 
- 25.8 Advertisements should not suggest that using a health product could enhance normal good health or be a substitute for a healthy diet and lifestyle.

- 25.9 Advertising shall not undermine current healthy-lifestyle advice. 🌱
- 25.10 Advertising and/or promotion shall not be aimed principally or exclusively at children (under the age of 12 years). 🌱
- 25.11 Advertising and/or promotion shall not show children using, or within reach of health products without adult supervision. 🌱
- 25.12 Advertising and/or promotion shall encourage responsible use of self-medication and should not encourage individuals to exclusively self-diagnose or self-medicate. 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 exclusion of more serious complaints or where use of the health product could mask the symptoms of a more serious condition. Advertisements should encourage individuals to share information with the pharmacist, clinic sister or healthcare practitioner so that they can ensure the health product will be suitable for the intended user. 🌱
- 25.13 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. 🌱
- 25.14 Advertising and/or promotion shall not offer to diagnose, advise, prescribe or treat persons by correspondence. 🌱
- 25.15 Advertising and/or promotion shall not claim guarantees on a health product's effects, safety or quality. Offers to refund money must not imply that the effects of the product are guaranteed. 🌱
- 25.16 Advertising and/or promotion shall not encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of any health product. 🌱
- 25.17 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. 🌱
- 25.18 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. 🌱
- 25.19 Advertising and/or promotion should not encourage consumers to discontinue the use of prescribed health products. 🌱
- 25.20 Advertising and/or promotion shall not contain recommendation of a product by scientists or Healthcare Professionals unless substantiated. 🌱
- 25.21 Advertising and/or promotion shall not include the appearance and/or recommendation and/or endorsement, whether directly or indirectly by a person who, because of their celebrity status in any field (notwithstanding whether this is a local or international celebrity status), may encourage consumers to use a particular health product. ¹ 🌱
- 25.22 Advertising shall not contain improper, alarming or misleading claims of a recovery.

25.23 Advertising shall not use misleading, alarming or improper visuals to represent changes in the human body.

25.24 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.

26 INFORMATION, CLAIMS AND COMPARISONS IN ADVERTISING AND/OR PROMOTION

26.1 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 health 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.

26.2 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.

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

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

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

26.6 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.

26.7 Proprietary or trade names of products of other companies shall not be used without permissions of the owner.

26.8 Hanging (open ended) comparisons are not allowed.

26.9 Notwithstanding the above, comparisons are only permitted in advertising and/or promotion or promotional material if:

26.9.1 They are not misleading or disparaging;

26.9.2 Health products or services for the same needs or intended for the same purpose are compared;

26.9.3 One or more materials, relevant and representative features, capable of substantiation, are compared;

26.9.4 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;
- 26.9.5 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;
- 26.9.6 No unfair advantage is taken of the reputation of a trademark, proprietary name or other distinguishing marks of a competitor;
- 26.9.7 Health products or services are not presented as imitations or replicas of goods or services bearing a competitor's trademark or trade name.
- 26.9.8 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.
- 26.10 Substantiation for any information, claim or comparison must be provided at the request of the MCA. It need not be provided, however, in relation to the validity of indications approved in the product registration. 🗑️
- 26.11 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. 🗑️
- 26.12 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. 🗑️
- 26.13 All artwork including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code. 🗑️
- 26.13.1 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.
- 26.13.2 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 health 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.
- 26.13.3 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. In this instance full substantiation must be provided. Claims should not imply that a health product or an active ingredient has some special merit, quality or property unless this can be substantiated.
- 26.13.4 The word 'new' may be used to describe any product, presentation or therapeutic indication, which has not been available in the market for more than 12 months in South Africa.
- 26.13.5 Advertising and/or promotion of a self-medication health product or complementary and alternative medicines (CAMs) shall not suggest that a product is a foodstuff, cosmetic or other non-medicinal product.
- 26.13.6 Although it is acceptable to indicate that a self-medication health product and complementary and alternative medicines (CAMs) are palatable,

advertising and/or promotion shall make clear that it is a medicine. To be contextualised to the nature of the product concerned.

- 26.13.7 Advertising and/or promotion shall not suggest, directly or indirectly, that a health product contains an unknown active ingredient.
- 26.13.8 A health product, or any of its attributes, shall not claim to be unique unless substantiated.
- 26.13.9 Advertising and/or promotion shall not mislead about the novelty of a preparation of the health product.
- 26.13.10 Advertising and/or promotion claims relating to speed of absorption, dissolution, distribution or other pharmacokinetic particulars are acceptable if supported by evidence and if in line with the product's registration dossier. Such evidence may however not be extrapolated to claims that a product offers improved efficacy or speed of efficacy, without supporting evidence to substantiate such claims.
- 26.13.11 Advertising and/or promotion shall not suggest that the safety, quality or efficacy of a health product is due to the fact that it is natural. Advertising and/or promotion shall not claim that a health product is 'natural', but where applicable it may be stated that a product contains natural ingredients.
- 26.13.12 Advertising and/or promotion shall not suggest that a health 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'.
- 26.13.13 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.

27 DISPARAGING REFERENCES

- 27.1 The health products and activities of other companies must not be disparaged.
- 27.2 The health professions and the clinical and scientific opinions of their members must not be disparaged.

28 SUITABILITY AND TASTE

- 28.1 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.
- 28.2 The name or photograph or film /DVD etc. of a member of a health profession must not be used in any way that is contrary to the conventions of that profession.
- 28.3 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.
- 28.4 Promotional material must not include any reference to the medicines regulatory authority unless this is specially required by the medicines regulatory authority.
- 28.5 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.

- 28.6 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.

29 PROHIBITIONS OR RESTRICTED REPRESENTATIONS

An advertisement for a self-medication medicine and complementary and alternative medicine (CAM) 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.

30 QUOTATIONS

Quotations relating to a health product 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.

31 TESTIMONIALS

- 31.1 Testimonials shall comply with the approved package insert / instructions for use and with the other principles of this Code.
- 31.2 Testimonials should be less than three years old and be the genuine views of the user.
- 31.3 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.

32 HEALTHCARE PROFESSIONALS

- 32.1 Advertising and/or promotion shall not claim that a health product is, or has been available on prescription. However, it is acceptable to state that a health product's active ingredient, formulation or preparation has been prescribed by a healthcare professional, provided there is evidence that this is the case.
- 32.2 Advertising and/or promotion shall not refer to a 'college', 'hospital', 'institute', 'laboratory' or similar establishment, unless the establishment genuinely exists.

33 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.

34 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.

35 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.

36 RELATIONS WITH THE GENERAL PUBLIC AND THE MEDIA

- 36.1 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 Healthcare Professional.
- 36.2 Companies are responsible for information about their products that is issued by their public relations agencies.
- 36.3 Medicines must not be advertised to the general public if they are Schedule 2 or higher.
- 36.4 Patient support and/or 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.
- 36.5 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/recommend a specific health product. This does not prohibit education or information relating to substitution of a health product or information on safe use, and/or storage of health products in general.
- 36.6 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.
- 36.7 Companies are responsible for information that is issued by their public relations agencies about their products.
- 36.8 Patient education ('help-seeking advertisements') directed at general public is acceptable, provided that the material ¹:
 - 36.8.1 Does not contain the name of the specific health product.
 - 36.8.2 Does not make or allude to a medicinal or therapeutic claim.
 - 36.8.3 Does not provide any risk information.
 - 36.8.4 Let the public know that treatment exists for a medical condition.
 - 36.8.5 "For more information, refer to your doctor or pharmacist (or healthcare professional)" is mentioned.

37 PROMOTIONS, GIFTS, PRIZES AND INDUCEMENTS

- 37.1 No company shall be involved in promotional schemes which are hazardous to the public or which bring the industry into disrepute.
- 37.2 Entry into consumer competitions shall not be dependent on the conditional purchase of a health product nor shall a health product be offered as a prize. The value of the

prize shall not exceed the limits set by the MCA from time to time.

38 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.

39 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.

40 HEALTHCARE SALES REPRESENTATIVES/CONSUMER PROMOTERS

40.1 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.

40.2 All materials including slides, hand-outs, trade presenters, digital detailers etc. shall comply with the requirements of the Code.

40.3 Product training must be consistent with the package insert / instructions for use of a health product.

40.4 Healthcare 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.

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

41 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. Refer to Part D of the Code.

PART C: MEDICAL DEVICES

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 EXHIBITIONS

Medical Devices and IVDs used for exhibition purposes are typically unsterilized single use medical devices and IVDs or mock-ups of such medical devices and IVDs that are used for Healthcare Professional and patient awareness, education, and training. For example, a Healthcare Professional may use an exhibition medical device and IVD to show a patient the type of device that will be implanted in the patient. Exhibition medical devices and IVDs typically are not intended to be used in patient care. Exhibition medical devices and IVDs also are typically identified as not intended for patient use by use of such designations as “Sample,” “Not for Human Use,” or other suitable designation on the medical device or product, the product packaging, and/or documentation that accompanies the product.

44 EVALUATIONS AND DEMONSTRATIONS

44.1.1 It is common practice for Medical Device and IVD companies to have local Healthcare Professionals evaluate and appraise a new device. Such *evaluations* may take place prior to a launch of the product nationally, or in combination with a launch.

44.1.2 Product evaluations: Medical Device and IVD evaluations should be conducted in accordance with the guidelines:

44.1.3 The provision of equipment for free has to take place within the applicable legislative provisions.

44.1.3.1 No payment may be made to the healthcare provider wishing to conduct a medical device or IVD product evaluation for their own purposes.

44.1.3.2 Reasonable compensation payments may be made to the healthcare provider involved in a product evaluation that has been requested by a company for justifiable medical or scientific reasons - provided that this reasonable compensation relates to the Healthcare Professionals resources spent on the evaluation (e.g. personnel costs, lab infrastructure, like electricity/water etc.) and this must be documented in a formal agreement.

44.1.3.3 Where an evaluation is conducted and payments made as part of a clinical trial or investigation or registered/approved research project, it should comply with the relevant provisions of the Medicines Act and National Health Act and the regulations.

45 LOAN OR PLACED EQUIPMENT

45.1 The sale or placement of equipment with a Healthcare Professional, where the contract between the company and the Healthcare Professional includes the

purchase of consumables/disposables associated with the equipment is subject to the provisions of HCPSA's Guidelines for Good Practice – Booklet 5, item 3.6 Technological Equipment as applicable to HCPs: "3.6 TECHNOLOGICAL EQUIPMENT"

- 45.2 The consumables are used to cross-merchandise the capital equipment in a manner which is defensible and fair.
- 45.3 The consumables relate to the specific piece of capital equipment being financed by means of the purchase of the consumables and is defensible in terms of, for example, the provisions of the National Credit Act.
- 45.4 The placement of equipment agreement should be in writing and, in cases of valid complaints, made available as per the complaints handling process in Part D: Dealing with Enforcement of the Code.

PART D - PROVISION FOR ENFORCEMENT OF THE CODE

46 SELF-REGULATORY ENFORCEMENT OF THE CODE OF MARKETING PRACTICE

- 46.1 The MCA is hereby recognised as the self-regulatory authority for health products, whose authority is properly constituted by means of a Constitution as a juristic body.
- 46.2 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.
- 46.3 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.
- 46.4 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.

47 ENFORCEMENT STRUCTURES

- 47.1 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:
- 47.1.1 The Executive Officer of the MCA acts as the custodian of the Code and the enforcement processes described in this Code;
- 47.1.2 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.
- 47.1.3 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.
- 47.1.4 An Ex Parte Committee, to deal with questions of members relating to the application of the Code and/or Guidelines to themselves. Disputes between members are explicitly excluded from the ambit of this Committee.
- 47.2 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.
- 47.3 Non-members of the MCA may agree to abide by, or be required by law to abide by, the enforcement mechanisms created by the Code.

48 LODGING OF COMPLAINTS

- 48.1 As a first course of action, parties must attempt to resolve any Code matter by means of the complainant approaching the respondent directly in an amicable fashion. Members may also choose to undertake this approach through a representative of their choice, who may raise the alleged contravention with the alleged offending member without divulging the name of the complainant company. This is only applicable in terms of the intercompany process or dialogue. Members may also deviate from this

requirement if the matter is of such importance that it raises issues of patient safety, off-label use, incorrect use, etc. A reasonable response time for the respondents is seven working days.

- 48.2 Should a member company or any individual person ('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:
- 48.2.1 Proof that the company and complainant have made all reasonable attempts to resolve the matter between themselves;
 - 48.2.2 If the complaint is based on scientific issues, supporting literature and any studies relied upon;
 - 48.2.3 Copies of any advertisements and/or promotional material and/or any other material (such as invitations, agreements, correspondence, etc.) which may be relevant;
 - 48.2.4 Any other information the Complainant considers relevant to the determination of the complaint.
- 48.3 The complaint shall make reference to the sections of the Code which may have been contravened and shall in addition be accompanied by:
- 48.3.1 The prescribed complaint fee applicable at the time;
 - 48.3.2 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;
 - 48.3.3 If the complaint is based on scientific issues, supporting literature and any studies relied on;
 - 48.3.4 Copies of any advertisements and/or promotional material which may be relevant;
 - 48.3.5 Any other information the Complainant considers relevant to the determination of the complaint.
- 48.4 The Complainant will send seven paginated copies of the pre-requisite documents to the MCA for distribution to the Respondent and the committee members when appointed.
- 48.5 The Executive Officer shall on receipt of the complaint, send a copy of the complaint to the Respondent and request a formal paginated response within seven working days from the date upon which the Respondent receives the complaint.
- 48.6 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 seven working days from the date upon which the Complainant receives the response. The reply, if any, will on receipt be sent to the Respondent.
- 48.7 The Respondent/s and Complainant must provide sufficient copies of the response to the MCA for distribution to the Complainant, the committee members when appointed and a copy of the documents for the MCA records.

Either party sending documents to the MCA bears the responsibility of ensuring timeous

delivery of the requisite documents in hard copy.

- 48.8 During the above exchange of documents, the Executive Officer shall form 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.
- 48.9 Supplementary information based on the initial case may be submitted in exceptional circumstances. The other party must be given an opportunity to state their stance with respect to supplementary information. The supplementary information will only be permitted should the Chairperson and Adjudicating committee be in agreement that the supplementary information would add value to the case. In the event that the committee does not agree with the submission of supplementary information, a formal application must be submitted to the MCA stating the grounds for relevance of the supplementary information.
- 48.10 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.

49 NOMINATED / PRO-FORMA COMPLAINANT

- 49.1 The Executive Officer may 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 may also monitor such other forms of conduct by companies as prescribed by this Code.
- 49.2 Should the Executive Officer be of the opinion that there has been a breach she/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.
- 49.3 The nominated Complainant will act as Complainant and in accordance with the processes outlined in this Code and no complaint fees will be payable.

50 ADJUDICATION

- 50.1 Adjudication may, in the discretion of the Adjudication Committee and depending on the complexity of the matter and/or clarity of information provided by the parties, take place in the form of either a paper-based or face-to-face hearing as adjudication.
- 50.2 The Adjudicating Committee shall consider the documents placed before it by the Executive Officer at a date occurring within fourteen working days after the last exchange of documents between the Parties.
- 50.2.1 Where documents are subject to amongst others Clause 7.8 (arbitration of confidential information), Clause 18 (evaluation of agreement between company and healthcare professional, including that of an honorarium) or Clause 19 (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 adjudication or at any time prior to the Adjudicating Committee making its finding.

- 50.3 An Adjudicating Committee will request the Executive Officer to advise the Complainant and Respondent of the date of the adjudication of the complaint, which date has to be set at least 14 working days after the exchange of documents, and may, at the discretion of the Adjudication Committee invite them to appear before the Adjudicating Committee to make such further submissions as may be allowed by the Adjudicating Committee.
- 50.4 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:
- 50.4.1 Allow a party to state its case in writing;
- 50.4.2 Ensure that no member of the Adjudicating Committee is conflicted in the matter which is being adjudicated upon.
- 50.5 No Party shall have legal representation that is in sole employment of that party 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 practicing attorney or practicing advocate or both.

51 POWERS OF AN ADJUDICATING COMMITTEE

- 51.1 As is set out in the Constitution of the MCA, the Executive Officer shall not be involved in the hearing, deliberations or discussions of the Adjudication Committee.
- 51.2 The Adjudication Committee shall interpret and apply the Code according to the principles of interpretation outlined in the Code.
- 51.3 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 sanction if applicable, has to be made within seven working days of the date of the hearing or adjudication of the matter.
- 51.4 The ruling of the Adjudicating Committee is final and no further clarification / correspondence may be sought from this committee. In the event that a party requires clarification on a sanction or ruling, an appeal must be lodged with the MCA.
- 51.5 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 sanction: 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 Healthcare 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.

- 51.6 The party in breach will notify the MCA in writing when they have complied with all aspects of the ruling and any fine imposed will be paid to the MCA, as custodian of this process.
- 51.7 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 sanctions:
- 51.7.1 A reprimand; caution or warning;
 - 51.7.2 A fine, within limits set from time to time by the MCA in terms of its Constitution;
 - 51.7.3 Issue a directive that the Respondent's internal procedures in relation to the Code be reviewed by a representative of the MCA and that a report be furnished to the Executive Officer after the conclusion of such review;
 - 51.7.4 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;
 - 51.7.5 That the Respondent, as represented by himself, or in the case of a company by its Chief Executive Officer, Country Manager, General 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;
 - 51.7.6 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;
 - 51.7.7 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;
 - 51.7.8 That the finding of the Adjudicating Committee be published to the Members and the Medicines' regulatory authority at the discretion of the committee;
 - 51.7.9 Such other order as may be considered appropriate to the Adjudicating Committee in the circumstances.
- 51.8 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. To the extent that legal costs need to be reimbursed then same shall be on the attorney and own - client scale.
- 51.9 A complainant could be declared vexatious and or malicious upon application by either a respondent or ex-parte, as determined by the adjudicating committee.
- 51.10 Once a complainant is so declared to be vexatious and or malicious then no structure within the MCA shall hear a complaint from that complainant for a period of twelve months

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

52 LODGING AN APPEAL

- 52.1 Appeals may, in the discretion of the Appeals Committee and depending on the complexity of the matter and/or clarity of information provided by the parties, take place in the form of either a face-to-face hearing or as a paper-based appeal.
- 52.2 An Appeal against a decision by the Adjudicating Committee shall lie with 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. The Executive Officer shall not be involved in the hearing (if any), deliberations or discussions of the Appeal Committee.
- 52.3 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 seven 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.
- 52.4 Every Notice of Appeal shall be accompanied by the prescribed Appeal fee and sufficient copies of the documents for the MCA records, the other party/ies and the committee members when appointed.
- 52.5 Once an Appeal has been lodged, the Executive Officer shall:
- 52.5.1 As soon as possible thereafter make a copy of the ruling of the Adjudicating proceedings to which the Appeal relates available to the Appellant;
 - 52.5.2 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 ruling.
- 52.6 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.
- 52.7 Where an Appeal has been lodged, the Respondent may within seven 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.
- 52.8 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.

- 52.9 An Appeal may be withdrawn by the Appellant at any time in which case the Appeal fee will be forfeited.
- 52.10 In the event of a nominated complaint, the Executive Officer shall have the discretion to extend the time periods as provided for in this Clause, and delegated to the Chairperson of the Adjudicating Committee which made the ruling forming the subject matter of the appeal.

53 APPEAL HEARINGS

- 53.1 An Appeal Committee, when hearing an Appeal, shall adopt such procedures as it, in its sole discretion, may determine.
- 53.2 The Executive Officer will set a date for the hearing by the Appeal Committee, which date shall be within 14 working days after the exchange of documents and shall, if it deemed appropriate by the Appeal Committee to have a face to face hearing, notify the parties of the date, venue and time of such hearing.
- 53.3 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 enquired into and the penalty which may be imposed, in its sole discretion determines that legal representation is desirable in light of the above factors and other relevant factors. In such case a Party shall be entitled to legal representation by an in-house legal representative or only a practicing attorney or practicing advocate or both.
- 53.4 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.
- 53.5 The operation of the finding, penalty or decision of the Adjudicating Committee concerned shall be suspended:-
- 53.5.1 During the Appeal process; and/or
 - 53.5.2 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.
- 53.6 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.

54 POWERS OF AN APPEAL COMMITTEE

- 54.1 The Appeal Committee shall interpret and apply the Code according to the principles of interpretation outlined in the Code.
- 54.2 An Appeal Committee, on hearing an Appeal, shall have the powers:
- 54.2.1 To allow the Appeal;
 - 54.2.2 To dismiss the Appeal;
 - 54.2.3 To substitute any finding or decision as it deems fit or substitute such sanction

as it deems fit, including any amended penalty;

- 54.2.4 Any fine imposed must be paid to the MCA as custodian of this process;
- 54.2.5 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;
- 54.2.6 To hear further evidence or receive any documents on such terms and conditions as it in its discretion may decide;
- 54.2.7 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;
- 54.2.8 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;
- 54.2.9 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 any of the parties.

54.2.10 To make such rulings as it in its sole discretion shall determine.

54.3 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.

54.4 Any fine imposed must be paid to the MCA as custodian of this process.

55 FAILURE TO REPLY, PROVIDE FURTHER INFORMATION OR TO ATTEND A MEETING OR HEARING

55.1 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.

55.2 To the extent that a party does not abide by the time restrictions set out above, it acknowledges and consents to judgement being given against it, if applicable.

55.3 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.

56 BREACH OF RULINGS OR UNDERTAKINGS

56.1 Should the Executive Officer receive a complaint from any party, including a nominated

complainant, based on an alleged violation of Clause 23 and/or Clause 41 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 a process as described in this clause.

- 56.2 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.
- 56.3 The respondent company shall, within seven working days after receiving the complaint, provide a response and copies thereof to the Executive Officer, who shall have constituted an Appeal Committee to decide on the matter.
- 56.4 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 seven working days after receiving all the documents. No rights of appearance of any party will be granted, unless on exceptional cause shown.
- 56.5 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 defense relating to the validity or correctness of the ruling or undertaking previously made.
- 56.6 The Appeals Committee shall provide a substantiated ruling as to whether a breach of Clause 23 or Clause 41 has indeed occurred, and shall have the power to:
 - 56.6.1 refer the matter to any appropriate forum or authority for consideration, including a recommendation that legal action be taken; and/or
 - 56.6.2 confirm any previous sanction imposed; and/or
 - 56.6.3 impose any further penalties, sanctions or fines on the respondent company within the limits set by the MCA from time to time; and/or
 - 56.6.4 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; and
 - 56.6.5 any other sanction, including orders as to cost and fees.

57 EX PARTE RULINGS

- 57.1 A member or non-member of the MCA or a trade association representing members of the MCA may make an Ex Parte application, upon payment of the prescribed fee and in the prescribed form, for an answer in relation to a question pertaining to the application of the Code and/or Guidelines to themselves.
- 57.2 The Adjudication Committee shall function as the Committee hearing an Ex Parte matter.
- 57.3 Insofar as is applicable, the procedures and timelines set for Adjudication Committees shall apply *mutatis mutandis*.
- 57.4 Ex Parte matters will be undertaken on paper, provided that the Adjudication Committee may request further information and/or clarity from the applicant.

57.5 An Adjudication Committee may refuse to admit a matter on the basis that the Applicant is attempting to address a dispute with another member of the MCA and/or on the basis that a member is using the Adjudication Committee in its Ex Parte role to avoid lodging an appeal.

57.6 The ruling of an Adjudication Committee in an ex parte matter shall –

57.6.1 Consider rulings previously made by Adjudication - and Appeal Committees of the MCA;

57.6.2 Be limited to the question posed by the Ex Parte applicant, i.e. whether a particular activity would be in line with the Marketing Code and/or Guidelines, within the circumstances as outlined by the applicant;

57.6.3 Provide a complete analysis of the facts, the provisions in the Code and/or Guidelines and the reasoning how it is applied to the case at hand to reach the outcome contained in the ruling.

58 VARIATION OF TIMELINES AND WAIVER OF FEES

58.1 The Executive Officer may, on good cause shown and subject to such conditions as she/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.

58.2 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.

58.3 To the extent that the adjudicating - or appeal committees are required to convene for any purpose prior to making a finding, and one or more members of such committee are not available to reconvene within the prescribed time period or reasonable time period thereafter, then the executive officer shall in his/her unfettered discretion appoint a substitute committee member who shall have full rights and responsibilities and shall exercise all such powers as if this person had been a member of the original committee.

TRADE ASSOCIATIONS INVOLVED IN DEVELOPMENT OF THE SOUTH AFRICAN MARKETING CODE

ASSOCIATIONS

INNOVATIVE PHARMACEUTICAL ASSOCIATION OF SOUTH AFRICA (IPASA)

PHARMACEUTICALS MADE IN SA (PHARMISA)

SELF-MEDICATION MANUFACTURERS ASSOCIATION OF SA (SMASA)

THE SOUTH AFRICAN ANIMAL HEALTH ASSOCIATION (SAAHA)

SOUTH AFRICAN MEDICAL DEVICE INDUSTRY ASSOCIATION (SAMEDI)

SOUTHERN AFRICAN LABORATORY DIAGNOSTICS ASSOCIATION (SALDA)

INDEPENDENT NON-ALIGNED MEMBERS (INDEP)

Amendments adopted by the MCA membership at the AGM on 16th November 2016

Version Control Form

First version for implementation	2010
Date for implementation	October 2010
Version 1: Updates proposed by SMASA, PIASA, SAMED, SALDA, Update according to ABPI, and EFPIA, IFPMA, EUCOMED	July 2012
Version 2: Change health products to medicines, IVD, medical devices; moved definitions to end of document, definition for promotional aid and material, Updated to ABPI code (Clause 7); added MSL for pharma; patient support groups added; added icons for application	February 2013
Version 3: Application of code Clause 24.20 Enforcement: Clause 54 Lodging a complaint; 55 Nominated complaints; 56 Adjudication closed process, not a hearing hence no representation including legal; Clause 59 –closed meeting	4 March 2013
Version 4: added proxy complaint process	14 March 2013
Version 5: Part D changes as per the Constitution;	28 March 2013
Version 6: added definition of ordinary day	2 April 2013
Version 7: new association IPASA (Innovative Pharmaceutical Association of South Africa (merger of PIASA and IMSA) and contact details of associations deleted. Minor typographical changes	16 April 2013
Version 8: Renumbered Part C. Part D updated to be aligned with Constitution	28 May 2013
Version 9: Updated to align with updated international codes. Part A: clauses 5.1; 7.1; 7.13; 18.5; 18.6; 18.8 (Patient registries), 19.4.2; 20; 22.2 Part B: 25.2; 25.5; 25.9; 25.11; 25.15, 25.22; 25.23; Part C: Deleted Clauses 42; 44; 45; 46; 47 – refer to Part A and B Part D: Note: timelines in multiples of 7; ordinary days changed to working days; Clause 4.1.4; 48; 49.2 (deleted entity); 49.4; 49.6-8; 50.2-3; 51.2-4; 51.6; 52.4; 52.7; 53.2; 53.4; 54.2.4; 56 (Title change); 56.3-4; Deleted 59.5 (old no.); 54.4; Added 57 Ex Parte Rulings; 57.6; 58.1;58.2; 58.4; 59.5; 57 (Title change); 57.3-4; 60.1.4	November 2014
Version 10: Updated to accommodate complementary and alternative medicines (CAMs) and the Health Products Association (HPA). Minor Typographical changes. As well as changes summarised in the change summary. The 2016 Code Changes include the following: <u>Date</u> The new dates to be reflected on the Code will be November 2016 as per the AGM <u>Introductory paragraph</u> Amended to remove the names of trade associations. The reason for this is because the role of independent members is taking on increasing importance in the MCA due to decisions by trade associations to be involved or otherwise in the MCA. <u>Glossary</u> Definition of Company Code Compliance Officer amended to limit the authorisation to matters of Code compliance.	November 2016

Definition of **Complimentary Medicines** included; *Complementary medicines means complementary medicines as defined in the Medicines and Related Substances Act 101 of 1965 as amended, and Regulations.*

Definition of **Health Product** added; for the purpose of this code, the term *Health Products includes medicines, complementary medicines including health supplements(CAMS), medical devices and IVDs.*

Definition of **Faculty** added; *Faculty means active participants/HCPs who speak, present or serve another specific function at a 3rd – party organised medical educational conference.*

Definition of **Health Supplements** added; *Health supplement means health supplements as defined in the Medicines and Related Substances Act 101 of 1965 as amended, and Regulations and Guidelines*

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Definition of **Healthcare Professionals** (HPC); definition has been broadened to include as health care professionals, *individuals (clinical or non—clinical) including physicians, nurses, technicians and research coordinators).*

Definition for **Council of Clinical Engineers**; Definition has changed the wording institutions, to *healthcare facilities.*

Definition of **Honorarium**; Additional alternate wording included, or *alternatively Fee for Service*, and removes the limitations on payment to a professional.

Definition of **Institution** added; *An organisation, establishment, foundation, society, or the like, devoted to the promotion of a particular cause. This includes private hospitals and clinics.*

Definition of **Registry** is added; *Registry is defined as an organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specific outcomes for a population defined by a particular disease, condition or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.*

Application and interpretation

2.2.6 moved up from section on non-application of the code to section on application of the code; *Wholesalers, distributors, medical/IVD devices importers and logistics companies to the extent that they may influence the demand for health products.*

Addition and deletion of contents listing products not covered by the code;

Deletions;

- *Trade catalogues to suppliers including price lists*
- *Complimentary medicines*

Addition:

- *sampling*

2.5 Scope of Application to include complementary and alternative medicines;

- The word *shareholders* in the industry has been included,
- The marketing and promotion of self – medication products to healthcare professionals now includes *complementary and alternative medicines (CAMS)*
- The marketing and promotion of self – medication products to the public

now includes *complementary and alternative medicines (CAMS)*.

- This change is pulled through into part A and B of the code.

Part C Medical devices

A more concise statement on Part C binds the marketing and promotion Medical Devices and IVDs to part A and B of the code except where otherwise indicated in Part C.

Part A of the Code

7.5.6 has been amended with the addition of; *unless doing so is permitted by intellectual property law and/or common law, as amended and developed from time to time*

7.6 Substantiation

7.6.2 added for complementary and alternate medicines (CAMS); *For complementary and alternative medicines(CAMS), substantiation for any product claim must be in accordance with the requirements of the applicable regulations to the Medicines Act and associated guidelines where such exist, in so far as they relate to the level of evidence required for a low risk versus a high risk type of claim. If the product is already registered, substantiation need not be provided in relation to the validity of approved indications in the package insert.*

7.11 Use of the word new

This clause has been changed to read as follows; *The word 'new' may be used to describe any product, presentation or therapeutic indication, which has not been available in the market for more than 12 months in South Africa. (Wording merely changes negative to a positive statement - no change in substance).*

9.6 Amended to read; *The telephone, SMS, email, mobile messaging, telex, facsimile machines, or any form of electronic communications as defined in the Electronic Communications and Transactions Act, No25 of 2002, as amended from time to time...*

Also added here; *This provision shall be subject to all national legislation in force from time to time, to the extent applicable.*

18.4 Stand- alone entertainment....; Paragraph 2 now reads 'No stand – alone entertainment or other leisure, social or sporting activities may be planned, arranged or funded by companies or *their brands* as these are unrelated to the promotion of scientific or educational objectives.

18.7 Other interactions with healthcare professionals

18.7.1.3 added; *No cash or cash equivalents (e.g. vouchers) are allowed for completion of a survey or as a prize for a competition.*

19.4 Competitions

19.4.3 added; *The prize cannot comprise of cash or a cash equivalents (e.g. vouchers) and, ...*

20 Items for patients and patient organisations

20.3 amended by the addition of '*and be in accordance with competition law*'.

20.9, 20.10, 20.11, 20.12, 20.13, 20.14; deleted

21 Samples

This section has been amended to read; *The supply of product(s) as the sample is not permitted to extend beyond the conditions as described under any relevant health legislation or any exemption/s thereto.*

CAMS and personal care products may not be provided together with any scheduled

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medicines

23 Compliance with undertakings and rulings

The wording has been amended to provide that undertakings must be *complied with within the specified timeframe*. The words *without delay* have been deleted.

Part B of the Code

24 Registration status of medicines

The 1st paragraph now reads; The promotion of a registered self-medication and *complementary and alternative medicines*(CAM) 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.

25.12 has been amended to include *clinic sisters*.

26.13.5 has been amended to include *complementary and alternative medicines* (CAMS).

26.13.6 has been amended to include *complementary and alternative medicines* (CAMS).

26.13.11 has been amended to provide that it may be stated where applicable that a product contains *natural ingredients*

29 Prepared prohibitions or restricted presentations

this clause has been amended to include *complementary and alternative medicines* (CAMS.)

36.3-36.8 has been moved from Part A to Part B

40.2 has been amended to include *digital detailers*.

48 lodging of complaints has been amended to make the company to company process, *compulsory*

48.7 has been amended by the addition of the following; *Either party sending documents to the MCA bears the responsibility of ensuring time is delivery of the requisite documents in hard copy.*

48.11 Has been added: *Where the complaint refers to a matter which appears to relate to non-compliance with the Medicines and Related Substances Act, regulations or guidelines, the MCA shall not accept the complaint but shall refer the matter to the medicines regulatory authority.*

49 has been amended so that the heading reads, *Nominated/Pro-Forma Complainant*.

51.7.5 has been amended to include *General Manager*.

51.7.8 has been amended to read as follows; *That the finding of the Adjudicating Committee be published to the members, and the medicines regulatory authority at the discretion of the committee.*

55.2 has been added as follows; *To the extent that a party does not abide by the time restrictions set out above, it acknowledges and consents to judgement being given against it, if applicable.*

59.3 has been added; *To the extent that the adjudicating or appeal committees*

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are required to convene for any purpose prior to making a finding, and one or more members of such committee are not available in the prescribed time period or reasonable time period thereafter, then the Executive Officer shall in his/her unfettered discretion appoint a substitute committee member who shall have full rights and responsibilities and shall exercise all such powers as if this person had been a member of the original committee.